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#### Biotech industry strong now – new innovation and R&D coming

Cancherini et al. 4/30 [Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company] “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide> //ajs

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Secondary patents are necessary for innovation of otherwise mediocre drugs—core to cancer and HIV treatments

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was **only years later that its potential application in the fight against AIDS was realized**. Follow-on research resulted in **a method-of-use patent** directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate.

Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, **used in the treatment of** osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime.

Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on **the active ingredient itself.**

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

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.

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

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#### Bipartisan antitrust bills passing now but continued PC needed to pacify republicans.

Perlman 9/3 [Matthew; 9/3/21; “*Interest Groups Back Big Tech Antitrust Bills In House,*” LAW360, <https://www.law360.com/competition/articles/1418789/interest-groups-back-big-tech-antitrust-bills-in-house>] Justin

Law360 (September 3, 2021, 7:25 PM EDT) -- A contingent of public interest groups are urging leaders of the U.S. House of Representatives to advance a package of legislation aimed at reining in Big Tech companies through updates and changes to antitrust law, though free market advocates have been jeering many of the bills. A total of 58 public interest and consumer advocacy groups signed on to a letter Thursday asking House leaders to swiftly pass the package of six antitrust bills that the Judiciary Committee approved in late June after a marathon markup session. The proposals include legislation prohibiting large platform companies from acquiring competitive threats, preferencing their own services and using their control of multiple business lines to disadvantage competitors in other ways. The proposals would also impose interoperability and data portability requirements on large tech platforms, increase merger filing fees and boost enforcement by state attorneys general. Charlotte Slaiman, competition policy director for Public Knowledge, which signed on to the letter, said in a statement Thursday that the package charts a path toward putting "people back in control of the digital economy." "The broad range of groups supporting this package shows just how widespread the problem of Big Tech dominance is, and that these bills deserve a full vote in the House imminently," Slaiman said. The letter contends that America has a monopoly problem that is resulting in lower wages, reduced innovation and increased inequality, while also undermining the free press and perpetuating "racial, gender and class dominance." "Big Tech monopolies are at the center of many of these problems," the letter said. "Reining in these companies is an essential first step to reverse the damage of concentrated corporate power throughout our economy." The proposals followed a 16-month investigation by the House antitrust subcommittee into Amazon, Apple, Facebook and Google that resulted in a sprawling report from Democratic members calling for a range of reform measures to rein in the dominance of the companies. While consumer advocacy groups have largely supported the measures, the tech companies themselves and other interest groups have been highly critical, including a coalition of more than 25 right-leaning groups that sent a letter to Congress ahead of the markup hearing. The letter called the bills a "Trojan horse package" aimed at cynically using conservative anger over Big Tech, particularly at perceived censorship by social media platforms, to seek bipartisan support for "European-style over-regulation." For its part, Facebook has called the proposals a "poison pill for America's tech industry at a time our economy can least afford it" and said the bills underestimate the fierce competition the U.S. companies face from abroad. Apple and Google also raised concerns about the impact the bills would have on innovation, as well as on privacy and security. And Amazon has warned about the potential consequences of the proposals for both small businesses that sell on its platform and the consumers who use it to shop. Ending Platform Monopolies Act Thursday's letter said that the Ending Platform Monopolies Act would address "the most problematic aspects of the Big Tech companies" by allowing enforcers to break-up or separate pieces of the businesses when they create conflicts of interest that give the platforms an advantage over potential competitors and business users. A fact sheet from Public Knowledge accompanying the letter said that the bill is an important tool to help the antitrust agencies "protect consumers from mammoth platforms and to ensure compliance with other parts of the package." But during the markup hearing, ranking Republican committee member Rep. Jim Jordan of Ohio blasted the bill as a regulatory overreach, calling it "quite literally central planning" and arguing that it has significant ambiguities, which is bad for business. The Competitive Enterprise Institute argued in a June statement that the bill "kills the goose that lays the golden egg," and would actually result in small businesses being unable to access the large platforms, which in turn would focus on their own offerings instead. The Chamber of Progress has warned that the proposal could bar