## CP

#### The member states of the WTO should increase patent protections for biodefense medicines using Petruzzi’s recommendations as a framework – key to stop bioterror.

Petruzzi, JD Candidate, 5

(Heather, 3L at George Washington University Law School, THE MISSING LINK: THE NEED FOR PATENT PROTECTION IN THE DEVELOPMENT OF BIODEFENSE VACCINES, Public Contract Law Journal, 37(1), Fall)

Due to the risk of a bioterrorist attack in the post-September 11 world, the Government must attract pharmaceutical companies to perform research and development for biodefense vaccines. In order to do so, the Government must amend the FAR clauses to reflect the need for increased patent protection and flexibility when negotiating agreements. Additionally, HHS must train its procurement contractors to draft contracts using the new provisions and to simplify the procurement process for the commercial sector. A. Changes to the FAR First, the FAR clauses must change to reflect current industry demands. Even after the FAR finally incorporates the Project BioShield Act, it still lacks the necessary patent protection to induce large pharmaceutical companies to contract with the Government. Instead, the FAR should follow a Department of Defense (DoD) model and adopt other transaction (OT) authority.145 The original purpose of OTs was to provide agencies that routinely enter research and development contracts a means by which to negotiate the terms of a gov ernment contract and acquire cutting-edge technology.146 Because OTs are not procurement contracts, they are not subject to the Bayh-Dole Act or the FAR.147 As a result, the government agency can contract with a commercial entity and use commercial contract language. There are currently two types of OTs. Research OTs are used in agree ments for basic, applied, and advanced research.148 Traditionally, the private company may not make a profit on the resulting research.149 Prototype OTs are used when a nontraditional contractor is working on a prototype that is directly applicable to a weapon DoD will soon acquire.150 In contrast to re search OTs, the company may make a profit on Prototype OTs.151 Under the OT model, the Government gains access to timely, affordable, and cutting-edge technology.152 DoD contractors are able to successfully ex ercise discretion and negotiate OT terms that satisfy both the contractor and the Government, even in challenging agreements where the product may have applicability in both the Government and the commercial sector.153 As a survey by the Defense Advanced Research Project Agency (DARPA)154 dis covered, pharmaceutical companies and biotech firms would not enter into a procurement contract with the Government in order to perform biological defense research, but they would enter OT agreements.155 Additionally, audits during the first thirteen years of DoD use of OTs do not show any evidence of fraud, waste, or abuse.156 Therefore, the Government should not hesitate to grant contractors a "free pen." In 2004, Congress extended DoD's OT authority, allowing DoD to con sult directly with HHS to permit research OTs157 and prototype OTs158 for biomedical countermeasures.159 However, this limited OT access is not in the FAR so it cannot be used in procurement contracts, and it is not broad enough. Instead, the FAR must include a separate provision that directly grants HHS the ability to use research OT agreements for the development of biodefense countermeasures.160 HHS should not be restricted by requirements that it timely consult with DoD or to find that procurement contracts, grants, or cooperative agreements are inadequate alternatives. Instead HHS should have independent authority to assess the Government's needs for vaccines and to enter OT agreements with pharmaceutical companies that meet those needs. Because OTs would allow the companies to enter contracts using similar terms to commercial contracts, they could include adequate pat ent protection. The flexibility of OT agreements also alleviates several other setbacks. It would circumvent the inconsistency between the statutory law and the FAR clauses, allowing government contracts to immediately reflect new procure ment challenges such as biodefense research and development. Instead, gov ernment contractors who are familiar with the law and the FAR would be able to negotiate with the pharmaceutical companies while also upholding the Government's policy goals in the biodefense area. Additionally, the FAR should be amended to redefine "subject invention," allow subcontractors and prime contractors to negotiate their respective pat ent rights, and simplify and standardize the administrative disclosure steps. Although these provisions would not be binding on an OT agreement, they are still bureaucratic and confusing provisions that do not reflect current needs. The term "subject invention" should be redefined to include any in vention that is conceived and first actually reduced to practice under the government agreement. This alleviates companies' concerns that they will lose rights to inventions conceived before entering into an agreement with the Government. The FAR also should allow the contracting parties to negoti ate this provision if the contract is for an improvement to an invention that the company already has conceived. Also, the FAR should not govern subcontractor patent rights. Instead, prime contractors should have patent rights over all subject inventions unless subcontractor agreements state otherwise. This would eliminate the need for the three prime contractor exceptions, thus simplifying the procurement pro cess. Additionally, the FAR should follow the proposal in Project BioShield II and eliminate march-in rights because they are rarely used and are often misunderstood by pharmaceutical companies. Finally, the FAR should update its disclosure steps to follow the timeline given by the PTO for a patent. When the company files a patent application with the PTO, it also should be re quired to file a notice with its respective contracting agency to alert the agency that the company is seeking patent protection. Under this model, the agency's that the company is seeking patent protection. Under this model, the agency's needs are met because it has notification that the company is seeking patent protection for the subject invention and the company's needs are met because it can follow the standard procedure for acquiring a patent and only file one additional notice. These proposed changes to the FAR make contracting with the Government a more user-friendly enterprise for the private sector. B. Changes Within HHS Second, HHS must undergo changes and train its government personnel to respond to the new OT authority and FAR provisions. Government personnel must become familiar with OTs. HHS should follow DoD and offer similar, effective training. The Government also should train personnel on incorporating the new, flexible provisions in the FAR while maintaining the policy goals reflected in the statutes.161 Finally, HHS should publish a manual that summarizes and consolidates the provisions that are applicable to research and develop/pment government contracts. It should list statutory language that has not been incorporated into the FAR and list the regulatory provisions that apply. The manual would serve a vital role in simplifying and clarifying the procurement procedure for pharmaceutical companies that are not accustomed to contracting for complex research and development with the Government. These proposed changes to the FAR and suggestions for additional HHS training represent important steps toward the improvement of the nation's defense against a bioterrorist attack. The Government recognized the importance of new procurement procedures in the biodefense arena by passing Project BioShield II and allocating money for the SNS. However, major pharmaceutical players will not contract with the Government until their patent interests are protected. By recognizing that pharmaceutical companies have unique interests and specifically addressing them, the Government can enhance its response to the risk of future bioterrorism.

