## 1NC

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

#### First, I would like to offer a couple of definitions:

The World Trade Organization describes its purpose as

WTO, , "Overview: WTO," World Trade Organization, https://www.wto.org/english/thewto\_e/whatis\_e/wto\_dg\_stat\_e.htm

The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development. The WTO also provides a legal and institutional framework for the implementation and monitoring of these agreements, as well as for settling disputes arising from their interpretation and application. The current body of trade agreements comprising the WTO consists of 16 different multilateral agreements (to which all WTO members are parties) and two different plurilateral agreements (to which only some WTO members are parties).

Trevor Brewer, a business lawyer specializing in regulations and transactions, writes in May 2019 that

Trevor Brewer, 5-16-2019, "What Are The 4 Types of Intellectual Property Rights?," BrewerLong, https://brewerlong.com/information/business-law/four-types-of-intellectual-property/SJKS

There are four types of intellectual property rights and protections (although multiple types of intellectual property itself). Securing the correct protection for your property is important, which is why consulting with a lawyer is a must. The four categories of intellectual property protections include: TRADE SECRETS Trade secrets refer to specific, private information that is important to a business because it gives the business a competitive advantage in its marketplace. If a trade secret is acquired by another company, it could harm the original holder. Examples of trade secrets include recipes for certain foods and beverages (like Mrs. Fields’ cookies or Sprite), new inventions, software, processes, and even different marketing strategies. When a person or business holds a trade secret protection, others cannot copy or steal the idea. In order to establish information as a “trade secret,” and to incur the legal protections associated with trade secrets, businesses must actively behave in a manner that demonstrates their desire to protect the information. [Trade secrets are protected *without* official registration](https://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm); however, an owner of a trade secret whose rights are breached–i.e. someone steals their trade secret–may ask a court to ask against that individual and prevent them from using the trade secret. PATENTS As defined by the [U.S. Patent and Trademark Office](https://www.uspto.gov/help/patent-help#patents) (USPTO), a patent is a type of limited-duration protection that can be used to protect inventions (or discoveries) that are new, non-obvious, and useful, such as a new process, machine, article of manufacture, or composition of matter. When a property owner holds a patent, others are prevented, under law, from offering for sale, making, or using the product. COPYRIGHTS Copyrights and patents are not the same things, although they are often confused. A copyright is a type of intellectual property protection that protects original works of authorship, which might include literary works, music, art, and more. Today, copyrights also protect computer software and architecture. Copyright protections are automatic; once you create something, it is yours. However, if your rights under copyright protections are infringed and you wish to file a lawsuit, then registration of your copyright will be necessary. TRADEMARKS Finally, the fourth type of intellectual property protection is a trademark protection. Remember, patents are used to protect inventions and discoveries and copyrights are used to protect expressions of ideas and creations, like art and writing. Trademarks, then, refer to phrases, words, or symbols that distinguish the source of a product or services of one party from another. For example, the Nike symbol–which nearly all could easily recognize and identify–is a type of trademark. While patents and copyrights can expire, trademark rights come from the use of the trademark, and therefore can be held indefinitely. Like a copyright, registration of a trademark is not required, but registering can offer additional advantages.

### Framework

#### I concede on the framework.

**1**

### Contention 1 is Innovation

#### Intellectual Property is the backbone of innovation, but the affirmatives removal of IP destroys it.

Pier DeRoo, from the University of Michigan Law School, writes in 2011

Pier DeRoo (J.D. Candidate 2011, University of Michigan Law School; A.B. 2006, Chemistry, Princeton University). “Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Go Pharmaceutical Drugs in Government Health Car ernment Health Care Programs.” Michigan Journal of International Law, vol. 32, issue 2. 2011. JDN. https://repository.law.umich.edu/mjil/vol32/iss2/3/

