### T – Must have plan text

#### Interpretation: The affirmative must have a clearly stated topical plan text that specifies all major actions of the aff.

#### Violation: they didn’t

#### Vote neg – They kill fairness – the aff can no link out of literally any argument we make because they don’t have a plan text to bind them to any one action – this means there is no stasis point for the debate to center around and gives the aff a huge advantage -- Either you drop them to set an example, or you don’t and we get guaranteed link to every argument we make

#### DTD –

#### A] Deters future abuse

#### B] Drop the arg cant solve – the abuse has already happened

#### Competing interps –

#### A] Reasonability is Arbitrary and invites judge intervention – impossible to determine what is reasonable, which means debating over specific interps is best and we don’t know you’re bs meter or what you think is reasonable

#### B] Intervention – judges have to intervene and determine what is reasonable which is bad bc it forces judges to make decisions along preferred biases, which causes biased and possibly discriminatory decisions.

#### C] Collapses – we would just debate over the bright line which is functionally competing interps

#### No RVI’s

#### A] Baiting – that invites maximally abusive praxis bc people will just prep out the shell

#### B] Chilling – if we drop by trying to enforce a norm that we think is good then we wont do it again – this means were never able to create norms which ows on magnitude

#### C] Illogical – you shouldn’t win for meeting your burden if that was the case, affs could just win by saying they affirm the topic.

### 1NC – Midterms DA

#### Dems win now – but the margins are razor thing – Texas abortion ban is going to rally dems to the polls – answers all thumpers

Behrmann & Bailey [2 days ago] 9-9 [Savannah Behrmann, Congressional Reporter at USA TODAY. Previously, she was a News Associate at CNN. Savannah hails originally from Utah, and attended George Mason University., Phillip M. Bailey, National political correspondent, 9-9-2021, “Texas abortion law could hurt Republicans in 2022 midterm elections, experts say” USA Today, Accessed 9-11-2021, <https://www.usatoday.com/story/news/politics/2021/09/09/texas-abortion-law-may-hurt-republicans-2022-midterms-experts-say/570180001/> ww

