# 2nr

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#### First, “incremental” innovations are a key aspect of R&D, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

#### Second, evergreening only proves flaws in the application process, not the legitimacy of patents themselves, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

In the context of pharmaceuticals, it has been suggested that patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs, different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness

# 1NC vs. Lexington JB

## Offs

### T

#### Interpretation: The affirmative must specify to what degree they reduce intellectual property protections.

#### Reduce requires quantification.

Passarello 13 – J.D. Candidate, Duke University School of Law, 2013. (Nicholas, NOTE: THE ITEM VETO AND THE THREAT OF APPROPRIATIONS BUNDLING IN ALASKA, 30 Alaska L. Rev. 125, Lexis)//BB

With respect to the item veto power, the question in the case was whether or not the governor could strike descriptive language without affecting the rest of the appropriation. The state constitution clearly guarantees the power to "strike or reduce items in appropriations bills." 61 To determine what exactly it is that the governor may strike, the Alaska Supreme Court here addressed the meaning of "item" for the first time. 62 The court concluded that "item" means "a sum of money dedicated to a particular purpose." 63 This holding rested on five lines of analysis, all of which indicate that the amount of an appropriation is the object affected by the item veto power. First, the court noted that the word "item" implies "a notion of unity between two essential elements of an appropriation: the amount and the purpose." 64 Altering the amount of an item is expressly allowed in the Constitution via the reduction power, 65 but to alter the purpose would destroy that unity by fundamentally changing the item into something else not enacted by the legislature. 66 Second, the use of the word "reduce" implies a quantitative effect**,** and the drafters likely intended the companion word "strike" to [\*136] have the same type of effect as well. 67 Third, "**reduce**" and "strike" **describe** the same **action applied to different extents:** **when an amount is "reduced**" **to the point where it is lessened to nothing**, **it is effectively "struck."** 68 **Thus, the object** of the "strike" **must be associated with an amount** of money **to the extent** **that it can be lessened**. 69 Fourth, the historical purpose of the item veto was to curtail the amount of state spending by mitigating the effects of log-rolling, a purpose most closely directed at the amount of the appropriation. 70 Fifth, "public policy disfavors a reading of "item' that would permit the executive branch to substantively alter the legislature's appropriation bills, resulting in appropriations passed without the protection our constitution contemplates." 71 For these reasons, the court concluded that the power to "strike" only refers to completely diminishing the amount of an appropriations item, not the descriptive language accompanying it.

#### Violation: they don’t

#### Vote neg

#### 1] Precision – they don’t defend the resolution, which opens the floodgates for what the aff could be – the resolution is the only stable point of contestation

#### 2] Shiftiness – vague plan wording wrecks Neg Ground since it’s impossible to know which DAs link or which CPs are competitive since different IP’s have different implications – absent 1AC specification, the 1AR can squirrel out of links by saying they don’t effect a certain protection or they don’t reduce IP enough to trigger the link.

#### 3] CX doesn’t check - 1] Skews pre-round prep – key to in-depth clash, 2] Judges don’t flow CX, 3] Unverifiable and Irresolvable,

#### Independently vote Negative on Presumption since the Aff gets struck down for being void-for-vagueness since they don’t have an explanation of what is reduced or remaining after the Plan.

#### 4] Topic Education – nuanced debates about IP requires specification since each form of IPR has specific issues related to it so generalization disincentivizes in-depth research. Topic Education is a voter since we only debate the topic for two months.

#### 5] Reductions Spec isn’t regressive – it’s a core discussion central to the literature, we’ve read a card proving predictability, and is a floor for topic debates.

