# NC

### 1

#### Counter plan text: The World Health Organization should harmonize its approach to CRISPR patents and the member nations of the World Trade Organization should follow these guidelines. Marlborough reading yellow.

Wachowicz 19 [(Jessica, a third-year student at the University of Washington School of Law whose primary area of study is emerging technologies and the legal issues associated therewith.) “The Patentability of Gene Editing Technologies such as CRISPR & the Harmonization of Laws Relating to Germline Editing, “ Intellectual Property Breif, 2019 https://digitalcommons.wcl.american.edu/ipbrief/vol10/iss1/2/] RR

At present, countries take different approaches in applying the ordre public doctrine to cases involving germline editing. In Japan, the patent office examines scientific guidelines pertaining to stem cell research in rendering its decisions.8 1 Others simply look to the values held by that particular country in determining whether the invention would benefit society.82

Looking at the values held by a particular community will lead to varying results. Some countries may value the welfare of individuals over the progression of science.83 Others argue that because these inventions can dramatically improve healthcare, and because healthcare is a human right, this public interest should override any bans on germline editing. 84

A similar dispute arose under TRIPS with respect to pharmaceuticals. As stated previously, some countries, India in particular, argued that patenting pharmaceuticals was immoral because it raised the cost of healthcare. In 2016, the World Health Organization published the "Guidelines for the examination of patent applications relating to pharmaceuticals."86 The purpose of this guideline was to assist legislators in crafting laws that would allow for the patentability of pharmaceuticals generally, while imposing limitations that would prevent healthcare from becoming unaffordable.

One plausible solution is for the World Health Organization to create a set of guidelines for determining the patentability of technologies such as CRISPR. The guideline can look to other international treaties that focus on the preservation of human rights and the improvement of healthcare.87 By encouraging countries to take these agreed upon policy objectives into consideration when examining these controversial patents, results among different patent offices may be slightly less varied. A guideline from the World Health Organization (WHO) or a similar organization may assist countries' legislatures in crafting laws that allow for progression in this field of science while protecting their communities from potential human rights violations, such as the destruction of viable embryos.

Attempts at harmonization have been made in the past. There are currently numerous international instruments that prohibit inventions involving genomes, such as the UNESCO Universal Declaration on Bioethics and Human Rights and the Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biotechnology and Medicine: Convention on Human Rights and Biomedicine. The former states that public welfare should be prioritized over the progress of science, and the latter states that genetic modification techniques should only be allowed if "serious hereditary sexrelated disease[s] [are] to be avoided."89 These agreements make clear that public welfare is of primary importance, and that germline editing techniques should only be applied where serious risks can be avoided. The Oviedo Convention limited the scope of the exception to the avoidance of sex-related diseases, but perhaps with the introduction of CRISPR, countries may need to consider the circumstances under which genome and germline editing may be permissible.

CONCLUSION

In summary, relying on the ordre public doctrine to determine the patentability of CRISPR technology will lead to dramatically varying results around the world. The need for a more harmonized approach is present. Despite countries' general avoidance of genome and germline editing, technology has developed in such a way that these practices may be highly beneficial to public welfare. Countries should reconsider their stances on such practices in light of the potential benefits CRISPR technology can offer and should attempt to reach a general consensus on the proper uses of CRISPR. Given recent events, the WHO should promptly issue guidelines to assist legislatures in crafting laws that promote progress in this area while maintaining consistency with concepts of morality.

#### The counter plan entails that the European Union would comply with the same patent rules as the rest of the WTO which solves the second advantage and means that there’s no foreign governments interfering which solves the patent disputes in the first advantage

### 2

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### CRISPR’s development cost is especially high. Irvine 19

Alison Irvine [science writer], 19 - ("Paying for CRISPR Cures: The Economics of Genetic Therapies," Innovative Genomics Institute (IGI), 12-16-2019, accessed 9-4-2021, https://innovativegenomics.org/blog/paying-for-crispr-cures/)//ML

Developing a gene therapy can cost an [estimated $5 billion](https://gskkr.files.wordpress.com/2015/01/biotechnology.pdf). This is more than five times the average cost of developing [traditional drugs](https://www.sciencedirect.com/science/article/pii/S2452302X1600036X). In addition to the costs of research, manufacturing and distribution, these biological therapeutics are subjected to multiple regulatory structures, which result in a long and expensive route to approval. When you factor in the limited number of eligible patients (customers), the motivation behind pricing becomes clear.¶ According to a base-case analysis conducted by the Institute for Clinical and Economic Review (ICER), Zolgensma’s subjective value to their patients has been estimated to be around $900,000 per treatment. Still, nothing is stopping Novartis from inflating the price. Zolgensma’s only other competition is Spinraza, which, in comparison, requires a procedure every few months and can cost a total of $30 million over a lifetime.

