**T Nebel**

### NC – T Nebel Medicines

**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.

**Vote neg:**

1. **Semantics outweigh:**
2. **T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here**
3. **Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution**
4. **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**

1. **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**.

1. **TVA solves – read as an advantage to whole rez**

**Paradigm issues:**

1. **Drop the debater – their abusive advocacy skewed the debate from the start**
2. **Comes before 1AR theory – NC abuse is responsive to them not being topical**
3. **Competing interps – reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation**
4. **No RVIs – fairness and education are a priori burdens – and encourages baiting – outweighs because if T is frivolous, they can beat it quickly**
5. **Fairness is a voter – necessary to determine the better debater**
6. **Education is a voter – why schools fund debate**

### Bioterror DA

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### 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.

#### 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.

### CP

#### The member nations of the World Trade Organization ought to reform intellectual property protections for bioterror medicines using the mechanisms described by MSF ’17.

**We allow secondary patents, but only under stricter patentability requirements, which solves innovation and high drug prices. MSF 17:**

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Countries can take a variety of steps to promote competition in vaccine manufacturing and help mitigate the complex patent thickets that could block, delay or increase uncertainties around access to multiple sources of vaccines. Governments should adopt public health-oriented IP policies, making full use of TRIPS flexibilities in both substantive and procedural aspects of national patent laws. Countries should:

• Encourage and accelerate follow-on development and competition of vaccines and vaccine technologies through the introduction and use of broad Bolar exemptions. This will support an early start for research and clinical studies by follow-on manufacturers, and support independent follow-on research and development.

• Apply strict patentability criteria for vaccine and vaccine technologies in patent examination and judicial proceedings. Countries should closely scrutinise patent applications concerning common methods of treatment, dosage forms and claims concerning specific age groups. Countries should reject trivial changes to known vaccine technologies, or composition patent applications that merely present the assembly of more ingredients using a known technology.

• Implement robust pre- and post-grant opposition procedures in national patent law systems that allow greater public scrutiny and opportunities to challenge unmerited patent applications from an early stage. Procedures that allow third-party observation but lack a mandatory hearing requirement could be improved to provide better transparency and accountability to the public.

• Improve use of compulsory licencing. Governments should strengthen the mechanisms of issuing compulsory licences to facilitate the most expedited access to multiple sources of vaccines and to safeguard public health.

• Strengthen technical capacity to ensure patent examiners apply strict patentability criteria and screen out unmerited applications in a timely manner. This will provide clarity on the patent landscape concerning important vaccines and technologies.

• Increase transparency of patent office filings to enable third parties to better understand the IP landscape, especially through procedures to promote disclosure of non-proprietary biological qualifier names74 of vaccines. Prospective manufacturers will be able to make decisions more efficiently if they understand the IP landscape clearly. Government procurement decision making will also be improved by addressing the current information asymmetry.

• Make full use of LDCs’ exemption from mandatory patent protection to accelerate access to quality assured follow-on new vaccines and encourage competition to improve affordability of vaccines.

• Demand that international organisations like WHO, Gavi, the Pan American Health Organization (PAHO) and the United Nations Children’s Fund (UNICEF) improve technical support for countries to: identify legal barriers, use flexibilities under IP laws and improve transparency of patent information to facilitate follow-on development and foster robust competition for new vaccines.75

## Case

#### Link turn - no companies will pursue bioterror technology innovation and will shift to others.

#### TURN bioterror – There are more bioterror attacks in the world of the aff, more information about bioterror is being released to different companies in order for them to manufacture medicines which increases risks of knowledge leaks to non state actors.

#### Cross apply innovation DA to show bioterror flows neg. We need innovation to combat bioterrorism.

### R. Daniel 18 [R. Daniel, PhD candidate in the Sustainable Development program at Columbia University in the City of New York and Chris Bakerlee, Ph.D. Candidate: Molecules, Cells and Organisms “"Designer bugs": how the next pandemic might come from a lab”. 12-6-2018. Vox. https://www.vox.com/future-perfect/2018/12/6/18127430/superbugs-biotech-pathogens-biorisk-pandemic. Accessed 8-11-2021; MJen]

