### PTX

#### Biden’s infrastructure bill will pass through reconciliation but absolute Dem Unity is key.

* Turns Structural Violence

Pramuk and Franck 8-25 Jacob Pramuk and Thomas Franck 8-25-2021 "Here’s what happens next as Democrats try to pass Biden’s multitrillion-dollar economic plans" <https://www.cnbc.com/2021/08/25/what-happens-next-with-biden-infrastructure-budget-bills-in-congress.html> (Staff Reporter at CNBC)//Elmer

WASHINGTON — **House Democrats just patched up a party fracture** **to take a critical step forward with a mammoth economic agenda**. But the **path ahead could get trickier** as party leaders try to thread a legislative needle to pass more than $4 trillion in new spending. **In** the **coming weeks**, **Democrats** **aim to approve** a $1 trillion bipartisan **infrastructure** plan and up to $3.5 trillion in investments in social programs. Passing both **will require a heavy lift**, as leaders will need to **satisfy** **competing demands of centrists** wary of spending **and progressives** who want to reimagine government’s role in American households. The House is leaving Washington **until Sept. 20** after taking key steps toward pushing through the sprawling economic plans. The chamber on Tuesday approved a $3.5 trillion budget resolution and advanced the infrastructure bill, as House Speaker Nancy Pelosi, D-Calif., promised centrist Democrats to take up the bipartisan plan by Sept. 27. The Senate already passed the infrastructure legislation, so **a final House vote would send it to Biden’s desk for his** signature. Now that both chambers have passed the budget measure, **Democrats can move without Republicans** to push through their spending plan **via reconciliation**. Party leaders want committees to write their pieces of the bill by Sept. 15 before budget committees package them into one massive measure that can move through Congress. Committees could start marking up legislation in early September. Party leaders **face a challenge** in coming up with a bill that will satisfy centrists who want to trim back the $3.5 trillion price tag and progressives who consider it the minimum Congress should spend. As **one defection in the Senate** — **and four in the House** — **would sink legislation,** **Democrats have to satisfy a diverse range of views** to pass their agenda. “We write a bill with the Senate because it’s no use doing a bill that’s not going to pass the Senate, in the interest of getting things done,” Pelosi told reporters on Wednesday. Given the magnitude of the legislation, passing it quickly could prove difficult. To appease congressional progressives who have prioritized passage of the budget bill, Democrats could move to pass both proposals at about the same time. While Pelosi gave a Sept. 27 target date to approve the infrastructure plan, the commitment is not binding. Still, she noted Wednesday that Congress needs to pass the bill before surface transportation spending authorization expires Sept. 30. “We have long had an eye to having the infrastructure bill on the President’s desk by the October 1, the effective date of the legislation,” she wrote in a separate letter to Democrats on Wednesday. Democrats say the bills combined will provide a jolt to the economy and a lifeline for households. Supporters of the Democratic spending plan, including Pelosi and Senate Budget Committee Chair Bernie Sanders, I-Vt., have cast it as the biggest expansion of the U.S. social safety net in decades. “This is a truly historic opportunity to pass the **most transformative** and consequential **legislation for families** in a century, and will stand alongside the New Deal and Great Society as pillars of **economic security**,” Pelosi wrote to colleagues Wednesday. The plan would **expand Medicare**, **paid leave** and child care, extend enhanced household tax credits and encourage **green energy adoption**, **while hiking taxes on corporations and the wealthy**. Democrats hope to sell a wave of new support for families as they campaign to keep control of Congress in next year’s midterms. Those elections, though, have helped to generate staunch opposition on the other side of the aisle. The GOP has cited the trillions in new spending and the proposed reversal of some of its 2017 tax cuts in trying to take down the Democratic budget bill. Republicans and some Democrats have in recent weeks said that another $4.5 trillion in fiscal stimulus could not only boost economic growth but have the adverse effect of fueling inflation.

#### Pharma backlashes to the Plan – they’re aggressive lobbyists and will do anything to preserve patent rights.

* Turns Case – Waters down the Plan due to lobbying
* Optional Card – still thinking on if its necessary [note from Elmer]

Huetteman 19 Emmarie Huetteman 2-26-2019 “Senators Who Led Pharma-Friendly Patent Reform Also Prime Targets For Pharma Cash” <https://khn.org/news/senators-who-led-pharma-friendly-patent-reform-also-prime-targets-for-pharma-cash/> (former NYT Congressional correspondent with an MA in public affairs reporting from Northwestern University’s Medill School)//Elmer

