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### 1

#### CP Text: Member nations of the World Trade Organization should create patent pool licensing platforms for genomic medicines.

#### Solves accessibility of medicines AND innovations

Their author Stramiello 18 [(Michael, PhD, an intellectual property litigation associate in Washington, DC. His practice focuses on the life sciences industry) “CRISPR: The New Frontier of Biotechnology Innovation” American Bar Association, Jan/Feb 2018. https://www.americanbar.org/groups/intellectual\_property\_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature/]//pranav

As CRISPR marches on, there may be an elegant solution for making it widely available without government intervention in licensing: patent pools. These joint licensing platforms enable owners to combine their IP rights into bundles that are made accessible, nonexclusively, to a broad range of users via a single transaction with predictable terms. As a result, licensors and licensees can concentrate on innovation and commercial development, respectively, while minimizing transaction costs and litigation risk.32 This model was popularized in the 1990s, when the consumer electronics industry adopted it to facilitate deployment of the MPEG-2 digital video standard, which has yielded about $5 trillion in worldwide product sales since 1997.33 A key coordinator of that effort, MPEG LA LLC, now invites CRISPR/Cas9 patent holders to participate in their own pool. MPEG LA has been gauging interest from CRISPR rights holders since at least April 2017.34 Broad and Rockefeller University announced that they had submitted nearly two dozen “key CRISPR-Cas9 patents,”35 from 10 families, “for evaluation of eligibility to participate in discussions facilitated by MPEG LA regarding creation of a CRISPR Joint Licensing Platform.”36 UC reportedly has no plans to follow suit, citing potential conflicts with its existing licenses.37 The effect that pooling would have on such arrangements may remain unclear until contributors finalize pool terms, which could take years. Early efforts might focus on pooling foundational patents, and there has also been speculation about specialized pools geared toward particular CRISPR applications (e.g., agriculture and industrial biotechnology).38 Pooling may prove to be more of a challenge with respect to human therapeutics, a field where rights holders typically expect exclusivity as a reward for their enormous investment in rigorous clinical trials.

### 2

#### **FDI is expected to recover but is tentative – uncertainties from pandemic and economic recovery**

UNCTAD 7/21, 6-21-2021, [United Nations Conference on Trade and Development "Global foreign direct investment set to partially recover in 2021 but uncertainty remains," UNCTAD, https://unctad.org/news/global-foreign-direct-investment-set-partially-recover-2021-uncertainty-remains]//anop

Looking ahead, global FDI flows are expected to bottom out in 2021 and recover some lost ground with an increase of 10% to 15% (Figure 2). “This would still leave FDI some 25% below the 2019 level. Current forecasts show a further increase in 2022 which, at the upper bound of projections, bring FDI back to the 2019 level,” said UNCTAD’s director of investment and enterprise, James Zhan. Figure 2 - Foreign direct investment outflows, top 20 home economies, 2017 and 2018 (Billions of dollars) Figure 2 - Foreign direct investment outflows Source: UNCTAD, World Investment Report 2021. Prospects are highly uncertain and will depend on, among other factors, the pace of economic recovery and the possibility of pandemic relapses, the potential impact of recovery spending packages on FDI, and policy pressures. The relatively modest recovery in global FDI projected for 2021 reflects lingering uncertainty about access to vaccines, the emergence of virus mutations and the reopening of economic sectors. “Increased expenditures on both fixed assets and intangibles will not translate directly into a rapid FDI rebound, as confirmed by the sharp contrast between rosy forecasts for capex and still-depressed greenfield project announcements,” Mr. Zhan said. The FDI recovery will be uneven. Developed economies are expected to drive global growth in FDI, both because of strong cross-border mergers and acquisitions (M&A) activity and large-scale public investment support. FDI inflows to Asia will remain resilient as the region has stood out as an attractive destination for international investment throughout the pandemic. A substantial recovery of FDI to Africa and to Latin America and the Caribbean is unlikely in the near term.

#### **The plan decreases foreign direct investment from negative signals – turns case**

Kogan 11, Lawrence A [Lawrence A. Kogan is founder and Managing Attorney of The Kogan Law Group, P.C., a New York City–based multidisciplinary professional services firm specialized in identifying and addressing emerging regulatory, policy and trade risks posed to multinational company assets, operations and supply-chains. (2011), "Commercial High Technology Innovations Face Uncertain Future Amid Emerging “BRICS” Compulsory Licensing and IT Interoperability Frameworks" San Diego International, https://digital.sandiego.edu/cgi/viewcontent.cgi?article=1091&context=ilj]//anop

Similarly, the enactment of national laws and regulations promoting the availability and flexible use by governments of a compulsory licensing mechanism as an exception or limitation to the patent right to secure foreign companies’ patented high technologies at less than their fair market value can increase economic risks and result in acts of regulatory arbitrage and protectionist opportunism by home country as well as foreign companies operating pursuant to divergent business models. The security of property rights has been placed into question where compulsory licenses have been issued or threatened against foreign patented high technologies. Studies have shown that a corresponding reduction in the flow of knowledge-based foreign direct investment (FDI) will follow.81 82 [T]he practice of compulsory licensing comes with a price: the temporary or permanent deprivation of some part of a patent owner’s right to exclude disrupts the investment-backed expectation of the property right. In the future, pharmaceutical companies and other industries dependent upon intellectual property rights may mistrust licensing nations’ promises to protect and enforce patent rights, not to mention copyrights, and trademarks. As a result, industries that find the security of property rights lacking in a given nation may avoid engaging in foreign direct investment with that nation. Because foreign direct investment (FDI) is a major potential source of economic growth for recipient nations, the loss of such investment resources arising from compulsory licensing practices could force developing nations to pay a particularly heavy cost for providing needed medicines for its citizens.83 While government patent policy by itself is an incomplete measurement of a country’s market and investment friendliness, it is generally agreed that such legal protections reflect a country’s interest in fostering business and technology development. Through effective deterrence of imitation, “patents reduce the costs of enforcing contracts and at the same time increase the expected returns on FDI and licensing, which will have a positive effect on technology transfer. Patent rights encourage technology transfer by providing owners with legal certainty.”84 Consequently, the passage of IP laws that do not include a provision for compulsory licensing, for example, may favorably signal to foreign investors that a government is willing to allow strategic business decisions without undue interference and ensure more transparent and unbiased application of commercial laws with the prospect of reduced government corruption.85 “There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly, for MDC’s [middle developing countries], a compulsory license can trigger the loss of significant FDI.”86 If patent ownership rights indicate to prospective investors a firm’s proper regard for its intellectual property security, then surely a company’s willingness to engage in a foreign market where the government has decided to adopt or enforce anti-patent measures will convey negative signals to the investment community about the company, the quality of its management, and the strength and economic value of its patents and associated projected revenue streams. Just as the sale of a product through a low-status selling channel of a product can signal a diminution in brand status to the consumer, exposure of a patent to an uncertain legal environment can signal that the firm may not consider the patent to be as valuable as others believe. Even the threat of an ‘anti-patent’ such as a compulsory license can impair firm equity, thereby reducing the attractiveness of a country as an investment partner. Any firm calculating its returns from FDI will have to account for the possibility of these signaling-based losses.87