WASHINGTON – As the United States pulled out of Afghanistan and chaos ensued, Republican lawmakers were swift to condemn President Joe Biden's handling of the withdrawal.¶ The violence that erupted in Kabul gave GOP officials an opening to attack the Democratic president, whose approach to the withdrawal was later met with disapproval in national polls. It quickly became political campaign fodder for Republicans who need a net gain of only five seats in the House and one in the Senate to recapture total control of Congress in next year's midterm elections.¶ Weeks later, conservatives were handed a victory when the Supreme Court sided with Texas Republicans in not blocking the most restrictive abortion law in the nation – in one of the United States' largest red states. But, unlike Afghanistan, it was met with a dim response from high-profile conservatives, most of whom didn't publicly celebrate the law that experts said could spell trouble for congressional Republicans when voters head to the polls next year.¶ 'Day of reckoning': GOP unified in blaming Biden for Afghanistan bombing, divided on refugees and next steps¶ Political strategists and academics pointed to a shifting narrative for people in the "middle" on abortion, and some suggested the new law may tilt too far to the right for even some in the Republican base. ¶ "Republicans have been bleeding support among suburban women throughout the Trump era," Republican pollster Whit Ayers told USA TODAY. "(Texas) makes that problem worse, not better."¶ A divided Supreme Court last week denied an effort by abortion rights groups to halt the new Texas law that bans people from having the procedure after six weeks of pregnancy. ¶ The Texas law, known as SB 8, and signed by Republican Gov. Greg Abbott in May, bans abortions when a fetal heartbeat is detected, usually at about six weeks. The law doesn't include traditional exceptions for abortion such as for rape or incest but allows women to have the procedure for "medical emergencies." ¶ 'Near-total ban': Texas doctors, women assess nation's strictest abortion law¶ The GOP base is largely religious and mostly anti-abortion. Around eight-in-ten Republican registered voters are Christian, and 63% of Republicans and those who lean toward the GOP say abortion should be illegal in all or most cases, according to Pew Research.¶ Brian Conley, professor of political science and director of the political science graduate program at Suffolk University, said that, especially following the Texas ruling and possibly others to come, the law may benefit the left because it may mobilize single-issue pro-choice voters. ¶ "It's galvanizing and solidifying as a single issue for a lot of folks because it appears as though we're on the precipice, if you will, of some type of meaningful change, some type of significant change in abortion rights in United States." ¶ Conley noted Afghanistan could have "really been a very big win for [Republicans] but then all of a sudden there's this other issue which, if you will, will probably displace discussions about Afghanistan."¶ New law may be too extreme¶ Although abortion remains one of the thornier issues in the country, surveys have shown a consistent consensus among most Americans who favor certain restrictions but oppose throwing out Roe v. Wade as a whole.¶ Asked whether the Supreme Court should “overturn” abortion or “let it stand” a month before the 2020 president contest, 62% of likely voters in a Fox News poll said the high court should let it remain.¶ Charles Bullock, a University of Georgia political science professor, said similar surveys showed the same thing.¶ A Quinnipiac University poll released during that time period found 66% of likely voters said they agreed with the 1973 decision establishing a woman’s right to terminate a pregnancy. And a Kaiser Family Foundation poll published in October 2020 showed 69% of Americans disagree with overturning Roe, including 76% of independents. ¶ Bullock said given the slim majorities controlling Congress, Republicans are pausing to calculate how the electorate will respond.¶ “Because while it may play very well in Texas, or at least in some legislative districts in Texas, (SB 8) may be a net loser nationwide,” he said.¶ If allowed to remain in force, the Texas law would be the most dramatic restriction on abortion rights in the U.S. since Roe v. Wade. Citing Roe, federal courts have shot down similar bans in other conservative states for years.¶ Pro-choice activists supporting legal access to abortion protest during a demonstration outside the US Supreme Court in Washington, D.C., in 2020.¶ But what makes the Texas law more controversial, and has rankled women's reproductive health advocates and providers – and may be difficult for Republicans to navigate in more moderate electorates – is a provision in the measure that deputizes individual citizens as the chief enforcer of the new anti-abortion rules.¶ Under that provision, private citizens can sue abortion providers and anyone involved in "aiding and abetting" abortions, including someone driving a person to an abortion clinic. A successful plaintiff could be entitled to at least $10,000 in damages, according to the law. ¶ Shana Kushner Gadarian, chair of political science at Syracuse University's Maxwell School of Citizenship and Public Affairs, said within the Republican Party the average voter is not necessarily supportive of these types of bills, "even though they're more supportive of restricting access, or moving the timeline of when women can access abortion back."¶ "This kind of very extreme ban is not super popular," she said.¶ Imani Gandy, senior editor of law and policy at Rewire.News, said it's hard to imagine the legal ramifications if the Supreme Court or lower federal bench doesn't move against that piece of the law.¶ "It really does create this sort of mercenary society where we're a nation of people who are snitching and surveilling each other," she said.¶ Some GOP pollsters say giving other citizens the right to pursue enforcement could spark privacy concerns among parts of the base that have resisted COVID-19 regulations.¶ "The enforcement mechanism is truly a bizarre and probably unconstitutional," Ayers said. "The libertarian wing of the party will be appalled by the enforcement mechanism in SB 8."¶ All the while, abortion is top-of-mind for voters. ¶ Gallup reported 47% of those polled in May, months before the Supreme Court's decision, said the issue of abortion will be one of the most important factors in voting for a candidate of a major office. Simultaneously, 24% say they will vote only for candidates who share their views on abortion. That number is significantly higher than in other years. ¶ Republicans largely silent ¶ Major Republicans and conservative organizations haven't been proactive in voicing support for the bill since it went into effect, or have shunned whether they back the law. ¶ The National Republican Senatorial Committee, the campaign arm for Senate Republicans, did not post about the new Texas law on Twitter in the days following, but posted more than 20 times on Afghanistan. The organization did not post a public statement.¶ The Republican Governor's Association has not made any statement either in the past week, but it has retweeted Abbott's messages about immigration, election security and business and infrastructure investments. ¶ Similarly, the National Republican Congressional Committee, which raises money for House Republicans, did not post about the Texas law on social media, and no public statement was found. ¶ USA TODAY reached out to the Republican party's campaign arms for comment or direction to public statements and was told none were available. ¶ Texas' Republican Sens. John Cornyn and Ted Cruz, have been mostly silent on social media regarding the law, and posted no public statements. ¶ Sen. John Cornyn R-TX speaks about border security during a press conference with Sen. Ted Cruz R-TX at the Anzalduas International Bridge in Mission, Tx on Thursday, Jan. 10, 2019. The senators accompanied president President Donald Trump on his trip to the southern border earlier in the day. (Via OlyDrop)¶ Cornyn retweeted a few posts analyzing the bill and USA TODAY was told from his office they didn't have more at the moment to add. Cruz's office did not point USA TODAY to any public statement.¶ A spokesman for Senate Minority Leader Mitch McConnell, R-Ky., told USA TODAY their office would forward any statements on the law if the GOP leader made any. But McConnell did offer a brief and reserved reaction about the law when speaking at an event in Kentucky last week.¶ “I think it was a highly technical decision,” he told reporters. “Whether it leads to a broader ruling on Roe vs. Wade is unclear at this point.”¶ House Minority Leader Kevin McCarthy, R-Calif., hadn't posted a public statement, either. The official GOP Twitter account also had not mentioned the abortion bill.¶ Sen. Bill Cassidy, R-La., said on ABC News he believes the Supreme Court will ultimately overturn the Texas law, despite its refusal to last week. ¶ "I think the Supreme Court will swat it away once it comes to them in an appropriate manner. If it is as terrible as people say it is, it will be destroyed by the Supreme Court," Cassidy said.¶ As for Democrats, they've attacked the bill with vengeance. ¶ "The Supreme Court’s cowardly, dark-of-night decision to uphold a flagrantly unconstitutional assault on women’s rights and health is staggering," said House Speaker Nancy Pelosi, D-Calif., in a statement. “SB8 delivers catastrophe to women in Texas, particularly women of color and women from low-income communities."¶ Pelosi said the House will vote later this month on a bill that would protect the right to abortion across the country by codifying Roe v. Wade.¶ Congress:Pelosi says House will vote on abortion access bill in response to Supreme Court decision on Texas law¶ The bill brings abortion into high-profile races¶ The Texas law will likely play a role in next year's battle for the Senate where there is currently a 50-50 party breakdown.¶ In the battleground state of Pennsylvania, for instance, candidates from both sides are rushing to succeed retiring Republican Sen. Pat Toomey.¶ Democratic candidate Val Arkoosh pounced on the Texas abortion law, tweeting: "Say it with me: End the filibuster. Codify Roe v. Wade. The Senate should come back and do it — now."¶ The five-person Pennsylvania GOP field, however, has been mostly quiet.¶ None of the Republican contenders responded to USA TODAY's request for comment except for Craig Snyder, a former chief of staff for the late former Sen. Arlen Specter who is running as an anti-Trump candidate.¶ Snyder, who said he supports the unborn and "autonomy" of women, said the law is "clearly unconstitutional" based on Supreme Court precedent. He said it represents a sharp departure from what most general election voters think about abortion.¶ "I think it's another victory for extremism over the views of what I think is the American majority," Snyder said.¶ In other states, Republican candidates have avoided touting Texas' law specifically while still framing the abortion fight as a weakness for Democrats.¶ One of the high-profile races in 2021 will be Virginia's gubernatorial contest between Republican Glenn Youngkin and Democrat Terry McAuliffe.¶ The Youngkin campaign fired off a press release Tuesday afternoon chastising McAuliffe for his past comments on abortion, but it made no mention of the Texas law.¶ Youngkin dodged a CNN reporter when asked three times on Tuesday if a similar 6-week ban such as the one in Texas should be made law in Virginia, only saying that he's "pro-life."¶ Youngkin campaign spokeswoman Macaulay Porter said from the start of the race he's been an anti-abortion candidate, who "believes in exceptions in the case of rape, incest and when the mother’s life is in jeopardy."¶ "Terry McAuliffe is trying to divide us and distract from his own extreme, pro-abortion position," she said in a statement. "The Texas law is not something that is here in Virginia. What is in Virginia is Terry McAuliffe’s extreme agenda, which advocates for abortion, all the way up through and including birth.”¶ The McAuliffe campaign has gone on the offensive with a series of attack ads to remind Virginians about Youngkin's anti-abortion stances. It also revived a video released by a liberal activist in July showing Youngkin telling a voter he is keeping quiet about his anti-abortion views.¶ McAuliffe said if elected to another term he will "enshrine" abortion rights into the state constitution, and fight for new protections. He also expressed confidence that left-leaning and independent voters will come out big this November as a warning shot to Republicans in 2022 about how they have overstepped.¶ "The future of this country is going to be a battle to protect and preserve woman's rights to make their own decisions about their own body," McAuliffe said.¶ Supreme Court back in the spotlight?¶ Democrats see the Texas law as a way to remind voters of the importance of the Supreme Court — and how Senate control plays into that longer game.¶ Historically, the party not in control of the White House has success in midterms, which could have a direct impact on the court because the Senate is tasked with confirming nominees. With three Donald Trump nominees on the bench, conservatives now hold a comfortable 6-3 majority. ¶ Jazmin Vargas, the national press secretary for the Democratic Senatorial Campaign Committee, said Democrats plan on highlighting the abortion ruling over the Texas law and the Supreme Court's power in the midterm elections.¶ “The freedom for women to make our own health care decisions is on the ballot in 2022 and in key Senate battleground states. Democrats will be holding Republican Senate candidates accountable for their anti-choice record and we will be reminding voters of the stakes in next year’s election – and why we must defend a Democratic Senate majority with the power to confirm or reject Supreme Court justices," she said in a statement to USA TODAY.¶ This Friday, Sept. 3, 2021, photo shows the Supreme Court in Washington. The Supreme Court's decision this past week not to interfere with the state's strict abortion law, provoked outrage from liberals and cheers from many conservatives. President Joe Biden assailed it. But the decision also astonished many that Texas could essentially outmaneuver Supreme Court precedent on women's constitutional right to abortion. (AP Photo/J. Scott Applewhite) ORG XMIT: DCSA117¶ The House Democrats' campaign arm also came out swinging on the new law. ¶ “We’re going to make clear to the American people that this type of draconian law – that targets people seeking reproductive care and places bounties on the heads of those who help them – risks becoming the norm under a Republican majority, and Democrats won’t allow that to happen," said Democratic Congressional Campaign Committee spokesperson Nebeyatt Betre.¶ But CNN political commentator Scott Jennings, a longtime Republican adviser, said Democrats and others should pump their brakes before thinking the lack of a GOP rally in the days after the Texas law took effect represents a tectonic shift in a nearly half-century old debate.¶ "Are there any voters out there who don't know that the Republican Party is the pro-life party and the Democratic Party is the abortion party? It's been a clear contour of our elections for a long time," he said.¶ Jennings said outside of Texas each conservative candidate at the Senate and gubernatorial level is making their own decision on how to handle the issue, but that the GOP isn't going to abandon its anti-abortion base. ¶ "There's an assumption by Democrats that they're going to be able to make an entire election about abortion, when you got runaway inflation, Afghanistan debacle and COVID is now re-surging," he said. ¶ Anti-abortion activists aren't fretting about Republican reticence thus far, saying that Texas legislators have inspired leaders in other Republican-controlled state legislatures to say they are looking to mimic the law.¶ "We are in the early days, so time will tell," said Kristan Hawkins, president of Students for Life of America. ¶ She said social conservative activists are inspired by the "innovative ways to protect life" that Texas Republicans used to enforce the 6-week ban and there is a growing expectation that politicians will follow through. ¶ "Empowering private citizens was a response to a legal and political class failing to do their jobs and enforce the law," Hawkins said.¶ The Supreme Court's work on abortion isn't over. The court is expected to hear a blockbuster challenge to Mississippi's ban on most abortions after 15 weeks of pregnancy.¶ That dispute, which could be argued at the court later this year and decided next summer right before the elections, is expected to address central questions about the constitutionality of abortion and restrictions on it imposed by states.¶ Ayers, the GOP pollster, said abortion will remain an "unresolvable moral issue" but added that Democratic and Republican campaigns are measuring how much Texas has tipped the political scales, even if by inches.¶ "Americans as a whole view abortion as a moral dilemma that I believe will never be fully resolved to the satisfaction of people on either extreme of the debate," he said.

