# 1NC

## Off-Case

### T

#### A. Interpretation-The affirmative must limit IP for medicines, not medical technology

#### 1. Medicines are consumable substances that treat or prevent disease

Kurrer 21 [Christian Kurrer, Policy Analyst at European Parliament. "Medicines and Medical Devices," European Parliament, 05-2021, accessed 9-2-2021, https://www.europarl.europa.eu/factsheets/en/sheet/50/medicines-and-medical-devices] HWIC

A. General rules on medicines

A medicinal product (medicine) is a substance or combination of substances that is used for the treatment or prevention of diseases in human beings. With the aim of safeguarding public health, the market authorisation, classification and labelling of medicines has been regulated in the EU since 1965. The evaluation of medicines has been centralised through the European Medicines Agency (EMA) since its creation in 1993 and a centralised authorisation procedure was put in place in 1995 to guarantee the highest level of public health and to secure the availability of medicinal products. The main pieces of legislation in this area are Directive 2001/83/EC[[1]](https://www.europarl.europa.eu/factsheets/en/sheet/50/medicines-and-medical-devices" \l "_ftn1) and Regulation (EC) No 726/2004[[2]](https://www.europarl.europa.eu/factsheets/en/sheet/50/medicines-and-medical-devices" \l "_ftn2), which lay down the rules for establishing centralised and decentralised procedures.

#### 2. CRISPR is a gene editing platform, it can help develop medicine(s) but it is not medicine

Editas No Date

(Editas Medicine is a leading genome editing company focused on translating the power and potential of the CRISPR/Cas9 and CRISPR/Cpf1 (also known as Cas12a) genome editing systems into a robust pipeline of medicines for people living with serious diseases around the world. https://www.editasmedicine.com/crispr-gene-editing/)

CRISPR (pronounced “crisper”) is an acronym for “Clustered, Regularly Interspaced, Short Palindromic Repeats,” and refers to a recently developed gene editing technology that can revise, remove, and replace DNA in a highly targeted manner. CRISPR is a dynamic, versatile tool that allows us to get to and edit nearly any location in the genome, and has the potential to help us develop medicines for people with a wide variety of diseases. We view CRISPR as a “platform” technology because of its ability to target DNA in any cell or tissue. CRISPR uses a combination of 2 types of molecules to edit disease-related genes or to modify cells: a nuclease (the gene editor) and guide RNA (which helps the nuclease find the right place to edit). CRISPR’s ability to only edit intended DNA targets and avoid off-target editing is known as its specificity. Achieving high levels of specificity requires the right combination of nuclease and guide RNA.

#### 3. A narrow definition of medicine is vital to education- broad definitions turn the case

Marcum, PhD, 08

(James A., Philosophy@Baylor, An Introductory Philosophy of Medicine Humanizing Modern Medicine )

Although Caplan's thesis for the non-existence for philosophy of medicine was critiqued mainly in terms of the criteria for establishing a discipline, his thesis was also criticized by a few with respect to his definition for philosophy of medicine. Some philosophers of medicine felt Caplan's definition was too narrow and wanted to broaden it. For example, Engelhardt and Kevin Wildes argued for an expanded conception of the philosophy of medicine. Although one could argue, pro Caplan, that philosophy of medicine engages no unique problems vis-n-vis philosophy of science or biology Engelhardt and Wildes held, contra Caplan, "there would still be merit in exploring the ways in which philosophical study and analysis can be directed to the understanding of medicine" (1995, p. 1683). Kenneth Schaffner and Engelhardt argued for an even broader conception for philosophy of medicine, "as encompassing those issues in epistemology, axiology, logic, methodology and metaphysics generated by or related to medicine" (1998, p. 264). They included not only the natural sciences but also the social sciences, e.g. George Engel's biopsychosocial model. In response to the broad or expansive definition for the philosophy of medicine, Pellegrino insisted that such a definition "dilutes the specificity of philosophy of medicine and weakens the identification of a definite set of problems" (1998, p. 319). He then proposed a more narrow definition for philosophy of medicine as "a critical reflection on the matter of medicine-on the content, method, concepts and presuppositions peculiar to medicine as medicine" (Pellegrino, 1998, p. 325). The goal of this relationship is to understand medicine per se, i.e. the ultimate reality of what constitutes medicine beyond the entities that are studied in medicine. To that end, Pellegrino claimed that the philosophy of medicine requires a precise or narrow definition of medicine.