#### **FDI is key to COVID recovery – increases employment and strengthens relations between countries.**

Chalamish et al 20 [Dr. Efraim Chalamish is a Senior Advisor with Duff & Phelps and an Adjunct Professor of Law at New York University. Nicole Y. Lamb-Hale is a former Assistant Secretary of Commerce in the International Trade Administration and Managing Director and Chair of the CFIUS and National Security Practice at Kroll, a division of Duff & Phelps. She is a member of the Board of Directors of the Center for International Private Enterprise. Andrew Wilson is the Executive Director of the Center for International Private Enterprise. ANDREW WILSON, DR. EFRAIM CHALAMISH, NICOLE Y. LAMB-HALE. Center for International Private Enterprise, 10-21-2020, "Foreign Investment in a Post-COVID-19 World," https://www.cipe.org/blog/2020/10/21/foreign-investment-in-a-post-covid-19-world/]//anop

Just as the adverse health effects of COVID-19 will not vanish immediately but will be resolved in stages, so too will the global economy recover in stages, across industries and around the world. As both Western economies and emerging markets consider approaches to accelerate post COVID-19 economic recovery, foreign direct investment (FDI) will be an important tool for success. FDI has been one of the primary drivers of global GDP growth in recent years. FDI not only benefits economies by creating good paying jobs, it also strengthens bilateral and regional diplomatic and commercial relations among countries. Further, FDI enables the private sector to “export” best business practices, such as good corporate governance, anti-corruption, and transparency. During the pre-COVID-19 economic boom, for example, FDI in the U.S. grew dramatically. In 2015, total foreign investment in America peaked at $477 billion. In 2018, FDI fell to $296 billion, but was still significant. Attracting FDI was also an important policy objective in emerging economies prior to the COVID-19 pandemic. According to the UNCTAD 2020 World Investment Report, in 2019, 54 countries introduced at least 107 measures affecting foreign investment, most of them focused on investment liberalization, promotion and facilitation. This effort was led by Asian developing countries and emerging economies. The goal of expanding investment incentives regimes in diverse sectors, from mining to financial services, and streamlining administrative procedures, has been to maintain and increase high volumes of FDI into developing markets. COVID-19 may lead to some changes in the tactics that countries employ to attract FDI. Governments will be under pressure to ensure that the quest for FDI is appropriately balanced with efforts to protect economic resilience and national security. Can FDI stimulate the world economy post-COVID-19? It appears likely, as many assets have seen reduced valuations that can attract foreign investment. Yet while both developed and emerging economies signal that they are open for investment, COVID-19 may lead to some changes in the tactics that countries employ to attract FDI. Governments will be under pressure to ensure that the quest for FDI is appropriately balanced with efforts to protect economic resilience and national security. This may mean increased screening by investment review agencies, such as the Committee on Foreign Investment in the United States (CFIUS). COVID-19 has exposed supply chain vulnerabilities in the U.S. and other countries and has shown how struggles to acquire the products to meet citizens’ healthcare needs can become a matter of national security. In COVID-19’s wake, the scope of transactions to be reviewed by entities like CFIUS from a national security standpoint may need to be expanded to include health care considerations, to ensure that FDI does not interfere with the ability to procure necessary supplies.

#### Continued recession causes war – stats support transition wars, resource conflicts, terrorism, and diversionary wars – other authors don’t base their analysis on global studies

Royal ’10 [Jedediah, Director of Cooperative Threat Reduction at the U.S. Department of Defense, “Economic Integration, Economic Signaling and the Problem of Economic Crises”, 2010, Economics of War and Peace: Economic, Legal and Political Perspectives, ed. Goldsmith and Brauer, p. 213-215]PM

Less intuitive is how periods of economic decline may increase the likelihood of external conflict. Political science literature has contributed a moderate degree of attention to the impact of economic decline and the security and defence behaviour of interdependent slates. Research in this vein has been considered at systemic, dyadic and national levels. Several notable contributions follow. First, on the systemic level. Pollins (2008) advances Modelski and Thompson's (19%) work on leadership cycle theory, finding that rhythms in the global economy are associated with the rise and fall of a pre-eminent power and the often-bloody transition from one pre-eminent leader to the next. As such, exogenous shocks such as economic crises could usher in a redistribution of relative power (sec also Gilpin. 1981) that leads to uncertainty about power balances, increasing the risk of miscalculation (Fearon, 1995). Alternatively, even a relatively certain redistribution of power could lead to a permissive environment for conflict as a rising power may seek to challenge a declining power (Werner, 1999). Separately. Pollins (1996) also shows that global economic cycles combined with parallel leadership cycles impact the likelihood of conflict among major, medium and small powers, although he suggests that the causes and connections between global economic conditions and security conditions remain unknown. Second, on a dyadic level. Copeland's (1996. 2000) theory of trade expectations suggests that 'future expectation of trade' is a significant variable in understanding economic conditions and security behaviour of states. He argues that interdependent states are likely to gain pacific benefits from trade so long as they have an optimistic view of future trade relations. However, if the expectations of future trade decline, particularly for difficult to replace items such as energy resources, likelihood for conflict increases. as states will be inclined to use force to gain access to those resources. Crises could potentially be the trigger for decreased trade expectations either on its own or because it triggers protectionist moves by interdependent states.4 Third, others have considered the link between economic decline and external armed conflict at a national level. Blomberg and Hess (2002) find a strong correlation between internal conflict and external conflict, particularly during periods of economic downturn. They write, The linkages between internal and external conflict and prosperity are strong and mutually reinforcing. Economic conflict tends to spawn internal conflict, which in turn returns the favour. Moreover, the presence of a recession lends to amplify the extent to which international and external conflicts self-reinforce each other. (Blomberg & I less. 2002. p. 89) Economic decline has also been linked with an increase in the likelihood of terrorism (Blomberg. Hess. & Wccrapana. 2004). which has the capacity to spill across borders and lead to external tensions. Furthermore, crises generally reduce the popularity of a sitting government. "Diversionary theory' suggests that, when facing unpopularity arising from economic decline, sitting governments have increased incentives to fabricate external military conflicts to create a 'rally around the flag' effect. Wang (1996), DcRoucn (1995), and Blomberg. Mess, and Thacker (2006) find supporting evidence showing that economic decline and use of force are at least indirectly correlated. Gelpi (1997), Miller (1999), and Kisangani and Pickering (2009) suggest that the tendency towards diversionary tactics are greater for democratic states than autocratic states, due to the fact that democratic leaders are generally more susceptible to being removed from office due to lack of domestic support. DcRoucn (2000) has provided evidence showing that periods of weak economic performance in the United States, and thus weak Presidential popularity, are statistically linked to an increase in the use of force. In summary, recent economic scholarship positively correlates economic integration with an increase in the frequency of economic crises, whereas political science scholarship links economic decline with external conflict at systemic, dyadic and national levels.5 This implied connection between integration, crises and armed conflict has not featured prominently in the economic-security debate and deserves more attention. This observation is not contradictory to other perspectives that link economic interdependence with a decrease in the likelihood of external conflict, such as those mentioned in the first paragraph of this chapter. Those studies tend to focus on dyadic interdependence instead of global interdependence and do not specifically consider the occurrence of and conditions created by economic crises. As such, the view presented here should be considered ancillary to those views.

