# 1NC vs Lex AM

## CP

**The member nations of the World Trade Organization ought to reduce intellectual property protections for vaccines related to the prevention, containment, and treatment of COVID-19**

#### Net benefits

#### 1] Companies like Novartis and Regeneron would be hurt in their development of antivirals like Remdesvir and other test drugs for covid. Remdesivir, favipiravir, merimepodib, sotrovimab are examples and many new drugs NEED FDA approval to be brought to market

#### 2] Companies are producing medicine because they know their IPP is protected – current vaccine production proves.

**Cueni 20**: Cueni, Thomas. [New York Times Company] “The risk in suspending vaccine patent rules” *Wion,* 2020. JP

It is unclear how suspending patent protections would ensure fair distribution. But what is clear is that if successful, the effort would jeopardize future medical innovation, making us more vulnerable to other diseases. Intellectual property rights, including patents, grant inventors a period of exclusivity to make and market their creations. By affording these rights to those who create intangible assets, such as musical compositions, software or drug formulas — people will invent more useful new things. **Development of a new medicine is risky and costly**. Consider that scientists have spent decades — and billions of dollars — working on Alzheimer’s treatments, but still have little to show for it. The companies and investors who fund research shoulder so much risk because they have a shot at a reward. Once a patent expires, generic companies are free to produce the same product. **Intellectual property rights underpin the system that gives us all new medicines, from psychiatric drugs to cancer treatments**. In trying to defend these rights, the drug industry has made mistakes in the past that have lost people’s trust. More than 22 years ago, for example, a group of drug companies sued the South African government for trying to import cheaper anti-AIDS drugs amid an epidemic. With price standing between patients and survival, the suit, which the companies eventually dropped, was a terrible misjudgment. The current situation is not parallel. **Several major drug companies, including AstraZeneca, GlaxoSmithKline and Johnson & Johnson, have pledged to offer their vaccines on a not-for-profit basis during the pandemic**. Others are considering differential pricing for different countries. **As of last month, four major pharmaceutical companies had already agreed to eventually produce at least three billion vaccine doses for low- and middle-income nations, according to one analysis**. In South Africa and India, pharmaceutical companies are already working with local partners to make their vaccines available. Johnson & Johnson has entered into a technology transfer partnership for its candidate vaccine with South Africa’s Aspen Pharmacare, and AstraZeneca has reached a licensing agreement with the Serum Institute of India to develop up to 1 billion doses of its vaccine for low-and-middle-income countries. **Companies can afford to license patents for free, or sell drugs at cost, precisely because they know that their intellectual property will be protected. That’s not a flaw in the system; it’s how the system ensures that pharmaceutical research will continue to be funded.**

#### 3] Their key 1AC internals are based on vaccines – Swan, kumar, fink, jecker & atuire, Erfani, lindsey, Jones, Navnit ALL talk about vaccines meaning we solve their key warrants

#### 4] They stunt medicine not brought to market yet and approved and there is a huge spillover effect on just perception.

## DA

#### Biotech industry strong now

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

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6 What about SPACs? The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story. Fundamentals continue strong When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances. In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development. Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries. Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising. For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic. More innovation on the horizon The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### Lack of IP protection makes medical innovation too risky and expensive

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### Empirics prove lower profit margins harms future innovation – R&D investments solve the aff by supplying drugs globally

Roberts 6-25 [James M. Roberts, Research Fellow For Economic Freedom and Growth at the Heritage Foundation with a master’s degree in international and development economics from Yale University, 6-25-2021, "Biden’s OK of Global Theft of America’s Intellectual Property Is Wrong, Dangerous," Heritage Foundation, <https://www.heritage.org/public-health/commentary/bidens-ok-global-theft-americas-intellectual-property-wrong-dangerous>]/Kankee

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them. Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process. But the Biden policy is bad for many other reasons. Developing breakthrough medications takes tremendous ingenuity and immense financial investments. It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks. Signaling that the United States will not fight to defend their intellectual property rights actively undermines innovation and manufacturing in American health care and medicines. It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world. Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value. But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the future development of vaccines needed to meet as-yet-unknown diseases. Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation. Ultimately, compulsory licensing legalizes the theft of intellectual property. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision. The U.S. patent protection system has served the nation well since its founding. It is and has been a bulwark of American prosperity, but the strength of that protection has been weakening in the past few decades. Compulsory licensing contributes to the erosion of that protection. As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats. The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production. That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes. Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### Disease causes extinction — defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), <http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028>

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population). In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2