#### The aff is massively unpopular – majority of voters oppose the aff – regardless of political affiliation

Schulte 5-4 [Gabriela Schulte, 5-4-2021, “Poll: Majority oppose proposal to temporarily waive intellectual property rights on COVID-19 vaccines” The Hill, Accessed 8-11-2021, <https://thehill.com/hilltv/what-americas-thinking/551797-poll-majority-oppose-proposal-to-temporarily-waive-intellectual> ww

A majority of voters oppose the proposal to temporarily waive intellectual property rights on COVID-19 vaccines, a new Hill-HarrisX poll finds.¶ The survey comes as the Biden administration faces mounting pressure to support a proposal led by India and South Africa that would waive an international intellectual property agreement that protects pharmaceutical trade secrets.¶ Backers of the move argue it would enable lower-income countries to manufacture the vaccines themselves while those opposed say it could make the vaccine less safe and damper production in existing locations.¶ Fifty-seven percent of registered voters in the May 3-4 survey said they oppose the proposal to waive intellectual property rights on COVID-19 vaccines. By contrast, 43 percent of respondents said they support the proposal. ¶ Sixty-four percent of Republican voters along with 52 percent of both Democratic and independent voters said they oppose waiving the intellectual property rights of vaccines.¶ "This is a complex issue with a remarkably sophisticated understanding by the public. The tension is as follows: On one hand you have the need to protect the intellectual property rights of the scientists and companies that brought about the fastest vaccine in history, and will likely need to produce new versions of the shot even faster to battle evolving strains," Dritan Nesho, chief researcher and CEO of HarrisX, told Hill.TV.¶ "On the other hand there’s the need to save lives, reaching global heard immunity and providing access to the vaccine as broadly and equitably as as possible," Nesho continued.¶ "Today a majority of 57 percent of U.S. voters would like to protect the intellectual property of vaccine makers, but as more and more people are vaccinated in advanced economies, voter pressure for broader and more equitable distribution will rise," Nesho added. "Already we see Democrats and independents here split on the issue of whether or not to waive IP rights to provide greater access to the vaccines."¶ President Biden is expected to weigh in on the proposal at a World Trade Organization meeting on Wednesday.¶ The most recent Hill-HarrisX poll was conducted online among 939 registered voters. It has a margin of error of 3.2 percentage points.

#### Midterm success k2 long term climate initiatives

Piotrowski et al 20 [Matt Piotrowski and Emma McMahon and Joshua McBee and Kyle Saukas, 12-14-2020, “Biden’s Climate Path Through the 2022 Midterms” Climate Advisers, <https://climateadvisers.org/blogs/bidens-climate-path-up-to-the-2022-midterms/> ww

\*Figures omitted\*

Joe Biden ran on a climate change agenda and has laid out his plans for early action, but what might the ‘medium-term’ for climate action and the 2022 midterms look like?¶ Beyond 2021¶ Although the configuration of the current Senate is not yet decided, political operatives are already looking forward to the 2022 mid-term election. If Democrats do not win both special elections in Georgia in January 2021, they will not have the majority in the Senate, which, as noted in earlier blogs, will greatly hamper the Democrats’ legislative agenda and make wide-ranging climate legislation a virtual impossibility.¶ However, they could capture the majority in 2022. U.S. Senators serve six-year terms, meaning that the same seats are up for re-election on a rotating six-year schedule. The seats up for re-election in 2022 pose better opportunities for Democratic gains than did the elections in 2018 or 2020, with three vulnerable Republican seats (see Figure 1 below).¶ It is too soon to tell what will happen in the mid-term elections, but the most recent data show Republicans are well-positioned to take back the House. Still, some Democrats are confident they can hold onto the House. If Democrats win majorities in both houses of Congress in 2022, then the second half of the Biden administration’s term could, unusually, be more productive than his first. This would give him greater opportunity to pass comprehensive climate legislation, which could include a carbon tax, major investments in green technology and infrastructure, and regulation of the energy sector. If Republicans maintain their lead in the Senate, with or without a majority in the House, it is unlikely that any of these would pass during Biden’s presidency.¶ With Congress shifting its focus to the mid-term elections in 2022, the Biden administration will still take advantage of its ability to advance climate initiatives in the executive branch. Increasing the use of clean fuels through government procurement, particularly in the military, is one major goal. The U.S. government spends approximately $500 billion per year on procurement, providing a large opportunity to develop a zero-emission transportation fleet. There will also be opportunities in rewriting agency rules and regulations (President Trump rolled back more than 100 environmental rules), increasing research and development in programs such as the Department of Energy’s Advanced Research Projects Agency-Energy, and prioritizing the climate issue in diplomacy.¶ At the state and local level, Republicans performed better than expected in this year’s election, gaining seats in state legislatures, giving them the advantage in the redistricting process next year. Whichever party has the ability to redraw districts, which is done every 10 years, has the power to increase the number of districts in their favor. This dynamic may help Republicans retake the U.S. House of Representatives and hold onto the majority for some time as they did from 2010-18. In the map below, the Republicans hold both the legislatures and the governorships of the states in red.¶ These state-level legislatures and governorships could set the political map for a decade to come in Republicans’ favor. This could lead to more state-level opposition to President Biden’s executive actions. The recently failed attempt by Texas’ Attorney General to sue swing states whose electoral votes secured Biden’s victory that was supported by the Attorney Generals of 17 other states is an early-warning sign of state vs. federal animosity. Additionally, these state wins for Republicans could influence voting laws to favor Republicans to be elected at the Federal level, further frustrating Biden and future Democrats’ efforts to pursue ambitious climate legislation.

#### Extinction.

Kareiva 18 [Peter,Ph.D. in ecology and applied mathematics from Cornell University, director of the Institute of the Environment and Sustainability at UCLA, Pritzker Distinguished Professor in Environment & Sustainability at UCLA, et al., September 2018, “Existential risk due to ecosystem collapse: Nature strikes back,” Futures, Vol. 102, p. 39-50