#### Fairness

#### Education

#### No RVI – a] logic b] baiting c] topic ed

#### DTD

#### Competing interps

### DA

#### US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages

Scott **Moore** **2020** [(Director of the Penn Global China Program at the University of Pennsylvania. Previously, Moore was a Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S.) “China’s Role In The Global Biotechnology Sector And Implications For U.S. Policy” <https://www.brookings.edu/wp-content/uploads/2020/04/FP_20200427_china_biotechnology_moore.pdf>] TDI // Recut NChu

EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

#### The aff’s waiving of IP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech

Josh Rogin 4-8. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] TDI // Recut NChu

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

#### China will convert biotechnology gains to military advantages, undermining US primacy – specifically true in the context of vaccines

Mercy A. Kuo 2017 [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI // Recut NChu

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, **which necessitates acquiring strategic tech**nological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? **Genomics** and computing research **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for biodefense.** This knowledge will lead to increasing developments at the forefront of medical countermeasures, **including vaccines**, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, **with potential applications in military enhancements**. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? **Gaining access to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in bio-military research.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, **malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.**

#### A lack of forward military power causes great power conflict that escalates to nuclear war extinction, Brands 18’

Hal Brands is the Henry Kissinger Distinguished Professor at Johns Hopkins-SAIS, senior fellow at the Center for Strategic and Budgetary Assessments, and a Bloomberg Opinion columnist. “Danger: Falling Powers” HAL BRANDS October 24, 2018 *The American Interest* <https://www.the-american-interest.com/2018/10/24/danger-falling-powers/> //LHP MWS

