# 1NC

## Off-Case

### T

#### A. Interpretation: the aff must defend reducing IP protections for more than 1 medicine

hurbles 17

(1-14, https://hinative.com/en-US/questions/1594102)

You say "take some medicine" medicine is a hard word because medicine is singular and plural. "Medicines" means many types of medicines, but you use "medicine" as singular and plural for a single type of medicine

#### The plural means different kinds of medicines

WordHippo

https://www.wordhippo.com/what-is/the-plural-of/medicine.html

The noun medicine can be countable or uncountable. In more general, commonly used, contexts, the plural form will also be [medicine](https://www.wordhippo.com/what-is/the-meaning-of-the-word/medicine.html). However, in more specific contexts, the plural form can also be [medicines](https://www.wordhippo.com/what-is/the-meaning-of-the-word/medicines.html) e.g. in reference to various types of medicines or a collection of medicines.

#### B. Violation – the aff only defends one medicine.

#### C. Reasons to prefer

#### 1. The affirmative interpretation is unreasonable - it creates a race to the bottom of smallest possible changes and obscure singular medicines to dodge links. These interpretations may be pragmatically appealing but are not grammatical – that outweighs because you only have the jurisdiction to vote on topical affs because they haven’t met the burden of affirming and the words in the resolution are the only stasis for prep.

#### 2. The negative interpretation is superior- it provides a limit on the topic because affirmatives must find unifying advantages to beat PICs.

#### 3. Multiple words support our interpretation meaning it has *resolutional synergism*: words gain meaning in context, a “hot dog” is not a warm puppy – absent specific definitions of all words we defined you should vote neg.

#### D. Topicality is a voting issue for predictable limits- it tells the negative what they do and do not have to prepare for. It should be evaluated through competing interpretations – reasonability is arbitrary and causes a race to the bottom based on questionable argumentation and you can’t be reasonably topical.

### Warp Speed CP

#### CP Text: The governments of the member nations of the World Trade Organization ought to buy medicines and distribute it for free as per Adler et al.

#### Solves COVID without reducing IP protections- Operation Warp Speed proves. Time frame is now and the CP is totally feasible and can be conducted through coordination from the WTO and its member nations

Adler et al. 8-4-21 [David Adler is author of the monograph The New Economics of Liquidity and Financial Frictions, coeditor of the forthcoming anthology The Productivity Puzzle, and an adviser on industrial strategy at the Common Good Foundation (UK). Reda Cherif is a Senior Economist at the International Monetary Fund (IMF). He joined the IMF in 2008 and worked in several departments on fiscal issues and macroeconomic analysis of emerging and developing countries. His research focuses on development economics, natural resources, fiscal policy, and growth and innovation. Reda holds a PhD in economics from the University of Chicago. Fuad Hasanov is a Senior Economist at the International Monetary Fund (IMF) and an Adjunct Professor of Economics at Georgetown University. Before joining the IMF, Fuad was an Assistant Professor of Economics at Oakland University in Rochester, Michigan in 2004-2007. Fuad received a PhD in economics from the University of Texas at Austin. “How to deliver 10 billion COVID-19 vaccines at Warp Speed.” World Economic Forum. August 4, 2021. <https://www.weforum.org/agenda/2021/08/how-to-deliver-10-billion-covid-19-vaccines-at-warp-speed/>] HW Alex Lee