#### B. Violation- the plan weakens patents on medical research technology, not medicine.

#### C. Reasons to Prefer

#### 1. The negative interpretation is superior- Prefer qualified evidence from experts with intent to define over contextual evidence from journalists that is less precise

#### 2.The affirmative interpretation is unreasonable -expanding beyond a strict definition of medicine opens the floodgates and makes neg prep impossible

FDA Fact Sheet No Date https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance

There are over 20,000 prescription drug products approved for marketing.FDA oversees over 6,500 different medical device product categories. There are over 1,600 FDA-approved animal drug products. There are about 300 FDA-licensed biologics products.

#### 3. Extra topicality and plan vagueness are voting issues- they cause 2NR meltdown as we are forced to go for T or a CP to get back to ground zero

#### D. Topicality is a voting issue for predictable limits- it tells the negative what they do and do not have to prepare for. It should be evaluated through competing interpretations- its not what you do its what you justify

### Innovation DA

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz 5-17-21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

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.

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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

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **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 the Western Abenaki (which suffered a staggering 98% loss of population).9 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 biotech**nology 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.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of **state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

## Case

### AT: Plan

#### If they don’t affect CRISPR they don’t solve the case-their evidence is about the central patent dispute over CRISPR-cas9-we’ve compiled a cliffs notes for you and will enter it into evidence. This should be a voting issue

#### 1. moving target- the aff can change what the plan does based on what is in the 1NC making negative strategy impossible. Since they get the last speech we can never respond to their final clarification

2. Limits- allowing cases that rely on misinformation explodes the topic and forces the neg to spend all their time doing background research rather than learning the topic

Sherkow 17 [(Jacob, Professor of Law at the College of Law and Affiliate of the Carl R. Woese Institute for Genomic Biology at the University of Illinois, where his research focuses on the legal and ethical implications of advanced biotechnologies, especially as related to intellectual property. He is a leading expert on IP protection for genome-editing technologies, including CRISPR. He is the author of over 60 articles published in both scientific journals and traditional law reviews, including Science, Nature, the Yale Law Journal, and the Stanford Law Review. Since 2018, Sherkow has also been a Permanent Visiting Professor at the Center for Advanced Studies in Biomedical Innovation Law (“CeBIL”) at the University of Copenhagen Faculty of Law) “Patent protection for CRISPR: an ELSI review” Journal of Law and the Biosciences 12/7/2017 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5965580/] BC

One notable aspect of the CRISPR patent dispute is that it is, by and large, a dispute between academic research institutions. It pits lawyers representing the University of California against lawyers representing the Broad Institute of MIT and Harvard.22 To be sure, university rivalries are common.23 But because universities share among themselves a larger mission to create and disseminate knowledge to the public, litigiousness among them has been historically rare.24

Reader 10/10 [(Ruth, writer for Fast Company, covers the intersection of health and technology) “2 women won the Nobel for CRISPR, but the battle for its patent rages on” Fast Company, 10/10/2020 https://www.fastcompany.com/90561762/nobel-prize-jennifer-doudna-emmanuelle-charpentier-crispr-patent-lawsuit] BC

CRISPR’S UNCERTAIN FUTURE

While the Nobel award certainly affixes Doudna and Charpentier’s place in history, the ongoing litigation continues to hang heavy over the development of CRISPR Cas-9’s editing capability. Some scientists feel that with so much public money involved in discoveries such as the ones around CRISPR Cas-9,