#### Reducing patents sets a precedent that spills over to all future diseases – Hopkins 21:

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The Biden administration’s unexpected support for [temporarily waiving Covid-19 vaccine patents](https://www.wsj.com/articles/u-s-backs-waiver-of-intellectual-property-protection-for-covid-19-vaccines-11620243518?mod=article_inline) won’t have an immediate financial impact on the companies making the shots, industry officials and analysts said. Yet the decision could mark a shift in Washington’s longstanding support of the industry’s valuable intellectual property, patent-law experts said. A waiver, if it does go into effect, may pose long-term risks to the vaccine makers, analysts said. [Moderna](https://www.wsj.com/market-data/quotes/MRNA) Inc., [MRNA -4.12%](https://www.wsj.com/market-data/quotes/MRNA?mod=chiclets) [Pfizer](https://www.wsj.com/market-data/quotes/PFE) Inc. [PFE -3.10%](https://www.wsj.com/market-data/quotes/PFE?mod=chiclets) and other vaccine makers weren’t counting on sales from the developing countries that would gain access to the vaccine technology, analysts said. If patents and other crucial product information behind the technology is made available, it would take at least several months before shots were produced, industry officials said. Yet long-term Covid-19 sales could take a hit if other companies and countries gained access to the technologies and figured out how to use it. Western drugmakers could also confront competition sooner for other medicines they are hoping to make using the technologies. A World Trade Organization waiver could also set a precedent for waiving patents for other medicines, a long-sought goal of some developing countries, patient groups and others to try to reduce the costs of prescription drugs. “It sets a tremendous precedent of waiving IP rights that’s likely going to come up in future pandemics or in other serious diseases,” said David Silverstein, a patent lawyer at Axinn, Veltrop & Harkrider LLP who advises drugmakers. “Other than that, this is largely symbolic.”

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences 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 con-text**.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 compe-tition 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 pharmaceu-tical 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 sec-tor.2 It is therefore unsurprising that we are seeing indus-try-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 com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als 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 accel-erate 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 rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure 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 com-bination product that is being tested for therapeutic poten-tial 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**, **bioterror-ism** 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 imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious 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 contribu-tions 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 innova-tion conditions.

#### Bioterror causes extinction---early response key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, Bill Gates will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose charitable foundationis funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

### 3

#### Interpretation: medicines is a generic bare plural. The aff may not defend that member nations of the World Trade Organization reduce intellectual property protections for a subset of medicines.

Nebel 19 Jake Nebel [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs.] , 8-12-2019, "Genericity on the Standardized Tests Resolution," Briefly, https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/ SM

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions. Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window. So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why. 1.1 “Colleges and Universities” “Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons. First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural. Second, “colleges and universities” fails the upward-entailment test for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals. Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universities generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution. Fourth, it is extremely unlikely that the topic committee would have written the resolution with the existential interpretation of “colleges and universities” in mind. If they intended the existential interpretation, they would have added explicit existential quantifiers like “some.” No such addition would be necessary or expected for the generic interpretation since generics lack explicit quantifiers by default. The topic committee’s likely intentions are not decisive, but they strongly suggest that the generic interpretation is correct, since it’s prima facie unlikely that a committee charged with writing a sentence to be debated would be so badly mistaken about what their sentence means (which they would be if they intended the existential interpretation). The committee, moreover, does not write resolutions for the 0.1 percent of debaters who debate on the national circuit; they write resolutions, at least in large part, to be debated by the vast majority of students on the vast majority of circuits, who would take the resolution to be (pretty obviously, I’d imagine) generic with respect to “colleges and universities,” given its face-value meaning and standard expectations about what LD resolutions tend to mean.

#### It applies to medicines:

#### Upward entailment test – spec fails the upward entailment test because saying that nations ought to reduce IPP for one medicine does not entail that those nations ought to reduce IPP for all medicines

#### Adverb test – adding “usually” to the res doesn’t substantially change its meaning because a reduction is permanent

#### Vote neg:

#### Semantics outweigh:

#### T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here

#### Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution

#### It’s the only stasis point we know before the round so it controls the internal link to engagement – there’s no way to use ground if debaters aren’t prepared to defend it

#### Limits – there are countless affs accounting for thousands of medicines – unlimited topics incentivize obscure affs that negs won’t have prep on – limits are key to reciprocal prep burden – potential abuse doesn’t justify foregoing the topic and 1AR theory and functional limits checks PICs

#### There are over 20,000 affs

FDA 11/18 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

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.

#### Ground – spec guts core generics like innovation that rely on reducing IP for all medicines because individual medicines don’t affect the pharmaceutical industry broadly – also means there is no universal DA to spec affs

#### TVA solves – read as an advantage to whole rez

#### Paradigm issues:

#### Drop the debater – their abusive advocacy skewed the debate from the start

#### Comes before 1AR theory – NC abuse is responsive to them not being topical

#### Competing interps – reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation

#### No RVIs – fairness and education are a priori burdens – and encourages baiting – outweighs because if T is frivolous, they can beat it quickly

#### Fairness is a voter ­– necessary to determine the better debater

#### Education is a voter – why schools fund debate