The US government's **Operation Warp Speed** (OWS) initiative **showed how successful public/private collaboration can be in rolling out a mass vaccination programme.** It provides a blueprint for how to build supply, regulate and distribute COVID-19 vaccines on a global scale. This kind of approach would focus on building capacity, supporting production in emerging or developing countries and encouraging rapid testing while vaccine production is underway. Operation Warp Speed (OWS), the US government initiative to accelerate the development, trials and production of COVID-19 vaccines, has been a **spectacular success. It showed that the state could work effectively with private firms to promote innovation and provide a powerful weapon against the virus.** It consisted of early and massive funding of R&D and investment in production of various vaccine candidates, as well as coordinating the value chain and addressing all regulatory and logistical hurdles. The result: several vaccines available within a year and widespread vaccination in most advanced countries. OWS showed that the state could effectively work with private firms to promote innovation and provide a powerful weapon against the virus. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) However, **the pandemic** is far from over. It **is still raging in the developing world.** The official global death toll has passed 4 million people while The Economist has estimated 7-13 million excess deaths, most of which are outside advanced countries. New, more contagious variants are also affecting a younger population, implying that many poorer countries may not be protected by the youth of their populations anymore. **An OWS for the World is needed.** Given the many uncertainties and risks about vaccine production and supply, regulation, distribution, and virus variants, the market will most likely fail to provide the necessary volume of vaccines. This will lead to long delays in reaching global herd immunity. **OWS represents a blueprint of effective industrial policy in action. Speed is of the essence in the face of a pandemic** While the development of a vaccine has been an amazing feat, vaccination campaigns in many parts of the world have been dismal. By mid-June, about a billion people globally have had at least one dose of a vaccine (with more than 2.3 billion doses administered), and most of them reside in advanced countries. Africa has so far inoculated less than 30 million people, little more than 2% of its population. The US, in comparison, has vaccinated more than 170 million people, more than half of its population. The G7 leaders have committed to provide 1 billion vaccine doses by end-2022. The US has pledged to buy a total of 500 million doses from BioNTech/Pfizer to provide to poor countries by mid-2022 (with 200 million doses by end-2021). Although these initiatives show that the race against time to vaccinate the world has started, many campaigners argue **these commitments fall short of what is needed to end the pandemic as fast as possible. To vaccinate the world, another 10 billion doses are urgently required.** Waiting until end-2022 would still wreak havoc on many parts of the world. Delivering 10 billion vaccines in a year A recent IMF proposal to end the pandemic within a year called for donations of extra doses, financing of vaccines for poor countries, and investments to increase vaccine manufacturing capacity by 1 billion doses by early 2022. Moreover, many downside risks considered in the proposal, such as export restrictions and supply chain bottlenecks, have already materialized. The EU and others have called for scaling up and diversification of production as a result. This kind of risk-based approach calls for further global action along the lines of OWS to ensure the delivery of 10 billion doses within a year, accounting for extra capacity and redundancy. This would involve **three main steps**: Purchasing the required capacity from key vaccine manufacturers directly - essentially building capacity, if necessary - to send the needed doses to other countries; Facilitating building or expanding vaccine production in emerging and developing countries, including through partnerships such as that of Senegal’s Institut Pasteur and a Belgian biotech firm; and Producing and distributing rapid tests for widespread testing while vaccines are on the way. Building capacity, facilitating collaboration and rapid testing Creating extra production capacity to produce hundreds of millions of doses a month within a year is **feasible and would cost a fraction** of advanced countries’ foreign aid budget. Producing 8 billion doses of mRNA vaccines would cost between $10 billion (BioNTech/Pfizer) and $25 billion (Moderna) and could be done within a year, according to recent research from Imperial College London. Procurement alone is likely to take longer than desired. Buying or building capacity is what OWS did, and is what economists such as Nobel laureate Michael Kremer have advocated. Coordinating all stakeholders and clearing bottlenecks would be key to the success of OWS for the World. It could be done by the US Biomedical Advanced Research and Development Authority (BARDA), in coordination with an EU or UK vaccine taskforce and WHO, or **any other global task force**. As we argue in the context of industrial policy against pandemics and OWS as a model, this task force needs to set up relevant objectives, clear resulting hurdles - whether in supply chain, distribution, or communication - and coordinate across government agencies, manufacturers, and in this case, global users. The EU vaccine task force has already mapped, tracked, and cleared bottlenecks. It retrofitted a German dengue vaccine bottling factory for Johnson & Johnson’s vaccine, for example. At the same time, advanced countries need to help others build their own production facilities and supply chains to manufacture vaccines and rapid tests. Indeed, this would create a more resilient vaccine production system globally, mitigating against uncertainties and risks when providing booster shots and other vaccines in the future for developing countries. Since vaccine production may take longer, producing rapid tests, which could be easier and faster, is a hedge against delays in vaccine production. Finally, while awaiting vaccines, many countries need to conduct universal or widespread testing to prevent outbreaks. Creating extra production capacity to produce hundreds of millions of doses a month within a year is feasible and would cost a fraction of advanced countries’ foreign aid budget. —Reda Cherif & Fuad Hasanov, IMF; David Adler, The Common Good Foundation (UK) Last year, we argued that testing would end the pandemic within a few months, but only a few countries experimented with it. Rapid worldwide vaccination could do the same. Reducing the length of the pandemic, even by days, **would save lives and is worth the investment. It is not too late to act.**

### Innovation DA

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

**Buchholz 5-17-21**

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

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

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

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

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

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The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