**That causes global nuclear war.**

Merlini ’11 [Cesare, was a nonresident senior fellow at the Center on the United States and Europe and is chairman of the Board of Trustees of the Italian Institute for International Affairs (IAI) in Rome, “A Post-Secular World?”, 03-30-2011, Routledge, https://www.brookings.edu/wp-content/uploads/2016/06/04\_international\_relations\_merlini.pdf]PM

Two neatly opposed scenarios for the future of the world order illustrate the range of possibilities, albeit at the risk of oversimplification. The first scenario entails the premature crumbling of the post-Westphalian system. One or more of the acute tensions apparent today evolves into an open and traditional conflict between states, perhaps even involving the use of nuclear weapons. The crisis might be triggered by a collapse of the global economic and financial system, the vulnerability of which we have just experienced, and the prospect of a second Great Depression, with consequences for peace and democracy similar to those of the first. Whatever the trigger, the unlimited exercise of national sovereignty, exclusive self-interest and rejection of outside interference would likely be amplified, emptying, perhaps entirely, the half-full glass of multilateralism, including the UN and the European Union. Many of the more likely conflicts, such as between Israel and Iran or India and Pakistan, have potential religious dimensions. Short of war, tensions such as those related to immigration might become unbearable. Familiar issues of creed and identity could be exacerbated. One way or another, the secular rational approach would be sidestepped by a return to theocratic absolutes, competing or converging with secular absolutes such as unbridled nationalism.

### 3

#### Biden PC is key to getting Manchin & Sinema on board and he won’t give up – it’s *try or die* & the margin of error is *literally* 0.

Strauss 10/13 [Daniel, Staff Writer @ The New Republic, “Has the Time Come for Biden to Knock Some Heads on Capitol Hill?”, 10-13-2021, https://newrepublic.com/article/163982/biden-reconciliation-cost-democrats]//pranav

At the same time, though, the White House has moved to a different phase of negotiations. Susan Rice, the director of the White House’s Domestic Policy Council, has become more visible in negotiations on the Hill, oftentimes spotted going in and out of meetings with White House National Economic Council director Brian Deese. Rice, according to multiple administration officials, has been involved in the reconciliation package talks for months, and lawmakers have looked to her as one of the point people within the administration on topics that fall under the DPC’s purview: Health care, childcare, housing. Deese and Rice have been “tag teaming” those meetings, one administration official said. “It’s just that as the negotiations have come to a head, she’s become a little more visible,” the official added. But veterans of past major Democratic policy battles warn about the limits of a White House that throws up its hands and says enough is enough. The White House has already gone out to the states, looking to rally support among the broader public by having Biden himself stump in key congressional districts. He has also used the power of the Oval Office to try to win over lawmakers like Sinema and Manchin. “Having dealt with situations like this, there is a point where the administration really doesn’t have a lot of leverage,” said former Democratic Senate Majority Leader Tom Daschle. “They can use the media. They can use the president’s Oval Office presence to bring people down and persuade as much as they can, but ultimately there isn’t a lot of leverage, and when you’re at 50–50 and almost 50–50 in the House, every person is in a position to veto a particular proposal.” But Daschle said, so far, the White House has played its hand well in the negotiations. “I think the administration has played it about right. They’ve got to give the leaders enough flexibility,” Daschle said. Phil Schiliro, who served as the White House director of legislative affairs during Barack Obama’s presidency, stressed that right now the White House is in the common-ground phase of negotiating with lawmakers. “It really is [about] trying to find the opportunities to reach common ground, and that’s just a process,” Schiliro said. Still, increasingly, Democrats are having to face picking one of two choices: spending less or including fewer programs in a domestic policy package they hoped just about every Democrat running in 2022 could run on. “Here, I don’t know that there’s any magic to any number, as much as there’s getting the policies right,” Schiliro said. Publicly, the White House is trying to exude calm. Its latest deadline for moving a package forward is still a few weeks away. White House press secretary Jen Psaki told reporters Tuesday that Biden’s role, right now, as he remains very involved in negotiations, is “to find common ground so that we can move forward with an agenda that the American people demand we pass.” Privately, though, the White House and Washington Democrats in general know they’re fast approaching a different deadline—the moment when someone is going to have to come out and say whether to shrink the overall spending and duration of the package or include fewer programs. That is the only way for Democrats to win over the members they need to pass anything at all. The only Democrat with the necessary stature and the ear of the people who matter most to make that call is the president. Biden was the one who promised to unite as much of Congress as possible behind as large a domestic policy agenda as anyone in Washington had ever seen. Now he has to cut it.

#### Big Pharma hates the plan – empirics – err neg our ev literally cites their press releases

PhRMA ’21 [The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone, “PhRMA Statement on WTO TRIPS Intellectual Property Waiver”, 05-05-2021, https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver]//pranav

WASHINGTON, D.C. (May 5, 2021) – Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen J. Ubl made the following statement after the United States Trade Representative expressed support for a proposal to waive patent protections for COVID-19 medicines: “In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines. “This change in longstanding American policy will not save lives. It also flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery. This decision does nothing to address the real challenges to getting more shots in arms, including last-mile distribution and limited availability of raw materials. These are the real challenges we face that this empty promise ignores. “In the past few days alone, we’ve seen more American vaccine exports, increased production targets from manufacturers, new commitments to COVAX and unprecedented aid for India during its devastating COVID-19 surge. Biopharmaceutical manufacturers are fully committed to providing global access to COVID-19 vaccines, and they are collaborating at a scale that was previously unimaginable, including more than 200 manufacturing and other partnerships to date. The biopharmaceutical industry shares the goal to get as many people vaccinated as quickly as possible, and we hope we can all re-focus on that shared objective.”

#### They lash out against infra and use COVID clout to kill it – they have public support, and a win now postpones reform indefinitely which turns case

Fuchs et al. 09/02 [Hailey Fuchsattended Yale University and was an inaugural Bradlee Fellow for The Washington Post, where she reported on national politics**,** Alice Ollstein is a health care reporter for POLITICO Pro, covering the Capitol Hill beat. Prior to joining POLITICO, she covered federal policy and politics for Talking Points Memo, Megan Wilson is a health care and influence reporter at POLITICO, “Drug industry banks on its Covid clout to halt Dems’ push on prices”, 09-02-2021, https://www.politico.com/news/2021/09/02/drug-prices-democrats-lobbying-508127]//pranav