The dangers created by a rising revisionist power are obvious. As a dissatisfied nation accrues greater strength, the state uses that strength to avenge perceived slights and attain greater influence. It enlarges its definition of national interests; and it defends those interests more vigorously. Constraints and threats that seemed tolerable when the state was weaker come to seem intolerable as it gains the power to affect them. And as the rising state behaves more assertively, its ambitions inevitably collide with the interests of established powers and their allies. Progressively sharper moves and counter-moves typically ensue; competition intensifies; the system plunges into military conflict. This sequence sounds familiar because it has played out many times. World War I was a lot of things, but it was partially a clash between Germany, which was seeking to translate its growing economic and military might into a position of European dominance and global power, and the United Kingdom, which was determined to protect its European interests and global primacy. During the Cold War, too, arguably the most dangerous moments came when the growth of Soviet military capabilities tempted the Kremlin to more boldly assert its interests against the West. Shortly after Stalin acquired nuclear weapons, he authorized the North Korean invasion of South Korea, causing global tensions to rise. When the Soviets subsequently acquired a ballistic missile capability, Nikita Khrushchev used this power to pursue gambits—trying to foreclose Western access to Berlin, deploying nuclear missiles to Cuba—that brought the world to the brink of war. Fear of being overtaken by the Soviets, in turn, sometimes pushed American leaders to consider risky policies of their own. In the late 1940s and early 1950s, some American strategists—and some wayward philosophers like Bertrand Russell—advocated waging preventive war before the Kremlin acquired usable nuclear weapons, for fear it would be impossible to contain Moscow once that threshold had been crossed.2 Fortunately, the Thucydidean formula never reached its grim conclusion during the Cold War. But the underlying pressures were there, and they have reappeared as great-power competition has surged anew. As Russia recovered from its post-Cold War weakness beginning in the early 2000s, it made progressively stronger moves to reclaim lost influence and prestige. By waging wars of conquest against vulnerable, Western-oriented neighbors such as Georgia and Ukraine, by projecting military power and geopolitical influence into the Middle East, by interfering in U.S. elections and using a variety of measures to sap the strength and cohesion of the nations opposing it, Russia has shown that it no longer accepts the unipolar order that prevailed after the Cold War. And as Chinese power has grown exponentially over the past quarter-century, Beijing has become steadily more assertive in challenging American influence in the Asia-Pacific and globally. Beijing’s creeping expansionism in the South China Sea and East China Sea, its efforts to draw the countries along its periphery and beyond into its economic and geopolitical orbit, and its development of more advanced military capabilities and projection of both military and economic power ever farther abroad have produced growing fears among Washington and its allies. Observers such as Harvard’s Graham Allison have warned, not implausibly, that Washington and Beijing may be headed for a great hegemonic war like the one between Athens and Sparta.3 There is, then, no disputing that rising powers can have profoundly disruptive effects. Yet such powers might not actually be the most aggressive or risk-prone type of revisionist state. After all, if a country’s position is steadily improving over time, why risk messing it all up through reckless policies that precipitate a premature showdown? Why not lay low until the geopolitical balance has become still more favorable? Why not wait until one has surpassed the reigning hegemon altogether and other countries defer to one’s wishes without a shot being fired? So while a rising revisionist power may be tempted to assert itself, it should also have good reason to avoid going for broke. Now imagine an alternative scenario. A revisionist power—perhaps an authoritarian power—has been gaining influence and ratcheting its ambitions upward. Its leaders have cultivated intense nationalism as a pillar of their domestic legitimacy; they have promised the populace that past insults will be avenged and sacrifices will be rewarded with geopolitical greatness and global prestige. Yet then the country’s potential peaks, either because it has reached its natural limit or because of some unforeseen development, and the balance of power starts to shift in unfavorable ways. It becomes clear to the country’s leadership that it may not be able to accomplish the goals it has set and fulfill the promises it has made, and that the situation will only further worsen with time. A roll of the iron dice now seems more attractive: It may be the only chance the nation has to claim geopolitical spoils before it is too late. In this scenario, it is not rising power that makes the revisionist state so dangerous, but the temptation to act before decline sets in. In this scenario, it is not rising power that makes the revisionist state so dangerous, but the temptation to act before decline sets in. In this sense, the dynamic bears a resemblance to the famous Davies J-Curve theory of revolution, wherein a populace is held to be more inclined to