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

**Phelps 15**

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

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

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

**Bacchus, JD, 20**

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

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

**The elimination of IPR would be disastrous to private R&D**

**Bacchus 20**

(James Bacchus,  member of the [Herbert A. Stiefel Center for Trade Policy Studies](https://www.cato.org/herbert-stiefel-center-trade-policy-studies), the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland, “An Unnecessary Proposal: A WTO Wavier of Intellectual Property Rights for COVID-19 Vaccines, December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>) LAM

**In the short term, undermining private IP rights may accelerate distribution of goods and services**—where the novel knowledge that went into making them already exists. **But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs.** This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19) As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “**A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights**.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

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

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

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

**That causes extinction, which outweighs.**

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

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of **state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

## Case

### AT: Disease War

#### Aff doesn’t attack all of the root causes of disease spread- lack of materials, equipment, and facilities when faced with skyrocketed demands means solving IP protections alone isnt enough

Brant & Burns 7-29 [Jennifer Brant, CEO and Founder of Innovation Insights, and Thaddeus Burns, Head of Life Science Government & Public Affairs at Merck and served in senior positions at the US Department of Commerce and the White House Office of the US Trade Representative, served as a member of the National Academy of Sciences Committee charged with preparing a report on the science and technology capabilities of the U.S. Department of State. “Trade restrictions are delaying the COVID response. The WTO must act.” July 29, 2021. <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>] AL

The COVID-19 pandemic hit at a time when bio-manufacturing was undergoing a process of democratization. Technological progress had enabled growing capacity in many countries including Brazil, Indonesia, South Africa, Tunisia, Argentina, and Egypt. By 2020, the business model for bio-manufacturing had fundamentally changed and it was becoming the norm for companies to distribute research, development and manufacturing across geographies and work with partners. As recently as 15 years ago, building a facility to produce biologics such as monoclonal antibodies or vaccines could require an investment of as much as €500m, and it would take up to 3 years to bring that facility online. New manufacturing technologies have made it cheaper and easier to build new facilities and to scale up existing ones. Today, an investment of €20m can get a bio-manufacturing plant up and running. Such changes are part of the reason the global community was able to launch production of new COVID-19 vaccines so quickly. The urgency of COVID-19 accelerated further innovations in bio-manufacturing equipment and processes, and compressed production time in a way that will have positive impacts in the future. But the pandemic also revealed major weaknesses in global value chains. It was difficult for manufacturers to keep up with the sudden surge for demand for raw materials and equipment, as many new research and development and manufacturing partnerships rapidly took off. To extend capacity, new employees, intensive training and collaboration, and more infrastructure were needed. The global community was faced with the reality that facilities cannot be built everywhere in an instant, and that there are bottlenecks in the supply chain. Government action in some cases made things worse. Some countries enacted export restrictions on COVID-related products, which made it extremely difficult to run a global supply chain. Another difficult issue has been the tariffs applied on biologics and the products needed for their manufacture. Eighteen months into the pandemic, biologics manufacturers are still trying to cope with a range of challenges. There is still surging demand for equipment and raw materials. In some cases, they have expanded manufacturing capacity to produce more equipment such as filters and bioreactors. This continues to require time and significant investments.

#### Squo solves--cost and bureaucracy are barriers to patent protection and other countries violate IP laws without punishment now.

Chao and Mody 15 (Tiffany Chao [Editor in Chief of Journal of Medical Insight, adjunct professor at Stanford Med School] and Gita Mody [MPH Harvard, assistant professor at UNC Chapel Hill Med School], The impact of intellectual property regulation on global medical technology innovation, BMJ Innovations, 3/5/2015, https://innovations.bmj.com/content/1/2/49) hwof

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.[i](https://innovations.bmj.com/content/1/2/49#fn-4) High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.[4](https://innovations.bmj.com/content/1/2/49#ref-4) This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.[5](https://innovations.bmj.com/content/1/2/49#ref-5) As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.

\*\* Mercurio is COVID specific but warrants apply generally too

#### The TRIPS agreement and cheap vaccines in the squo solve the aff--independently, lack of manufacturing power and licensing transparency deck solvency.