Sterlin 20 [(Ian, JD from the University of Michigan Law School, Executive Editor of the Michigan Technology Law Review) “The CRISPR War Drags On: How the Fight to Patent CRISPR-Cas9 Creates Uncertainty in the Biotechnology Sphere,” Michigan Technology Law Review, 3/2020] JL

Researchers at the University of California were the first to (“UC”) demonstrate that isolated CRISPR-Cas9 components could effectively function in an *in vitro* environment. UC subsequently filed a patent application in May 2012 broadly claiming a method to using CRISPR-Cas9 without referencing specific cellular environments. In December 2012, a research team led by Feng Zhang at the Broad Institute filed a patent application directed to a method of using CRISPR-Cas9 in mammal cells. UC unsuccessfully sought to invalidate Dr. Zhang’s patents in an interference proceeding in front of the Board. UC appealed the Board’s ruling to the Federal Circuit, arguing that the Board employed an improperly rigid obviousness test and that it erred in dismissing evidence that other researchers simultaneously applied CRISPR-Cas9 to non-bacterial (eukaryotic).

### Their own cards say CRISPR is not a medicine

#### CRISPR is segemnt of DNA that uses proteins to modify other strands of DNA

Lexico ND [(Lexico dictionary) <https://www.lexico.com/en/definition/crispr>] BC

CRISPR

NOUN

1 Biochemistry

A segment of DNA containing short repetitions of base sequences, involved in the defense mechanisms of prokaryotic organisms to viruses.

CRISPR sequences encode RNAs that can recognize specific target sequences in a genome, at which base pairs can be cut or added. They act in a complex with a specific protein that functions like a pair of molecular scissors, with which they are used as a tool in genetic engineering

1.1A genetic engineering tool that uses a CRISPR sequence of DNA and its associated protein to edit the base pairs of a gene.

#### And it is a drug that treats diseases and cures illnesses

Sfera 2/24 [(Dan, entrepreneur. Clinical Trials) “CRISPR Therapeutics creates gene-based medicines”, Real Dan Sfera, 2/24/2021. <https://therealdansfera.medium.com/crispr-therapeutics-creates-gene-based-medicines-25a66c674998>] BC

Gene-Editing Genius

CRISPR (clustered regularly interspaced short palindromic repeats) has been making news about research and investment. Scientists learned that CRISPR, a naturally occurring gene-editing function of bacteria, has potential for treating genetic diseases. Now a number of companies are using gene-editing to try to cure illnesses caused by errors on a single gene. They include sickle cell disease, hemophilia and cystic fibrosis.

Swiss-based CRISPR Therapeutics, a biopharmaceutical company attempting to create transformative gene-based medicines for serious diseases, “has produced results that could not only make it a winner in single-gene disorders, but position it to tackle much more complex — and profitable — diseases in the years ahead,” according to Jason Hawthorne of The Motley Fool (https://www.fool.com/investing/2020/12/15/where-will-crispr-therapeutics-be-in-10-years/). CRISPR Therapeutics, a gene-editing company, attempts to develop gene-based medicines for serious diseases using its proprietary CRISPR/Cas9 platform. CRISPR/Cas9 is a gene-editing technology that allows for precise, directed changes to genomic DNA. The company has a wholly-owned U.S. subsidiary, CRISPR Therapeutics, Inc., and R&D operations based in Cambridge, Massachusetts, and business offices in London, United Kingdom.

CRISPR’s CTX001 is a potential drug to treat sickle cell disease and beta-thalassemia, disorders that affect the oxygen-carrying cells in the blood. After harvesting a patient’s own cells from his or her own bone marrow, medical professionals use CTX001 to edit the gene responsible for red blood cell production and infuse the cells back into the body. In 2015, CRISPR entered into a partnership with Vertex Pharmaceuticals to develop a number of treatments using this technology, receiving cash, equity and future royalties, while Vertex obtained the rights to market the treatments to be developed.