As Democrats prepare a massive overhaul of prescription drug policy, major pharmaceutical companies are mounting a lobbying campaign against it, arguing that the effort could undermine a Covid fight likely to last far longer than originally expected. In meetings with lawmakers, lobbyists for the pharmaceutical industry have issued warnings about the reconciliation package now moving through both chambers of Congress that is set to include language allowing Medicare to negotiate the price of some drugs, which could generate billions of dollars in savings. In those conversations, K Street insiders say, lobbyists have explicitly mentioned that the fight against the coronavirus will almost certainly extend beyond the current surge of the Delta variant. And they’re arguing that now isn’t the time to hit the industry with new regulations or taxes, particularly in light of its successful efforts to swiftly develop vaccines for the virus. “For years, politicians have been saying that the federal government can interfere in the price of medicines and patients won’t suffer any harm,” said Brian Newell, a spokesperson for the Pharmaceutical Research and Manufacturers of America, or PhRMA, in a statement. “But in countries where this already happens, people experience fewer choices and less access to prescription medicines. Patients know if something sounds too good to be true, then it usually is.” The escalating warnings from the pharmaceutical industry are part of what is expected to be one of the more dramatic and expensive lobbying fights in recent memory, and a heightened repeat of the industry’s pushback to actions by former President Donald Trump to target drug prices. The proposal now under consideration in Democrats’ reconciliation package could save the federal government hundreds of billions of dollars by leveraging its ability to purchase prescription drugs, according to a report from the Congressional Budget Office. Without those funds, Democrats won’t be able to pay for the rest of the health care agenda they’ve promised to voters, including expansions of Medicare, Medicaid and Obamacare. But the plan has political power as more than a revenue raiser. Party leaders — from President Joe Biden to Senate Budget Chair Bernie Sanders (I-Vt.) — are touting it as one of the most important components of the $3.5 trillion package, with the potential to lower out-of-pocket health spending for tens if not hundreds of millions of people. Outside advocates have also zeroed in on it as the most consequential policy fight on the horizon. “This is the best chance that we have seen in a couple of decades to enact meaningful reforms to drug pricing policy in the United States that will lower the prices of prescription drugs, and it’s very clear that the drug companies are going all out to stop it,” said David Mitchell, founder of Patients for Affordable Drugs. “This is Armageddon for pharma.” Progressive Democrats and their outside allies believe they’re closer than they’ve been in decades to imposing some price controls, and worry that failure to do so this year will delay progress indefinitely given the possibility of the party losing one or more chambers of Congress in the 2022 midterms. In April, the House passed a fairly aggressive version — H.R. 3 (117) — though a handful of moderate Democrats friendly to the industry have threatened to block it when it comes back to the floor for a vote later this fall. Leadership has largely shrugged off this threat, banking on the fact that the most vulnerable frontline Democrats are vocally in favor of the policy, while most of the dissenters sit in safe blue districts. The Senate is designing its own version, outlined by Sen. Ron Wyden (D-Ore.) in June, as a middle ground between HR3 and the more narrow, bipartisan bill he and Sen. Chuck Grassley (R-Iowa) put forward last Congress. A senior Senate Democratic aide confirmed to POLITICO that the bill is nearly complete and that they’re in the process of shopping it around to undecided senators to make sure it has enough support to move forward in the 50-50 upper chamber. “It makes sense to get buy-in before releasing it rather than releasing it with fingers crossed and then tweaking it once members complain,” the aide said. But the reform push is coming at a time when the pharmaceutical industry is working hand-in-hand with government officials to combat the pandemic and enjoying a boost in public opinion as a result, even as drug costs continue to rise. The companies claim that fundamental changes to their bottom line — in addition to the Medicare provision, the reconciliation bill will likely raise corporate tax rate significantly, as high as 28 percent (a jump of 7 percentage points) — will threaten its current investments in research and development at a historically critical juncture. With the final draft of the bill expected in the coming weeks, the Pharmaceutical Research and Manufacturers of America, the lobbying arm of the pharmaceutical industry, is taking its case public. The group has recently spent at least seven figures on ads pressuring Congress not to change Medicare drug policy.

#### Big pharma always wins – independently kills aff solvency bc it causes the plan to be watered down so much that de facto monopolies can survive

Florko & Facher ‘19 [Nicholas Florko is a Stat News Washington correspondent and Lev Facher is Stat News health and life sciences writer, “How pharma, under attack from all sides, keeps winning in Washington”, 07-16-2019, Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]//pranav

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. The pharmaceutical industry is still winning in Washington. In the past month alone, drug makers and the army of lobbyists they employ pressured a Republican senator not to push forward a bill that would have limited some of their intellectual property rights, according to lobbyists and industry representatives. They managed to water down another before it was added to a legislative package aimed at lowering health care costs. Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, drug makers have successfully deployed dozens of lobbyists and devoted record-breaking sums to their federal advocacy efforts. But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept both lawmakers and the Trump administration from landing any of their prescription-drug punches. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s most powerful lobbies, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was struggling to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive interventions to water down legislation. “In lots of ways they’re like the [National Rifle Association], because they have an incredible power to squash out any negative opinion, nor to feel any of the ill effects of those things,” said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “Shaming is something drug makers don’t seem worried about.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s list of policy victories goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to stave off defeat. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric, both Trump and progressives have begun to fret that Washington’s efforts have proven to be all bark and no bite. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

#### Infra’s k2 stopping existential climate change – warming is incremental and every change in temperature is vital

Higgins 8/16 [Trevor, Senior Director, Domestic Climate and Energy, “Budget Reconciliation Is the Key to Stopping Climate Change”, 08-16-2021, https://www.americanprogress.org/issues/green/news/2021/08/16/502681/budget-reconciliation-key-stopping-climate-change/]//pranav

The United States is suffering acutely from the chaotic changes in climate that scientists now directly attribute to the burning of fossil fuels and other human activity. The drought, fires, extreme heat, and floods that have already killed hundreds this summer across the continent and around the world are a tragedy—and a warning of worsening instability yet to come. However, this week, the Senate initiated an extraordinary legislative response that would set the world on a different path. Enacting the full scope of President Joe Biden’s Build Back Better agenda would put the American economy to work leading a global transition to clean energy and stabilizing the climate. A look at what’s coming next through the budget reconciliation process reveals a ray of hope that is easy to miss amid the fitful negotiations of recent months: At long last, Congress is on the verge of major legislation that would build a more equitable, just, and inclusive clean energy economy. This is our shot to stop climate change. Building a clean energy future must start now Until the global economy stops polluting the air and instead starts to draw down the emissions of years past, the world will continue to heat up, blundering past perilous tipping points that threaten irreversible and catastrophic consequences. Stemming the extent of warming at 1.5 degrees Celsius rather 2 degrees or worse will reduce the risk of crossing such tipping points or otherwise exceeding the adaptive capacity of human society. Every degree matters. Stabilizing global warming at 1.5 degrees Celsius starts with cutting annual greenhouse gas emissions in the United States to half of peak levels by 2030. This isn’t about temporary offsets or incremental gains in efficiency—it’s about the rapid adoption of scalable solutions that will work throughout the world to eliminate global net emissions by 2050 and sustain net-negative emissions thereafter. Building this better future will tackle climate change, deliver on environmental justice, and create good jobs. It will give us a shot to stop the planet from continuously warming. It will alleviate the concentrated burdens of fossil fuel pollution, which are concentrated in systemically disadvantaged, often majority Black and brown communities. It will empower American workers to compete in the global clean energy economy of the 21st century. There is no time to lose in the work of building a clean energy future.

## Case

### Adv

#### Top Level –

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

#### Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

#### Innovation high and evergreening is false – postdates your ev and we have stats

Ezell 20. Stephen Ezell, July 2020, “Ensuring U.S. Biopharmaceutical Competitiveness,” Information Technology and Innovation Foundation, <http://www2.itif.org/2020-biopharma-competitiveness.pdf> sean!