Early last year, as lawmakers vowed to curb rising drug prices, Sen. Thom Tillis was named chairman of the Senate Judiciary Committee’s subcommittee on intellectual property rights, a committee that had not met since 2007. As the new gatekeeper for laws and oversight of the nation’s patent system, the North Carolina Republican signaled he was determined to make it easier for American businesses to benefit from it — a welcome message to the drugmakers who already leverage patents to block competitors and keep prices high. Less than three weeks after introducing a bill that would make it harder for generic drugmakers to compete with patent-holding drugmakers, Tillis opened the subcommittee’s first meeting on Feb. 26, 2019, with his own vow. “From the United States Patent and Trademark Office to the State Department’s Office of Intellectual Property Enforcement, no department or bureau is too big or too small for this subcommittee to take interest,” he said. “And we will.” In the months that followed, tens of thousands of dollars flowed from pharmaceutical companies toward his campaign, as well as to the campaigns of other subcommittee members — including some who promised to stop drugmakers from playing money-making games with the patent system, like Sen. John Cornyn (R-Texas). Tillis received more than $156,000 from political action committees tied to drug manufacturers in 2019, more than any other member of Congress, a new analysis of KHN’s Pharma Cash to Congress database shows. Sen. Chris Coons (D-Del.), the top Democrat on the subcommittee who worked side by side with Tillis, received more than $124,000 in drugmaker contributions last year, making him the No. 3 recipient in Congress. No. 2 was Sen. Mitch McConnell (R-Ky.), who took in about $139,000. As the Senate majority leader, he controls what legislation gets voted on by the Senate. Neither Tillis nor Coons sits on the Senate committees that introduced legislation last year to lower drug prices through methods like capping price increases to the rate of inflation. Of the four senators who drafted those bills, none received more than $76,000 from drug manufacturers in 2019. Tillis and Coons spent much of last year working on significant legislation that would expand the range of items eligible to be patented — a change that some experts say would make it easier for companies developing medical tests and treatments to own things that aren’t traditionally inventions, like genetic code. They have not yet officially introduced a bill. As obscure as patents might seem in an era of public **outrage** **over** drug prices, the fact that **drugmakers** gave most **to** the **lawmakers working to change the patent system** belies how important securing **the exclusive right to market a drug, and keep competitors at bay, is to their bottom line**. “**Pharma will fight to the death to preserve patent rights**,” said Robin Feldman, a professor at the UC Hastings College of the Law in San Francisco who is an expert in intellectual property rights and drug pricing. “Strong patent rights are central to the games drug companies play to extend their monopolies and keep prices high.” Campaign contributions, closely tracked by the Federal Election Commission, are among the few windows into how much money flows from the political groups of drugmakers and other companies to the lawmakers and their campaigns. Private companies generally give money to members of Congress to encourage them to listen to the companies, typically through lobbyists, whose activities are difficult to track. They may also communicate through so-called dark money groups, which are not required to report who gives them money. Over the past 10 years, the **pharmaceutical industry** has **spent** about $**233 million per year on lobbying**, according to a new study published in JAMA Internal Medicine. That is more than any other industry, including the oil and gas industry. Why Patents Matter Developing and testing a new drug, and gaining approval from the Food and Drug Administration, can take years and cost hundreds of millions of dollars. Drugmakers are generally granted a six- or seven-year exclusivity period to recoup their investments. But drugmakers have found ways to extend that period of exclusivity, sometimes accumulating hundreds of patents on the same drug and blocking competition for decades. One method is to patent many inventions beyond a drug’s active ingredient, such as patenting the injection device that administers the drug. Keeping that arrangement intact, or expanding what can be patented, is where lawmakers come in. Lawmakers Dig In Tillis’ home state of North Carolina is also home to three major research universities and, not coincidentally, multiple drugmakers’ headquarters, factories and other facilities. From his swearing-in in 2015 to the end of 2018, Tillis received about $160,000 from drugmakers based there or beyond. He almost matched that four-year total in 2019 alone, in the midst of a difficult reelection campaign to be decided this fall. He has raised nearly $10 million for his campaign, with lobbyists among his biggest contributors, according to OpenSecrets. Daniel Keylin, a spokesperson for Tillis, said Tillis and Coons, the subcommittee’s top Democrat, are working to overhaul the country’s “antiquated intellectual property laws.” Keylin said the bipartisan effort protects the development and access to affordable, lifesaving medication for patients,” adding: “No contribution has any impact on how [Tillis] votes or legislates.” Tillis signaled his openness to the drug industry early on. The day before being named chairman, he reintroduced a bill that would limit the options generic drugmakers have to challenge allegedly invalid patents, effectively helping brand-name drugmakers protect their monopolies. Former Sen. Orrin Hatch (R-Utah), whose warm relationship with the drug industry was well-known, had introduced the legislation, the Hatch-Waxman Integrity Act, just days before his retirement in 2018. At his subcommittee’s first hearing, Tillis said the members would rely on testimony from private