### AT: Innovation

**Strong IP rights for pharma companies are necessary for stopping future pandemics.**

**Roberts 21**

Brooklyn Roberts, opinion contributor, 6-3-2021, "Pandemic proves importance of pharmaceutical innovation," The Hill, <https://thehill.com/opinion/healthcare/556633-pandemic-proves-importance-of-pharmaceutical-innovation> (MLT)

If there is one big lesson learned from the COVID pandemic, it is the importance of innovation in this country. We have seen clothing manufacturers making face masks, alcohol producers making hand sanitizer and companies like GM manufacturing ventilators. All of which are examples of American ingenuity in the face of crisis. But there is another example that is undeserving of the bad rep it sometimes receives — pharmaceutical innovation. The [vast majority](https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness) of the world’s pharmaceutical innovation comes out of the U.S. We produce some of the most vital drugs for people around the globe. In the case of COVID, our pharmaceutical companies have risen to the challenge and have developed vaccines in less than a year. These vaccines will play a critical role in allowing life to get back to normal for most Americans. In addition to the quick development of the vaccines, manufacturers were ready to go as soon as they had FDA approval. As a result, [more than half the population](https://thehill.com/policy/healthcare/556029-over-50-percent-of-total-us-population-has-received-at-least-one-dose-of) has gotten at least one dose of the vaccine in roughly four months. The incredible effort it took to accomplish that should not be overlooked. Pharmaceutical companies have taken a beating in the media for the last several years over drug pricing and accessibility, and in response, state legislatures have supported bad policies like price controls and importing drugs from Canada. But the current pandemic shows us the importance of innovation in this area and why investment in pharmaceutical innovation is vital to the health and safety of Americans. On average, taking a drug from a molecule to a marketable medicine costs $2.6 billion and is a [10-year process](https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291). Companies that develop the drugs have a patent on their product for 20 years. The patent life starts to run while the company is developing the drug, often leaving a company only a handful of years to recoup their investment in that drug — and that is if the drug makes it through clinical trials and gets FDA approval. New drugs routinely fail during clinical trials, costing companies millions. Yet, these companies continue to develop and innovate. That is why [President Biden](https://thehill.com/people/joe-biden)’s recent decision to waive patents for the vaccine is so detrimental. **The U.S. leads in pharmaceutical innovation due to our strong intellectual property protections** and free market pricing system. Patents are a necessary part of innovation. Without them, companies would not take on the massive cost of developing new drugs. By waiving the patents for the vaccine, President Biden is starting us down a slippery slope which could result in other patents being waived or challenged leading us to a much larger problem. It is a dangerous precedent to set. Sen. [Richard Burr](https://thehill.com/people/richard-burr) (R-N.C.) [recently commented](https://thehill.com/homenews/senate/552956-gop-senator-urges-biden-to-withdraw-support-for-covid-vaccine-patent-waiver) on the patent waiver saying, “Intellectual property protections are part of the reason we have these life-saving products. **If these protections are not in place for innovators of life-saving medicines, we will not have them for the next pandemic**. It’s that simple,” and he’s right. Pharmaceutical innovation has saved countless lives and allows us to live longer and have a better quality of life. Instead of treating drug manufacturers like the villain, [policymakers should be looking for ways](https://www.alec.org/publication/the-state-legislators-guide-to-prescription-drug-policy/) to support and encourage their work. The COVID pandemic has illustrated just how important it is to our everyday life.

**Patent protections are key to the development of industries such as biotech—mountains of economic data proves.**

**Phelps 15**

Marshall Phelps, former chief of global intellectual property operations for IBM and Microsoft, 9-16-2015, "Do Patents Really Promote Innovation? A Response To The Economist," Forbes, <https://www.forbes.com/sites/marshallphelps/2015/09/16/do-patents-really-promote-innovation-a-response-to-the-economist/?sh=7331bbe91921> (MLT)