revolt not when it is maximally oppressed but rather when raised expectations are shown to be in vain. Obviously, rational analysis does not always prevail in world politics. Rising states can become intoxicated with their own strength; they may simply get tired of waiting to attain the status they desire; or some domestic pressure may impel leaders to act dangerously. But revisionists whose power has begun to decline, or who have hit a rogue bump in the road, may not feel that they even have the option of waiting. Consider again the outbreak of World War I. From a long-term perspective, Germany may have been a rising and increasingly confident power prior to the war, but Berlin’s decision-making in 1914 took place against the more immediate backdrop of deep pessimism caused by the fear of impending decline. In the east, Germany was menaced by the growth of Russian military power and the approaching completion of an improved railroad network that would dramatically shorten Russia’s mobilization timetable. In the west, changes in French conscription laws were rapidly enhancing the military manpower of another rival. The result, in Berlin, was mounting apprehension that Germany’s ability to fight a two-front war—the cornerstone of its military strategy—was about to collapse, and that its geopolitical aspirations were about to be crushed in a Franco-Russian-British vise. If that happened, internal frictions might become unmanageable: Nationalism and geopolitical ambition might no longer be able to dampen the shocks caused by intensifying conflicts between rival social and political groups. This is why Germany ran such enormous risks in the July 1914 crisis—by pushing Austria-Hungary to take an uncompromising position against Serbia after the assassination of Archduke Franz Ferdinand, by promising to back the Dual Monarchy come what may, by implementing the Schlieffen Plan for a knock-out blow against France despite the danger that this would bring Britain into the war. Chief of General Staff Helmuth von Moltke acknowledged the danger of a “war which will annihilate the civilization of almost the whole of Europe for decades to come,” but he and his colleagues pushed forward on grounds that Germany’s dreams of greatness would become hopeless illusions if not realized soon.4 Similar motives were at work in World War II. Hitler’s Germany had the most radical designs of any revisionist power in history, and it is inconceivable that Hitler would not have used Germany’s revived economic and military might to precipitate a major conflict at some point. Yet Hitler’s calculations about when and how to do so—namely, by invading Poland in 1939—were strongly influenced by fears of imminent decline. Due to rapid rearmament, the Germany economy was overheating by 1938-39, creating concerns that Berlin’s relative economic power would soon fade absent additional conquests. Just as importantly, German officials believed that their early rearmament and the absorption of resources from Austria and Czechoslovakia had given them a critical military advantage over other European powers, but that this advantage would fade as those countries—and the United States—began mobilizing. It had become necessary “to begin immediately,” Hitler explained to Mussolini to following year, “even at the risk of thereby precipitating the war intended by the Western powers.”5 In the same vein, the sense that the future would only be worse—that Germany had reached the apex of its power, that it must act boldly while it still could—underpinned the decision to invade the Soviet Union in June 1941. As Timothy Snyder has argued, Hitler believed that Germany had only a finite window to seize and colonize Soviet lands—thereby solving the Third Reich’s food supply problems and making it strategically invulnerable—before ongoing British resistance and America’s feared entry into the war began to undermine Berlin’s position.6 Japan, too, was likely influenced by calculations of impending decline. The Japanese empire had been steadily expanding between 1931 and 1940, advancing toward dominance in the Asia-Pacific. But what ultimately provoked the Japanese to strike at America was the realization that the possibilities for attaining that dominance were fading. American rearmament, symbolized by the Two-Ocean Navy Act of 1940, was bound to vitiate Japanese military advantages. “Anyone who has seen the auto factories in Detroit and the oil fields in Texas knows that Japan lacks the national power for a naval race with America,” warned Admiral Yamamoto Isoroku.7 Likewise, the U.S. oil embargo of 1941 had the unintended effect of convincing Japanese leaders that they had to move quickly before they lost the economic wherewithal to wage war. Imperial Japan, like Nazi Germany, was an aggressive power with enormous ambitions; but its penchant for aggression grew strongest when it started to fear those aspirations might not be realized. This history has implications for understanding great-power rivalry today. Both Russia and China have broadened their geopolitical horizons in recent years; both are often thought of as rising or resurgent powers. Yet both Russia and China face the prospect—whether immediate or more distant—that their relative strength may ebb, a phenomenon that could make these countries more aggressive rather than less. The specter of decline surely haunts Vladimir Putin. Russia has compiled an impressive record of expansion over the past decade; it has achieved a significant military overmatch vis-à-vis NATO on the alliance’s eastern flank; it has attained