## OFF

#### 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 universal and permanent

#### Violation: the aff only defends biological elements used outside of their country of origin

#### 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

#### 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 – potential abuse doesn’t justify foregoing the topic and 1AR theory 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 – 1NC construction was premised on

#### Deters abuse – debaters won’t read args they can’t win on – their interp means reading extra T affs has zero risk

#### 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

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

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

## OFF

### NC – CP

#### The member nations of the WTO should

#### Create harsher laws on Phrama for patenting all medicines and check if they are indigenous. Allow indigenous people to patent their medicines and inventions later or not have them patent. Criminal proceedings that WTO would enforce

#### impose a mandatory lockdown until there is no more than one new case per day per 100,000 people after which local officials will modulate lockdown levels based on local case numbers. Governments should compensate both individual workers and small businesses that suffer substantial or irreparable economic loss as a result of lockdowns.

#### Only the lockdown solves- it curbs COVID spread until the vaccine

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[Michael T. and Mark Olshaker, writer and documentary filmmaker, "America Needs to Lock Down Again," Foreign Affairs, 9-16-20, https://www.foreignaffairs.com/articles/united-states/2020-09-16/coronavirus-america-needs-lock-down-again, accessed 10-29-20]

In our essay “Chronicle of a Pandemic Foretold,” for the July/August issue of Foreign Affairs, we described the struggle against COVID-19 in terms of a baseball game and estimated that the United States was in about the third inning of a nine-inning contest. At this point, however, it may be more helpful to shift to an altogether different analogy. The unfolding story of the pandemic is a three-act play, in which the country is now midway through the second act.

The first act saw the disease spread from China to the rest of the world and to a woefully unprepared United States. The second witnessed Americans tire of restrictions and effectively surrender to the pandemic. Infection rates across the country soared during the summer and will likely rise again in the autumn as schools and universities reopen. To truly get the novel coronavirus under control, the United States must do what it has not done so far: impose real and stringent lockdowns across the country for roughly two months. Controlling the spread of the disease in this way will save lives ahead of the eventual end of this drama in the pandemic’s final act—the arrival of a safe, effective vaccine.

THE CURTAIN RISES

Act I opened in late 2019 with the emergence in China of a novel coronavirus that spread throughout much of the world with breathtaking speed and effect. Nations and regions faced the challenge in different ways and with varying levels of success. After a horrendous start, for example, Italy managed to get transmission substantially under control by imposing a near-complete shutdown of the northern part of the country. In the United States, both New York City and New York State saw catastrophic levels of infection that overwhelmed the entire health-care system. It is difficult to forget the images of refrigerated trailers sitting outside hospital emergency rooms to accommodate the dead. But under the leadership of Governor Andrew Cuomo—and thanks to a coordinated state public health response—New York locked down to get the number of cases to a manageable level and then maintain the low numbers, turning a disaster into a model for the rest of the United States.

The issue of testing loomed over Act I. Some Asian nations that had experience with SARS began widespread testing of possible cases early and therefore were able to do contact tracing and largely control viral transmission. The United States did not do that. The White House denied the potential seriousness of the coronavirus (allegedly in a bid to prevent “panic”), while the Centers for Disease Control and Prevention (CDC) developed a test for national use that was faulty, leaving the virus difficult to track and making case isolation and contact tracing ineffective as a means to control transmission. That forced the country onto a much more disruptive path: an attempt to control and mitigate the virus’s effects through a national lockdown of all nonessential personnel.

The price was steep, with millions of jobs lost, schools closed, and all public events and gatherings officially canceled. In mid-April, the United States was seeing 32,000 new cases a day. But a month later, that figure had dropped to 22,000 and Americans felt they had turned a corner, that the pandemic was subsiding and the battle was won.

THE DISTANT PEAK

Act II of this drama began around Memorial Day weekend in late May. Pandemic fatigue had set in. Americans seemed to collectively declare, “We’re done,” taking any decrease in daily case counts or deaths as a sign that the virus had been curtailed. The warm-weather months drew people into social settings, and the White House and a host of pundits encouraged this natural yearning to get back to business—and leisure—as usual. The administration and its allies posited a zero-sum choice between continuing to slow transmission of the disease and saving the economy. In fact, the country had the fire only under limited control, and if you stop fighting a fire at that point, it will naturally flare up again and continue to burn.