### We also need to [invest more](https://www.openphilanthropy.org/research/cause-reports/research-and-development-decrease-biosecurity-risks-viral-pathogens#Antivirals_for_pandemic_preparedness) in developing antivirals that hit a wider range of targets. Such broad-spectrum drugs may stand a better chance of slowing the proliferation of an engineered bug than treatments specific to single known pathogens. And we should also develop “platform” technologies that allow rapid vaccine development. Currently, the process of designing, testing, and manufacturing a vaccine to prevent the spread of a new pathogen takes years. Ideally, we could immunize all at-risk individuals within months of identifying the pathogen. Accelerating vaccine development will require us to innovate new and likely unconventional technologies, such as [vectored immunoprophylaxis](https://tdtmvjournal.biomedcentral.com/articles/10.1186/s40794-017-0046-0) or [nucleic acid vaccines](https://www.who.int/biologicals/areas/vaccines/dna/en/). Even as we pursue and accelerate such research, we should also be mindful of the possibility of self-inflicted wounds. To avert a terrible accident, the international biomedical community should establish firmer cultural guardrails on the research into pathogens. Currently, career advancement, financial gain, and raw curiosity motivate biologists at all levels to push the envelope, and we all stand to gain from their efforts. However, these same incentives can sometimes lead researchers to take substantial and perhaps unjustified risks, such as evolving dangerous strains of influenza to be more contagious or publishing instructions for cultivating a close cousin of the smallpox virus. It’s important for biologists to do their part to promote a culture in which this adventurous intellectual spirit is tempered by caution and humility. Encouragingly, synthetic biology luminaries like [Esvelt](https://www.vox.com/science-and-health/2018/5/31/17344406/crispr-mosquito-malaria-gene-drive-editing-target-africa-regulation-gmo) and [George Church](https://www.recode.net/2014/12/8/11633602/the-time-traveler-george-church-is-racing-into-the-future-and) of Harvard University are doing just that, pioneering [technological](https://www.media.mit.edu/projects/daisydrives/overview/) [safeguards](https://www.nature.com/news/gm-microbes-created-that-can-t-escape-the-lab-1.16758) to mitigate accidental release risks and [advocating](http://seedmagazine.com/content/article/safeguarding_biology/) [policies and norms](https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1007286) that would make 21st-century biology a less perilous pursuit. As the tools of synthetic biology spread to other disciplines, their example is one that others should follow. Underlying the prescriptions above is the need to approach the problem with the sense of urgency it warrants. As our biotechnological capabilities grow, so too will the threat of engineered pathogens. An engineered pandemic won’t announce itself with a towering mushroom cloud, but the suffering of the individuals it touches will be no less real.

#### The plan doesn’t solve because developing countries won’t be able to produce their own medicines against bioterror without the proper infrastructure and raw materials.

#### Their cards are just about innovation in general, esp downstream innovation, not bioterror.

#### No solvency due to circumvention– no medical innovation is labeled as a bioterror countermeasure from the start.

#### Vote on the DA, because innovation is the prerequisite to creating the drugs that people need to protect themselves against bioterrorism. Cross apply mcdole and ezzell

#### Reductions in IP do not improve accessibility, and some protections are necessary for balancing public and private interests.

**Krattiger ‘13** (Anatole Krattiger,; Adjunct Professor, School of Integrative Plant Science Plant Breeding and Genetics Section ; September 2013; "Promoting access to medical innovation"; https://www.wipo.int/wipo\_magazine/en/2013/05/article\_0002.html, WIP Magazine, accessed 7-29-2021; JPark)

The rationale of the intellectual property (IP) system in general, and the patent system in particular, is to **make investment in innovation attractive** and to offer a mechanism which ensures that **the knowledge contained in patent applications is accessible to society**. In this way, it seeks to balance competing private and public interests. Anyone applying for a patent is required to disclose the details of their technology so that the public is aware of, and can eventually use, the knowledge contained in patent documents. Patent information available through public databases, such as WIPO′s PATENTSCOPE, offers useful insights about innovation trends and freedom-to-operate, and can help shape patenting and licensing strategies. Data indicate overall long-term growth in patenting of medical technologies (a sign of renewed investment in this area) and that an increasingly diverse range of public and private users (see Figures 2 and 3), including from emerging economies, are using the international patent system. While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated. Just as **the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access.** As noted in the WHO′s Framework for Access to Medicines, **access to medicines is rarely dependent on a single factor**; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems, among others. Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector, since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. The WTO′s Doha Declaration on the TRIPs Agreement and Public Health of 2001, clarified a number of rules specific to IP and helped reassure the global community that IP should not prevent access to the medicines needed in developing countries. Medical technologies are usually very expensive to develop but relatively cheap to reproduce. Without the protection conferred by a patent it would not be financially viable for companies to continue investing in research, product development and regulatory approval. If competitors could “free ride” on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby weakening any incentive to develop new products.