Amazon from offering its Prime services and its Amazon Basics private label products, since they would compete against other sellers on the platform. Other groups have also warned it could also force tech companies to divest popular apps, including Google's Maps and YouTube, Facebook's WhatsApp and Instagram and Apple's iMessage and FaceTime. American Innovation and Choice Online Act The American Innovation and Choice Online Act is aimed at barring the platform companies from preferencing their own products and services over those of rival businesses and from excluding or discriminating against rivals. Thursday's letter said this proposal would "promote innovation and competition" by preventing the platforms from protecting their monopolies. The right-leaning think tank American Enterprise Institute and others have argued that the bill could prevent Apple from pre-installing certain apps on its mobile phones, since that would advantage it over competing app developers. It could also prevent Google from integrating maps or customer reviews into search results, among other things. "At a minimum, the act would significantly disrupt these platforms' business models in ways that undermine consumer value," Daniel Lyons, a senior fellow for the group wrote in a blog post in June. Platform Competition and Opportunity Act The Platform Competition and Opportunity Act is aimed at preventing platform companies from acquiring potential or nascent competitors and its supporters argued in Thursday's letter that it would prevent the tech giants from enhancing or maintaining their market power. The bill would presumably have blocked Facebook's purchases of WhatsApp, Instagram and other services it has acquired, as well as a slew of deals by Google over the past two decades. Detractors have contended that this bill would limit investments in startups because it restricts their ability to be acquired by the larger technology firms, which they say is a key way for founders to benefit from their success. An American Enterprise Institute blog post from June argues that "opportunities for acquisition have been important drivers of innovation in tech" and also said the bill would prevent the tech companies from entering new areas of business to compete with each other. ACCESS Act The Augmenting Compatibility and Competition by Enabling Service Switching, or ACCESS Act, imposes requirements for the tech companies to make user data portable and able to be used by competing services. The bill's supporters argued in Thursday's letter that this prevents the tech giants from locking users into their services, since users can take their data with them and use it on other networks. Privacy and security implications have been flagged as potential problems for the proposal, with the Competitive Enterprise Institute saying in a statement in June that it's an "anti-privacy bill" that forces companies to turn over private user information to others. The group also said the bill would try to micromanage "complex, dynamic, and highly competitive markets" that are beyond understanding for most politicians and regulators. The American Enterprise Institute has also contended that the requirements would actually make rivals even more dependent on the incumbent platforms. Filing fees and state enforcement Of the antitrust bills approved by the House Judiciary Committee, the ones with the most bipartisan support appear to be the Merger Filing Fee Modernization Act and the State Antitrust Enforcement Venue Act, though it took a day of debate before the committee passed them. A Senate version of the filing fee bill passed that chamber in June as part of the U.S. Innovation and Competition Act. It would raise the fees merging parties pay when reporting large transactions, while lowering fees for smaller deals, in order to raise more resources for the antitrust agencies. Information Technology & Innovation Foundation argued in an August blog post that the legislation does not give Congress enough oversight over how the agencies will use the funds that it raises and called for the bill to include provisions requiring the money be used to hire more staff dedicated to antitrust enforcement. The Competitive Enterprise Institute also raised concerns about congressional oversight and contended that the bill would increase the cost of doing business at a time when the economy is sputtering. "U.S. consumers need innovative services and affordable products, not higher prices passed onto them by businesses avoiding new, unnecessary regulatory compliance costs," the group said in a June blog post. The state enforcement bill would prevent antitrust cases brought by state attorneys general from being transferred to a different venue by the Judicial Panel on Multidistrict Litigation, similar to protections afforded to federal enforcers. The bill is intended to prevent companies targeted by state-led enforcement actions from trying to move the cases to more favorable venues, and it also has an analog in the Senate. Information Technology & Innovation Foundation acknowledged in their August post that having cases included in multidistrict litigation can handicap state enforcers, but contended the changes should only apply to criminal matters and that the current version is wrong to block transfers of civil cases too. Thursday's letter from supporters of the bills said the proposals were carefully crafted to address the abusive practices of Big Tech, informed by the House antitrust subcommitee's sprawling investigation and "historic" 450-page report. "We believe that these bills will bring urgently needed change and accountability to these companies and an industry that most Americans agree is already doing great harm to our democracy," the letter said.