By July 20, with people resuming socializing in large groups, the country’s daily new case count shot up to more than 66,000. It should be noted that the many protests that followed the death of George Floyd in late May did not contribute much to the spread since the demonstrations occurred outdoors, where the virus rapidly dissipates in the air. The spring weekend beach gatherings of young people, by contrast, led to more serious transmissions because revelers often ended up indoors, particularly in close and crowded confines such as bars and houses.

The rate of daily new cases dipped to a little over 42,000 by the end of August, largely because of major containment efforts in California, Florida, Georgia, and Texas. As encouraging as that was on the face of it, the United States was still seeing about 1,000 COVID-19-related deaths per day, hardly a victory by any standard. Americans can expect these crests and troughs in new infections to continue, with each successive peak higher than the one before, until either an effective vaccine becomes widely available or herd immunity is established in the population through person-to-person transmission.

Herd immunity is often discussed but widely misunderstood. Each infectious disease has a different threshold for what percentage of a given population must be immune before the rate of transmission begins to drop. For a highly infectious agent transmitted through the air, such as measles, that percentage can be as high as 95 percent. For COVID-19, most public health infectious disease experts estimate it to be between 50 and 70 percent. One theory holds that the best way to approach the virus is to try to achieve herd immunity as quickly as possible through natural infection so everything can get back to normal, while protecting the older and most vulnerable people. This is the method seemingly employed by Sweden. Its transmission and mortality rates were significantly higher than those of neighboring Denmark and Norway, but the country does not appear to be substantially closer to reaching herd immunity than its Scandinavian neighbors, all of which are still far short of the threshold. Moreover, there is emerging evidence that exposure to the virus may confer only temporary immunity, possibly as brief as several months. And achieving herd immunity—if that is even possible—would only slow transmission, not halt it.

By the most liberal estimates, only about ten to 12 percent of the U.S. population has been infected thus far and, as Sweden’s experience has shown, reaching the threshold will be a long-drawn-out process that could result in the deaths of more than two million Americans. As it is, with about four percent of the world’s population, the United States has racked up about a quarter of all confirmed COVID-19 fatalities. The country failed to protect vulnerable populations, as witnessed in the many outbreaks in nursing homes and extended-care facilities. The virus has also taken a toll on young and healthy individuals; even some with mild or asymptomatic variants of the disease have become “long haulers,” who experience a range of symptoms, including chronic fatigue and cardiac and respiratory issues, weeks or months after getting infected.

SHUT IT DOWN

Herd immunity is a distant and unrealistic prospect, but Americans still have the opportunity to mitigate the suffering and death caused by the disease. The reality is that the only way for the United States to get through Act II with low levels of morbidity and mortality is through more complete lockdowns than were previously implemented in areas with high incidence of infection. Currently, the upper Midwest is the “hottest” area in the country for community-wide transmission, but other areas will see increasing case totals deeper into the fall. The aim at this point, quite simply, should be to cut transmission of the virus as much as possible until the creation and distribution of an effective vaccine.

Such lockdowns should last six to eight weeks with a goal of reaching no more than one new case per day per 100,000 people. This low rate is necessary for testing and contact tracing to have any meaningful effect. Once that rate is achieved, however, local officials will be able to adjust lockdown measures more accurately and with the flexibility the pandemic demands. If the White House and federal government will not lead, which is unfortunately likely under the current administration, the governors of each state, in coordination with their neighboring states, must take the initiative themselves. Some might think this is unrealistic, but New York has been able to maintain this low rate of new infections for the past three months.

Stringent lockdowns, of course, would depend on the continued labor of essential workers, a category we estimate to be no more than 35 percent of the workforce and possibly less. What about other workers? As part of its broader anti-COVID-19 strategy, the federal and state governments should compensate both individual workers and small businesses that suffer substantial or irreparable economic loss as a result of lockdowns. Such support negates the false choice between public and economic health. If carried out successfully, the near-complete shutdowns would be not open-ended but limited in time. And the government has the means to prop up adversely affected workers and businesses. As Minneapolis Federal Reserve Bank President Neel Kashkari outlined in an op-ed in The New York Times cowritten with one of us (Osterholm), this fiscal obligation could be covered by the money most Americans who have not lost income are saving by not spending as much during the pandemic—the personal savings rate of Americans has grown from eight percent in January to 20 percent in August. Domestic savings can fund investment in the national economy, a concept that should work equally well in other developed nations. Banks, whose holdings have been boosted by the additional savings, could loan the money necessary for protecting jobs and businesses; Americans would essentially be repaying themselves rather than taking the more traditional route of incurring foreign debt. We believe many people would support a more robust lockdown if they understood that they would not suffer financially. Such a subsidy will actually save money in the long term by preserving jobs and small businesses.