#### Decreasing IPR for medicines will slow efforts to scale up medicine production – COVID proves.

**Kappos et al. 21** [David J.Kappos, Former Under Secretary of Commerce for Intellectual Property of United State. “Waiving Covid-19 vaccine patents won't get shots in arms faster. It slows down new vaccines.”. 5-25-2021. NBC News. [https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099. Accessed 8-10-2021](https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099.%20Accessed%208-10-2021); MJen]

On that small point, at least, we agree: The nations that spearheaded the petition to waive the patent rights at the WTO, India and South Africa, have been unable to provide any evidence that the international system of respecting intellectual property rights under the law have impeded the development, production or distribution of Covid-19 vaccines and treatments. And it is hard to imagine that any such evidence will be forthcoming, as **intellectual property is facilitating — not inhibiting — the pharmaceutical industry's pandemic response.** Normally fierce rival companies have been able to cooperate on vaccine production precisely because inventors know their property rights are — and will remain — secure. For instance, Johnson & Johnson invited Merck to help manufacture its viral-vector vaccine, while Pfizer and BioNTech, which jointly developed their revolutionary mRNA vaccine, are similarly working with French drug giant Sanofi to boost its production. And generics manufacturers are already working around the clock on a contract basis with innovator firms to produce vaccines. For instance, India's largest generics manufacturer, the Serum Institute, is producing billions of doses of the AstraZeneca vaccine for low-income countries, while South Africa's largest generics firm, Aspen Pharmacare, is producing hundreds of millions of doses of Johnson & Johnson's vaccine. India and South Africa's petition to nullify intellectual property protections, were it to have been in effect, would have made those collaborations impossible. Suspending intellectual property rights will not get shots in arms any faster at this point and would, in fact, undermine efforts to scale up vaccine production. As Okonjo-Iweala herself pointed out last week, though it will take time to negotiate a wholesale change to WTO treaties, the capacity to manufacture Covid-19 vaccines already exists in Pakistan, Bangladesh, Indonesia, Thailand, Senegal and South Africa but is currently sitting idle despite existing frameworks giving manufacturers in those places the right to start. The EU, in the meantime, has [offered a counterproposal](https://www.reuters.com/world/europe/eu-present-wto-plan-boost-vaccine-production-2021-05-19/) to waive or minimize export restrictions on vaccines and vaccine components, to pledge to supply vaccines to countries with shortages at cost and to allow more countries to take advantage of existing WTO rules that allow countries to license intellectual property without the consent of the patent holders, essentially allowing for an increasing production capacity without waiving the patent rights altogether. So **while the appeal of an intellectual property waiver is tempting in the short-run, doing so imperils our ability to develop new medicines and combat future pandemics.** The Biden administration, however, announced its support for such a petition earlier in May and progressive groups cheered, contending that the intellectual property suspension would hasten and make more equitable the global vaccine rollout by enabling more manufacturers to produce the vaccines developed by Western firms. And, certainly, the rapid and equitable distribution of Covid-19 vaccines is absolutely critical to ending this pandemic. But sacrificing the innovation ecosystem in order to achieve this end would be myopic policy. There are already very real challenges to inoculating the world, including a widespread lack of proper refrigeration (let alone the ultracold storage required for some vaccines), a shortage of trained professionals to administer them and conduct follow-up evaluations, and a lack of patient compliance with the two-dose regimen for the Pfizer-BioNTech and Moderna jabs. Plus, there have already been issues with fakes and a lack of trust in the government that have come into play. In Mexico and Poland, [authorities have identified](https://urldefense.com/v3/__https:/www.wsj.com/articles/pfizer-identifies-fake-covid-19-shots-abroad-as-criminals-exploit-vaccine-demand-11619006403__;!!PIZeeW5wscynRQ!5im4XdWEGVpKy_ctvTTJNvidGqa0qNpMLCmOYVDuZgi0OzUdPpczT-h4tNU-_CdcL6-x$) counterfeit versions of the Pfizer-BioNTech vaccine. In Malawi, [the New York Times reported](https://urldefense.com/v3/__https:/www.nytimes.com/2021/04/14/world/europe/western-vaccines-africa-hesitancy.html__;!!PIZeeW5wscynRQ!5im4XdWEGVpKy_ctvTTJNvidGqa0qNpMLCmOYVDuZgi0OzUdPpczT-h4tNU-_JTNQHUw$) that "people are asking doctors how to flush the AstraZeneca vaccine from their bodies." Suspending intellectual property rights will not remove any of these roadblocks and would likely exacerbate them. Without certain quality controls implemented by original patent holders, especially in places with existing levels of government or industrial corruption, we could see ineffective vaccines manufactured using substandard processes, and then administered without adequate refrigeration, professional handling or required counseling and follow up. In this moment, leaders and policymakers in the developed world should focus their efforts on helping other nations overcome these challenges, rather than debating the finer points of intellectual property law at the WTO. The latter is a waste of precious time, especially since without intellectual property protections, there might never have been vaccines to debate — at least not yet