a degree of global influence greater than that enjoyed by any government in Moscow since the 1980s. Yet Putin cannot be confident about Russia’s long-term trajectory. After all, Russia’s economic revival from the early 2000s onward was largely a function of high energy prices; the collapse of those prices after 2014 revealed the long-term weakness of an economy that is probably destined—absent another sustained period of high energy prices—to stagnate over time. Russia is already losing ground against its rivals: Its inflation-adjusted GDP declined from 2014 through 2017, while that of the United States increased by over $1 trillion.8 And although Russia’s demographic trajectory is no longer as catastrophic as it once was, population growth will be anemic at best and negative at worst in coming decades. These trends, combined with the impact of Western economic sanctions, are beginning to upset Putin’s plans for continued military modernization: Kremlin defense spending declined, perhaps by as much as 20 percent, from 2017 to 2018, as Russia also began to cut spending on key social programs and pensions. Finally, fear of political instability is omnipresent for Russian leaders, who must deal with separatist forces in the North Caucasus as well as dissent provoked by their own repression and policy incompetence. Putin surely understands that these challenges imperil his goals of reasserting Russian dominance within the near abroad and playing a pivotal role in a more multipolar world—which is precisely what makes his statecraft so dangerous. Putin has already established a reputation as a risk-taker who uses bold strokes to compensate for Russia’s limited resource base. His method is to know what he wants and to catch stronger adversaries napping. (That tendency has only become more pronounced in recent years as Russia’s economic prosperity has faded and Putin’s domestic popularity has begun to wane.) He has argued that Russia requires authoritarian rule to be influential abroad; he has promised the Russian populace that the hardships it has endured will be rewarded by greater global stature. “Enormous sacrifices and privations on the part of our people,” he has declared, are the cost of “occupying a major place in world affairs.”9 If Putin perceives that he has only limited time to deliver on these promises, if he senses that the opportunity to redress his longstanding grievances against the West is slipping away, the effect may be to encourage still greater risk-taking. Russian risk-taking could take varied forms: more aggressive behavior in a crisis with NATO in the Baltic or Black Sea regions, perhaps aimed at discrediting NATO’s Article 5 guarantee; a more confrontational posture with respect to America and its partners in Syria or another Middle Eastern hotspot; intensified Russian efforts to disrupt U.S. and European electoral processes; more damaging cyberattacks on critical Western infrastructure; efforts to stir up additional “frozen conflicts” in the former Soviet space; a stronger propensity for escalation—perhaps involving limited use of nuclear weapons—should conflict between Moscow and Washington break out. Whatever the specifics, Washington could find itself facing a competitor with a “now-or-never” mentality—always a dangerous mindset for an authoritarian, revisionist state to have. By contrast, the Chinese leadership still seems to have a “time is on our side” mindset. Even as Beijing’s energy and assertiveness have surged, Chinese leaders have proven less risk-acceptant than their Russian counterparts. They have remained satisfied to advance China’s aims through small, incremental steps—such as island-building and coercion in the South China Sea—rather than dramatic, aggressive lunges. Yet even Chinese leaders cannot be confident that the country’s upward trajectory will continue unbroken for very much longer. In a geopolitical sense, Chinese officials must worry about whether the country’s window is opening or closing with respect to issues like Taiwan. For while China has greater military capability than ever before to pursue reunification through forcible means, Taiwanese support for peaceful unification is at rock-bottom levels, the development of a distinctive Taiwanese national identify becomes more unmistakable every year, and the political pendulum in Taipei is clearly swinging away toward greater resistance to Chinese pressure. There are also warning lights flashing—perhaps flashing in the distance, but flashing nonetheless—when it comes to the fundamentals of Chinese power. Economic growth has been broadly declining for at least a decade (although it may have ticked upward slightly last year), according to official government estimates that are almost certainly inflated. China suffers from astronomic debt levels and has seen dizzying volatility in its stock market, both of which may be precursors to bigger economic troubles ahead. The demographic problems China confronts are even more severe than Russia’s: The rapid aging of the population will strain social spending, inhibit growth, and confront Chinese leaders with sharper guns-versus-butter trade-offs. Beneath the façade of stability imposed by increasingly repressive governance, moreover, dissatisfaction with a corrupt and autocratic elite is increasing: Chinese officials stopped publicly reporting the number of “mass incidents” in 2005, but the frequency of such incidents is widely believed to be rising. If the drastic domestic security measures taken in areas such as Xinjiang and Tibet are any indication, major sections of