#### Aff requires negotiations that saps PC.

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

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

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

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

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

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

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

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

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

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

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

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

#### Antitrust is key to the DIB – brink is now.

Sitaraman 20 [Ganesh; Vanderbilt University Law School; “The National Security Case for Breaking Up Big Tech,” Knight First Amendment Institute at Columbia; 3/12/20; <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3537870>] brett // Re-Cut Justin

Concentration in the tech sector also threatens the defense industrial base due to higher costs, lower quality, less innovation, and even corruption and fraud.71 Each of these dynamics has already been a problem for America’s over-consolidated defense industrial base. As technology becomes more and more central to defense and national security, it is likely that these same dynamics will replicate themselves with big tech companies. This will become a national security threat, both directly, in terms of the quality and speed of procurement, and indirectly, by reducing innovation and functionally redirecting defense budgets from research spending to higher monopoly profits.72 Conventional economic theory suggests that monopolists have the ability to increase prices and reduce quality because consumers are captive.73 When it comes to defense spending, the Government Accountability Office commented in 2019 that “competition is the cornerstone of a sound acquisition process and a critical tool for achieving the best return on investment for taxpayers.”74 At the same time, the GAO observed that “portfolio-wide cost growth has occurred in an environment where awards are often made without full and open competition.”75 Indeed, it found that 67 percent of 183 major weapons systems contracts had no competition and almost half of contracts went to a handful of firms. Of course, consolidation also means that the Defense Department is in a symbiotic relationship with these big contractors. Some startup executives wanting to sell to the government thus see the Pentagon as “a bad customer, one that is heavily skewed in favor of larger, traditional players,” and they don’t feel like they can break into the sector.76 Standard stories about political economy and capture also suggest that these firms will have outsized power over government.77 As Frank Kendall, the former head of acquisitions at the Pentagon, has said, “With size comes power, and the department’s experience with large defense contractors is that they are not hesitant to use this power for corporate advantage.”78 In the defense context, that means monopolists retain power (and profits), even if they overcharge taxpayers and risk the safety of military personnel in the field. In an important article in The American Conservative on concentration in the defense sector, researchers Matt Stoller and Lucas Kunce argue that contractors with de facto monopoly at the heart of their business models threaten national security. They write that one such contractor, TransDigm, buys up companies that supply the government with rare but essential airline parts and then hike up the prices, effectively holding the government “hostage.”79 They also point to L3, a defense contractor that had ambitions to be a “Home Depot” for the Pentagon, as its former CEO put it. L3’s de facto monopoly over certain products, according to Stoller and Kunce, means that it continues to receive lucrative government contracts, even after admitting in 2015 that it knowingly supplied defective weapons sights to U.S. forces.80 Consolidation also threatens U.S. defense capacity. The decline of competition, according to a 2019 Pentagon report, leaves the military vulnerable to “sole source suppliers, capacity shortfalls, a lack of competition, a lack of workforce skills, and unstable demand.”81 With a limited number of producers, there is less talent and knowhow available in the country if there is a need to build capacity rapidly.82 In 2018, the Defense Department released a report on vulnerable items in the military supply chain, including numerous items in which only one or two domestic companies (and, in some cases, zero domestic companies) produced the essential goods.83 How did the United States lose so much of its industrial base? The combination of consolidation and global integration is part of the story. As Stoller and Kunce argue, companies consolidated in the 1980s and 1990s while shifting emphasis from production and R&D to Wall Street-demanded profits. Globalization then allowed them to shift production overseas at a lower cost. The result was to gut America’s domestic industrial base—and, in many cases, to shift it to China, which engaged in a decades-long strategic plan to develop its own industrial base. The result, in the words of the 2018 Defense Department report, is that “China is the single or sole supplier for a number of specialty chemicals used in munitions and missiles.” In other areas too, the risks of losing access to critical resources are real. Describing the problem of limited carbon fiber sources, the same Pentagon report notes, “[a] sudden and catastrophic loss of supply would disrupt DoD missile, satellite, space launch, and other defense manufacturing programs. In many cases, there are no substitutes readily available.”84 As technology becomes more integral to the future of national security, it is hard to see how big tech will not simply go the way of the big defense contractors. Corporate mottos not to “be evil” are long gone,85 and big tech companies spend millions on conventional Washington, D.C., lobbying efforts.86 Over time, as contracts move to tech behemoths, there will no longer be competitive alternatives, and the Pentagon will likely be locked into relationships with big tech companies—just as they currently are with big defense contractors.87 Some commentators suggest that robust antitrust policies are a problem because only a small number of tech companies can contract for defense projects.88 But there is another way to look at it: The goal should be to encourage competition in the tech sector so that there are multiple contractors available. As former secretary of homeland security Michael Chertoff has said, defending the antitrust case against Qualcomm, “a single-source national champion creates an unacceptable risk to American security—artificially concentrating vulnerability in a single point. ... We need competition and multiple providers, not a potentially vulnerable technological monoculture.”89 The consequence of consolidation in tech is that taxpayers will likely see higher bills even as innovation slows due to reduced competition. Worse still, every taxpayer dollar that goes to monopoly profits—whether in the form of higher prices or fraud and corruption—is a dollar that is not going toward innovation for the future. A concentrated defense sector means not only less innovation due to the lack of competition in the sector; it means that funding that could have been available for innovation instead gets redirected via monopoly profits to the pockets of big tech executives and shareholders.

#### That solves extinction through great power war.

Marks 19 [Michael; Former Senior Policy Advisor to the Under Secretary for Security Assistance, Science and Technology at the U.S. Department of State; "Strengthen US Industry To Counter National Security Challenges," American Military News; 10/10/19; <https://americanmilitarynews.com/2019/10/strengthen-us-industry-to-counter-national-security-challenges/>] Justin