In summary, six of the nine proposed planetary boundaries (phosphorous, nitrogen, biodiversity, land use, atmospheric aerosol loading, and chemical pollution) are unlikely to be associated with existential risks. They all correspond to a degraded environment, but in our assessment do not represent existential risks. However, the three remaining boundaries (climate change, global freshwater cycle, and ocean acidification) do pose existential risks. This is because of intrinsic positive feedback loops, substantial lag times between system change and experiencing the consequences of that change, and the fact these different boundaries interact with one another in ways that yield surprises. In addition, climate, freshwater, and ocean acidification are all directly connected to the provision of food and water, and shortages of food and water can create conflict and social unrest. Climate change has a long history of disrupting civilizations and sometimes precipitating the collapse of cultures or mass emigrations (McMichael, 2017). For example, the 12th century drought in the North American Southwest is held responsible for the collapse of the Anasazi pueblo culture. More recently, the infamous potato famine of 1846–1849 and the large migration of Irish to the U.S. can be traced to a combination of factors, one of which was climate. Specifically, 1846 was an unusually warm and moist year in Ireland, providing the climatic conditions favorable to the fungus that caused the potato blight. As is so often the case, poor government had a role as well—as the British government forbade the import of grains from outside Britain (imports that could have helped to redress the ravaged potato yields). Climate change intersects with freshwater resources because it is expected to exacerbate drought and water scarcity, as well as flooding. Climate change can even impair water quality because it is associated with heavy rains that overwhelm sewage treatment facilities, or because it results in higher concentrations of pollutants in groundwater as a result of enhanced evaporation and reduced groundwater recharge. Ample clean water is not a luxury—it is essential for human survival. Consequently, cities, regions and nations that lack clean freshwater are vulnerable to social disruption and disease. Finally, ocean acidification is linked to climate change because it is driven by CO2 emissions just as global warming is. With close to 20% of the world’s protein coming from oceans (FAO, 2016), the potential for severe impacts due to acidification is obvious. Less obvious, but perhaps more insidious, is the interaction between climate change and the loss of oyster and coral reefs due to acidification. Acidification is known to interfere with oyster reef building and coral reefs. Climate change also increases storm frequency and severity. Coral reefs and oyster reefs provide protection from storm surge because they reduce wave energy (Spalding et al., 2014). If these reefs are lost due to acidification at the same time as storms become more severe and sea level rises, coastal communities will be exposed to unprecedented storm surge—and may be ravaged by recurrent storms. A key feature of the risk associated with climate change is that mean annual temperature and mean annual rainfall are not the variables of interest. Rather it is extreme episodic events that place nations and entire regions of the world at risk. These extreme events are by definition “rare” (once every hundred years), and changes in their likelihood are challenging to detect because of their rarity, but are exactly the manifestations of climate change that we must get better at anticipating (Diffenbaugh et al., 2017). Society will have a hard time responding to shorter intervals between rare extreme events because in the lifespan of an individual human, a person might experience as few as two or three extreme events. How likely is it that you would notice a change in the interval between events that are separated by decades, especially given that the interval is not regular but varies stochastically? A concrete example of this dilemma can be found in the past and expected future changes in storm-related flooding of New York City. The highly disruptive flooding of New York City associated with Hurricane Sandy represented a flood height that occurred once every 500 years in the 18th century, and that occurs now once every 25 years, but is expected to occur once every 5 years by 2050 (Garner et al., 2017). This change in frequency of extreme floods has profound implications for the measures New York City should take to protect its infrastructure and its population, yet because of the stochastic nature of such events, this shift in flood frequency is an elevated risk that will go unnoticed by most people. 4. The combination of positive feedback loops and societal inertia is fertile ground for global environmental catastrophes. Humans are remarkably ingenious, and have adapted to crises throughout their history. Our doom has been repeatedly predicted, only to be averted by innovation (Ridley, 2011). However, the many stories of human ingenuity successfully addressing existential risks such as global famine or extreme air pollution represent environmental challenges that are largely linear, have immediate consequences, and operate without positive feedbacks. For example, the fact that food is in short supply does not increase the rate at which humans consume food—thereby increasing the shortage. Similarly, massive air pollution episodes such as the London fog of 1952 that killed 12,000 people did not make future air pollution events more likely. In fact it was just the opposite—the London fog sent such a clear message that Britain quickly enacted pollution control measures (Stradling, 2016). Food shortages, air pollution, water pollution, etc. send immediate signals to society of harm, which then trigger a negative feedback of society seeking to reduce the harm. In contrast, today’s great environmental crisis of climate change may cause some harm but there are generally long time delays between rising CO2 concentrations and damage to humans. The consequence of these delays are an absence of urgency; thus although 70% of Americans believe global warming is happening, only 40% think it will harm them (http://climatecommunication.yale.edu/visualizations-data/ycom-us-2016/). Secondly, unlike past environmental challenges, the Earth’s climate system is rife with positive feedback loops. In particular, as CO2 increases and the climate warms, that very warming can cause more CO2 release which further increases global warming, and then more CO2, and so on. Table 2 summarizes the best documented positive feedback loops for the Earth’s climate system. These feedbacks can be neatly categorized into carbon cycle, biogeochemical, biogeophysical, cloud, ice-albedo, and water vapor feedbacks. As important as it is to understand these feedbacks individually, it is even more essential to study the interactive nature of these feedbacks. Modeling studies show that when interactions among feedback loops are included, uncertainty increases dramatically and there is a heightened potential for perturbations to be magnified (e.g., Cox, Betts, Jones, Spall, & Totterdell, 2000; Hajima, Tachiiri, Ito, & Kawamiya, 2014; Knutti & Rugenstein, 2015; Rosenfeld, Sherwood, Wood, & Donner, 2014). This produces a wide range of future scenarios. Positive feedbacks in the carbon cycle involves the enhancement of future carbon contributions to the atmosphere due to some initial increase in atmospheric CO2. This happens because as CO2 accumulates, it reduces the efficiency in which oceans and terrestrial ecosystems sequester carbon, which in return feeds back to exacerbate climate change (Friedlingstein et al., 2001). Warming can also increase the rate at which organic matter decays and carbon is released into the atmosphere, thereby causing more warming (Melillo et al., 2017). Increases in food shortages and lack of water is also of major concern when biogeophysical feedback mechanisms perpetuate drought conditions. The underlying mechanism here is that losses in vegetation increases the surface albedo, which suppresses rainfall, and thus enhances future vegetation loss and more suppression of rainfall—thereby initiating or prolonging a drought (Chamey, Stone, & Quirk, 1975). To top it off, overgrazing depletes the soil, leading to augmented vegetation loss (Anderies, Janssen, & Walker, 2002). Climate change often also increases the risk of forest fires, as a result of higher temperatures and persistent drought conditions. The expectation is that forest fires will become more frequent and severe with climate warming and drought (Scholze, Knorr, Arnell, & Prentice, 2006), a trend for which we have already seen evidence (Allen et al., 2010). Tragically, the increased severity and risk of Southern California wildfires recently predicted by climate scientists (Jin et al., 2015), was realized in December 2017, with the largest fire in the history of California (the “Thomas fire” that burned 282,000 acres, https://www.vox.com/2017/12/27/16822180/thomas-fire-california-largest-wildfire). This catastrophic fire embodies the sorts of positive feedbacks and interacting factors that could catch humanity off-guard and produce a true apocalyptic event. Record-breaking rains produced an extraordinary flush of new vegetation, that then dried out as record heat waves and dry conditions took hold, coupled with stronger than normal winds, and ignition. Of course the record-fire released CO2 into the atmosphere, thereby contributing to future warming. Out of all types of feedbacks, water vapor and the ice-albedo feedbacks are the most clearly understood mechanisms. Losses in reflective snow and ice cover drive up surface temperatures, leading to even more melting of snow and ice cover—this is known as the ice-albedo feedback (Curry, Schramm, & Ebert, 1995). As snow and ice continue to melt at a more rapid pace, millions of people may be displaced by flooding risks as a consequence of sea level rise near coastal communities (Biermann & Boas, 2010; Myers, 2002; Nicholls et al., 2011). The water vapor feedback operates when warmer atmospheric conditions strengthen the saturation vapor pressure, which creates a warming effect given water vapor’s strong greenhouse gas properties (Manabe & Wetherald, 1967). Global warming tends to increase cloud formation because warmer temperatures lead to more evaporation of water into the atmosphere, and warmer temperature also allows the atmosphere to hold more water. The key question is whether this increase in clouds associated with global warming will result in a positive feedback loop (more warming) or a negative feedback loop (less warming). For decades, scientists have sought to answer this question and understand the net role clouds play in future climate projections (Schneider et al., 2017). Clouds are complex because they both have a cooling (reflecting incoming solar radiation) and warming (absorbing incoming solar radiation) effect (Lashof, DeAngelo, Saleska, & Harte, 1997). The type of cloud, altitude, and optical properties combine to determine how these countervailing effects balance out. Although still under debate, it appears that in most circumstances the cloud feedback is likely positive (Boucher et al., 2013). For example, models and observations show that increasing greenhouse gas concentrations reduces the low-level cloud fraction in the Northeast Pacific at decadal time scales. This then has a positive feedback effect and enhances climate warming since less solar radiation is reflected by the atmosphere (Clement, Burgman, & Norris, 2009). The key lesson from the long list of potentially positive feedbacks and their interactions is that runaway climate change, and runaway perturbations have to be taken as a serious possibility. Table 2 is just a snapshot of the type of feedbacks that have been identified (see Supplementary material for a more thorough explanation of positive feedback loops). However, this list is not exhaustive and the possibility of undiscovered positive feedbacks portends even greater existential risks. The many environmental crises humankind has previously averted (famine, ozone depletion, London fog, water pollution, etc.) were averted because of political will based on solid scientific understanding. We cannot count on complete scientific understanding when it comes to positive feedback loops and climate change.