Economists have repeatedly demonstrated that inventors are driven primarily by the expectation of profiting from owning the rights to their inventions. Zorina Khan of [Bowdoin College](http://www.forbes.com/colleges/bowdoin-college/), whose 2005 classic The Democratization of Invention: Patents and Copyrights in American Economic Development was awarded the prestigious Alice Hanson Jones Prize for outstanding work in economic history, observed that “Ordinary people [are] stimulated by higher perceived returns or demand-side incentives to make long-term commitments to inventive activity.” She also found that “their patterns of patenting were procyclical [and] responded to expected profit opportunities.” Along with her colleague the late Kenneth Sokoloff of UCLA, Professor Khan then [summarized the role of patents](http://www.nber.org/papers/h0042.pdf?new_window=1) in helping U.S. startup businesses grow the economy from an agrarian backwater into the most powerful industrial economy on the face of the earth: The U.S. patent system had a powerful impact on the patterns of inventive activity. Its provision of broad access to property rights on new inventions, coupled with the requirement of public disclosure, was extremely effective at stimulating the growth of a market for technology and promoting technological change [emphasis added]. Then, as now, the American formula for success was simple: **Startups + patents = jobs and economic growth**! Over the last 50 years, economists have found that patents continue to foster ex ante innovation — meaning, they induce people to invent because of the prospect of profiting from those inventions. The work of economists such as Arrow (1962), Griliches (1963), Schmookler (1966), Kitch (1977), Reinganum (1981), Klemperer (1990), Romer (1990), Giulbert and Shapiro (1990), Grossman and Helpman (1991), Scotchmer (1999), and Gallini (2002) on this issue is mostly available for free online at the [Social](http://www.ssrn.com/en/)[Science](http://www.forbes.com/science/) Research Network. One especially interesting 2007 study by Arora, Ceccagnoli, and Cowen entitled ["R&D and the Patent Premium"](https://www.scheller.gatech.edu/directory/faculty/ceccagnoli/pubs/ceccagnoli_ijio.pdf) found that "the patent premium for innovations that were patented is substantial. Firms earn on average a 50% premium over the no patenting case, ranging from 60% in the health related industries to about 40% in electronics.” Sure, one should be cautious about academic research, especially given the old joke about how an economist opens a can of soup. (Answer: assume a can opener.) But real-world economics clearly confirms the research findings. Consider, for example, that the biggest job-creating new industries of the last 60 years — semiconductors (consumer electronics), PCs, software, biotech, mobile telephony, and Internet e-commerce — were all launched and grew strong on the basis of patented inventions created by startup businesses. As the CEO of Juno Therapeutics, Hans Bishop, and ARCH Venture Partners co-founder Bob Nelson [recently wrote in Forbes](http://www.forbes.com/sites/matthewherper/2015/03/24/new-patent-law-would-trash-disease-cures/): “Let us be clear: **investments in the biotech industry are based entirely on patents. Without strong patents, we cannot raise money to find cures for disease.”** Moreover, the evidence that patents foster innovation is not confined to the U.S., nor is it limited only to developed countries. In 2008,[a study](http://nw08.american.edu/~wgp/park_lippoldt08.pdf) by the Organization for Economic Co-operation and Development (OECD) found that “stronger levels of patent protection are positively and significantly associated with inflows of high-tech product [and] expenditures on R&D.” And in [another study](http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=0ACC6C3B3E81D0484614C3293871858C?doi=10.1.1.199.6247&rep=rep1&type=pdf)that attracted wide attention, Shih-Tse Lo of Concordia University in Montreal found that the 1986 reforms strengthening the Taiwanese patent system “stimulated additional inventive activity, especially in industries where patent protection is generally regarded as an effective strategy for extracting returns, and in industries which are more R&D intensive. The reforms also seemed to induce additional foreign direct investment in Taiwan.” Interestingly, the evidence also shows that rather than hindering knowledge sharing, as the Economist claims, patents actually promote it. [Acemoglu, Bimpikis, and Ozdaglar (2008)](http://economics.mit.edu/files/6780)observed that “patents improve the allocation of resources by encouraging rapid experimentation and efficient ex-post transfer of knowledge across firms.” Indeed, it turns out that the patent system