B. The Pharmaceutical Development Outlook

Government health care programs, however, when combined with compulsory licensing and important pharmaceutical markets, represent a corresponding threat to the current R&D infrastructure of drug development, which is funded both by purchasers of pharmaceutical products and by taxpayers via public research entities. With **only one of every 5,000**-10,000 **tested compounds** reaching the market and taking an average of **11**.8 **years to get there**, drug R&D investment requires a high risk premium. Although the exact amount is disputed, current estimates to develop an innovative, new molecular entity drug range from $802-$868 million, and costs continue to rise. o0 Pharmaceutical development is also far from a purely private enterprise, with the NIH annually spending over $31 billion in taxpayer dollars in basic medical research, which supports downstream drug development by the pharmaceutical industry.'o4 R&D therefore usually targets drugs that have an expected return high enough to generate substantial profit and fund subsequent R&D. Because R&D investment decisions are guided by the expected economic return for a particular line of research, **palatability of risk is proportional to the magnitude of the expected returns.**'" Assuming that research into risky, unexplored areas of health is desirable, low expected returns, whether due to a small market for a particular drug or weakened patent exclusivity rights as a result of **compulsory licensing**, may chill such R&D. After a pharmaceutical drug runs the gamut of patenting, clinical trials, and regulatory approval procedures, the patent specification and a wealth of safety and efficacy data are available to the public, resulting in **serious appropriability concerns.**' In the absence of strong patent protection and regulatory data exclusivity, generic producers are able to rapidly reverse-engineer drugs, obtain regulatory approval by relying on the patent holder's safety and efficacy data, and sell the generic version on a competitive market against the innovative firm that incurred the stratospheric R&D and original regulatory approval costs.0o Without such protection, the innovative pharmaceutical developer could expect little return on investment, and private R&D would dissipate. Indeed, pharmaceutical appropriability in India resulted in a commodified Indian pharmaceutical market devoid of R&D. In the Indian Patents Act of 1970, India abolished pharmaceutical compound patentability in favor of short seven-year pharmaceutical production-process patents, creating incentives to devise increasingly efficient production processes while permitting any manufacturer to produce the pharmaceutical compound itself.'" Drug **firms flooded the market** as the number of licensed manufacturers grew from 2,237 enterprises in 1969-70 to an estimated 16,000 by 1992-93, illustrating that barriers to entry into the pharmaceutical market were not onerous. Profitability predictably plunged over that period, reducing R&D expenditures from 15.5% of sales prior to the 1970 Patents Act to a **mere 1.4%** in 1992-93 because of comparative declines in expected returns on R&D investment due to the absence of exclusivity for drug compounds.'" 1.4% does not fund much R&D: India has become the world's leading generic pharmaceutical producer, but contributes little to the development of new pharmaceutical medicines."2 The most powerful developing countries followed India in prohibiting patent protection for pharmaceuticals. Between 1971 and 1996, Brazil prohibited patents for both pharmaceutical products and processes."' Mexico and Argentina had similarly lowered pharmaceutical patent protection prior to TRIPS." 4 As a result, today only a handful of developed countries have a sufficiently sophisticated pharmaceutical industry and research base to conduct complex R&D. Compulsory licensing, if widely used as an escape-hatch from patent protection, presents a potential threat to continued research by relegating innovative producers to a level playing field with generic producers.' Once a compulsory license is granted, licensees simply have to send a royalty check to the patent holder.7 These royalty payments are uniformly puny. For example, Indonesia offered a mere **0.5%** royalty on the generic sale price for its HIV/AIDS compulsory licenses,"' Zambia offered 2.5%,"' and Mozambique offered 2%.120 Meanwhile, Thailand has offered 0.5% to 2.0%.121 The pharmaceutical market has already encountered the likely bleak effects of widespread compulsory licensing and its low royalty rates. The post-1970 Indian pharmaceutical industry demonstrated that extremely low margins do not incentivize R&D.122 In a similar vein, the Egyptian pharmaceutical industry is currently discovering that its cost-plus pricesetting system, using the costs of ingredients as the benchmark, establishes a profit ceiling that acts as a de facto limit on R&D expenditures.123 Limiting economic returns on pharmaceutical R&D through abusive compulsory licensing, especially if in one or more of the few countries with innovative pharmaceutical industries,'2 **therefore poses a threat to continued R&D** into unexplored areas of medicine.

#### Pharmaceutical innovation is key to stop bioterrorism and antimicrobial resistance

Carolina Feijao, a Ph.D in biochemistry from the University of Cambridge, writes in 2020

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism con-text.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation.

Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives.

This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic.