### 1NC – Price Controls CP

#### Text: The member nations of the world trade organization should reform their price control polices for Pharmaceuticals

#### That solves

**Lee Et Al 5-6** [Kah Seng Lee, Yaman, Nur Akmar Taha, Zainol Akbar Zainal, Faculty of Pharmacy, University of Cyberjaya, Cyberjaya, Selangor, Malaysia. Walid Kassab, Faculty of Pharmacy, Universiti Teknologi MARA, Puncak Alam, Selangor, Malaysia. “A systematic review of pharmaceutical price mark-up practice and its implementation” Exploratory Research in Clinical and Social Pharmacy, Volume 2, available online 5-6-2021, Accessed 6-27-2021, <https://doi.org/10.1016/j.rcsop.2021.100020>. Ww

4. Discussion¶ Our current review examines the schematic and regulatory framework of pharmaceutical distribution and mark-ups in the identified countries. Technically, the medicine price is considered as fair if it is affordable to the patient while covering the retailer's costs plus a reasonable profit margin. Contradictorily, from the patient's point of view, a drug price is considered as “fair” when it is affordable, sustainable, and value for money. Perhaps it is contentious to determine the accepted profit margin of a medicine price. This is because fairness in drug prices does not solely reflect the benefit of buyers. Fairness means the policy is advantageous towards the patients too. A fair price should be **inclusive of** manufacturing **costs**, research and development costs, licensing costs, and a reasonable amount of profit. This is known as the price floor. The **price ceiling** is **determined by these factors**. A **fair price** which benefits both parties should be **within the** range of price **floor** **and** price **ceiling**. If a policy places the drug pricing under the price floor, it is undeniable that drug manufacturers and sellers would be forced to delay the production of drugs. Likewise, if a policy favours the sellers and sets drug prices above the ceiling, people would not be able to afford them, thus jeopardizing the balance of supply and demand.¶ Different countries adopt their own methods of pharmaceutical market management. Some countries employ various medical and pharmaceutical policies to balance the incurred healthcare costs and income generated from mark-ups. Others, like Italy, Norway and France, provide subsidies or do not charge for medication in public healthcare facilities. Most countries have implemented price control mechanisms as recommended by the WHO, such as external reference pricing which is commonly used by most European countries to determine the mark-up margin.38,39 The external reference pricing uses the price of a pharmaceutical product in one or several countries to derive a benchmark or reference price in order to set or negotiate the price of the product in the host country.2 Such a mechanism is not without its drawbacks. First, pricing estimation using external reference pricing will be inaccurate if the market intelligence collected the wrong medicine pricing details, including in terms of strength, dosage size, pack size and active ingredients.38,39 Second, setting a low price for a medicine measured using external referencing pricing could potentially lead to a medicine going out of stock in a particular country simply because the pharmaceutical companies will tend to divert supply to neighbouring countries that offer a better price.40¶ Our findings indicate that the majority of studies on drug pricing mark-ups have been conducted in European countries. In fact, there is a lack of pharmaceutical price control especially in developing countries, for example Chile, Ghana and Somalia.41 The absence of price control policies leads to unregulated selling price. Although the price of drugs may be cheaper in such regions compared to Europe and the USA, the quality of drugs might be compromised.42,43 Furthermore, it is difficult to compare drug-pricing mark-ups among different countries, since not all of them are applying mark-up controls consistently across all type of medicines. A clearer picture will be presented if more studies focusing on medicine mark-ups are done according to the drug pharmacological grouping.¶ Among the nine Western countries examined, only the UK imposed a price cap system, which controlled the maximum retail mark-ups at 21% of the wholesale price. Italy was the sole country where fixed fees and regressive fixed fees were regulated at the retailer level.30 In general, price mark-ups across the pharmaceutical supply chain in Western countries fall within the range of 4% to 25%, which is almost 50% lower than Asian countries. This may be a consequence of the countries' varying political stances, financial situations, and pharmaceutical regulations.44,45 Most Europeans are protected by a national medical scheme or health insurance.46 The reason behind these measures might be that the original price of the drug is already high.47 Many pharmaceutical companies manufacture their products in Asia, due to the cheaper labour costs and easier access to raw materials. It seems prudent to propose that an import cost is should be added on top of the original drug price, making it difficult to raise the mark-up ceiling level in Western countries.¶ The advent of effective and reliable biologics and precision medicines are taking the pharmaceutical industry a big step forward. But new, highly individualized **drugs are meaningless** if most patients are **unable to afford** them. Similarly, there is no point in pumping funds into pharmaceutical research and development when the investors are unable to sustain the pharmaceutical lifecycle management. Hence, **every country should have a price control policy to protect the lives of patients**, and the livelihood of pharmaceutical industry players.48¶ **With price regulation, patients are able to afford medications which in most cases are extremely important to keep them healthy**.49 In the USA, it is often being cited that prescription medications are more expensive than in other countries in the region. It is estimated that around **30% of patients in the USA are unable to afford their prescriptions**, and later succumb to their illnesses.50,51 Since drugs are essential to healthcare, some companies are taking advantage of their blockbuster drugs that monopolize the market. With price control measures in place, **this situation could be avoided**. However, controlling the selling price of medicine might lead to price fluctuation in other parts of the pharmaceutical supply chain. For example, drug utilization tends to increase if the price of a drug is decreased tremendously. On the contrary, in tandem with the price drop, unfavourable marketing could lead to less demand and subsequent rationing. The equilibrium of drug supply and demand might be at risk due to the manufacturers' unwillingness to produce the required volume of drugs. In most cases, pharmaceutical companies rely on high profit margins of drug sales to sustain research and development. For instance, the leading pharma companies have drastically slashed budgets for antibiotic innovation due to an unfavourable return of investment caused by the fast development of antibiotic resistance.52,53

### 1NC – Xi lashout DA

#### Xi’s regime is stable right now, but that can quickly change – a setback puts his power in danger

Roberts 4-14, (Dexter Tiff Roberts is a senior fellow in the Asia Security Initiative. He previously was China Bureau Chief at Bloomberg News. “How much support does the Chinese Communist Party really have?”), Atlantic Council, 4-14-21, <https://www.atlanticcouncil.org/blogs/new-atlanticist/how-much-support-does-the-chinese-communist-party-really-have/> // MNHS NL