The alternatives to serious lockdowns are insufficient. In areas where the disease is still rampant, masks and physical distancing alone will not get the job done. Business as usual for another six to eight months—until an effective vaccine is widely available—will send current rates of transmission even higher, especially as schools and colleges reopen. By the middle of September, some universities had already canceled in-person classes owing to widespread transmission on campus. Consider how much pain, suffering, and death Americans have endured so far, with no more than ten to 12 percent of the population infected. The next phase could be overwhelming and make Americans look back with nostalgia at the time when new infection rates were still under 100,000 per day.

A DIFFICULT DENOUEMENT

The final act will begin when—and if—one vaccine or more becomes broadly available. A vaccine will eventually bring this long drama to an end, but it will raise a whole new set of questions. Will enough Americans be willing to take it, given our national schizophrenic view of vaccines and science in general? How effective will a vaccine be, and how long will it confer immunity? What will the rules be for approving the vaccine, in the United States and the rest of the world? Who should, or will, get it first? There has been little official or public discussion about answers to these important questions.

It would be dangerous if a possible vaccine became politicized, either to achieve power, prestige, and influence for the country that produces it or to gain partisan advantage within the United States. Many in the public health sphere are afraid that a vaccine will be made available for use before it has been demonstrated to be safe and effective. Never before has the authority and confidence in U.S. government scientific institutions been so undermined by real or perceived political pressure from the White House. At the beginning of September, the CDC directed localities to prepare for the distribution of a vaccine in two months, at the beginning of November, right around the time of the presidential election. One possible mechanism for this expedited rollout would require the president to direct the Food and Drug Administration or the secretary of the Department of Health and Human Services to grant Emergency Use Authorization for a vaccine candidate that looks promising but has not been through the entire validating process.

There is indeed an inescapable tension between wanting a vaccine as soon as possible to prevent further transmission of the disease (and the resulting illnesses and deaths) and taking the necessary time to produce a safe vaccine, whose efficacy and effects on people of various ages and health situations are well understood. But public health and political officials should be extremely wary of any attempt to grant Emergency Use Authorization to a vaccine that hasn’t completed phase three trials, the final and most rigorous stage in which the product is tested over a broad range of thousands of subjects. In most instances in which such authorization is granted, it is for extremely sick or even dying patients. In this case, it would be granted to administer a vaccine to healthy people before the formula is perfected and before any potential negative effects have been documented. In 1955, one company’s production of the original Salk polio vaccine turned out to be defective, causing 40,000 cases of polio. Ten children died. In 1976, a rush to produce a vaccine against a perceived threat of swine flu left approximately 450 recipients with Guillain-Barré Syndrome paralysis.

One of the key reasons for a full phase three review, which includes at least 30,000 test subjects in a double-blind administration (meaning neither the subject nor the administrator knows who has been given the vaccine and who has been given a placebo), is to determine the vaccine’s impact and effects, positive and negative, on a range of different risk groups. What might be safe and effective for young adults, for example, might be ineffective or even harmful for seniors or those with certain underlying conditions. It is also possible that the effect on children could be different or unpredictable. These results will probably take months to sort out. Even more troubling, present plans do not call for either children or the elderly to be included in the phase three test group. Moreover, the first vaccines for this virus probably won’t be home runs (to go back to baseball analogies for a moment) like the smallpox, polio, and measles vaccines. They are more likely to be singles and doubles like the annual influenza vaccine, which in a good year is about 50 percent effective. Americans won’t be going back to the “old normal” anytime soon.

The best outcome in Act III will be the development and distribution of the vaccine as quickly and widely as possible, without shortcuts on safety or testing for effectiveness. The U.S. government should establish and publicize the criteria by which a vaccine will be considered ready for wide-scale public use as well as make clear which groups of people will receive the vaccine first. A proven safe and effective vaccine should first be given to physicians, hospital personnel, and first responders; then to essential workers with underlying risks for serious disease; and after that, to children so that they can stay in school.

But right now, the United States should just be trying to get through the rest of Act II—the coronavirus winter—and hold out until the arrival of a vaccine-enabled spring. It must impose severe lockdowns to truly curb the spread of the disease. New York has shown it can be done. It remains to be seen whether the rest of the country possesses the collective grit and determination to follow suit. A happy ending to this drama will very much be determined by how Americans decide to craft the rest of this current act.