businesses to guide them. He promised to hold hearings on patent eligibility standards and “reforms to the Patent Trial and Appeal Board.” In practice, the Hatch-Waxman Integrity Act would require generics makers challenging another drugmaker’s patent to either take their claim to the Patent Trial and Appeal Board, which acts as a sort of cheaper, faster quality check to catch bad patents, or file a lawsuit. A study released last year found that, since Congress created the Patent Trial and Appeal Board in 2011, it has narrowed or overturned about 51% of the drugmaker patents that generics makers have challenged. Feldman said the drug industry “went berserk” over the number of patents the board changed and has been eager to limit use of the board as much as possible. Patent reviewers are often stretched thin and sometimes make mistakes, said Aaron Kesselheim, a Harvard Medical School professor who is an expert in intellectual property rights and drug development. Limiting the ways to challenge patents, as Tillis’ bill would, does not strengthen the patent system, he said. “You want overlapping oversight for a system that is as important and fundamental as this system is,” he said. As promised, Tillis and Coons also spent much of the year working on so-called Section 101 reform regarding what is eligible to be patented — “a very major change” that “would overturn more than a century of Supreme Court law,” Feldman said. Sean Coit, Coons’ spokesperson, said lowering drug prices is one of the senator’s top priorities and pointed to Coon’s support for legislation the pharmaceutical industry opposes. “One of the reasons Senator Coons is leading efforts in Congress to fix our broken patent system is so that life-saving medicines can actually be developed and produced at affordable prices for every American,” Coit wrote in an email, adding that “his work on Section 101 reform has brought together advocates from across the spectrum, including academics and health experts.” In August, when much of Capitol Hill had emptied for summer recess, Tillis and Coons held closed-door meetings to preview their legislation to stakeholders, including the Pharmaceutical Research and Manufacturers of America, or PhRMA, the brand-name drug industry’s lobbying group. “We regularly engage with members of Congress in both parties to advance practical policy solutions that will lower medicine costs for patients,” said Holly Campbell, a PhRMA spokesperson. Neither proposal has received a public hearing. In the 30 days before Tillis and Coons were named leaders of the revived subcommittee, drug manufacturers gave them $21,000 from their political action committees. In the 30 days following that first hearing, Tillis and Coons received $60,000. Among their donors were PhRMA; the Biotechnology Innovation Organization, the biotech lobbying group; and five of the seven drugmakers whose executives — as Tillis laid out a pharma-friendly agenda for his new subcommittee — were getting chewed out by senators in a different hearing room over patent abuse. Cornyn Goes After Patent Abuse Richard Gonzalez, chief executive of AbbVie Inc., the company known for its top-selling drug, Humira, had spent the morning sitting stone-faced before the Senate Finance Committee as, one after another, senators excoriated him and six other executives of brand-name drug manufacturers over how they price their products. Cornyn brought up AbbVie’s more than 130 patents on Humira. Hadn’t the company blocked its competition? Cornyn asked Gonzalez, who carefully explained how AbbVie’s lawsuit against a generics competitor and subsequent licensing deal was not what he would describe as anti-competitive behavior. “I realize it may not be popular,” Gonzalez said. “But I think it is a reasonable balance.” A minute later, Cornyn turned to Sen. Chuck Grassley (R-Iowa), who, like Cornyn, was also a member of the revived intellectual property subcommittee. This is worth looking into with “our Judiciary Committee authorities as well,” Cornyn said, effectively threatening legislation on patent abuse. The next day, Mylan, one of the largest producers of generic drugs, gave Cornyn $5,000, FEC records show. The company had not donated to Cornyn in years. By midsummer, every drug company that sent an executive to that hearing had given money to Cornyn, including AbbVie. Cornyn, who faces perhaps the most difficult reelection fight of his career this fall, ranks No. 6 among members of Congress in drugmaker PAC contributions last year, KHN’s analysis shows. He received about $104,000. Cornyn has received about $708,500 from drugmakers since 2007, KHN’s database shows. According to OpenSecrets, he has raised more than $17 million for this year’s reelection campaign. Cornyn’s office declined to comment. On May 9, Cornyn and Sen. Richard Blumenthal (D-Conn.) introduced the **Affordable Prescriptions for Patients Act,** which proposed to define two tactics used by drug companies to make it easier for the Federal Trade Commission to **prosecute** them: “**product-hopping**,” when drugmakers withdraw older versions of their drugs from the market to push patients toward newer, more expensive ones, and “**patent-thicketing**,” when drugmakers amass a series of patents to drag out their exclusivity and slow rival generics makers, who must challenge those patents to enter the market once the initial exclusivity ends. **PhRMA opposed the bill.** **The next day, it gave Cornyn $1,000**. Cornyn and Blumenthal’s bill would have been “very tough on the techniques that pharmaceutical companies use to extend patent protections and to keep prices high,” Feldman said. “The **pharmaceutical industry lobbied tooth and nail against it**,” she said. “And **when the bill finally came** out of committee, the strongest provisions — the **patent-thicketing provisions — had been stripped**.” In the months after the bill cleared committee and waited to be taken up by the Senate, Cornyn blamed Senate Democrats for blocking the bill while trying to secure votes on legislation with more direct controls on drug prices. The Senate has not voted on the bill.