While U.S. defense budgets have recently been on the rise, it is likely that we will see a spending decline in the coming years as competition for non-defense federal budget dollars increases and deficits grow. The United States, therefore, must take action to ensure that we maintain our technological edge against our adversaries by empowering the private sector to provide cost-effective innovation for America’s defense. Since the end of the Second World War the U.S. has relied on qualitative superiority over its potential adversaries, especially those like the Soviet Union/Russia and China, who enjoyed comparative quantitative advantages. These qualitative advantages were vital to maintaining global stability and helped enable our nation to become the preeminent global economy, but they have been eroded over the last few decades. In 1960, the U.S. share of global research and development (R&D) spending stood at 69%. U.S. defense-related R&D alone accounted for 36% of total global expenditures. Soon thereafter other nations recognized the need to increase their R&D expenditures and build their own defense industrial bases to compete with the United States. From 2000-2016, China’s share of global R&D rose from 4.9% to 25.1% while the U.S. share of global R&D dropped to 28%. U.S. defense-related R&D meanwhile now makes up a mere 4% of global R&D spending. There can be no doubt that Russia and China are determined to challenge America’s qualitative advantage. From the rebirth of Russian military power under Vladimir Putin to the ever-growing Chinese military prowess across the board, their efforts show no sign of slowing down. Russia has been and continues to undergo a major modernization of its armed forces. For example, they are in the midst of a ten-year program to build hundreds of new nuclear missiles and have set a goal of modernizing 70% of the Russian Ground Force’s equipment by 2020. One of the most frightening examples of Russia’s resurgence is its development of a hypersonic missile that could be ready for combat as early as 2020. Worryingly, the US is currently unable to defend against this type of missile. To accompany these developments came the emergence in 2017 of Russia as the world’s second-largest arms producer, ready and able to support nations hostile to US interests. China, on the other hand, used to be a country that only manufactured cheap products and knockoffs, but that is no longer true. Technology development and innovation figure prominently in all of China’s national planning goals, with plans to make the country the global leader in science and innovation and the preeminent technological and manufacturing power by 2049, the 100th anniversary of the Chinese communist revolution. This, of course, has huge implications for China’s military capability. The country now has the second-largest national defense budget behind the U.S. and wants to be Asia’s preeminent military power. Beijing is developing next-generation fighter jets, ICBMs and shorter-range ballistic missiles, as well as advanced naval vessels. The People’s Liberation Army has reached a critical point of confidence and now feel they can match competitors like the United States in combat. This has implications for the security of Taiwan, Japan, other US allies in the region as well as to America itself. To make matters worse, there are a growing number of experts that see China developing asymmetric technologies, combined with conventional and nuclear systems that could create an existential threat to the U.S. pacific based assets. It is in the wake of these growing threats to our national security American industry will likely be expected to shoulder an even larger responsibility concerning investment in defense-related R&D. One of the ways we can empower companies to make these additional investments and lead next-generation defense innovation is to allow commonsense mergers between important defense and aerospace companies. Horizontal consolidation eliminates the redundancy of enormous fixed costs, leading to savings passed down to customers. Mergers can also create economies of scale and existing synergies that help the combined company realize access to larger numbers of engineers and innovators, while keeping costs low and improving the timeline for taking a product from concept to development. FA recent example of how this can work is the proposed Raytheon and United Technologies merger. The two parties project that the new combined company will employ more than 60,000 engineers, hold over 38,000 patents and invest approximately $8 billion per year in research and development. This will allow the development of new, critical technologies more quickly and efficiently than either company could on its own. Such private sector investments in innovation will be critical in the face of the growing challenges to American military dominance. America’s R&D advantage, crucial to maintaining military superiority, is increasingly at risk. As China and Russia continue to challenge America’s military dominance and pressures on the defense budget continue to mount, the federal government will likely turn more and more to contractors and commercial companies to develop next-generation defense capabilities. Strengthening U.S. industry, therefore, will be critical to countering our national security challenges.

### 3

#### Counterplan: States should:

#### Impose price controls on medicines designed to reduce projected excess costs to 0 dollars

#### Reimburse pharmaceutical companies for any reduced profit margins caused by price controls

### 4

#### CP: The member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over whether to The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent and exclusivity protection. Member nations should support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation boosts strong leadership, authority, and cohesion among member states – key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

#### Ought means should

Merriam Webster n.d. – Merriam Webster’s Learner’s Dictionary, “ought”, <http://www.learnersdictionary.com/definition/ought>  
ought /ˈɑːt/ verb  
Learner's definition of OUGHT [modal verb] 1 ◊ Ought is almost always followed by to and the infinitive form of a verb. The phrase ought to has the same meaning as should and is used in the same ways, but it is less common and somewhat more formal. The negative forms ought not and oughtn't are often used without a following to. — used to indicate what is expected They ought to be here by now. You ought to be able to read this book. There ought to be a gas station on the way. 2 — used to say or suggest what should be done You ought to get some rest. That leak ought to be fixed. You ought to do your homework.

#### Should means must and is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling in praesenti.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16) [CONTINUES – TO FOOTNOTE] [13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) In praesenti means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is presently or immediately effective, as opposed to something that will or would become effective in the future *[in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

### Case

### Solvency

#### They don't solve their aff -- all they do is ensure companies only get one protection per invention -- either orphan drug rights, a patent, or data exclusivity -- but theres no brightline for whats a new or old invention, so they cant stop evergreening. Companies will just slightly modify their invention and get a separate new patent and the aff has no litmus test for when an invention is significantlly new/different enough from past inventions

#### Minor tweaks of drugs are key to ensure adequate treatment- otherwise patients skip doses or medicines fail in hot climates – forces people to go underground to get effective new drugs which decks aff solvency

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day.

Other examples of improved formulations that provide real benefits to patients are **oral**ly administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular **injection**, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

#### There’s a reason the aff’s authors are blogs not lawyers – Evergreen doesn’t prolong patents -- secondary patents *only* cover the improvement, but the original patent dies regardless.

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

“Evergreening” – an Incoherent Concept

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.