is one of the most effective tools for knowledge-sharing and technology transfer ever devised. [A 2006 study](http://www.microeconomix.fr/sites/default/files/import2/FL-YM-PatentsInnovationJanuary07.pdf) by French economists Francois Leveque and Yann Meniere found that 88 percent of U.S., European, and Japanese businesses said they actually rely upon the information disclosed in patents to keep up with technology advances and direct their own R&D efforts. This is hardly a new phenomenon. The 19th century inventor Elias E. Reis [reported](http://www.nber.org/chapters/c10229.pdf) that when he read about an 1886 patent issued to Elihu Thomson for a new method of electric welding, “there immediately opened up to my mind a field of new applications to which I saw I could apply my system of producing heat in large quantities.” Thomas Edison was known to frequent the patent office in order to study other inventors’ patents and hopefully spark ideas of his own. As for Edison himself, [a 2013 study](http://works.bepress.com/cgi/viewcontent.cgi?article=1073&context=rkatznelson) found that rather than blocking further invention, his seminal 1880 incandescent lamp patent (No. 223,898) actually “stimulated downstream development work” that resulted in “new technologies of commercial significance [including] the Tesla coil, hermetically sealed connectors, chemical vapor deposition process, tungsten lamp filaments and phosphorescent lighting that led to today’s fluorescent lamps.” A simple thought experiment suggests why this is so. As UCLA’s Sokoloff and Yale’s Naomi Lamoreaux [observed in a 1997 paper,](http://www.nber.org/papers/h0098.pdf?new_window=1) “The very act of establishing exclusive property rights in invention not only protected patentees but also promoted the diffusion of information about technology. To see why, imagine a world in which there was no patent system to guarantee inventors property rights to their discoveries. In such a world, inventors would have every incentive to be secretive and guard jealously their discoveries from competitors [because those discoveries] could, of course, be copied with impunity. This is the world of trade secrets. “By contrast,” the authors noted, “in a world where property rights in invention were protected, the situation would be very different. Inventors would now feel free to promote their discoveries as widely as possible so as to maximize returns either from commercializing their ideas themselves or from [licensing] rights to the idea to others. The protections offered by the patent system would thus be an important stimulus to the exchange of technological information in and of themselves. Moreover, it is likely that the cross-fertilization that resulted from these information flows would be a potent stimulus to technological change.” In the real world, one need only look at the smartphone industry to see the truth in that thought experiment. Does anyone believe that global smartphone use would have experienced such extraordinarily rapid growth under a trade secret regime? Impossible. Only a strong patent system enabling the licensing and cross-licensing of proprietary technology across four very disparate industries —telephony, electronics, computing and software — could have produced the hugely successful smartphone industry that we enjoy today. The response of some critics to all this evidence is, “Yes, but you can’t prove causation.” And it’s true, one cannot prove theoretically that the patent system by itself causes higher rates of innovation and economic growth. That’s because the exogenous factors — the dynamism of markets, the efficacy of legal and governmental institutions, the availability of capital, and the role of countless other factors — are far too complex and interdependent to isolate causation to patents alone. It’s like trying to pinpoint ultimate causation in the weather. It can’t be done. But by the same token, one also cannot prove that free market capitalism — isolated from all the legal, educational, economic, governmental and cultural institutions that surround it in any country — causes more economic growth than a government-run socialist economy. Yet we all know without a doubt from real-world experience — including the fact that 74 years of socialism in the Soviet Union failed to produce even a decent refrigerator — that free markets are strongly correlated with greater economic prosperity. The same is true of the patent system: on balance and over the long term, **patents are strongly correlated with increased innovation,** knowledge sharing, and economic growth. I’m all for stopping the patent trolls who pillage innocent businesses rather than create anything useful. But if we want America to keep inventing the future, we’d better keep patenting.