#### They choose Infrastructure as backlash – they bill costs Pharma millions – lobbyists can derail the Agenda.

Brennan 8-2 Zachary Brennan 8-2-2021 "How the biopharma industry is helping to pay for the bipartisan infrastructure bill" <https://endpts.com/how-the-biopharma-industry-is-helping-to-pay-for-the-bipartisan-infrastructure-bill/> (Senior Editor at Endpoint News)//Elmer

Senators on Sunday finalized the text of **a massive, bipartisan infrastructure bill** that contains little **that might** **impact the biopharma industry** other than two ways the legislators are planning to pay for the $1.2 trillion deal. On the one hand, senators are **seeking to** further **delay** a **Trump-era Medicare** Part D **rule** **related to drug rebates**, this time until 2026. Senators claim the rule could end up saving about $49 billion (and that number increased this week to $51 billion), but the PBM industry has attacked it as it would remove rebates from a safe harbor that provides protection from federal anti-kickback laws. The **pharmaceutical industry**, however, is in favor of the rule and **opposes this latest delay** as it continues to point its finger at the PBM industry for the rising cost of out-of-pocket expenses. Debra DeShong, EVP of public affairs at PhRMA, said via email: Despite railing against high drug costs on the campaign trail, lawmakers are threatening to gut a rule that would provide patients meaningful relief at the pharmacy. If it is included in the infrastructure package, this proposal will provide health insurers and drug middlemen a windfall and turn Medicare into a piggybank to fund projects that have nothing to do with lowering out-of-pocket costs for medicines. This would be an unconscionable move that robs patients of the prescription drug savings they deserve to help fill potholes and fund other infrastructure projects. The **other provision** **in the infrastructure bill**, which is estimated to save about $3 billion, **would save money for Medicare** **on discarded medications** from large, single-use drug vials. **Manufacturers will be required to pay refunds** for such discarded drugs, and each manufacturer will be subject to periodic audits on the refunds issued. If manufacturers don’t comply, HHS can fine them the refund amount that they would have paid plus 25%. Drugs that will be excluded from these refund payments include radiopharmaceuticals or imaging agents, as well as those that require filtration during the drug preparation process. So do these two pay-fors mean that the pharma industry is getting off without any serious drug pricing reforms? Not quite, according to Alex Lawson, executive director of Social Security Works. Lawson told Endpoints News in an interview that he still fully expects major drug pricing reforms to make their way through Congress between now and the end of September as Sen. Ron Wyden (D-OR) refines his plan, part of an early fall spending package. Senate Majority Leader Chuck Schumer has promised both the infrastructure and spending package will pass before the Senate leaves for August recess. At the very least in terms of drug pricing provisions, expect to see a combination of the Wyden bill he co-wrote with Sen. Chuck Grassley (R-IA) last year, alongside further Medicare negotiations, Lawson said. “Talk is still optimistic,” Lawson said on the prospects of a drug pricing deal getting done, while noting that **pharmaceutical** company **lobbyists** are **swarming Capitol Hill** at the moment because of **not just drug pricing plans**, but **tax provisions** and the **TRIPS waiver** that the biopharma industry is worried about. “These are **challenges to their entire existence**, **so they’re willing to protect them at any cost**,” Lawson said, noting the target for drug pricing is about $500 billion in savings. As the House has jetted off to enjoy what might be an abbreviated summer recess, the Senate has just this week to get its work done, unless its recess is cut short too. “There’s a **real possibility** that **the whole thing blows up** and we get nothing on either side,” Lawson said.

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

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

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

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

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

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

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

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

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

#### Grid collapse causes extinction.

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

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

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

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

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

#### Turns case—more disease and no innovagtion

### PIC

Except the us ought to

, Resolved: The member nations of the

World Trade Organization ought to reduce intellectual property protections for

Medicines

Takes ought 1AC argument about why we defend all IP=less ethical—that’s incorrect

### 1NC Shell

#### Vulnerabilities exposed by COVID have invigorated availability and interest in bioterror, but technical challenges remain as barriers to acquisition.

Koblentz and Kiesel 7/14 [Gregory D. Koblentz (Deputy Director of the Biodefense Graduate Program and Assistant Professor of Government and Politics in the Department of Public and International Affairs at George Mason University) and Stevie Kiesel (Biodefense PhD Student, Schar School of Policy and Government, George Mason University). “The COVID-19 Pandemic: Catalyst or Complication for Bioterrorism?”. Studies in Conflict & Terrorism. Published online 14 Jul 2021. Accessed 7/22/21. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2021.1944023?journalCode=uter20> //Xu]

Since COVID-19 was declared a pandemic in March 2020, there has been no major bioterrorist incident that challenges or validates the core beliefs of the optimists, pessimists, or pragmatists. Extremists with violent apocalyptic or accelerationist ideologies—chiefly jihadists and far-right extremists—have sought to capitalize on the pandemic, but they still rely on conventional weapons. Based on available open-source information, terrorist interest in weaponizing SARS-CoV-2 seems limited. While some individuals and groups who subscribe to violent apocalyptic or accelerationist ideologies have shown some interest in crudely spreading the virus, most terrorists have sought to exploit the conditions the pandemic created rather than the virus itself. An increase in the risk of bioterrorism cannot be completely discounted as the equipment, knowledge, and expertise to work with high-risk pathogens is increasingly available and there are a small number of groups with the ideologies and objectives consistent with the use of biological weapons. Still, important technical barriers to acquiring and using a biological weapon capable of causing mass casualties, even far below the effects of a pandemic pathogen, will remain even after the pandemic is contained. While COVID-19 graphically demonstrated the vulnerability of modern societies to infectious diseases, the lessons learned from this experience, if properly implemented, should significantly improve the capability of governments around the world to detect and respond to future pandemics as well as deliberate disease outbreaks. Counterterrorism and biodefense efforts should not be dictated by the latest “‘risk of the month’ policies crafted in the wake of visible or highly publicized events.”117 Instead, strategies for reducing the likelihood and consequences of bioterrorism in the wake of the COVID-19 pandemic should be based on a realistic appraisal of the risk and investments should be optimized to strengthen preparedness against the full spectrum of biological threats.