the country seem to be seething with discontent. Add in the fact that China’s behavior is stirring greater fears not just in Washington but throughout the Asia-Pacific and beyond, and Beijing may soon find itself dealing with greater geopolitical pushback, including the development of military capabilities designed specifically to neutralize the leverage provided by China’s own build-up. As unlikely as it may seem right now, it is entirely possible that sometime in the next decade or two, Chinese leaders may have to face a future that is not so bright and shining as seems the case now. When this happens, will Beijing become more or less aggressive on the global stage? The answer may well be “more.” Xi Jinping and other Chinese leaders have been promising that the nation is on the verge of achieving national rejuvenation, that it can now take center stage in world affairs. The regime has assiduously stoked Chinese nationalism; it has staked out inflexible positions on maritime disputes and other issues; it has even begun to issue soft deadlines for reunification with Taiwan. It has done so on the assumption that the continued growth of national power will enable Beijing to make good on its pledges and back up its demands. If that assumption does not hold, if the “Chinese Dream” begins to elude its dreamers, Chinese leaders may be tempted to take more dramatic steps rather than admitting that they cannot deliver. In these circumstances, an attempt to retake Taiwan by force or coercion, to teach Japan a lesson in the East China Sea, to break Vietnamese or Filipino resistance in the South China Sea, or to rupture America’s alliance system in the Asia-Pacific would still be highly dangerous. But these initiatives might come to seem more attractive than simply remaining passive while Beijing’s relative power fades. Robert Kaplan has put it aptly: If a confident China has been pursuing a “methodical, well-developed” strategy of revisionism, an insecure China could shift to “daring, reactive, and impulsive behavior.”10 Limiting the damage done to U.S. interests by a rising China will be a test of epic dimensions for American policymakers. But the moment of peak danger in the relationship may actually come when China starts to fade from its own wishful trajectory. All this poses a genuine dilemma for U.S. policymakers, who must contain the ambitions of today’s revisionist powers without encouraging desperate behavior that might lead to war. One way of addressing this dilemma would be simply to take steps that ease American rivals’ perceptions of insecurity and decline—by conceding them larger spheres of influence that might satisfy their ambitions, or by declining to build military capabilities or strengthen alliances that might undercut those rivals’ positions and thereby exacerbate their fears. Yet the downside of this approach is obvious: It would require Washington to sacrifice some key interests and forego some of the strengths needed to sustain them. The United States might decrease the danger that a declining challenger would behave rashly, but only by exposing itself to other perils. What will be required instead is a combination of careful prudence with great strength and resolve. U.S. leaders must not gratuitously antagonize U.S. rivals or put them in situations where they fear they must use their power before they lose it.U.S. leaders must not gratuitously antagonize U.S. rivals or put them in situations where they fear they must use their power before they lose it. This means staying away from efforts to overthrow or seriously destabilize the Russian and Chinese regimes (although perhaps not from more measured efforts to raise the costs of authoritarianism within those countries). It means avoiding acts, such as supporting a Taiwanese declaration of independence or excluding Russia from the SWIFT payments system—that would foster a “little to lose” mentality in Moscow or Beijing. Additionally, when Washington must issue explicit warnings—about Beijing’s behavior in the South China Sea, or about Russia’s meddling in U.S. political processes—it should do so privately, to minimize the reputational cost that American competitors must pay by backing down. As Dwight Eisenhower said during another great-power competition, America should carefully consider “how much we should poke at the animal through the bars of the cage.”11 Such caution is especially important when the animal is already frightened. Yet the counterpart to prudence must be unmistakable military strength and geopolitical resolve. The challenge in dealing with declining revisionists is that their calculations of risk and reward may shift suddenly, and in potentially explosive ways: Actions that seemed unattractive or unthinkable before become more appealing as the perceived costs of inaction rise. The imperative, therefore, is to manifest a level of power and commitment sufficient that even a more risk-acceptant rival will understand that a geopolitical gamble is highly unlikely to pay off. This requires restoring the military supremacy necessary to defeat Russian or Chinese gambits in the Baltic, the Western Pacific, and elsewhere, and cultivating—across the entire array of U.S. foreign policy decisions—a reputation for credibility in upholding American commitments against revisionist challenges. The better the record the United States compiles in standing up to Chinese and Russian probing behavior in the near-term, the less likely the leadership of those states will be to think that more dramatic action will succeed at some point down the road.