The onslaught of negative news about the United States is part of an effort to make the Chinese Communist Party (CCP) look capable in contrast to a floundering US administration, thereby convincing the Chinese people that they should be pleased with their current leadership. This is important, as China has ever fewer supporters abroad while US President Joe Biden works to strengthen alliances in Europe and Asia (though Beijing has announced its intention to boost ties with its old allies Russia and North Korea). A recent survey by Gallup revealed that American perceptions of China are at an all-time low, worse eventhan after the Tiananmen Square massacre of 1989. The Chinese people have typically viewed other nations and particularly the United States showing respect for China as a source of legitimacy for the party and a demonstration of its growing global heft. Serious challenges to China’s future economic growth make it doubly important to bolster popular support for the leadership. China’s gross domestic product (GDP) grew by 6.5 percent in the final quarter of last year—faster than almost any country—and policymakers expect to easily meet their target of over 6 percent growth for this year. But the impressive numbers mask problems. In order to keep their economies humming during the pandemic, China’s local governments built up a potentially destabilizing $2.3 trillion of hidden debt in 2020, according to a Bloomberg report citing a Chinese government-affiliated think tank. Income inequality in China has gotten worse thanks to a lopsided recovery from the COVID-19 crisis that has mainly benefitted the wealthy and jeopardized the household consumption of the less well-off. Last year, China’s richest 20 percent had an average disposable income of over 80,000 yuan ($12,000), 10.2 times that of the poorest one-fifth. That surpassed the United States, where the multiple was about 8.4, according to the Organization for Economic Co-operation and Development. As one study put it, “the pandemic has exacerbated [China’s] preexisting inequalities.” For now, however, Chinese leaders are touting their success in controlling the pandemic and returning the economy to normalcy far faster than most of the world has. At the same time, Beijing has squashed questions about COVID-19’s origins and the government’s initial cover-up of the outbreak. And even as China struggles to vaccinate its own people, it has sent Chinese-developed vaccines around the world—sometimes charging high prices for them—as a gesture of its magnanimous goodwill. Meanwhile, the Chinese media has denigrated US vaccines as unsafe. So is all of this a sign of strength or weakness? It seems to be both. China’s leaders are emboldened by their economy outpacing global growth as they witness the West’s real problems. But they are also deeply worried about whether the economic momentum, and the public support that comes with it, will last. “This is a party that lives in a state of catastrophic anxiety,” Matt Pottinger, the former deputy US national security advisor, said in a recent dialogue I moderated at the Mansfield Center in Montana. This year and next are of critical importance to the Chinese leadership. They are planning celebrations heralding the hundredth anniversary of the Chinese Communist Party, falling on July 1 this year, which will highlight the elimination of extreme poverty, rising living standards, and economic growth, among the nation’s other successes. A quinquennial party congress—the country’s top political gathering—will be held in the fall of 2022, setting key policies that will define China’s future path and deciding the top leaders for the next decade. The Winter Olympics will be held in Beijing later that year. At the center of all this is Xi Jinping, who has established himself as China’s most powerful and ambitious leader in decades and is expected to break political norms and stay on for at least a third five-year term at next year’s twentieth Party Congress. Xi’s decision to abandon former leader Deng Xiaoping’s mantra of tao guang yang hui, or “keep a low profile and bide one’s time,” and push much more rapidly for national glory is the driving force behind China’s actions—from its bellicose diplomats to the angry pushback against international criticism of the horrendous human-rights tragedy in Xinjiang. In Xi’s vision, China must replace the West as a global model by “blazing a new trail for other developing countries to achieve modernization” and by offering “Chinese wisdom and a Chinese approach to solving the problems facing mankind,” as he [put it](https://www.chinadaily.com.cn/china/19thcpcnationalcongress/2017-10/18/content_33398070.htm) in 2017. Might Xi and the party face internal opposition? There is no doubt that powerful political families have been upset to see their wealth diminished by Xi’s sweeping crackdown on corruption. Party cadres and intellectuals are unhappy with Xi’s unprecedented power grab and decision to discard the rule-by-consensus norm that Deng set. Private entrepreneurs are spooked by Xi’s extension of party control over their businesses. But for now, Xi’s unrivaled power has cowed any serious opposition and his push to raise China’s global influence is widely supported. Xi, according to Pottinger, “is actually representing the grand strategy and aspirations that the Chinese Communist Party has held for a long time. It’s simply that he has accelerated them.” With the major caveat that limits on free expression affect the Chinese people’s willingness to openly criticize their leaders, polls show growing support for the party. And that is understandable. People’s lives have gotten much better over the last few decades, and it is natural for the Chinese to take pride in the growing strength of their country after years of feeling like a little brother to an often hectoring United States. Progress on combating the pandemic has also lifted support for the Chinese regime, and a barrage of propaganda from China’s press constantly reinforces the idea that life in China is now better than it is in the rest of the world. But positive sentiments can quickly evaporate. Research in China by Wang Chengli of the Shanghai University of Finance and Economics and Huang Haifeng of the University of California, Merced has shown that when a government is exposed as having misled or deceived its own people, such revelations can have “lasting effects on government credibility and can erode citizen satisfaction with the government.” Even more significant is the peril of elevated expectations. Many young Chinese have only known rising GDP and living standards. The CCP could face blowback if the economy slows substantially or, for example, following a failed Chinese military foray into Taiwan. The latter scenario would be an enormous blow to the prestige of a government that has based one plank of its legitimacy on reunifying a divided China and protecting the country’s sovereignty. And the economic costs of an attempted invasion would damage the party’s standing too. “Satisfaction and support must be consistently reinforced,” write Edward Cunningham, Tony Saich, and Jesse Turiel of the Harvard Ash Center. “[T]his is a double-edged sword. Citizens who have grown accustomed to increases in living standards and service provision will expect such improvements to continue, and citizens who praise government officials for effective policies may blame them when policy failures affect them.” The precarious balancing act that China’s leaders have struck—one that mixes strident nationalism and policies that push overheated economic growth with overwrought propaganda—will continue to present them with daunting challenges.

#### Strong IPR key to long term Xi strat and national security – he’s willing to fight if threatened

Ho 2-2 [Matt Ho “Chinese President Xi Jinping says intellectual property protection is key part of country’s development plans” Published: South China Morning Post, February 2, 2021] [https://www.scmp.com/news/china/politics/article/3120118/chinese-president-xi-jinping-says-intellectual-property?module=perpetual\_scroll&pgtype=article&campaign=3120118] [Ho: Matt Ho has covered the dynamics of China’s changes for the Post since 2010. Before joining the Post, he was deputy Beijing bureau chief for Hong Kong Commercial Radio and a Hong Kong government international trade specialist.] //MNHS NL || cut SM

Chinese President Xi Jinping has said intellectual property protection occupies a central position in China’s new development strategy and promised that the state will strengthen its support for businesses operating overseas.

He also said Beijing will also curb anticompetitive activities at home and abroad and support fairer global intellectual property governance, according to a newly released transcript of a speech he made to a Politburo “group learning session” in November.

Encouraging innovation is a key element of the medium and long-term development plans outlined by the leadership the previous month, and Xi told the event: “Innovation is the No 1 driver for development. Protecting intellectual property is protecting innovation.”

Beijing is also alarmed by the export ban on technology imposed by the Donald Trump administration, which has highlighted Beijing’s vulnerability when relying on others for critical technology.

Xi said cadres should see intellectual property protection as a “national strategy”, adding: “Intellectual property is the core factor of global competitiveness and has become a focus of many international disputes. We should dare to fight and fight well. We shall never give up our legitimate rights and national core interests.”

In the speech, published in the latest issue of the Communist Party journal Qiushi or Seeking Truth, Xi told the cadres to crack down on intellectual property violations and overcome local protectionism.

“We can only improve our business environment and elevate the opening up of our country to a higher level and quality if we strictly enforce IP protection,” Xi told the meeting, adding that the protection of intellectual property is also key to safeguarding China’s national security and home-grown core technologies.

#### A threatened CCP starts multiple regional conflicts – SCS, Japan, US, and Taiwan

J. Michael **Cole 14**. Senior fellow with the University of Nottingham’s China Policy Institute, associate researcher at the French Center for Research on Contemporary China, senior officer of the Thinking Taiwan Foundation, and former analyst at the Canadian Security Intelligence Service with a Master’s Degree in War Studies from the Royal Military College of Canada, “Where Would Beijing Use External Distractions?” The Diplomat, July 10, 2014, <http://thediplomat.com/2014/07/where-would-beijing-use-external-distractions/> recut // MNHS NL