#### IP protections are the only limit on proliferating dual-use biotech – losing patents puts financial pressure on companies to outsource R&D, which skyrockets bioterror acquisition.

Finlay 10 [Brian Finlay (President and Chief Executive Officer of the Stimson Center, M.A. from the Norman Patterson School of International Affairs at Carleton University, a graduate diploma from the School of Advanced International Studies, the Johns Hopkins University and an honors B.A. from Western University in Canada). “The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”. The Fletcher Forum of World Affairs. Vol. 34, No. 2 (Summer 2010), pp. 51-64. <https://www.jstor.org/stable/45289504?seq=1#metadata_info_tab_contents> //Xu]

Until recently, these investment risks were frequently mitigated by income generated from past drug development successes. In most markets, that income was guaranteed by strict patent protections that closed the window to outside competition for a set period of time. More recently, however, the uncertainty of R&D investments has been complicated not only by the global economic downturn, but more importantly by looming patent expirations that will open many of big pharma's patent-protected drugs to generic competition. Between 2007 and 2012, more than three dozen drugs will lose patent protection, removing an estimated $67 billion from big pharma's annual sales.33 With existing drug development pipelines unable to fill the gaps, biopharmaceutical companies are under intense pressure not only to cut costs - which would provide only temporary relief to the bottom line - but also to rapidly replenish their development pipelines. Some industry analysts have described this "perfect storm" as an "existential" moment for big pharma.34 Many pharmaceutical companies have approached this challenge by accelerating and widening the outsourcing and off-shoring of both R&D and manufacturing, and by aggressively buying promising assets from small biotech companies through acquisitions and strategic alliances. Interestingly, these partnerships are less frequently linked with American or even Western-owned and-operated companies than in the past. Many pharmaceutical giants like Indiana-based Eli Lilly are turning to alliances with firms in Asia and elsewhere around the world, outsourcing key technical operations. Instead of functioning as fully integrated firms, big pharma companies have found value in networked relationships with independent small to large firms, universities, and non-profit biotechnology laboratories around the globe.35 The net result has accelerated technology proliferation - for both beneficial and nefarious uses - far beyond the traditional hubs for biotech innovation. Pharma's increasingly desperate search to seed and ultimately acquire innovative new biotechnologies means that foreign (non- Western) markets are pulling ahead in biotech innovation. Indeed, the quantity of biotech companies outside the United States has grown remarkably in recent years: in Israel, the number grew from 30 in 1990 to about 160 in 2000; in Brazil, from 76 in 1993 to 354 in 2001; and remarkably, in South Korea, from one in 2000 to 23 in 2003. 36 More generally, the Asia-Pacific region has emerged as one of the world s fastest-growing biotechnology hubs, with the growth of publicly traded companies handily outpacing growth in the United States and Europe over recent years.37 As fruitful partnerships lead big pharma to increasingly generate resources, technologies, and knowledge, these capacities spin off new competitor firms in a self-executing multiplier effect. With the number of facilities and highly trained individuals increasing, the likelihood of a serious biological accident or nefarious incident will similarly rise, which will be particularly risky when dual-use technologies are introduced into insufficiently regulated markets. CONCLUSIONs In statements, U.S. officials continue to cite several countries believed to have or to be pursuing a biological weapons capability.38 But globalization exports the challenge of bioproliferation far beyond these geographic boundaries and transcends multiple societal layers well beyond government actors. As a result, it is increasingly clear that states no longer have a monopoly on dual-use biological R&D. Recent evidence suggests a growing threat of terrorist acquisition of biological weapons. As technological advancement in the life sciences is progressively pushed into countries of the Global South, some of which are also potential hotbeds for terrorist activity, the nexus of science and terrorism becomes especially acute. While far from perfect, the current system of stringent controls levied by Western governments over the biopharmaceutical sector has proven remarkably effective, especially given the diffusion of technologies and the ease of their redirection for hostile purposes. As the biotech revolution continues to widen, however, advanced industrialized governments are increasingly playing catch-up with changing technological realities. As these technologies proliferate, security analysts have become uneasy with the lack of controls in many states. The dearth of legal controls, the lack of rigor in their enforcement, and the growth in private-actor involvement in dual-use activities has sobering implications for global security.

#### COVID resulted in mass on-shoring of R&D – only price incentives can convince them to stay.

Mullin 20 Rick Mullin 4-27-2020 "COVID-19 is reshaping the pharmaceutical supply chain" <https://cen.acs.org/business/outsourcing/COVID-19-reshaping-pharmaceutical-supply/98/i16> (BA English Literature, Drew University, 1980. Business journalist covering engergy, chemicals, pharmaceuticals, and information technology for various publications including Chemical Week since 1983)//Elmer

“We do not pretend to have a unique explanation to the potential shortage of medicine,” Perfetti says. “But every day we are facing consequences of unavailability of starting materials from not only China but the Eastern part of the world.” This issue was brought in sharp focus with the closure of plants—and even entire industrial parks—**in China’s 2017 environmental crackdown**, he says. Industry executives acknowledge the irony that the very companies that spent the past 20 years outsourcing the supply of chemicals and APIs to China are now **asking for support to bring it back**. But they dismiss the criticism, responding that capitalist industries have to compete globally on price. Their request for support, they say, aims to establish a more level, competitive playing field. “We have to deal with the reality that pricing plays an important role in the availability of drugs, primarily if they are generic,” the BPTF’s DiLoreto says. “We have to find a way to provide **additional incentives for manufacturing to come back to the US**. Whatever those financial incentives are, the government will have to start taking it seriously.”