Mercurio 21 (Bryan Mercurio [Simon F.S. Li Professor of Law at The Chinese University of Hong Kong], WTO WAIVER FROM INTELLECTUAL PROPERTY PROTECTION FOR COVID19 VACCINES AND TREATMENTS: A CRITICAL REVIEW, Virginia Journal of International Law, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820>, 2/12/2021) hwof

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26 Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level. Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31 While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs. Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices. Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

### AT: Gov Funding

**Government can’t fund innovation on its own. It’s best when pharma and government collaborate.**

**Atkinson 16** (Robert, PhD City and Regional Planning @ UNC, President of Information Technology and Innovation Foundation. “5 Myths About Life Science Innovation in the United States,” Huffington Post, April 6, 2017. https://www.huffpost.com/entry/5-myths-about-life-scienc\_b\_9517256)

**5. Government could lead drug discovery without industry.**

To the extent that left-wing populists acknowledge that cutting into industry’s revenues with price controls or weaker intellectual property protections would lead to lower levels of private R&D, they contend government easily could make up the difference. To that end, they have floated a variety of proposals, from having employers pay medical research fees, to instituting compulsory licensing for drug patents, to simply turning the whole task of research and discovery over to the NIH.

There are any number of problems with these proposals, but the first is that **there is no chance Congress would appropriate the necessary funding.** Consider that the NIH budget is about $30 billion, while the U.S. biopharma industry invests more than $50 billion in R&D. Even if the drug populists were correct that half of this funding is unnecessary, taxes would still have to be raised by tens of billions of dollars to cover the gap. Fat chance that will happen in the current environment

None of this means the U.S. system is perfect or cannot be improved. It certainly can—for example, by increasing federal funding for NIH (which is lower now than it was as a share of the economy in the mid-2000s); by exploring cooperative research models that focus on particular diseases; and by making the tax code more supportive of high-risk R&D with expanded tax credits and a new “innovation box” that lowers the corporate rate on profits derived from intellectual property. But **policymakers should reject the false choice between public-sector leadership and private-sector leadership. America leads the world because its system maximizes the strengths of both**.

# 2NR

## Case

### AT: Wildlife

Did not properly link wildlife to case. Too late to change plan because I have very limited time to respond to it.

## Off-Case

### T

Completely dropped T, cannot respond to it in the 2AR. He has lost the debate because he has not been able to prove why his case is topical under the neg’s interpretation. Ballot should vote neg because of reasons given under neg interp.

### AT: Innovation bad

Aff does not get this offense because he doesn’t solve. Switching over from private to public funding for R&D doesn’t suddenly magically make innovation focus (if his card were true)

**External RnD is crucial to increasing ROI and driving pharma innovation.**

**Booth 16** (Bruce, Partner @ Atlas Venture, “Positive Impact Of External Sourcing On Pharma R&D Productivity,” Forbes, December 16, 2016, https://www.forbes.com/sites/brucebooth/2016/12/16/positive-impact-of-external-sourcing-on-pharma-rd-productivity/?sh=1ea170dd3863)

Pharma R&D productivity continues to be a critical issue for the industry. Making smart investments in R&D requires an understanding of the risk and return drivers across the product development cycle, as well as some good fortune.

This week the topic of phama productivity was once again in the spotlight with a Deloitte report out that highlighted a continued decline in the ROI of R&D--primarily focusing on impact of lower revenue forecasts on a “stabilized” R&D cost basis. It was widely covered across the trade media (here, here), so instead of focusing on its conclusions I thought it worth highlighting the risk part of the R&D equation–the success rate of programs in R&D.

Last summer’s BIO Industry report covered this topic in great depth across disease areas; in summary, the BIO data showed that the industry over the last decade had a 9.6% probability of success from IND to approval. This is in line with similar analyses from McKinsey in Nature Reviews Drug Discovery from May 2016. The trend upwards (favorably) in the recent cohort (2012-2014) may just be an anomaly, but optimists like me think there could be real drivers behind the improvement (e.g., higher proportion of genetically validated programs, more patient stratification biomarkers, etc).

External R&D models have also been proliferating across the industry, as companies adjust the proportion of investment directed to internal vs. externally sourced programs in their R&D budgets. The increased visibility of these “External R&D” models–like Celgene’s R&D partnership approach, Takeda’s Center for External Innovation and Allergan’s Open Science model–shows how important they’ve become across the industry.

The goal of these efforts is to access the vast pools of innovation outside the walls of the in-house R&D organization and tap into the entrepreneurial risk-taking culture of biotech to secure a future pipeline, while avoiding the well-appreciated and suffocating burden of larger bureaucracies on creative research.