Throughout history, embattled governments have often resorted to external distractions to tap into a restive population’s nationalist sentiment and thereby release, or redirect, pressures that otherwise could have been turned against those in power. Authoritarian regimes in particular, which deny their citizens the right to punish the authorities through retributive democracy — that is, elections — have used this device to ensure their survival during periods of domestic upheaval or financial crisis. Would the Chinese Communist Party (CCP), whose legitimacy is so contingent on social stability and economic growth, go down the same path if it felt that its hold on power were threatened by domestic instability? Building on the premise that the many contradictions that are inherent to the extraordinarily complex Chinese experiment, and rampant corruption that undermines stability, will eventually catch up with the CCP, we can legitimately ask how, and where, Beijing could manufacture external crises with opponents against whom nationalist fervor, a major characteristic of contemporary China, can be channeled. In past decades, the CCP has on several occasions tapped into public outrage to distract a disgruntled population, often by encouraging (and when necessary containing) protests against external opponents, namely Japan and the United States. While serving as a convenient outlet, domestic protests, even when they turned violent (e.g., attacks on Japanese manufacturers), were about as far as the CCP would allow. This self-imposed restraint, which was prevalent during the 1980s, 1990s and 2000s, was a function both of China’s focus on building its economy (contingent on stable relations with its neighbors) and perceived military weakness. Since then, China has established itself as the world’s second-largest economy and now deploys, thanks to more than a decade of double-digit defense budget growth, a first-rate modern military. Those impressive achievements have, however, fueled Chinese nationalism, which has increasingly approached the dangerous zone of hubris. For many, China is now a rightful regional hegemon demanding respect, which if denied can — and should — be met with threats, if not the application of force. While it might be tempting to attribute China’s recent assertiveness in the South and East China Seas to the emergence of Xi Jinping, Xi alone cannot make all the decisions; nationalism is a component that cannot be dissociated from this new phase in Chinese expressions of its power. As then-Chinese foreign minister Yang Jiechi is said to have told his counterparts at a tense regional forum in Hanoi in 2010, “There is one basic difference among us. China is a big state and you are smaller countries.” This newfound assertiveness within its backyard thus makes it more feasible that, in times of serious trouble at home, the Chinese leadership could seek to deflect potentially destabilizing anger by exploiting some external distraction. Doing so is always a calculated risk, and sometimes the gambit fails, as Slobodan Milosevic learned the hard way when he tapped into the furies of nationalism to appease mounting public discontent with his bungled economic policies. For an external distraction to achieve its objective (that is, taking attention away from domestic issues by redirecting anger at an outside actor), it must not result in failure or military defeat. In other words, except for the most extreme circumstances, such as the imminent collapse of a regime, the decision to externalize a domestic crisis is a rational one: adventurism must be certain to achieve success, which in turn will translate into political gains for the embattled regime. Risk-taking is therefore proportional to the seriousness of the destabilizing forces within. Rule No. 1 for External Distractions: The greater the domestic instability, the more risks a regime will be willing to take, given that the scope and, above all, the symbolism of the victory in an external scenario must also be greater. With this in mind, we can then ask which external distraction scenarios would Beijing be the most likely to turn to should domestic disturbances compel it to do so. That is not to say that anything like this will happen anytime soon. It is nevertheless not unreasonable to imagine such a possibility. The intensifying crackdown on critics of the CCP, the detention of lawyers, journalists and activists, unrest in Xinjiang, random acts of terrorism, accrued censorship — all point to growing instability. What follows is a very succinct (and by no means exhaustive) list of disputes, in descending order of likelihood, which Beijing could use for external distraction. 1. South China Sea The South China Sea, an area where China is embroiled in several territorial disputes with smaller claimants, is ripe for exploitation as an external distraction. Nationalist sentiment, along with the sense that the entire body of water is part of China’s indivisible territory and therefore a “core interest,” are sufficient enough to foster a will to fight should some “incident,” timed to counter unrest back home, force China to react. Barring a U.S. intervention, which for the time being seems unlikely, the People’s Liberation Army (PLA) has both the numerical and qualitative advantage against any would be opponent or combination thereof. The Philippines and Vietnam, two countries which have skirmished with China in recent years, are the likeliest candidates for external distractions, as the costs of a brief conflict would be low and the likelihood of military success fairly high. For a quick popularity boost and low-risk distraction, these opponents would best serve Beijing’s interests. 2. Jammu and Kashmir, Arunachal Pradesh Although Beijing claims that it is ready for a settlement of its longstanding territorial disputes with India, the areas remain ripe for the re-ignition of conflict. New Delhi accuses China of occupying 38,000 square kilometers in Jammu and Kashmir, and Beijing lays claim to more than 90,000 square kilometers of territory inside the Indian state of Arunachal Pradesh. A few factors militate against the suitability of those territories for an external distraction, chief among them the difficult access in winter, and the strength of the Indian military, which would pose a greater risk to PLA troops than those of Vietnam or the Philippines in the previous scenario. Nevertheless, memories of China’s routing of the Indian military in the Sino-Indian War of 1962 could embolden Beijing. Though challenging, the PLA would be expected to prevail in a limited conflict with Indian forces, and China would have taken on a greater regional power than Vietnam or the Philippines, with everything that this entails in terms of political benefits back home. 3. East China Sea and Japan Sparking a war with Japan, presumably over the disputed Senkaku/Diaoyu islets, would represent a major escalation on Beijing’s part. Assuming that rational actors are in control in Beijing, a decision to begin hostilities with the modern and skilled Japan Self-Defense Forces would only be made if domestic instability were serious enough. Still, high resentment of the Japanese stemming from Japanese aggression before and during World War II and the competitive nature of the bilateral relationship make Japan the perfect candidate for an external distraction. More than any other conflict, hostilities with Japan would rally ordinary Chinese to the flag and tap into hatred that the leadership knows it could exploit if necessary. Although the chances of prevailing would be much smaller than in the South China Sea or Indian scenarios (especially if the U.S. became involved), the dividends of victory against Japan — anything from teaching Tokyo a lesson to redressing historical injustices — could be such as to become a major factor in appeasing major domestic unrest in China. Unless the CCP were on the brink of collapse, it is unlikely that the leadership in Beijing would escalate tensions with Japan beyond the disputed islets. In other words, military action probably would not extend to other parts of Japan’s territory, unless, of course, the conflict widened. Containing the conflict by limiting it to the Senkaku/Diaoyus would therefore be part of Beijing’s strategy. 4. Taiwan The “reunification” of Taiwan remains a so-called “core interest” of China and a major component of the CCP’s legitimacy with the public. Despite rapprochement in recent years, a substantial component of the PLA remains committed to a Taiwan contingency. Although the risks of war in the Taiwan Strait are low at the moment, China never shelved its plans to annex the island by force if necessary, and has vowed to do so should Taipei seek to unilaterally change the status quo by declaring de jure independence. Under Xi, Beijing has also signaled that while it is willing to be patient with Taiwanese and would prefer to use financial incentives to gradually consolidate its grip on Taiwan, it does not intend to be patient forever. In other words, foot-dragging on Taiwan’s part, or the election of a political party that is less amenable to rapprochement than the ruling Kuomintang (KMT), could prompt Beijing to choose a more aggressive course of action. Serious unrest on the island could also provide Beijing with the “justification” it needs to involve the PLA, which would be deployed to “protect” Taiwanese “compatriots.” Given that definitions of progress on “reunification” are very much Beijing’s to decide, any incident could theoretically warrant the use of force against Taiwan, especially if major domestic unrest compelled the CCP to seek an external distraction. Militating against such a decision is the fact that anything short of a full invasion of the island would probably forever kill any chance of “peaceful unification” with Taiwan, as the 1995-1996 Taiwan Strait missile crisis demonstrated. A limited military campaign against Taiwan is therefore probably not a good option for an external distraction, as the backlash against aggression would undo years of calibrated Taiwan policy and destroy hopes of unification, which would greatly discredit the CCP with the Chinese public, not to mention the PLA. A full invasion of Taiwan would then provide greater chances of success, at least if we measure success by its impact on public opinion amid serious unrest in China. However, the growing power imbalance in the Taiwan Strait notwithstanding, invading the island would be an extraordinarily difficult — and costly — task; talk of a “quick, clear war” remains just that, and pacifying the island would be a formidable challenge. Should the conflict drag on, as it most certainly would, whatever advantage the CCP may have accumulated by tapping into nationalist sentiment could dwindle and further contribute to resentment against the party. Consequently, unless the CCP were on the brink of collapse, Taiwan would be an extremely poor candidate for external distraction, worse even than Japan, where the chances of success in a limited campaign are higher. 5. United States The last, and least likely, candidate for external distraction would be for the PLA to turn its sights on U.S. forces in the Pacific. For obvious reasons, such a course of action would be a last resort, a last-ditch effort to prevent the complete collapse of the CCP due to domestic factors. The chances of prevailing in a direct military confrontation with U.S. forces in the region would be next to nil. A decision to attack the U.S. would qualify as irrational, a departure from the realm of calculations that would buttress decisions in any of the alternative scenarios discussed above. Still there are examples of countries that embarked on what, in hindsight, can only be described as suicidal adventures by attacking a much more powerful enemy. Japan demonstrated that this is possible during World War II. A likelier source of conflict between the PLA and U.S. forces would be indirect, such as U.S. involvement in limited hostilities between China and any of the countries mentioned above (with Japan and Taiwan as the likeliest). As the PLA is configured not to take on the U.S. military directly but rather asymmetrically, China would increase its chances of scoring domestic points by playing to its strengths — by inflicting damage on U.S. forces with its anti-access/area-denial, or A2/AD. Sinking an aircraft carrier on its way to the East China Sea or towards the Taiwan Strait, for example, could do wonders in terms of public opinion and provide temporary cover for an embattled CCP. Ultimately, however, the costs of taking on the U.S. military, added to the extremely low likelihood that Chinese troops could secure the kind of victory that would be necessary to rescue the CCP from internal strife, mean that the U.S. is an especially bad candidate for external distraction. Facing serious domestic instability that does not immediately threaten to topple the CCP, Beijing’s likeliest candidates for succor in external distraction would be Options 1 and 2; much more substantial unrest would probably make Option 3 the most appealing. Given the costs and low chances of success, Options 4 and 5 are extremely poor choices.