Medicines are critical to health. Since 2000, the FDA has approved more than 500 new medicines. 2 As of 2020, biopharmaceutical companies in the United States have more than 3,400 drugs under clinical development, accounting for almost half of the estimated 8,000 medicines under development globally (1,100 of which are being developed to treat various forms of cancers).3 And while some have asserted that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is that most of the drugs currently under development seek to tackle some of the world’s most intractable diseases, including Alzheimer’s, cancer, and communicable diseases. This includes 130 coronavirus vaccines under development globally as well as 144 active trials of coronavirus therapeutic agents, and another 457 development programs for new therapeutic agents, which the FDA is tracking through its Coronavirus Treatment Acceleration Program.4 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA’s Center for Drug Evaluation and Research (CDER) approved 41 new medicines (the most since 1996 at that point), many of which were first-in-class medicines, meaning they represent a possible new pharmacological class for treating a medical condition.5 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases. In 2018, CDER approved a record 59 novel drugs, and in 2019, 48 novel drugs, making 2019 the third-largest approval class in the past 25 years.6 As of 2020, 74 percent of medicines in clinical development in the United States are potentially first-in-class medicines, including 86 percent for Alzheimer’s, 70 percent for various forms of cancer, and 73 percent for cardiovascular diseases

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### AMRs:

#### Risk of transmission is overstated—conventional checks solve

Smith 17—former R&D director at MicroPhage and SomaLogic (Drew, “Can A Superbug Cause A Global Pandemic?,” <https://www.forbes.com/sites/quora/2017/02/10/can-a-superbug-cause-a-global-pandemic/#3cb04e2c59aa>, dml)

Death rates from bacterial infections dropped over 90% from historic levels before the introduction of penicillin. Sanitation and vaccines are far more effective methods to control bacterial infections than antibiotics ever were or ever will be. Boring old soap and water, filtration, bleach, and alcohol kill superbugs just fine. None of these things are in short supply.

The acquisition of multiple drug resistances generally (but not always) causes bacteria to become a bit less fit and unable to infect otherwise healthy adults. The victim of this particular superbug was in her seventies and had been in and out of hospitals for over a year. This is a fairly typical profile for victims of multi-drug resistant bacteria.

The worst-case scenario, if we continue to abuse and overuse antibiotics in feedlots and hospitals, is that these bugs will pick up compensatory mutations and become more virulent. Many fairly routine procedures - chemotherapy, thoracic and orthopedic surgery - will become much more risky.

But the risk will still be largely confined to hospitalized patients. MDR bacteria are extremely unlikely to cause a global pandemic on the scale of the 1919 influenza or AIDS epidemics, so long as we continue to provide clean food and water to the public.

#### Feldman [\*\*and Wang\*\*] is a joke.

Risch 17 [Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs.

My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0.

Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue.

Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use.

Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

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.

#### SQ solves – experiments and action now mean the plan isn’t “key” – none of their uniqueness evidence is specific to antibioitics

Biochemical Society 17 (Biochemical Society, “How to solve a problem like antibiotic resistance”, March 3, 2017, ScienceDaily, https://www.sciencedaily.com/releases/2017/03/170303100429.htm)

There has been much recent talk about how to target the rising tide of antibiotic resistance across the world, one of the biggest threats to global health today. While there is no doubting the size of the problem facing scientists, healthcare professionals and the pharmaceutical industry, there are innovative ways we can target antibiotic resistance in the short term, which are discussed in three articles published in Essays in Biochemistry. With only a few antibiotics in development and a long drug development process (often 10-15 years), there is concern that what is being done to combat antibiotic resistance may be 'too little, too late'. "If bacteria continue developing resistance to multiple antibiotics at the present rate, at the same time as the antibiotic pipeline continues to dry up, there could be catastrophic costs to healthcare and society globally," said senior co-author on one of the articles, Dr Tony Velkov, an Australian National Health and Medical Research Council (NHMRC) Career Development Fellow from Monash University, Victoria, Australia. While any antimicrobial resistance is concerning, the increasing incidence of antibiotic-resistant Gram-negative bacteria has become a particular problem as strains resistant to multiple antibiotics are becoming common and no new drugs to treat these infections (eg, carbapenem-resistant Enterobacteriaceae) will be available in the near future. These Gram-negative bacteria are considered the most critical priority in the list of the 12 families of bacteria that pose the greatest threat to human health that was just released by the World Health Organization. The reasons for the high levels of antimicrobial resistance observed in these critical Gram-negative organisms are explained in another paper in the same issue written by the Guest Editor of the journal, Dr Rietie Venter, University of South Australia, Adelaide, and colleagues. According to the authors, one of the main contributing factors to the increased resistance observed in Gram-negative bacteria is the permeability barrier caused by their additional outer membrane. An innovative strategy that is gaining momentum is the synergistic use of antibiotics with FDA-approved non-antibiotics. Using this novel approach, an FDA-approved non-antibiotic drug is combined with a specific antibiotic that enables it to breach the outer membrane barrier and so restore the activity of an antibiotic. The Monash University authors discuss how combining antibiotics with other non-antibiotic drugs or compounds can boost their effectiveness against Gram-negative 'superbugs'. For example, loperamide, an anti-diarrheal medication sold in most pharmacies, enhances the effectiveness of eight different antibiotics (all in the tetracycline class). In particular, when added to the tetracycline antibiotic minocycline, along with the Parkinson's disease drug benserazide, it significantly increased antibiotic activity against multi-drug resistant Pseudomonas aeruginosa, a causative agent in hospital-acquired infections such as ventilator-associated pneumonia. Polymyxins are a type of antibiotics that target Gram-negative bacterial infections and have traditionally been used as a last resort to treat serious infections such as those caused by Gram-negative 'superbugs' Klebsiella pneumoniae, P. aeruginosa and Acinetobacter baumannii. Resistance to polymyxins is not common, but in late 2015 the first transferable resistance gene to colistin (polymyxin E) was discovered (plasmid-borne mcr-1 gene). This caused significant concerns, as once resistance to polymyxins is established, often no other treatments are available. A number of researchers, including the team based at Monash University, have been testing different combinations of drugs or compounds with polymyxins to try and improve their effectiveness against these bacterial 'superbugs'. "Without new antibiotics in the near future, we must explore innovative approaches to preserve the clinical utility of important last-line antibiotics such as the polymyxins." commented senior co-author on the paper, Professor Jian Li, Head of the Laboratory of Antimicrobial Systems Pharmacology from Monash University, Victoria, Australia. Some interesting findings have ensued, with a number of different combinations having a beneficial effect. Some notable examples that increased antibiotic activity when combined with polymyxin B include: ivacaftor and lumacaftor, two new drugs used to treat cystic fibrosis; and closantel, a drug used to treat parasitic worm infections. Another interesting combination that has shown promise against methicillin-resistant Staphylococcus aureus (MRSA), according to Schneider and co-authors, is combining the antibiotics ampicillin or oxacillin with berberine. Berberine is extracted from the roots, stems and bark of plants such as barberry. In another paper in the same issue of Essays in Biochemistry, Dr Mark Blaskovich, Program Coordinator, Community for Open Antimicrobial Drug Discovery and colleagues from the University of Queensland, Brisbane, Australia, describe the key ways they believe antimicrobial resistance can be targeted. "In the short term, the greatest potential for reducing further development of antimicrobial resistance lies in developing a rapid test that can quickly tell whether or not you have a bacterial infection (as opposed to a viral cold or flu), and whether you really need an antibiotic," commented Blaskovich. "Even better if the test could say what type of bacteria, and what types of antibiotics it is resistant to. You could then treat an infection immediately with the appropriate antibiotic, rather than the trial and error method now used. These tests could be ready within the next 5 years, and would have a huge impact on reducing unnecessary antibiotic use, preserving our existing antibiotics and reducing the spread of antibiotic resistance." Regarding antibiotics in particular, Blaskovich and colleagues describe a number of possible strategies to pursue. The first of which is to improve existing antibiotics. For example, the authors recently created a modified version of the antibiotic vancomycin to increase its potency and reduce its toxic side effects. Another option is to rediscover 'old' antibiotics. In the 1950s and 60s many potential antibiotic drugs were described in the scientific literature, but due to so many choices being available at the time, only some were developed for human use. An example of this is octapeptins, which are newly rediscovered antibiotics that are now being developed to combat Gram-negative 'superbugs'. Repurposing drugs originally developed and approved for other uses has also had some success. In 2005, the Drugs for Neglected Diseases initiative identified fexinadole as a potential treatment for sleeping sickness and it is now undergoing a Phase III trial. This drug had been developed as an antimicrobial in the 1970s, but only reached pre-clinical development. In addition to the above, researchers are looking for new, untested sources of antimicrobial activity to try and develop new drugs. A recent success in this area was, teixobactin, a new antibiotic developed by NovoBiotic Pharmaceuticals, discovered by using an 'iChip' to culture and isolate soil bacteria in situ. A final option, mentioned by Blaskovich and colleagues, is crowdsourcing new antibiotics. Using this approach, the Community for Open Antimicrobial Drug Discovery, is searching for new chemical diversity by searching compounds sourced from academic chemists from around the world. "It's hard to predict which one of these methods will be the most successful in the future, but we really need to be trying all of them to have any chance of overcoming antibiotic resistance," said Blaskovich. "Non-antibiotic strategies are just as important, such as developing vaccines or probiotic therapies to prevent infections, as they can help to reduce the overuse of antibiotics. They will never completely replace antibiotics, but can help to preserve our existing antibiotics so they still work when needed." Overall, these articles and others in the new antimicrobial resistance themed issue of Essays in Biochemistry give us hope that there are viable solutions being developed to this seemingly unsurmountable global problem. It is important that all possible avenues are considered, as some less obvious approaches may end up being sources of future success. Dr Derry Mercer, Principal Scientist at NovaBiotics Ltd, a company that specialises in developing new antimicrobials, commented: "Research and development into new antimicrobials remains a vitally important pursuit for combatting the problem of antibiotic resistance, but alternative approaches to this problem are also urgently needed." He added: "Such methods include those described in the papers in the latest issue of Essays in Biochemistry, as well as vaccine development and bacteriophage therapy, to name a few. Approaches that target microbial virulence, for example targeting biofilms and/or quorum sensing, rather than more traditional directly antimicrobial drugs should also be urgently examined."