In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6

The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10

Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror and biotechnology are the largest medical threat—only generating innovative drugs can prevent millions from death

Bakerlee 21 Chris Bakerlee is a Ph.D. candidate studying evolutionary genetics at Harvard University and a fellow in the Council on Strategic Risks’s Fellowship for Ending Bioweapons Programs. "Mother Nature is not 'the ultimate bioterrorist' - STAT." STAT, 8 Jan. 2021, www.statnews.com/2021/01/08/mother-nature-is-not-the-ultimate-bioterrorist. [Quality Control]

Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a mistake to underestimate the threats from natural pathogens. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology to cause harm on a staggering scale, by either cruelty or carelessness.

Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts.

The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with no attention to maintaining or improving traits that enhance fitness in other environments.

If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of an especially persistent horde of 5-year-olds, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time.

By contrast, modern biologists are gaining the ability to see the whole field, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens poses serious concerns.

It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist.

It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about 23 are known or suspected to have maintained biological weapons programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ vulnerability to biological threats, has done little to mitigate this danger.

Accidental releases pose an additional source of anthropogenic biorisk. Thanks to the U.S. government’s monitoring program, we know that dozens of agents and toxins with the potential to pose a severe threat to public health and agriculture are reported accidentally lost or released from U.S. labs every year. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength.

Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing.

Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.

**2**

### Contention 2 is Quality

#### The aff addresses the problem incorrectly- lack of materials is the reason for our resource shortage- the aff exacerbates this issue by causing a scramble for resources from inexperienced companies which decreases vaccine quality.

Kevin Breuninger, a specialist at CNBC, writes in May 2021

[Kevin; Specialist at CNBC; “Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues,” CNBC; 5/7/21; <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html>] Justin

“Currently, infrastructure is not the bottleneck for us manufacturing faster,” Bourla wrote in a dear colleague letter posted on LinkedIn. “The restriction is the scarcity of highly specialized raw materials needed to produce our vaccine.”

Pfizer’s vaccine requires 280 different materials and components that are sourced from 19 countries around the world, Bourla said. He contended that without patent protections, entities with much less experienced than Pfizer at manufacturing vaccines will start competing for the same ingredients.

“Right now, virtually every single gram of raw material produced is shipped immediately into our manufacturing facilities and is converted immediately and reliably to vaccines that are shipped immediately around the world,” Bourla wrote.

He predicted that the proposed waiver “threatens to disrupt the flow of raw materials.”

“It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine,” Bourla wrote.

“Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk,” the CEO wrote.

#### The aff discourages critical investment and creates low-quality vaccines that hurt our pandemic response.

The Center for Intellectual Property and Innovation Policy writes in June 2021

[Center for Intellectual Property x Innovation Policy; “A View from Both Sides: COVID-19, the TRIPS Waiver, IP Rights, and How to Increase the Supply of Vaccines,” Antonin Scalia Law School / George Mason University; 6/22/21; <https://cip2.gmu.edu/2021/06/22/a-view-from-both-sides-covid-19-the-trips-waiver-ip-rights-and-how-to-increase-the-supply-of-vaccines/>] Justin

Low-quality vaccines could do more harm than good

Former USPTO Director Andrei Iancu voiced concern recently at a World IP Day event, asking, “if we waive IP rights, and exclude the original manufacturers, how are we going to control the quality of the vaccines that go into people’s arms? How are we going to control for the fake vaccines? Just last week we saw fake Pfizer vaccines.” And as Philip Thompson points out for IPWatchdog, when investigators are forced to “determine if adverse events or sub-par effectiveness originate from ‘real’ vaccines or fake doses, we should expect global production starts and stops to become much more frequent.”

It will discourage investment in the most critical areas

Pharmaceutical developers invest unfathomable amounts of money into bringing drugs to market. The path to success is long, expensive, and highly uncertain. But what is certain is that successful drugs can yield a profit that covers the loss from failures. Now critics are deeply worried that this waiver will skew future cost-benefit analyses against important classes of medicine. All other things being equal, a developer has a better chance at a positive return by investing in drugs that pose no risk of seizure during a global emergency. As Amanda Glassman of the Center for Global Development writes, the waiver sends the wrong message to innovators and investors: “don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita.” The scramble amongst pharmaceutical giants to develop a vaccine was an all-out race, with good reason, and that’s exactly how it should be. If those companies believe that forfeiture is waiting at the finish line next time around, we might see fewer contestants.