### AT ORIOLA

This card doesn’t actually mention compulsory licensing in the text. Access issues in the case of a bioterrorism attack could be solved through donations etc.

### AT son

#### Incredibly vague, doesn’t really have a conclusion – just says that there is an association, not a relationship

### AT avedissian

Incredibly old, prefer mcdolle and ezell

### Safety

#### Reducing IPs Increases Counterfeit and Non-Regulated Products – COVID proves.

**Ezell and McDole 21,** - McDole: a senior policy analyst covering intellectual property (IP) and innovation policy at the 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); Ezell: vice president, global innovation policy, at the ITIF. He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues. He is the coauthor of Innovating in a Service-Driven Economy: Insights, Application, and Practice (Palgrave Macmillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012).

[Ezell, Stephen, and Jaci McDole. “Ten Ways Ip Has Enabled Innovations That Have Helped Sustain the World through the Pandemic.” Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic, Information Technology and Innovation Foundation, 29 Apr. 2021, itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through. Accessed 2 August 2021]

Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the realityis **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. 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.** **In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world. 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. Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products. Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. In Mexico, fake vaccines sold for approximately $1,000 per dose Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.** Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down. 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.** 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.

#### Generic medicine is dangerous—contamination and unsanitary manufacturing conditions.

White 19 [(C. Micheal, Professor and Head of the Department of Pharmacy Practice, University of Connecticut) “Why your generic drugs may not be safe and the FDA may be too lax” The Conversation, 12/4/19. <https://theconversation.com/why-your-generic-drugs-may-not-be-safe-and-the-fda-may-be-too-lax-125529>] RR

This leads to a vital question: Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes. Unfortunately for those who turn to generics to save money, the FDA relies heavily on the honor system with foreign manufacturers, and U.S. consumers get burned. Eighty percent of the active ingredients and 40% of the finished generic drugs used in the U.S. are manufactured overseas.

As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities.

Do experts have something to add to public debate?

Where are your drugs being made?

A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo

Generic drug manufacturers either make bulk powders with the active ingredient in them or buy those active ingredients from other companies and turn them into pills, ointments or injectable products.

In 2010, 64% of foreign manufacturing plants, predominantly in India and China, had never been inspected by the FDA. By 2015, 33% remained uninspected.

In addition, companies in other countries are informed before an inspection, giving them time to clean up a mess. Domestic inspections are unannounced.

Faking results

The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo

As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects.

Unscrupulous foreign producers shredded documents shortly before FDA visits, hid documents offsite, altered or manipulated safety or quality data or utilized unsanitary manufacturing conditions. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. and making intentionally false statements. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine.

These quality and safety issues can be deadly. In 2008, 100 patients in the U.S. died after receiving generic heparin products from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines.

Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin.

One of the heparin manufacturers inspected by the FDA received a warning letter after it was found to have used raw material from uncertified farms, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities.

These issues continue to this day. Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds N-nitrosodimethylamine or N-nitrosodiethylamine.

One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores.

This raises a critical question: How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced? Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But the potential for harm is still great.