#### Disease outbreaks solidifies the Biological Weapons Convention.

Kaufman 10 [Stephen Kaufman, IIP Staff Writer December 10, 2010. Biological Weapons Pact Offers Cooperation Against Pandemics, [http://geneva.usmission.gov/2010/12/10/biological-weapons-pact-offers-cooperation-against-pandemics Accessed 2/8/18](http://geneva.usmission.gov/2010/12/10/biological-weapons-pact-offers-cooperation-against-pandemics%20Accessed%202/8/18)] BBro

Kennedy said the **parties to the BWC** want the arms control and nonproliferation **agreement** to be used to bring together the scientific and health communities, law enforcement professionals and governments in assisting states to develop an integrated approach to any kind of prevention and treatment program for pandemic diseases. “It’s linking up international assistance, and it’s providing the expertise that could conduct the investigations to determine the outbreak. So it’s a whole host of tools at our disposal,” Kennedy said. Along with highlighting the overlap between deliberate and nondeliberate pandemics, the meeting in Geneva discussed the World Health Organization’s (WHO) 2005 International Health Regulations, which require countries to cooperate in the prevention and treatment of diseases. The WHO and BWC, both located in Geneva, have different mandates, but their roles complement one another, Kennedy said. The BWC also established a network of national points of contact in the event of a disease outbreak. Kennedy said there is still a need to help countries better react to pandemic situations by helping them develop their capacities, laws and practices. “It’s plugging gaps. It’s linking up and sharing information, and getting those networks in place” at the local, national and international levels, she said. “**This is achieved through** multilateral **diplomacy**, providing technical assistance to countries and conducting workshops with the help of partner states.” She said the December 6-10 meetings “put us on a very good trajectory” for the Seventh BWC Review Conference, scheduled for Geneva, December 5-22, 2011. The BWC also plans to hold a preparatory conference in April 2011, as well as a series of regional workshops, including in Kenya, Nigeria and Jordan, and additional experts meetings and seminars around the world, she said. The Obama administration is pleased by the level of global interest and hopes soon to see “every single state signed up and fully active in the convention.” “That’s certainly our overarching goal, and I think we’re making progress,” Kennedy said. “This is an arms control regime … and the **implementation** has great benefits for every country around the world.”

#### Solves bioweapons and turns the aff – only the BWC can stop pandemics before vaccines are even necessary

Enemark 10. Christian Enemark (Professor of economics and business at the University of Sydney), 2010, “The role of the Biological Weapons Convention in disease surveillance and response,” The London School of Hygiene and Tropical Medicine, <https://academic.oup.com/heapol/article/25/6/486/583576> sean!