#### That solves pricing and monopoly- the improvement might be patented but generics of the original compound become incredibly cheap

**Holman 2016** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis. “IN DEFENSE OF SECONDARY PHARMACEUTICAL PATENTS: A RESPONSE TO THE UN’S GUIDELINES FOR PHARMACEUTICAL PATENT EXAMINATION” *Indiana Law Review* 50, 2016)DR 21

Rather than the blanket presumption against patents on new formulations endorsed by the Guidelines, which would tend to deny patent protection for both minor improvements and highly significant improvements, the needs of patients would be better served if the market and the judgment of patients and healthcare providers were allowed to determine the value of a new formulation on an existing drug. If the improvement is of such significance that it justifies a substantial cost premium, then society has benefited from the development of this improved mode of drug delivery, and payment of the premium is justified, in the same way that it is by development of a therapeutically useful new active ingredient. If the improvement is nominal, then payers should refuse to pay the premium, which they can do by simply purchasing the original formulation from generic companies at a discounted price. If there are market inefficiencies that somehow induce payers to pay the premium even though the improvement is minimal, then those market inefficiencies should be addressed, rather than attempting to address it by changing the standard for patentability in a discriminatory manner that targets specific categories of inventions.

#### It's illegal to extend a patent on the same drug—only new compounds can be patented

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

When critics of the pharmaceutical industry initially began talking about "evergreening," the discussion often seemed to imply that pharmaceutical companies were literally re-patenting the same product. However, those more familiar with patent law have responded by pointing out that, as a general matter, pharmaceutical companies are not simply re-patenting a product, and that various doctrines of patent law work in conjunction to prevent a company from obtaining new patents on a product that is **already on the market**. For example, at a May 7 Congressional Hearing entitled Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition, Professor David Olson of the Boston College Law School explained to lawmakers that:

It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong .... New patents can be filed on different formulations of a previous drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.

If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, **the new patent** is either **invalid** or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing. 9

#### Decades of illicit drugs should thump

### !D AMR Superbugs

#### Alt cause—billions of livestock use more antibiotics than humans

#### No evidence post-plan innovations are aimed at AMR or quick enough to solve

#### Plan kills innovation- revolutionary drugs for AIDS and Cancer came from secondary patents- flips the impact

#### Only vaccines can solve superbugs, NOT changing treatments- AC Sobti

Sobti 19 [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] DR 21

Redfield emphasized the importance of vaccination during the global superbug crisis, stating that “the only way we have to eliminate an infection is vaccination.” He added that investing in innovation is key to solving the crisis. While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “not insurmountable,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and secure the future from drug-resistant diseases.”

#### New vaccine tech will be rapid and solve AMR

* Lol says new vaccines in the next decade solve cancer too- hidden defense to the other advantage

**Rappuoli 2021** (Rino Rappuoli, Ennio De Gregorio, Giuseppe Del Giudice, Sanjay Phogat, Simone Pecetta, Mariagrazia Pizza, and Emmanuel Hanon. All authors work at the Research and Development Centre, GlaxoSmithKline in Italy. "Vaccinology in the post− COVID-19 era." *Proceedings of the National Academy of Sciences* 118, no. 3 2021 Graph omitted.)DR 21

Reverse vaccinology, structure-based design, synthetic biology, and adjuvants are the tools that we have today to design vaccines that can be delivered as purified antigens, or by RNA and viral vectors. The COVID-19 pandemic has accelerated the maturation of RNA and viral vectors by at least a decade and made these new platforms available not only for emerging infections but also for the other health priorities such as antimicrobial resistance (AMR), chronic infections, and cancer that our world will need to face with urgency as soon as the COVID-19 emergency is over. To analyze the new challenges for vaccines, in [Fig. 3](https://www.pnas.org/content/118/3/e2020368118#F3), we divided vaccines into four groups. On the opposite sides, there are vaccines that we already have or that can be made with existing technologies (group A; [Fig. 3A](https://www.pnas.org/content/118/3/e2020368118#F3)) and vaccines that we cannot yet approach with today’s knowledge (group D; [Fig. 3D](https://www.pnas.org/content/118/3/e2020368118#F3)). Vaccines in groups B and C ([Fig. 3 B and C](https://www.pnas.org/content/118/3/e2020368118#F3)) are intermediate. A closer look at these groups shows that we can divide vaccination into two big categories, depending on whether we vaccinate a naïve immune system or vaccinate an immune system that has already encountered the antigen (primed immune system).

Vaccines for a Naïve Immune System.