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public **again and again.** It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

### Case

Good life means extinction neessecaryi outweighs bc its premature death that can be avoided

#### Waivers fail

Ana Santos Rutschman and Julia Barnes-Weise, 5-5-2021, (Assistant Professor of Law at Saint Louis University School of Law & Executive Director of the Global Healthcare Innovation Alliance Accelerator.,"The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal," Bill of Health, <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/>) Ngong

Waiver proposals have attracted the support of prominent names in public health. Dr. Tedros Adhanom Ghebreyesus, the Director-General of the World Health Organization, endorsed patent waivers as a tool to address the current vaccine scarcity problem in an article titled Waive Covid Vaccine Patents to Put World on “War Footing.” Others — including, most recently, Dr. Anthony Fauci — have been critical of waiver proposals.

In this piece, we explain the mechanics of patent waivers and argue that waivers alone are the wrong policy tool in the context of the COVID-19 pandemic. We agree with supporters of the waivers in their ultimate goal — that of scaling up the manufacturing of COVID-19 vaccines, and then distributing them according to more equitable models than the ones adopted thus far. However, we doubt that the particular types of goods at stake here can be easily replicated and produced in substantially larger quantities simply through a waiver of intellectual property rights.

Vaccines and Intellectual Property: The Informational Function of Patents

**Intellectual property rights, and especially patent rights, are governmental grants embedded into national legal systems across the world for utilitarian reasons: longstanding intellectual property theory and policy rests on the idea that the prospect of obtaining a patent will incentivize players in research and development (R&D) to invest in areas that might be otherwise underfunded.** While a vast body of research demonstrates that this utilitarian approach is not universally applicable to all types of goods (and especially to certain types of health goods), it remains the main driver of modern patent regimes.

In exchange for getting this particular type of intellectual property rights, patentees disclose critical information about the invention covered by the patent. On the one hand, a patent gives the patentee lead time on the market for a relatively lengthy period of time (formally 20 years, in practice less than that, especially for products like vaccines that must undergo review and approval by drug regulators). On the other hand, by requiring that the patent applicant share information about the invention that is subsequently published by the patent office, the patent system promotes the flow of scientific and technical information that can be used by other innovators in the field.

It is well known by now that existing COVID-19 vaccines — including the ones that represent the application of a new type of vaccine technology, mRNA vaccines — are covered by multiple layers of patent rights. Proponents of a patent waiver for COVID-19 vaccine emphasize the problems created by the exclusivity created by intellectual property rights, and they are correct in their diagnosis.

Having adopted a legal regime that grants patent rights to any inventions meeting the substantive criteria set forth in international and national patent laws (a threshold that many of the current patent applications on COVID-19 will, in all likelihood, clear), we now face the logical consequences of such a regime: absent some kind of intervention, vaccine patent holders have the ability to refuse licensing their technology to others, even against a backdrop of vaccine scarcity.

A waiver is thus portrayed as a mechanism to overcome this exclusionary ability that traditionally inheres to a patent: in light of the tragic proportions of our shared public health problem, let us do away with the exclusionary right for a certain period of time and other companies will be able to 1) replicate existing vaccines and 2) manufacture at scale so that considerably more doses of vaccine will start flowing towards populations in the Global South.

These two propositions would be accurate if the information disclosed in patents were enough to increase the supply of COVID-19 vaccines. Unfortunately, it is not.

A Mismatch Problem: The Informational Limitations of Patents

Patents cover both processes and products. In the case of vaccines, the former category includes methods of vaccine production, while the latter covers a myriad of vaccine components, from antigens (substances used to elicit a reaction from the immune system), to inactive ingredients, such as adjuvants (substances that help enhance the immune response, like oil-in-water emulsions) and stabilizers (substances that help maintain the potency of the vaccine, like sugars), to the vaccine delivery mechanism.

In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem.

First, we are still left with a significant informational problem: as many commentators have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine.

From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere.

Second, even if all types of legal restrictions on the use of vaccine technology were lifted — or had never existed in the first place — there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals. We have long faced a global vaccine manufacturing problem that will not be fully resolved during the current pandemic. In the case of vaccines that need to be kept at ultra-cold temperatures, these problems intensify.

One of us (Barnes-Weise) has been involved in the contractual negotiations for the development, manufacturing and transfer of technology related to COVID-19 vaccines. In addition to the informational gaps described above, COVID-19 vaccine manufacturers are most concerned about how well the recipients of the technology transfer will understand and be able to implement such knowledge in making vaccines of the necessary quality. Shortages do not merely affect materials necessary to manufacture vaccines and facilities adequate to manufacture the vaccines; they also affect the availability of personnel qualified to instruct the licensee and recipient of this information. Sending an employee of this caliber out of the original manufacturing site to a partner site risks reducing the capacity of the first site. And remote instruction, necessitated by the pandemic, has its own shortcomings.