A recent review of 14 international disease surveillance and response programmes identified deficiencies (particularly in the developing world) in the critical areas of health infrastructure, technical resources, and financial and human resources that pose challenges for effectively detecting and responding to disease outbreaks around the globe (Hitchcock et al. 2007: 221–2). Insofar as framing a problem in security terms has the potential to generate greater attention to and financial resources for solving that problem, the partial securitization afforded by discussing disease surveillance and response in a BWC context is a welcome development. Regardless of whether an outbreak occurs naturally or as a result of BW use, there is a detection and response imperative. For this reason, broadly applicable measures aimed at limiting vulnerability to infectious disease threats are a worthwhile area in which to invest financial resources and political attention. Many of the basic measures needed to protect populations against naturally emerging infectious diseases—for example, syndromic surveillance, diagnostics and medical therapies—are the same as would be required to mitigate a biological attack. The Chinese Communist Party leader Mao Zedong recognized this as far back as 1952 when, amidst the controversy over alleged biological attacks by the USA during the Korean War (to be discussed later in this article), he launched China’s first Patriotic Hygiene Campaign. The slogan for the campaign was: ‘Mobilise to promote hygiene, to reduce disease, to raise the level of the people’s health, and to smash the germ warfare of the American imperialists!’ (Huang 2003: 2). More recently, China has stated that the ‘fundamental purpose of disease surveillance is to prevent and control the spread of disease, but it is also important in the prevention of bioterrorism attacks’ (China 2004: 3). This resonates with the view of the WHO (Cosivi 2005: 151): ‘‘Confronted with the potential threat to global health security by the intentional release of biological agents, the World Health Organization ... advocates ‘dual-use’ investment in national, regional and global public health operations and infrastructure for early detection and immediate response. One of the most effective methods of preparedness against deliberate epidemics is to strengthen public health surveillance and response activities for naturally and accidentally occurring diseases.’’ With highly sensitive and well-connected systems for local disease surveillance in place, outbreaks of deadly, contagious diseases could be detected and contained rapidly wherever in the world they occurred. Enhancing disease surveillance sensitivity requires, for example, training clinicians to recognize the signs and symptoms of diseases they would not normally encounter in their medical practices. It also requires expanded local diagnostic capacity worldwide to ensure existing laboratories are not swamped with samples. In a highly interconnected world, there is an inevitable international dimension to public health responses. An outbreak event inside one country is potentially a problem for others, especially if the disease in question is contagious. In East Asia, the need to prioritize public health responses to infectious disease outbreaks spans the region. Poorer countries such as Cambodia, Laos and Myanmar are particularly vulnerable to disease outbreaks occurring in their territory because of a paucity of health resources. Wealthier countries like Japan, Singapore and South Korea are also vulnerable despite the higher standards of health care enjoyed by their citizens. This is largely because the public health systems of these countries, less accustomed to infectious disease threats, are ill-prepared for dealing with the morbidity, mortality and social anxiety burden of an outbreak. In the case of China, the largest and most populous country in East Asia, its vulnerability to such an event stems largely from the fact that health resources are allocated so unevenly as to open up gaps in outbreak response capacity. The region as a whole would be better able to resist infectious disease threats if wealthier countries worked to enhance the outbreak response capacity of poorer countries’ health systems as well as their own. In addition, well-resourced countries closely connected to but outside East Asia, such as the United States and Australia, have an interest in ensuring an outbreak does not spread within and beyond the region. Arguments along these lines are routinely advanced at meetings of international health organizations like the WHO. However, the BWC is increasingly being used as an additional forum for states and NGOs to exchange information and ideas on detecting and responding to disease outbreaks, be they of natural or deliberate origin. In addition to standard arms control provisions banning BW possession and proliferation, Article X of the BWC requires that member states ‘facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes’ (BWC 1972). At the Fourth BWC Review Conference in 1996, member states acknowledged ‘worldwide concern about new, emerging and re-emerging infectious diseases’ and regarded international responses to these as offering ‘opportunities for increased cooperation in the context of Article X application and of strengthening the Convention’ (BWC 1996: 25). The Conference welcomed efforts to establish a system of global monitoring of disease and encouraged member states to support WHO programmes ‘to strengthen national and local programmes of surveillance for infectious diseases and improve early notification, surveillance, control and response capabilities’ (BWC 1996: 25). The 2004 meeting of BWC member states was an opportunity to focus on the details of potential public health capabilities that would be useful in the event of a major disease outbreak, however caused. In one sense, states’ contributions to this meeting consisted simply of reports on what each was doing or would do for foreign policy, humanitarian or self-interest reasons. With respect to recent outbreaks of SARS and avian influenza in East Asia, for example, Japan reported that it had ‘strengthened national response measures, and during these outbreaks, provided medical equipment and medicines, as well as dispatching experts to affected countries’ (Japan 2004). Nevertheless, it was genuinely helpful for individual states to learn more about foreign systems, institutions, laws, policies and capabilities for disease surveillance and response. The message of the USA to other delegates was that the 2004 meeting was an opportunity ‘to share insights that will greatly improve the ability of the international community to respond to dangerous outbreaks of disease, whether naturally occurring or deliberate’ (United States 2004). The South Korean delegate noted (Republic of Korea 2004) that the meeting: ‘‘brought us a better understanding of the diverse systems and mechanisms for the surveillance, detection, diagnosis and combating of infectious diseases and for responding to, investigating and mitigating the effects of alleged use of biological weapons or suspicious outbreaks of disease. As a consequence, we now know more clearly what has to be done and what remains to be done for the improved effectiveness of those systems and mechanisms.’’ Some states, however, were interested in receiving more than just information and ideas. Indonesia, for example, called for enhanced laboratory capacity in developing countries (Indonesia 2004), and Malaysia was adamant that ‘the outcome of all research regarding the surveillance, detection, diagnosis and combating of infectious diseases affecting humans, animals and plants should also be made available to all [BWC] states parties on a non-discriminatory basis’ (Malaysia 2004). China called for wealthier BWC member states to fund improvements in disease surveillance and response in poorer states, and for assistance (in the form of technology, resources and information) to be provided ‘on the basis of equality, cooperation and mutual respect’ (BWC 2004: 21–2). China also suggested that BWC member states share their experiences in disease prevention and control by promoting technological cooperation and personnel exchanges (BWC 2004: 27). Some developed countries seemed receptive to such ideas, with the US representative remarking: ‘We too see utility in the provision of technical assistance... particularly in framing and/or expanding ... national systems of disease surveillance and response’ (United States 2004). Australia in turn took the view that the 2004 meeting of BWC member states had ‘usefully informed initiatives to improve disease surveillance and diagnostic laboratory capacity in the Asia-Pacific region’ (Australia 2004).

#### Bioweapons cause extinction and OW disease

Ochs 02 [Richard, MA in Natural Resource Management 2002 –from Rutgers University and Naturalist at Grand Teton National Park, “BIOLOGICAL WEAPONS MUST BE ABOLISHED IMMEDIATELY,” Jun 9, [http://www.freefromterror.net/other\_articles/abolish.html Accessed 2/8/18](http://www.freefromterror.net/other_articles/abolish.html%20Accessed%202/8/18)] BBro

Of all the weapons of mass destruction, the genetically engineered **biological weapons**, many without a known cure or vaccine, **are an extreme danger** to the continued survival of life on earth. Any perceived military value or deterrence pales in comparison to the great risk these weapons pose just sitting in vials in laboratories. While a "nuclear winter” resulting from a massive exchange of nuclear weapons, could also kill off most of life on earth and severely compromise the health of future generations, they are easier to control. Biological weapons, on the other hand, can get out of control very easily, as the recent anthrax attacks has demonstrated. There is no way to guarantee the security of these doomsday weapons because very tiny amounts can be stolen or accidentally released and then grow or be grown to horrendous proportions. **The Black Death** of the Middle Ages **would be small** in comparison to the potential damage bioweapons could cause. Abolition of chemical weapons is less of a priority because, while they can also kill millions of people outright, their persistence in the environment would be less than nuclear or biological agents or more localized. Hence, chemical weapons would have a lesser effect on future generations of innocent people and the natural environment. Like the Holocaust, once a localized chemical extermination is over, it is over. With nuclear and biological weapons, the killing will probably never end. Radioactive elements last tens of thousands of years and will keep causing cancers virtually forever. Potentially worse than that, bio-engineered agents by the hundreds with no known cure could wreck even greater calamity on the human race than could persistent radiation. AIDS and ebola viruses are just a small example of recently emerging plagues with no known cure or vaccine. Can we imagine hundreds of such plagues? HUMAN **EXTINCTION IS** NOW **POSSIBLE**.