#### Solves case – heg contains conflict incidence and escalation, Blagden 15

David Blagden, phD at the University of Oxford, the Adrian Research Fellow in International Politics at Darwin College, and a Research Associate with the Centre for Rising Powers in the Department of Politics and International Studies, both at the University of Cambridge, “Global multipolarity, European security and implications for UK grand strategy: back to the future, once again” International Affairs 91: 2, 2015, pg 340-342

Third, a multipolar world of elevated Great Power security competition is likely to be one with considerable potential for military crises, which could embroil European states—either inadvertently, or because their vital interests are affected. Whereas under unipolarity, the United States could pacify all potential major power conflicts by threatening to defeat one or—if necessary—both sides, that is no longer the case under multipolarity. Indeed, the difficulty in predicting future international conflict suggests that European grand strategy should at least partially hedge against embroilment in such as yet unforeseen emergencies.

### DA

#### Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

#### Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

## Case

### Democracy

#### 1] The proposed waiver won’t solve because of how complicated it would be to mandate disclosure and transfer of trade secrets—the plan is insufficient to trigger the advantages, Donahoe

<https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto>, 24 Aug 2021, Donahoe, Casey D.

While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. Katherine Tai, the U.S. Trade Representative, has not publicly committed to any position beyond waiving patent protections in particular. [Karpan 2021-07-01] Moderna has temporarily waived its COVID-19 vaccine patent rights, but the vaccine is still protected, at least in the U.S. and EU by regulatory marketing exclusivity. [Collins 2021-06-11] **With respect to patents, existing TRIPS flexibilities already allow for countries to issue compulsory licenses for domestic production in the face of public health crises and, under additional criteria, compulsory licenses for export.** But proponents of the waiver argue that the existing processes, which can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines. [Labonte 2021-01-09, The Conversation]; [Public Citizen, tradewatch.org] In fact, compulsory licensing to exporting manufacturers under Article 31b is has only been successfully used once in the past twenty years, [Public Citizen, tradewatch.org] when Canada issued a compulsory license authorizing the manufacture and export of an AIDS medication to Rwanda. [WTO 2007-10-04] Additionally, multiple countries may be involved in the pipeline for manufacturing a single packaged vaccine to be distributed in a country in need. Further, one key advantage to a unanimously agreed-upon waiver over attempting to utilize existing TRIPS flexibilities, would be that countries could more comfortably exploit the waiver without the threat of trade complaints or sanctions from other nations. [Lopez 2021-05-07] Proponents of the waiver point to alleged U.S. and European retaliatory trade measures against nations that have attempted to use existing TRIPS flexibilities to skirt IP protections. [Public Citizen, tradewatch.org] While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. **However, even if patent protection were not an issue, manufacturing and distribution of the vaccines would remain a substantial obstacle to achieving global immunity.** [Paton 2021-05-07 Bloomberg] **Aspects of vaccine manufacturing and regulation raise further issues of what TRIPS calls “undisclosed information,” encompassing trade secrets and know-how. Such undisclosed information may be particularly crucial in scaling up manufacture in a commercially viable fashion**. [Garrison 2020-12-16]. Article 39 of TRIPS requires members to protect the confidentiality of undisclosed information, including data submitted to regulatory agencies for marketing approval of pharmaceuticals. **As related to vaccines, undisclosed information could include clinical data** (e.g., related to effectivity, including negative results), **manufacturing processes, medical formulas, cell lines, genomic information, technical designs and specifications, instruction manuals, process controls and monitoring, quality control procedures, technical training, working practices, etc.** [Garrison 2020-12-16]; [Levine 2020-07-10]; [Eakin 2021-05-25 Law360] **The Pfizer and Moderna vaccines,** in particular, are expected to be **extremely difficult to replicate** given **they rely on new mRNA technology.** The WTO touts the COVID-19 Clinical Research Coalition, which aims to provide a platform for voluntary data-sharing, and the WHO-backed COVID-19 Technology Access Pool (C-TAP), which provides a platform for technology developers to bundle intellectual property rights, knowledge, and data into non-exclusive licenses with each other and with multiple quality-assured manufacturers, as examples of voluntary efforts to fill-in the know-how gap. [WTO Report 2020-10-15] In general, the voluntary transfer of know-how between two parties is highly contractually stipulated, usually allowing the licensor strict control over the dissemination of its know-how and protecting rights to improvements and developments that may derive from the collaboration, some of which might be patentable in themselves. [Bracho 2021-05-24 Bloomberg]. **The proposed waiver**, though, **wades into relatively unchartered territory of compulsory transfers of undisclosed information. Likely the biggest threat felt by vaccine manufacturers is that the compulsory transfer of undisclosed information will not simply diminish their return on investments in COVID19 vaccines, but would jeopardize entire proprietary technological platforms that support a wide range of potential products.