In relation to the patents on the vaccines themselves, most of the concerns that the vaccine manufacturers express are around the protection of their vaccine platforms for the purposes of making future or non-COVID-19 vaccines. Moderna shared information about its patents in summer 2020. The manufacturers, as evidenced by the number of licenses to manufacture granted to date, are eager to find partners with the capabilities to expand production. It is not to their benefit to produce an inadequate supply of a highly sought-after vaccine. However, even willingness to transfer patented vaccine technology has faced numerous practical hurdles to date: 1) infrastructural limitations; 2) scarcity of raw materials; 3) concerns about licensees having the ability to actually manufacture effective vaccines in light of the infrastructural and product scarcity, even in situations in which there might be no informational gaps.

A patent waiver would not address any of the practical concerns currently at the root of tech transfer negotiations involving COVID-19 vaccine technology. Compounding these problems is the fact that, should a waiver be issued, there is no legal mechanism that can compel the transfer of certain types of know-how or trade secrets should a company be unwilling to license its intellectual property — which, again, at this point in the pandemic, is not a problem we have observed.

Finally, it is important to keep in mind that a waiver would be temporary: supporters of current waiver proposals should consider what will happen once demand for vaccines begins diminishing and fewer manufacturers remain on the market. Moreover, they should consider the legal and practical uncertainty that a waiver would introduce, as it is unclear how technology transfer between companies would cease (or continue) once the waiver expires.

Vaccines and the Long-Term Intellectual Property Game: Why Waivers Are Not the Right Tool

Countries in the Global South have had to implement intellectual property regimes that largely codify the commercial interests of the Global North. It is in their best interest to use all legal and policy mechanisms available to minimize the skewed allocative effects produced by the current patent culture — especially when patent rights cover goods that are critically needed for public health reasons.

In the past, some of these countries have used legal tools in highly effective ways. The TRIPS Agreement — the main legal international intellectual property framework, now implemented by virtually all countries — allows for the compulsory licensing of patented products in situations that include public health crises such as a pandemic or epidemic. Compulsory licensing does not extinguish or suspend patent rights, but rather consists in the governmental granting of licenses to third parties against the wishes of the patent holder. The licensee is then able to use the patent-protected technology against the payment of a royalty.

Many countries in the Global South issued compulsory licenses throughout the first decade of the twenty-first century on drugs needed for the treatment of HIV/AIDS. Just to list a few examples, Malaysia issued a compulsory license in 2004 for HIV/AIDS drugs patented by the pharmaceutical companies GlaxoSmithKline and Bristol-Myers Squibb; Thailand issued a compulsory license in 2007 for an HIV/AIDS drug patented by Abbot. Several other lower-income countries resorted to this mechanism, succeeding in having these drugs produced and sold in their markets at low cost. Brazil famously and wisely used the threat of compulsory licensing as a bargaining tool when negotiating the price of an HIV/AIDS patented by Merck.

The critical difference between the compulsory licensing dynamics in the context of HIV/AIDS and the present situation is that compulsory licensing helped solve the problem faced by populations in these countries: critical drugs were being provided at unaffordable prices; compulsory licenses dislodged exclusivity problems; and third parties were able to manufacture the relevant drugs once a license was issued, bringing prices down.

Unlike vaccines, the drugs at stake then were much less difficult to replicate, and third parties availing themselves of a compulsory license faced no significant knowledge deficit. Moreover, there was sufficient production capacity and the necessary raw materials for these drugs to be produced and distributed. Compulsory licensing was thus the right tool for this particular public health problem.

By contrast, a waiver of COVID-19 vaccine patents is the wrong legal and policy tool because it does not address the lack of knowledge sharing nor the shortage of raw materials and manufacturing capacity. Furthermore, the use of a waiver is politically fraught — as was the use of compulsory licenses in the context of HIV/AIDS. We submit that battles of the political economy are best fought when prevailing on the use of a legal tool that actually solves the underlying practical problems. For the reasons stated above, that is not the case with waivers.

It can be appealing to see a patent waiver as an attractive short-term solution. Yet, even the short-term needs are too intense and the challenges too complex for waivers to fully address the infrastructural and knowledge gaps, as well as the additional problem of inequitable distribution of existing vaccines.

We Have Contractual and Infrastructural Problems, Not an Intellectual Property Problem

We agree that it is accurate to say that we have an intellectual property problem if talking about the patent system at a more fundamental level — as the main legal regime designed to encourage investment in biopharmaceutical R&D. Most vaccines needed for the prevention or response to epidemics and pandemic fare poorly under predominantly market-driven R&D funding models, as one of us (Rutschman) has discussed in other venues. In this specific sense, we may question the excessive reliance on current legal regimes designed to spur innovation, which subject vaccine R&D to the same utilitarian principles that apply to vastly different types of goods.

However, in a more immediate sense — and in the context of the COVID-19 pandemic — the real problems are infrastructural and contractual. It is imperative that we address the current limitations on vaccine production capacity ahead of future pandemics — a problem that several countries have already turned to by investing or planning to invest in the construction of infrastructure for vaccine manufacturing.

It is also imperative that, against the current backdrop of vaccine scarcity, we address the allocation problems that the world has experienced so far, which have resulted in most available doses being given to populations in the Global North. We regard this as a contractual problem: currently, there is no legal mechanism that prevents two parties — a country and a vaccine manufacturer — from subjecting negotiations involving pandemic vaccines to the same bargaining and contractual dynamics that govern the production and allocation of most other commodifiable goods.

