# 1NC

#### I negate the resolution resolved that: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### C1: Distribution

**The United States federal government could instead substantially increase production and global distribution of the COVID-19 Vaccine, specifically providing all necessary vaccines to India and South Africa, and also cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.**

**That comparatively solves better than what the aff advocates for– IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint and the real issue with vaccines to other countries.**

Hans **Sauer 6-17** [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

### C2: Disease Innovation

#### Studies currently show that IPR has been effective in pharmaceutical innovations that help with diseases. The only incentive for companies to researches new drugs is reduced competition which the affirmative destroys. The huge risk that goes into developing a drug would otherwise not make its innovation worthwhile.

Will Rinehart, Director of Technology and Innovation Policy at the American Action Forum 14, Director of Technology and Innovation Policy at the American Action Forum, 7-29-2014, "Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer," https://www.americanactionforum.org/research/intellectual-property-underpinnings-of-pharmaceutical-innovation-a-primer/

Being that it is an exclusive right to a piece of knowledge, patents are often considered to be a kind of monopoly. Criticism has been heaped upon patents in exactly the way one would expect given this definition. The creation of intellectual property rights creates an allowable exclusivity. Yet, it should be immediately apparent that patents do not automatically confer a monopoly over an industry. For example, a pharmaceutical company that invents a new and improved cancer medicine is still in competition with alternatives from other companies, which ultimately acts as a constraint on their ability to charge prices above a competitive level. Commercial success is tied to more than just an innovative idea; superior marketing, management, positioning, and other factors are likely to be more important than the patent itself. Moreover, individuals and companies will seek multiple solutions to the same problem, whether that might be in new commercial arrangements or products. By limiting a particular avenue for competitors, patents have the potential effect of promoting further innovation by encouraging others to develop new products. PATENTS IN PHARMACEUTICALS The medical field presents a strong case for patents, and because of its unique features, allows for a better understanding of the current tensions in other areas of patent policy. The medical field has a lone inventor myth, which is exemplified in the belief of the cure for cancer. The truth is that there is unlikely to be any sole cure, but rather through research and applied innovation, effective methods and treatments for dealing with these diseases will be found. Of course, this means that the entire endeavor will be expensive. As with any piece of property, the bounds of intellectual property must be set, which is where we first encounter the variance that can exist between industries under patent protection. Compared to software patents where there is far less clarity in breadth of patents, medical patents tend to be more discreet in their delineation. It is relatively clear what constitutes a new drug and what does not. Pharmaceutical companies also differ from other industries in their cost structure, including the time and resources needed to bring an innovation to market. Both the research phase and the regulatory approval process are costly and time intensive. Biopharmaceutical discovery has benefited from a remarkable shift in research and technology. Even in the last 10 years, the methods to innovation have been revolutionized, spurred on by better understandings of genetic relationships. Take for example, Gleevec, a treatment for chronic myeloid leukemia. Before the drug was introduced, less than a third of those diagnosed with chronic myeloid leukemia were alive five years later, but after it became available that figure jumped to 90 percent. The method of research responsible for its development was extremely innovative and as such the total development was costly. Gleevec and the drugs that followed it are part of a new breed of drugs that are far more complex than their predecessors. Even with biopharmaceutical innovations, estimates place the average cost of bringing a successful new drug to market at around $1.2 billion. After compounds are screened for use to treat a condition, only about 1 out of the 6 that make it to clinical trials will eventually obtain FDA approval. The table below shows that total industry research and development (R&D) has increased in recent years. The marginal cost of another pill is often miniscule compared to the initial investment cost. Prices for generic drugs are substantially lower than the original brand because these new firms don’t have to amortize the initial R&D costs over a drugs patent life. Additionally, pharmaceutical firms face high risks in their ventures as well as high costs of entry compared to other industries. Clinical trials provide an example of the costs to develop a market ready drug. As the Tufts Group has shown, the average length of a clinical trial increased by 70 percent from 1999 to 2005. In that same time period, the average number of routine procedures per trial increased by 65 percent. To add to that, the average clinical trial staff work burden increased by 67 percent. To top it all off, enrollment criteria and trial protocols resulted in 21 percent fewer volunteers being admitted into trials and 30 percent more enrollees dropping out before completion of the tests. Overall, the regulatory process of drug approval levies a heavy risk for manufacturers and innovators. For every one drug that passes through the regulatory approval process, manufacturers usually assess 5,000-10,000 substances. This is a time consuming and expensive process where innovators hope to see a return on their investment over the long-term. The FDA aims to strike a balance between access to life-saving treatments and assuring the public with standards of safety in all pharmaceuticals. The final step in pending drug approval usually involves hundreds to thousands of participants in a blind study of the drug. This part of the process now represents about 40 percent of pharmaceutical companies’ R&D expenditures. However, this often-cited statistic actually understates the amount spent. R&D expenditures include all pharmaceutical candidates that a company tests—including hundreds that never reach this trial stage. An analysis conducted by the Manhattan Institute found that for the drugs that are actually approved, these clinical trials typically represent 90 percent or more of the cost of developing an individual drug all the way from laboratory to pharmacy. CONCLUSION Medical treatments are among the best cases where intellectual property law has gotten things right. Patents are an important way to ensure that the benefits of research are captured by the creator. Solving the 21st Century’s problems will require complex solutions that will only come about because of intense research and development. Patents ensure that this research takes place. Even though some have criticized aspects of the patent regime, the system itself still serves as a testament to and an enabler of American innovation.

#### **Innovating new drugs that deal with disease is crucial to humanity’s well being – history shows that pandemics, from smallpox to influenza to COVID, we should always be finding new drugs**

Dennis Pamlin & Stuart Armstrong, Executive Project Managers of Global Risks 15, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even worldwide. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the greatest causes of mortality in history. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a power law with a small exponent: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the single largest pandemic. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 There are other grounds for suspecting that such a highimpact epidemic will have a greater probability than usually assumed. All the features of an extremely devastating disease already exist in nature: essentially incurable (Ebola268), nearly always fatal (rabies269), extremely infectious (common cold270), and long incubation periods (HIV271). If a pathogen were to emerge that somehow combined these features (and influenza has demonstrated antigenic shift, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that modern transport and dense human population allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the ripple effect of the fatalities and the policy responses. These would include political and agricultural disruption as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the epidemic fragments and diminishes human society to the extent that recovery becomes impossible277 before humanity succumbs to other risks (such as climate change or further pandemics). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.