** Such giveaways would likely impact small-to-medium sized enterprises especially, which account for approximately 75% of US COVID-19 treatments, and particularly small university spin-outs, which are highly depend on IP for valuation. [Balfour 2021-06-30] As details of a waiver have not yet been hammered out, it remains unclear exactly who might have access to such undisclosed information (e.g., the general public or only generic manufacturers) and the mechanisms by which such transfers would be achieved. Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. [Labonte 2021-01-09, The Conversation**] The most obvious means would be for regulatory agencies to disclose data and manufacturing protocols submitted by vaccine manufacturers that they are ordinarily required to keep confidential.** In fact, the issue of data confidentiality has already been raised in the U.S. as an obstacle to developing a competitive generic biologics market, with some pointing to the Federal Pesticide Act (FPA) as a successful model which allows more free dissipation of regulatory data by the EPA. [Heled 2019] There are some exemptions to confidentiality of data supplied to regulatory drug agencies implemented in the U.S. and Europe, particularly where public funding helped finance the underlying research. For example, for research funded by the U.S. government, the Bayh-Dole Act provides some additional licensing provisions to the government which could potentially extend to some know-how; however, these provisions are largely untested and may be contractually restricted. [Collins 2021-06-11]. **But there is no precedent for compulsory transfer of confidential information in general**. [Levine 2020-07-10] **Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. Additionally, knowledge holders may be located outside the jurisdiction of a member state desiring to compel transfer,** [Garrison 2020-12-16] **and waiving an obligation for member states to protect undisclosed information does not necessarily compel other member states to do so.  Notably, India, one of the waiver proponents that actually has substantial pharmaceutical manufacturing capacity, does not even presently require submission of test data for marketing approval.**  [Haugen 2020-12-01]  **Compulsory disclosure of undisclosed information is further complicated by the fact that the knowledge holders for manufacturing a single vaccine may be dispersed across multiple entities and/or even multiple jurisdictions, particularly where a supply chain of highly technical components is utilized or certain processes are outsourced to contractor entities.**  [Garrison 2020-12-16]  **The legislative levers that might be needed to fully enforce compulsory disclosure of undisclosed information or that could be pulled to halt executive branch action, as well as the lawsuits that might be filed would seem likely to stall any grand gestures of governmental action related to undisclosed information.** [Eakin 2021-05-25 Law360]  **For instance, compulsory disclosures would likely spurn allegations of violating the Takings Clause of the Fifth Amendment**, although the Supreme Court had found previously in *Ruckelshaus v. Monsanto Co*. that the FPA had not done so [Heled 2019].  Still, compulsory disclosure facilitated by regulatory agencies may not be sufficient to fill the knowledge gap for the successful manufacture of the vaccines, leaving room for countries to consider other creative avenues.  Brazil, for instance, has proposed one of a kind legislation which would tie patent rights to the compulsory disclosure of all information needed to make COVID-19 vaccines.  [Eakin 2021-05-25 Law360] Opponents argue that **bottlenecks in manufacturing capacity and supplies would stymie the effect of the waiver, despite the transfer of undisclosed information, and that even with full technology transfer, it would take months or years for factories to come up to speed on vaccine production.**  [Leonard 2021-05-06, Bloomberg]; [Paton 2021-05-07 Bloomberg]  **Manufacturing capacity is particularly limited for mRNA-based vaccines and there’s not even necessarily a sufficient population of people with expertise capable of manufacturing them.**  [Karpan 2021-05-11 Law360]  **Some also warn that redistributing crucial supplies to manufacturers without existing capabilities to manufacture the high-quality vaccines with regulatory approval would actually hinder vaccine distribution efforts.**  [Karpan 2021-05-11 Law360]; [Lima 2021-05-08 Bloomberg]; [Paton 2021-05-07 Bloomberg]  Even manufacturing facilities with access to all IP rights are experiencing production delays from regulatory reviews.  [Baschuck 2021-05-06]  Opponents also resound that such efforts to undermine IP rights will only discourage future innovation, including research that targets new variants of the coronavirus.  [Bacchus 2020-12-16 Cato Institute];  [Paton 2021-05-07 Bloomberg] The large divide between fervid proponents of the waiver and even those who have expressed some mild support suggests any significant compromise may be some time coming.  Many view the waiver controversy any way as less of a problem-driven exercise and more of an opportunity for the usual players to debate both the power of big pharma in the U.S.  [Collins 2021-06-11] and the stifling effects IP protections can have on the least developed nations around the world.  Also, the angst amongst some proponents of the waiver, some believe, may stem more from policies of vaccine nationalism than of TRIP impediments. [Clarke 2021-04-22 Lexology] Regardless, the decisions reached at the WTO during this crisis are likely to shape future policy discussions for years to come.

#### 2]

#### 3] A vaccine waiver greenlights counterfeit medicine – independently turns Case.

**Conrad 5-18** John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.