**I’m convinced these efforts are likely to increase the overall R&D productivity of the industry**. Precisely defined, R&D productivity involves both risk and spend. The risk part of the equation is particularly impactful–thousands of molecules are made to prepare a candidate for development, and only one in ten make it from IND to market. While there are clear cost-benefits of working with leaner and more capital-efficient partners (who lack the burden of large fixed-legacy R&D infrastructure) especially as variable costs), I believe this risk component to the R&D productivity equation is where external R&D efforts are likely to have a big impact.

Here’s some historic and recent data to support that conclusion: over the past 20 years, externally sourced programs (“in-licensed”) have delivered almost a twofold higher rate of success in development versus in-house programs. This was true in the 1990s (Figure 6b here), and its true more recently (here).

Why is this?

It’s certainly not the quality of the science itself. Lots of good science, worked on by good scientists, exists inside large pharma organizations as “in-house” projects. We and others have successfully “externally sourced” great programs from pharma as the substrate for startups in biotech–and this is happening across many companies and disease areas today.

The differential success rate of externally sourced programs is more likely a reflection of the sociology of organizations and the diligence process: the higher bar that an external asset must go through in order to find a place in a pharma company’s R&D pipeline. An externally sourced project has to displace other programs. It’s also competing with hundreds of other “external” projects for those limited licensing or partnership slots.

Beyond the operational and financial aspects driving this level of diligence, it’s also reinforced by conventional behaviors: the increased process rigor can be from paranoia (“these guys are hiding something, I should diligence harder”), internal career pressure (“I really don’t want to be the person that recommends buying a bad project”) or a host of other social factors (e.g., remnants of NIH syndrome--not invented here).

Overall, **this competitive pressure around externally sourcing creates a level of stringency and discipline in the diligence process that leads to, in general, the onboarding of higher-quality assets**. These data suggest the delta is considerable, and hasn’t greatly diminished in two decades.

These data are part of what underpins the differential in FDA approvals: two-thirds of the last five years of new drugs originated from smaller companies, but two-thirds are launched by the larger companies. **External sourcing has clearly been a big part of R&D success--and will likely be increasingly important going forward.**

Lastly, are there things that can be done to improve internal R&D to shrink the gap in clinical success rates? BCG’s recent report on R&D performance highlighted operational effectiveness as a key distinguisher of the best organizations. I’d like to call attention to the last of the “imperatives” they highlight as part of truly effective R&D: “Promote truth-seeking behavior rather than progression-seeking behavior.” This is a critical point: it’s a culture change for many organizations, but super-impactful. As they suggest, productivity might improve if a better advancement process was “implemented for evaluating internal assets, similar to the evaluation that is typically made on possible external assets.” There’s certainly a good deal of merit behind this recommendation.

These data, and the sociology they reflect, are further evidence for why the open-source models of pharma R&D are not only important today but likely to be even more important in the future.

**Capital investment drives innovation.**

**Platzer no date, President @Content First** (Michaela, President @ Content First, “Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation,” Content First, http://www.contentfirst.com/NVCAPatientCapital.pdf)

Patient Capital: How **Venture Capital Investment Drives Revolutionary Medical Innovation** demonstrates that many of the nation’s most innovative medical breakthroughs have been brought to market by billions of dollars of venture capital investment in life sciences companies. The economic impact and medical contributions of these life sciences companies have been enormous.1 The revolutionary medical breakthroughs produced by venture capital backed companies such as Amgen, Genentech, Genzyme, Gilead Sciences, Kyphon, Intuitive Surgical, and Scimed Life Systems, along with hundreds of smaller innovative life sciences companies, amount to highly tangible and valuable improvements to the U.S. economy and to people’s lives. **Today, small venture backed companies often serve as the research and development (R&D) pipeline for the larger life sciences corporations who seek to acquire the most promising innovations**. Whether these emerging companies someday grow to the size of a For tune 500 corporation or are acquired for their groundbreaking products, they all rely on the venture capital industry to get their start.

Venture capital investors seek and invest in the most promising therapies and technologies to combat costly and too often fatal chronic conditions such as heart disease, cancer, stroke, and diabetes. Venture investment allows small startup life sciences companies to develop these technologies and commercialize them so that millions of Americans can have access to the most advanced treatments available. The monetary support and expert business counsel provided by venture capitalists speed the time it takes to move novel medical therapies and technologies from the lab to the patient. Due to the high risk, the uncertainty of outcomes, and the long-term nature of life sciences commercialization, venture investment is often the only funding option for these small companies.

### AT: OWS Bad

#### No actual refutations. Not increasing or “solving” innovation, simply saying we didn’t fix it.