The vaccine against smallpox developed more than two centuries ago and the vaccines in development today against COVID-19 are based on a similar principle. They both introduce, into the body, antigens that had never been seen before by the immune system, aiming at stimulating a long-term protection for a future encounter with the virus. The large majority of the vaccines in use today are also based on antigens that had never been seen before by the naïve immune system (diphtheria toxin, tetanus toxin, measles, mumps, rubella, poliomyelitis, hepatitis B, papillomavirus, and infant vaccination against influenza, pneumococcus, and meningococcus) ([Fig. 3A](https://www.pnas.org/content/118/3/e2020368118#F3)). When these vaccines are used, the antigens are taken up by professional antigen-presenting cells and presented to naïve B and T cells which mount an adaptive immune response. An important step in this process is the formation of germinal centers where follicular T helper cells and B cells cooperate to increase the potency of the B cells specific for the new antigen, via affinity maturation of antigen-reactive antibodies. This is the textbook vaccination for which we have both mechanistic and animal models, and is the vaccinology that we study when we inject animals (mostly mice) with a variety of antigens that are new for their immune system. In most cases, we have sufficient technologies and knowledge to develop vaccines against pathogens for which the immune system is naïve. There are cases, however, where we are not yet able to make vaccines. Examples are HIV, where the virus changes so rapidly that vaccines are not effective, or malaria, where the antigenic profile is very complex, and we struggle to make effective vaccines.

Vaccines for a Primed Immune System.

Some of the vaccines described above, when delivered to adolescents, adults, or the elderly, may find an immune system that has already been exposed to the antigen, following natural infection or by other microorganisms carrying cross-reacting antigens ([Fig. 3B](https://www.pnas.org/content/118/3/e2020368118#F3)). In this case, the immune system is not naïve any longer, and the vaccines are required to modify the preexisting immunity of antigen-experienced people. Seasonal influenza is probably the best example. In this case, we deliver a vaccine specific for a new influenza virus strain to an immune system that has already gone through the process of developing the response to the same antigen and has already generated specific memory B and T cells. The new vaccine quickly expands the preexisting memory B cells and, at the same time, triggers the expansion and affinity maturation of naïve B cells ([38](https://www.pnas.org/content/118/3/e2020368118#ref-38)). However, it is clear that the first exposure to the antigen has already shaped forever the way the immune system reacts to subsequent encounters with the same antigen. This phenomenon is known as “antigenic sin” ([39](https://www.pnas.org/content/118/3/e2020368118#ref-39)). Another recent example is vaccination against dengue virus. In this case, a vector-based vaccine was effective in boosting a preexisting immunity in seropositive people, while it was unable to effectively prime the naïve immune system of naïve children where it induced antibody-dependent disease enhancement, which increased the risk of hospitalization ([40](https://www.pnas.org/content/118/3/e2020368118#ref-40)). Meningococcal and pneumococcal conjugate vaccines are another example ([41](https://www.pnas.org/content/118/3/e2020368118#ref-41)). When they are given to naïve infants, they prime the immune system to the new antigen, and it takes at least two immunizations to have a good immune response. However, when the same vaccine is given to adolescents or the elderly, who have already been exposed to these pathogens, one dose of vaccine is sufficient to get an excellent immune response. Although there are no definitive studies in humans describing the germinal center response in this context, it is likely that the single vaccination elicits an immediate antibody response—probably by an extrafollicular transformation of memory B cells into plasma cells—and then the immune system becomes refractory to any booster immunization for a long period (as long as 2 y). In this period, more affinity maturation happens, and new memory B cells are generated. Only after that, the immune system is ready to respond to a booster immunization with a massive level of antibodies which can be as high as 10 times the response to the first immunization ([41](https://www.pnas.org/content/118/3/e2020368118#ref-41)). Unfortunately, we do not have animal models able to reproduce what is described in the examples above, and we do not have a mechanistic understanding of what it takes to vaccinate an “experienced” immune system. The absence of animal models and the lack of knowledge are serious limitations for the development of new vaccines that target pathogens to which most people have already been exposed by natural infection.

A big and urgent example in this category is bacteria resistant to antibiotics and responsible for recurrent infections. AMR is a slowly evolving pandemic, with predicted catastrophic consequences for health and economy during the next 10 to 20 y ([42](https://www.pnas.org/content/118/3/e2020368118#ref-42)). Vaccines can help to tackle AMR ([43](https://www.pnas.org/content/118/3/e2020368118#ref-43)). We urgently need vaccines for pathogenic Escherichia coli, Staphylococcus aureus, Clostridium difficile, Klebsiella pneumoniae, Pseudomonas aeruginosa, Neisseria gonorrhoeae, Salmonella typhi, Shigella, Acinetobacter baumannii, Enterococcus faecium, and Campylobacter ([Fig. 3B](https://www.pnas.org/content/118/3/e2020368118#F3)). Experimental vaccines against some of these pathogens are based on proteins or polysaccharides which induce normal or low response to the first vaccination when tested in naïve mice, followed by a better response to the second and third vaccinations. However, when adult volunteers were immunized with the same vaccines, a strong response was observed already after the first immunization, with no increased response to the second vaccination (at least in the short term). The main reason for this is that adult volunteers have already been colonized by these bacteria or by their relatives, and they already have memory B and T cells that recognize them and respond to vaccination. In this setting, adjuvants failed to increase the antibody response. The consequence is that, during vaccine development, in most cases, we make the choice to make a one-dose vaccine without adjuvant ([44](https://www.pnas.org/content/118/3/e2020368118#ref-44)). However, we are not sure whether this is the right choice for long-term protection, and some of the vaccines failed even the primary efficacy endpoint ([45](https://www.pnas.org/content/118/3/e2020368118#ref-45)). While we do not yet fully understand the mechanistics of immunizing a primed immune system, or the lack of a protective immune response that allows reinfection, we have enough technologies and empirical knowledge to develop new vaccines for AMR. Similarly, we have enough knowledge to develop vaccines for some viral diseases such as respiratory syncytial virus, dengue, and Zika viruses even in adults and the elderly, where the immune system has been usually primed by natural infection.