### AT: Price Control

#### No empiric of leading to nuclear war – ev just suggests it but tis not backed so err neg

#### No impact to nationalism – their ev is hype.

Strobaek ’17 (Michael; 6/5/17; Chief Investment Officer, free-lance journalist, and political analyst for CNBC; CNBC, “From the cacophony of populism, is a stronger middle emerging?” <http://www.cnbc.com/2017/07/05/from-the-cacophony-of-populism-is-a-stronger-middle-emerging.html)>

One would presume that anger breeds irrationality, radicalism and political as well as economic instability. But it need not. Anger – or let us call it, less dramatically, dissatisfaction with current affairs – can also lead to **renewal and progress**. Indeed, this year's elections in **Europe** suggest that voters are rather heading in that direction, i.e. seeking greater stability as well as reform while rejecting angry populism which has no real solutions to offer for today's major issues. With this in mind, it should thus come as no surprise that the radical **right was soundly defeated** in **Austria**, the **Netherlands** and **France**, and that the AfD (Alternative for Germany) is in rapid decline in **Germany**. In Finland, the radical right has just split into two, pragmatists and "purists." In Italy, too, recent local elections suggest that populist promises alone do not convince the electorate. Similarly, the **setbacks for the Conservatives** in the U.K. election in part represented a rejection of simplistic chauvinistic slogans. Leftist populism in demise? Conversely, we see few signs that the radical left is benefiting from this trend. Those who believe that the gains of the Labour party in the U.K. – headed by a rather dogmatic old-style socialist – suggest that leftist populists stand a good chance to govern are likely to be disappointed. Quite to the contrary, even in countries that have suffered deep crises – Spain and Greece come to mind – voters have **become disillusioned** with their recipes. Bernie Sanders would not, we believe, have won the U.S. election had he been the Democratic opponent of Donald Trump. Returning to what looks like a detail of the U.K. election, the very strong performance of the Conservative leader in Scotland, Ruth Davidson, an avowed "(EU) remainer" and opponent of the Scottish National Party suggests that separatism, another form of "anger," may also be **on the way out**. The outcome of the Catalan vote in the fall, should it take place, will be a further test of this thesis. Finally, beyond Europe, recent **political shifts** in Argentina and the upheaval in Brazil also suggest that leftist populism is in demise. Let us hope that Venezuela will soon be able to rid itself of one of its more extreme forms. Return to the center Putting these observations together suggests to me that voters have in fact started to head away from the extremes back to the center. Emmanuel Macron won the French election on an **openly centrist** platform. The state elections in Germany recently boosted Angela Merkel's centrist CDU, but even if the SPD and Martin Schulz were to win in September, this would hardly signal a turn of the electorate in a radical direction. Voters seem to be seeking politicians who offer pragmatic solutions to the complex problems of the day rather than simplistic recipes. The next U.S. president, I dare predict, is quite likely to be an avowed centrist as well. Maybe the **disillusionment with radicalism** – in this case of a truly brutal nature – will even strengthen forces of compromise in the Middle East at some point in the not-too-distant future. All in all, fears of significant political destabilization and systemic disruptions thus seem **overdone**, which may be one reason why markets, equities in particular, have been so **stable and calm** until recently despite rather stretched valuations. Does this mean that we will, after all, experience the unabashed victory of economic and political liberalism that Francis Fukuyama proclaimed? This remains rather unlikely, in my view, for three reasons: First, our multipolar world suggests that national and regional interests will take precedence over those promoting free markets and unfettered globalization. Second, distrust of market solutions has not been overcome, not least due to the "misdeeds" during the financial crisis.

#### No impact to rural-urban inequality – democracy is resilient against populism.

Miller 18 (James Miller is professor of liberal studies and politics, and faculty director of creative publishing and critical journalism at the New School in New York, and the author of Examined Lives (2012, Picador) and Can Democracy Work?; “Could populism actually be good for democracy?”; The Guardian; October 11, 2018; <https://www.theguardian.com/news/2018/oct/11/could-populism-actually-be-good-for-democracy>) Accessed 6/24/21//eleanor

Current affairs may seem especially bleak, but fears about democracy are nothing new. At the zenith of direct democracy in ancient Athens, in the fifth century BC, one critic called it a “patent absurdity” – and so it seemed to most political experts from Aristotle to Edmund Burke, who considered democracy “the most shameless thing in the world”. As the American founding father John Adams warned, “there never was a democracy yet that did not commit suicide”. For almost 2,000 years, most western political theorists agreed with Aristotle, Burke and Adams: nobody could imagine seriously advocating democracy as an ideal form of government. It was only at the end of the 18th century that democracy reappeared as a modern political ideal, during the French Revolution. Ever since, popular insurrections and revolts in the name of democracy have become a recurrent feature of global politics. It needs to be stressed: these revolts are not an unfortunate blemish on the peaceful forward march toward a more just society; they form the heart and soul of modern democracy as a living reality. It is a familiar story: out of the blue, it seems, a crowd pours into a city square or gathers at a barnstorming rally held by a spellbinding orator, to protest against hated institutions, to express rage at the betrayals of the ruling class, to seize control of public spaces. To label these frequently disquieting moments of collective freedom “populist”, in a pejorative sense, is to misunderstand a constitutive feature of the modern democratic project. Yet these episodes of collective self-assertion are invariably fleeting, and often provoke a political backlash in turn. The political disorder they create stands in tension with the need for a more stable, peaceful form of collective participation. That is one reason why many modern democrats have tried to create representative institutions that can – through liberal protections for the freedom of religion, and of the press, and the civil rights of minorities – both express, and tame, the will of a sovereign people. Thus the great French philosopher Condorcet in 1793 proposed creating a new, indirect form of self-rule, linking local assemblies to a national government. “By ingrafting representation upon democracy,” as Condorcet’s friend Tom Paine put it, the people could exercise their power both directly, in local assemblies, and indirectly, by provisionally entrusting some of their powers to elected representatives. Under the pressure of events, another ardent French democrat, Robespierre, went further and defended the need, amid a civil war, for a temporary dictatorship – precisely to preserve the possibility of building a more enduring form of representative democracy, once its enemies had been defeated and law and order could be restored. But there was a problem with these efforts to establish a modern democracy at scale. Especially in a large nation such as France or the US, representative institutions – and, even worse, dictatorial regimes claiming a popular mandate – inevitably risk frustrating anyone hoping to play a more direct role in political decision-making. This means that the democratic project, both ancient and modern, is inherently unstable. The modern promise of popular sovereignty, repeatedly frustrated, produces recurrent efforts at asserting the collective power of a people. If observers like the apparent result of such an effort, they may hail it as a renaissance of the democratic spirit; if they do not, they are liable to dismiss these episodes of collective self-assertion as mob rule, or populism run amok. No matter. Even though the post-second world war consensus over the meaning and value of liberal democratic institutions seems more fragile than ever – polls show that trust in elected representatives has rarely been lower – democracy as furious dissent flourishes, in vivid and vehement outbursts of anger at remote elites and shadowy enemies.

#### No impact to inequality.

Liddiard 19 (Patrick Liddiard has served as a political analyst in the US Government. His research focuses on democratic institutions, democratization and political instability.; “Is Populism Really a Problem for Democracy?” Wilson Center; August 2019; <https://www.wilsoncenter.org/publication/populism-really-problem-for-democracy>) Accessed 6/25/21//eleanor

The emergence of populist parties, of course, does not lead deterministically to democratic breakdowns. Party system change and the electoral success of new political actors have historically reflected political entrepreneurs mobilizing new constituencies that had previously lacked representation, and most populist parties that do gain control of government will govern without democracy collapsing. Populist parties can also moderate their anti-establishment stances while in office, particularly if party leadership has previous political experience. For example, Greece’s left-wing populist SYRIZA party, once in power, toned down its polarizing rhetoric and moderated its policies as it was confronted with domestic and international political and economic constraints. lxiii SYRIZA’s Alexis Tsipras came to the premiership with considerable experience in the workings of large political organizations, having held various leadership positions in leftist political parties for 20 years beforehand.