# Case

## Waivers

### Solvency – Not Patents

#### Waivers don’t solve – the issue is in lack of materials. Moderna literally tried the aff

Tabarrok 21

Alex Tabarrok (Bartley J. Madden Chair in Economics at the Mercatus Center and am a professor of economics at George Mason University). “Patents are Not the Problem!” Marginal Revolution. 6 May 2021. JDN. https://marginalrevolution.com/marginal revolution/2021/05/ip‐is‐not‐the‐constraint.html [Brackets in original] || cut SM

Patents are not the problem. All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. Licenses are widely available. AstraZeneca have licensed their vaccine for production with manufactures around the world, including in India, Brazil, Mexico, Argentina, China and South Africa. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but technology transfer isn’t easy and there are limited supplies of raw materials:

Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to transfer their technology there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country.

Plastic bags are a bigger bottleneck than patents. The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, another potential mRNA vaccine, is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As Derek Lowe said:

Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a lot of potential choke points and rate‐limiting steps in them, and there is no wand that will wave that complexity away.

Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). Why do you think China hasn’t yet produced an mRNA vaccine? Hint: it isn’t fear about violating IP. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can.

### Solvency – Root Cause – Garde

#### Waiving IPR is just symbolic – the aff alone cannot solve bc it does nothing about the root cause of vaccine shortages

Garde et al 5-6 [Damian Garde, National Biotech Reporter Damian covers biotech, is a co-writer of The Readout newsletter, and a co-host of "The Readout LOUD" podcast. , Helen Branswell , Senior Writer, Infectious Disease, Helen covers issues broadly related to infectious diseases, including outbreaks, preparedness, research, and vaccine development., and Matthew Herper, Senior Writer, Medicine, Editorial Director of Events Matthew covers medical innovation, 5-6-2021 , “Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive” STAT, Accessed 8-14-2021, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/> ww

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic.¶ For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. ¶ Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022.¶ Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said.¶ “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.”¶ That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents.¶ Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. ¶ “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.”¶ Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production.¶ “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said.¶ In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses.¶ That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines.¶ “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting.¶ While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.¶ “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. ¶ There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing.¶ Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. ¶ “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said.¶ He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing.¶ “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.”¶ As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.”

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## Accessess

### Alt Causes – Branding

#### Alt cause – companies increase prices to protect their brand name and signal quality

Kyle 14[(Margaret Kyle is a noted authority on competition and intellectual property in the pharmaceutical industry.), et al. NBER WORKING PAPER SERIES INTELLECTUAL PROPERTY RIGHTS and ACCESS to INNOVATION: EVIDENCE from TRIPS. , 2014.] PW

There are alternative explanations for a change in prices unrelated to non-IP policy shifts or political pressures. First, if originators are more willing to launch new products when they are protected by IPRs, the set of products available in a market will expand. This larger set of products may include those for which patents shifted the expected quantity sold by the innovator more than the price commanded (especially in relatively poor countries, where demand may be more elastic). In other words, the adoption of patents may have encouraged the launch of products with lower prices, for which innovators could not cover the fixed costs of launch without the assurance of 100% market share. Another explanation is related to the form of competition in developing markets. While generic products in developed countries are usually considered (nearly) perfect substitutes for the original product, emerging markets often see competition between “branded” generics, where real or perceived quality may vary across firms. In these environments, firms may incur some costs to develop and protect their brand names, or use price to signal quality. It is possible that by allocating the entire market to the originator, TRIPS-related IPRs have eliminated the need to differentiate from other producers of the same molecule; lower costs allow lower prices.

No extinction impact means don’t care

## Innovation

### U/Q – Generic

#### Innovation high now, but continued investments are crucial to meet the demands

Furstenthal et al 20 [(Laura Furstenthal serves healthcare clients globally as well as not-for-profit organizations, governments, and Nobel laureates, guiding innovation in strategy, organization, research and development, commercialization, and operations), et al. “Healthcare Innovation: Building on Gains Made through the Crisis.” McKinsey & Company, McKinsey & Company, 12 Nov. 2020, www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/healthcare-innovation-building-on-gains-made-through-the-crisis. Accessed 6 Aug. 2021.] PW

Leaders should consider the lessons and achievements of the COVID-19 crisis in forging new innovation aspirations—and the mechanisms needed to execute them. Medicine is a living science that prides itself on continual discovery. In recent years, healthcare innovators have brought us artificial-intelligence algorithms that arguably read chest X-rays as well as or better than radiologists, inexpensive genomic sequencing that can guide personalized cancer treatments, and vast improvements in population health management through big data and analytics, to name just a few examples. While the COVID-19 pandemic has placed unparalleled demands on modern healthcare systems, the industry’s response has vividly demonstrated its resilience and ability to bring innovations to market quickly. But the crisis is likely far from over and the sector’s innovation capabilities must continue to rise to the challenges presented both by COVID-19 and the economic fallout from its spread. While many industries are facing unprecedented disruption, medicine and healthcare are uniquely affected given the nature of this crisis. For example, pharmaceutical companies racing to develop vaccines must also manage complex supply chains, new models for engagement with healthcare professionals, a largely remote workforce, and disruption to many clinical trials. Similarly, hospitals are caring for COVID-19 patients with evolving protocols while maintaining continuity of care for others, often against the backdrop of vulnerable staff, supply and equipment shortages, and, for some, accelerating financial headwinds. While the COVID-19 pandemic has placed unparalleled demands on modern healthcare systems, the industry’s response has vividly demonstrated its resilience and ability to bring innovations to market quickly. The effects of the pandemic on the industry continue to be profound. The shifts in consumer behavior, an [acceleration of established trends](https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-great-acceleration), and the likely deep and lasting economic impact will potentially affect healthcare companies no less—and quite possibly more—than those in other sectors. Around the world, more than [90 percent of executives](https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/innovation-in-a-crisis-why-it-is-more-critical-than-ever) we polled believe COVID-19 will fundamentally change their businesses, and 85 percent predict lasting changes in customers’ preferences. Among healthcare leaders, two-thirds expect this period to be the most challenging in their careers.1 To meet both the humanitarian challenge and the obligation to their stakeholders, leaders of healthcare organizations need to meet the innovation imperative. History tells us that organizations that invest in innovation during a crisis [outperform their peers in the recovery](https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-great-acceleration) (exhibit). What’s more, a crisis can create an urgency that rallies collaborative effort, breaks through organizational silos, and overcomes institutional inertia. Exhibit During the course of this year, the healthcare industry has produced inspiring examples of innovation in products, services, processes, and business and delivery models, often in partnership with other sectors. For example, Sheba Medical Center in Israel is working with TytoCare to keep COVID-19 patients in their homes by supplying them with special stethoscopes that both listen to their hearts and transmit images of their lungs to a care team that can intervene as appropriate.2 In the United States, Zipline, which specializes in delivering medical supplies to remote areas, quickly formed a partnership with Novant Health in North Carolina to distribute supplies to hospitals via drones.3 The adoption of telehealth has exploded, from 11 percent of consumers using it in 2019 to [46 percent in April 2020](https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality), and well more than half of healthcare providers polled indicate higher comfort with this care-delivery method than before. Given the speed of recent changes, it is likely that parts of the healthcare ecosystem will operate in different ways in the coming years. To keep pace with the industry’s evolution, healthcare leaders should consider assessing their organizations’ readiness to innovate at scale and whether the needed capabilities are in place. Our past research shows that successful innovation in large organizations stems from a commitment to eight principles and practices: aspire, choose, discover, evolve, accelerate, scale, extend, and mobilize. These [eight essentials of innovation](https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-eight-essentials-of-innovation), when applied as a group, enable businesses to innovate more successfully and [outperform their peers](https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/the-innovation-commitment). Here is how healthcare players can consider applying them to their unique context at this extraordinary time.

### Link – Generic

#### IPP is key to sustaining innovation – without protection pharma companies are not willing to take the risk of investing in a new drug out of fear they can’t make profit competing with generics

Grabowski Et Al 15[Henry G. Grabowski, Is a professor of economics at Duke University, in Durham, North Carolina., Joseph A. DiMasi, director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long, is a senior advisor at the Analysis Group, in Boston, Massachusetts. February 2015, “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation” Health Affairs, Accessed 7-29-2021, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047> ww

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