Vaccines for an Immune System Primed by Controlled Chronic Infections.

The difficulty of making vaccines increases when the immune system not only has already been primed by the exposure to the pathogen but somehow has already been defeated by it. The immune system has not been able to clear the pathogen, which has established a lifelong chronic infection. In some cases, once chronic infections are established, the immune system is still able to keep at bay the pathogen for most of the time. This is the case for herpes viruses (zoster, HSV1 and HSV2, EBV, and CMV) and for bacteria such as Mycobacterium tuberculosis ([Fig. 3C](https://www.pnas.org/content/118/3/e2020368118#F3)). The pathogen establishes a latent infection and persists quietly in the body without causing disease. However, due to concomitant infections, immunosuppressive pharmacological treatments, or aging, the immune system becomes weak, and the pathogen takes over, causing disease.

Up to a few years ago, we had not a single example of a successful vaccine against chronic infections. It took us 20 y of research to start conquering some of them. The first step in this direction was the licensure of the live attenuated vaccine against herpes zoster in 2006 ([46](https://www.pnas.org/content/118/3/e2020368118#ref-46)). Although this vaccine was not able to eliminate the chronic infection, it was able to keep the chronic virus silent and avoid reactivation in 60% of the cases. Recently, a new vaccine composed of a protein antigen and the potent AS01 adjuvant (a liposome containing a TLR4 agonist and a saponin) showed an efficacy of 97% against herpes zoster ([47](https://www.pnas.org/content/118/3/e2020368118#ref-47)). This was followed by encouraging results against tuberculosis, where the combination of a protein antigen and the AS01 adjuvant was able to prevent reactivation and disease in 50% of the chronically infected people ([48](https://www.pnas.org/content/118/3/e2020368118#ref-48)). The successful vaccines against herpes zoster and the encouraging results against tuberculosis represent an incredible milestone in the history of vaccination, because, for the first time, we have been able to make effective vaccines against chronic infections.

Vaccines for a Primed and Failed Immune System.

There are cases in which the immune system has been exposed to pathogens and has been completely defeated. Examples are chronic infections, such as HIV, papillomavirus, hepatitis C virus (HCV), hepatitis B virus (HBV), and cancer, where the immune system is not able to control the pathogen or the cancer cells, which continue to replicate forever ([Fig. 3D](https://www.pnas.org/content/118/3/e2020368118#F3)). So far, we have not been able to make successful vaccines against these diseases, and we do not have the scientific knowledge to make them. However, even this area is not without hope, because the progress made by immunotherapy in the area of cancer has shown that the defeated immune system is characterized by dormant regulatory T cells that can be activated using antibodies against the checkpoint inhibitors, removing the constrains imposed on the immune system ([49](https://www.pnas.org/content/118/3/e2020368118#ref-49)). The success of immunotherapy in the field of cancer and the increased understanding of mechanistic features of the defeated immune system suggest that, in the near future, vaccination may also be able to conquer cancer and chronic diseases.

**Conclusions**

The urgent need for COVID-19 vaccines has accelerated the time required to develop vaccines and the availability of powerful technologies. It is possible that evolution of the new technologies fast-tracked for COVID-19 (RNA vaccines, viral vectors, and protein-based vaccines with potent adjuvants) combined with the learning coming from immunotherapy will be the answer for some of the new challenges of modern society such as emerging infections, AMR, chronic infections, **and cancer**. For instance, RNA vaccines and viral vectors may be designed to encode not only antigens but also molecules able to reactivate the dormant immune system.

#### BUT they’re only possible with high pharma profits – clinical trials are too expensive already

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The rising of AMR is a threat to modern medicine and new measures to control antibiotic-resistant bacteria are desperately needed including the development of new antibiotics. Nevertheless, the discovery of new effective chemical compounds with an appropriate balance of antibacterial activity, drug metabolism, pharmacokinetics properties and safety it is a daunting task. In fact, the pipeline run dry ~40 years ago ([54](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B54)). In addition, challenging logistics and high costs of large clinical trials make them nearly impossible to bring to market. Even if successful, the clinical utility of antibiotics will decline as resistance to them inevitably rises ([55](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B55)). Improving hygiene and the correct use of antibiotics while expanding their access in low- and middle-income countries are important tools to limit the burden of AMR, despite the fact these measures alone are not enough ([50](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B50)). Hence, vaccines may become a valuable and effective weapon to fight AMR. An important aspect is that resistance mechanisms are of less concern in vaccination. As reported above the mechanisms of resistance to antibiotics are mediated by the generation of spontaneous mutations or the acquisition of mobile genetic element by HGT. These mechanisms confer to bacteria the ability to tackle the killing effect of a drug and survive. Antibiotics are therapeutic measures since generally prescribed after the settling down of an infection when hundreds of millions of bacteria are infecting the body. On the contrary, vaccines are designed to prevent diseases. Their prophylactic use allows the host to build an immune response before encountering the pathogen or even at the beginning of an infection when only a few hundred or thousands bacteria are present. As the occurrence of resistance mechanisms can stochastically arise among billions of bacteria, it is evident that this is less likely to occur following vaccination. Furthermore, most antibiotics have a single target while vaccines have multiple targets inducing host-specific antibody and/or T cell responses. Even in this case, more mutations are likely needed to confer resistance to vaccines making the development of microbial resistance even harder ([56](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B56), [57](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B57)). Therefore, vaccines can be effective against antimicrobial resistance in different ways:

(I) By lowering the inappropriate use of antimicrobial compounds. Perhaps counterintuitive is the evidence that viral vaccines are also very effective in reducing AMR. For instance, vaccines against influenza virus reduce the incidence of fever and sickness which affect a significant proportion of community-dwelling elderly population each year in the US ([58](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B58)). By preventing a proportion of these cases, vaccines can reduce both, the inappropriate use of antibiotics prescribed in case of viral infections and the need of antibiotic treatment to cure secondary bacterial infections ([59](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B59)).

(II) By reducing the insurgence of resistant serotypes. For example, the pneumococcal polysaccharide conjugate vaccines had an effect of direct protection of infants and of herd immunity in adults initially not targeted by routine immunization ([60](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B60)). Remarkably, also the antibiotic prescriptions and the prevalence of antibiotic resistant strains decreased. In the 1990s, before the introduction of a 7-valent pneumococcal conjugate vaccine (PCV7), more than 63,000 cases of invasive pneumococcal disease occurred each year in the US. Between 2000 and 2004, a 57% reduction in the incidence of penicillin-non-susceptible invasive pneumococcal disease (IPD) and 84% reduction in the rate of multidrug-resistant strains were achieved. These data indicate that vaccination is effective, regardless of the bacterial resistance phenotype. However, the universal use of PCV-7 led to increased prevalence of serotype 19A, a non-vaccine serotype with high rate of penicillin resistance ([61](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B61)). Introduction of 13-valent PCV in 2010, which contains 6 additional serotypes, including 19A, further reduced the incidence of IPD and of antibiotic-resistant pneumococci. Nevertheless, the risk of the evolution of AMR in pneumococcal serotypes not contained in the vaccine is still high. In this context, the design of a vaccine aimed to specifically target resistance determinants or resistant strains is highly valuable ([62](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B62)).

(III) By reducing infection rate of resistant strains in closely related species. Between 2004 and 2008, in New Zealand, 1 million people were vaccinated with the Outer Membrane Vesicles (OMV) based vaccine (MeNZB) to fight a meningococcus B outbreak. A retrospective case-control study has shown that the immunization with MeNZB resulted in 31% reduction of Neisseria gonorrhoeae infection ([63](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B63)). N. gonorrhoeae is one of the most common bacterial sexually transmitted diseases (STDs), with ~100 million cases worldwide. One of the main concerns of gonococcal infection is the emergence of strains resistant to nearly all classes of antibiotics including the expanded-spectrum cephalosporins and the lack of an effective vaccine. Hence, N. gonorrhoeae infections are becoming as the most prevalent and difficult to treat. Despite causing very different diseases, N. meningitidis and N. gonorrhoeae share 80–90% nucleotide identity at the genome level. Therefore, it is reasonable to assume that antibodies against common antigens could induce a cross-protective effect ([64](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B64)). Bioinformatic analyses has revealed that 57 OMPs are of N. meningitidis are conserved also in 970 N. gonorrhoeae strains isolated in US ([65](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B65)). Among them, PilQ, Omp85 (BamA), NspA, MtrE, MetQ, and LbpA show 93% amino acid sequence similarity to N. gonorrhoeae, suggesting their potential contribution to cross-protection ([64](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B64)). Further investigations are needed to evaluate the effectiveness of MenB-4C vaccine in preventing gonococcal infections ([66](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B66)).

(IV) By directly targeting antibiotic resistant microorganisms. Although many different **vaccine formulations have been proposed** to prevent infection by antimicrobial resistant pathogens, (such as S. aureus, E. coli, Clostridium difficile etc.) no successful phase III clinical trial data have been published yet ([67](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B67), [68](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B68)). A possible reason for the failure in developing vaccines against these pathogens are the multiple virulence mechanisms a vaccine should target, as well as the absence of animal models that are representative of human diseases ([69](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B69), [70](https://www.frontiersin.org/articles/10.3389/fimmu.2020.01048/full#B70)). A better understanding of host-pathogen interactions such as immune evasion, and increased knowledge in the epidemiology and variability of the main antigens, could help in the development of novel effective vaccine. However, new incentives may be necessary for the development of novel vaccines leading to the refinement of health care system against AMR infections and eventually saving millions of lives.

#### Infectious diseases don’t cause extinction

Owen Cotton-Barratt 17, et al, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39