Setting aside cases of voluntarism, there are no enforceable legal requirements compelling higher-income countries able to appropriate large amounts of vaccine doses to share them with other countries. This is a problem worth deep discussion ahead of the next pandemic.

But it also the area in which immediate policy efforts are presently best deployed. Instead of advocating for a waiver, countries in the Global South, international organizations, activists, commentators and other interested parties should concentrate their efforts on mitigating the unbridled effects of existing contractual frameworks by nudging governments in the Global North to adopt more equitable approaches to the global sharing of vaccine doses. And this is also an area in which the United States, with its regained commitment to international cooperation, should have started to lead by example earlier in the pandemic.

#### Takes out the two pronged approach

#### Global south cant develop vaccines

#### Us cant distribute all of them anyways

#### IP rights are key to ensure vaccines are high quality and pass regulatory institutions – that’s key to prevent vaccine hesitancy and scale up production.

Stevens, Philip, and Mark Schultz 1/14. “Why Intellectual Property Rights Matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19.” Geneva Network, 14 Jan. 2021, geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/. Philip Stevens in the Founder and Executive Director of Geneva Network. He is also a Senior Fellow at the Institute for Democracy and Economic Affairs, Malaysia.; Professor Mark F. Schultz is the Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law, the Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. He was a professor at Southern Illinois University School of Law for 16 years and was co-founder and a leader of the Center for Protection of Intellectual Property (CPIP) at George Mason University in Washington, D.C., where he remains a non-resident Senior Scholar. He also serves as a Senior Fellow of the Geneva Network. //sid

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to [The Lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext): “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

[John-Arne Røttingen](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext), chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, [he says](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext).

Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a [range of issues](https://www.statnews.com/2020/12/15/dont-repeat-mistakes-past-vaccine-supply-chains/) need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population.

The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official [estimate](https://www.ft.com/content/58b11945-71b1-4f96-b389-695e162642fb) of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic.

IP is part of the solution

Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s [BioKangtai](https://www.fiercepharma.com/manufacturing/astrazeneca-takes-covid-19-vaccine-to-china-biokangtai-deal-for-200m-dose-capacity-by) (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of [2 billion doses](https://www.fiercepharma.com/manufacturing/astrazeneca-takes-covid-19-vaccine-to-china-biokangtai-deal-for-200m-dose-capacity-by) by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other [Indian vaccine manufacturers](https://www.contractpharma.com/content-microsite/covid-19/2020-10-20/india-emerges-as-hot-spot-for-manufacturing-covid-19-vaccines). Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middle-income countries.

IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment.

Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The [Lancet Global Health](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(19)30266-9/fulltext#seccestitle150)concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear inter-company competition and economies of scale.

#### Generic companies are just incompetent – means even without patents, they wouldn’t be able to produce.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.

#### Pharma innovation is doing great now – answers all your warrants.

Lisa **Jarvis**, 1-17-20**20**, "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the past 3 years of approvals represent drug companies’ most productive period in more than 2 decades. Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of new molecular entities (NMEs), making up 67% of overall approvals in 2019, the list also includes several antibody-drug conjugates, an antisense oligonucleotide therapy, and a therapy based on RNA interference (RNAi). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

#### **Reducing IP protections chills future investment – even the perception of wavering commitment scares off companies.**

Grabowski et al. ’15 (Harry; Professor Emeritus of Economics at Duke, and a specialist in the intersection of the pharmaceutical industry and government regulation of business; February 2015; “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation”; Health Affairs; <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>; Accessed: 8-31-2021; AU)

Patents and other forms of **intellectual property** **protection** play **essential roles** in encouraging innovation in biopharmaceuticals. As part of the “21st Century Cures” initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand. We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting. We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances. Technological innovation is widely recognized as a key determinant of economic and public health progress. 1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is **long, costly, and risky**, and the costs of imitation are low. After a new drug has been approved and is being marketed, its **patents protect it** from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. **For firms** to have an **incentive** to **continue to invest** in innovative development efforts, they must have an **expectation** that they can **charge enough** during this period to **recoup** costs and make a profit. After a drug’s patent or patents expire, **generic rivals** can enter the market at **greatly reduced development cost** and prices, providing added consumer benefit but **eroding** the **innovator drug** company’s revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug’s marketing exclusivity while providing a regulatory framework for generic drug approval. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases. Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the “21st Century Cures” initiative, 3 following earlier recommendations by the President’s Council of Advisors on Science and Technology on responding to challenges in “propelling innovation in drug discovery, development, and evaluation.” 4 In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. We also review the R&D incentives that complement patents in certain circumstances. Finally, we consider the pros and cons of selected voluntary (“opt-in”) or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition. The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection **particularly important** to **innovation incentives** for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a **billion** dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the **few successful, on-market products** (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections** that allow marketing exclusivity, innovative firms would be **unlikely** to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, **they do not guarantee demand**, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an **essential role** in the economic “ecosystem” of **discovery and investment** that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the **strength of intellectual property protection** plays a **key role** in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### Prefer legal studies.

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

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product

once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.