## OFF

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**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.

## Case

### Framing

1. **Moral uncertainty means preventing extinction should be our highest priority.  
   Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
   These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.
2. **Reducing the risk of extinction is always priority number one.   
   Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. [http://www.existenti...org/concept.pdf](http://www.existential-risk.org/concept.pdf)Even if we use the most conservative of these estimates, which entirely ignores the   possibility of space colonization and software minds, **we find that the expected loss of an existential   catastrophe is greater than the value of 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  lives of ordinary length) makes the same point even   more starkly.  Even if we give this allegedly lower bound on the cumulative output potential of a   technologically mature civilization a mere 1% chance of being correct, we find that the expected   value of reducing existential risk by a mere one billionth of one billionth of one percentage point is worth   a hundred billion times as much as a billion human lives. **One might consequently argue that even the tiniest reduction of existential risk has an   expected value greater than that of the definite provision of any ordinary good, such as the direct   benefit of saving 1 billion lives.**  And, further, that the absolute value of the indirect effect of saving 1  billion lives on the total cumulative amount of existential riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.

### Advantage

#### Patents prevent biopiracy

Erstling 09 [(Jay, Emeritus Professor of Law at Mitchell Hamline School of Law, J.D., Cornell University Law School, 1974) “Using Patents to Protect Traditional Knowledge,” Texas Wesleyan Law Review, 2009] JL

Finally, while the patent system has been accused of facilitating biopiracy by tolerating third-party patenting of TK, using the patent system appropriately to protect TK can serve more to prevent biopiracy than to permit it. Biopiracy generally refers to the exploitation of traditional knowledge or genetic resources-typically by multinational companies-without the authorization of the holders of that knowledge, and/or the patenting of inventions based on traditional knowledge without the consent of the knowledge holders or payment of compensation.24 Several cases of alleged biopiracy, including patents granted for neem, turmeric, the enola bean, and quinoa, have aroused controversy and focused attention on how patenting can lead to unjust results.25 Although it is extremely difficult to estimate the extent to which biopiracy actually takes place in any particular country, protecting TK could provide some assurance against misappropriation by clarifying the duty that third parties owe to the holders of the knowledge when the knowledge has contributed to an invention that is the subject of a patent application.

#### Unpatented medicine cause counterfeits—

Lynbecker 16 [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated:

“The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1]

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.

While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3]

[Kristina]

According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5]

While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report,

“INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11]

Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless.

#### “Medicine” is

Lexico ND [(Lexico dictionary) https://www.lexico.com/definition/medicine] BC

The science or practice of the diagnosis, treatment, and prevention of disease (in technical use often taken to exclude surgery)

#### They don’t solve 2/4 types of IP their solvency adv says are key –

Patents on transgenic techniques and constructs, and transgenic plants, animals and micro-organisms (better known as genetically modified organisms); and · Patents on nuclear transplant cloning (for example, the techniques that produced Dolly the sheep).

#### BioD isn’t existential

Kareiva & Carranza 18 (Peter Kareiva & Valerie Carranza. Institute of the Environment and Sustainability,. “Existential Risk Due to Ecosystem Collapse: Nature Strikes Back.” Volume 102, September 2018, Pages 39-50)

The interesting question is whether any of the planetary thresholds other than CO2 could also portend existential risks. Here the answer is not clear. One boundary often mentioned as a concern for the fate of global civilization is biodiversity (Ehrlich & Ehrlich, 2012), with the proposed safety threshold being a loss of greater than .001% per year (Rockström et al., 2009). There is little evidence that this particular .001% annual loss is a threshold—and it is hard to imagine any data that would allow one to identify where the threshold was (Brook et al., 2013; Lenton & Williams, 2013). A better question is whether one can imagine any scenario by which the loss of too many species leads to the collapse of societies and environmental disasters, even though one cannot know the absolute number of extinctions that would be required to create this dystopia. While there are data that relate local reductions in species richness to altered ecosystem function, these results do not point to substantial existential risks. The data are small-scale experiments in which plant productivity, or nutrient retention is reduced as species number declines locally (Vellend, 2017), or are local observations of increased variability in fisheries yield when stock diversity is lost (Schindler et al., 2010). Those are not existential risks. To make the link even more tenuous