**IP Protections are vital to innovation and economic growth-reject myopic moralizing about human rights**

**Bacchus, JD, 20**

(James, adjunct scholar at the Cato Institute, a professor of global affairs at the University of Central Florida, An Unnecessary Proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines <https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf>, 12-16)

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of **any rights to IP**. As one group of United Nations human rights experts expressed: “There is no room for . . . profitability in decision-making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 **This view is myopic**. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up **if such a “human rights” approach does not result in meeting those urgent public needs**? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, **does not reflect the practical reality** of a world in which many **medicines would simply not exist** if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long-standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the **latest global occasion** for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are **incentives for innovation**, which is **the main source for long-term economic growth** and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to **inspire other innovations**. The protection of IP rights **promotes the diffusion**, domestically and internationally, of innovative technologies and new know-how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the **creation of knowledge**, which **adds enormously to “the wealth of nations.”** Digital and other economic growth in the 21st century is increasingly **ideas-based and knowledge intensive. Without IP rights as incentives**, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would **eliminate the incentives that inspire innovation**, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

# 2NR

### AT: Sfera

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### AT: WTO

#### No nuke winter- science and history.

Kroenig, PhD, ‘18

(Matthew, PoliSci@UCBerkeley, AssocProfGov’t&ForeignService@Gtown, SeniorFellowInt’lSecurity@AtlanticCouncil, The Logic of American Nuclear Strategy: Why Strategic Superiority Matters, Oxford University Press) BW

At this point, some may object to the above attempt to measure gradations of nuclear war by claiming that the effects of any nuclear war would be unimaginable and could potentially even result in “nuclear winter” and complete human extinction. The possibility of nuclear winter, however, has long been dismissed by leading scientists.14 In the early 1980s, the scientist and public intellectual Carl Sagan and colleagues popularized the idea of “nuclear winter.”15 He and other experts argued that the heat from a nuclear explosion would set ablaze wooden structures and other flammable material in cities, sending large quantities of smoke into the Earth’s atmosphere, thus blocking out the sun’s rays. This would have the effect of reducing the Earth’s temperature and wiping out global agricultural production. Crude climate models at the time estimated that the effect could be so large as to result in mass starvation and possibly even human extinction. The arguments had a profound effect on elites and the general public on both sides of the Iron Curtain. Then–Soviet Premier Mikael Gorbachev later admitted that fear of nuclear winter was a factor motivating him to end the Cold War.16 Subsequent research employing more sophisticated climate modeling has demonstrated, however, that early fears about nuclear winter resulting in human extinction were overblown.17 Even scientists who initially proposed the idea, including the physicist Richard P. Turco (the person who coined the phrase “nuclear winter”) disavowed these arguments just a few years later. Climate scientists working in this area today sometimes refer instead to the possibility of “nuclear autumn.” The smoke from a large-scale nuclear exchange could indeed obstruct sunlight and reduce agricultural production, but the effects would be milder than Sagan and others warned in the early 1980s. Evidence against nuclear winter comes not only from better climate models but also from data obtained from analysis of other events that emitted large quantities of smoke into the Earth’s atmosphere, such as the firebombing of Dresden and Tokyo during World War II, Saddam Hussein’s ignition of 600 oil wells in Iraq during the first Gulf War, and the volcanic eruptions at Krakatoa and Tambora.18 Tambora, for example, was a 33-gigaton explosion, equivalent to the simultaneous detonation of 2.5 million Hiroshima-size bombs. These events all spewed large amounts of soot into the Earth’s atmosphere, but only Tambora resulted in a noticeable decrease in the Earth’s temperature, and the effects were not catastrophic. (Indeed, it is said that Mary Shelly was inspired to write Frankenstein during an unusually gloomy European summer in 1816 that, unbeknownst to her, was the result of the Tambora volcano in faraway Indonesia).19 Depending on the size, timing, and location of a nuclear attack, agricultural production could be affected and this could result in disruptions to food supplies in vulnerable populations around the world. As such, “nuclear autumn” is included as a possible source of casualties in the above discussion. Most importantly for our purpose in this section, however, nuclear war, at least with nuclear forces heretofore accumulated, would not mean nuclear winter, human extinction, or the end of the world.