#### Increasing patent protection is key specifically to fight bioterror – aff evidence is politicized and exacerbates the growing lack of innovation and preparedness in the U.S.

Goldberg, PhD, 5

(Robert, Politics @ Brandeis, “Terrorising Patents”, Expert Opinion on Therapeutic Patents, 3)

Government funded efforts to produce state of the art anthrax and smallpox vaccine before September 11, ignored the basic need for real patent protection and returns on investment. The results have been demoralising and disastrous. We have the science and technology in hand and did so years ago, but we failed to develop and deploy such defences for the same reason that there are flu vaccine shortages in the US and no new generation vaccines for many infectious diseases that kill millions of people in the developing world: there isn't a lot of money to be made in making vaccines. To make vaccine research and biotech research more attractive we could use stronger patent protection. Instead, those who want to add patent seizures to the policy mix, insuring it will be less profitable in the years to come lobby policymakers in Washington. 30 Years ago there were 20 companies making vaccines, today there are only four; Merck, Wyeth-Lederle, Glaxo-SmithKline and Aventis Pasteur. Each year, these companies seriously consider concluding their vaccine operation because they don't make money. There used to be four companies making one of the basic childhood vaccines, the diphtheria, pertussis and tetanus combination. Now there are two. A commission established by Congress has also recom-mended that the government become involved in the business of developing all new vaccines through a National Vaccine Authority (NVA). The NVA would make vaccines and other products needed to fight bioterrorism and childhood illnesses where, according to experts from the National Academy of Sci-ences, the private sector doesn't see much profit in such mar-kets. No patent rights are involved because the government would, in theory, invent all the new medicines and vaccines. Do we need any more evidence of what seizing patents or limiting patent rights under the guise of bioterror drive public health threat will do to biomedical innovation? It is apparent that activists believe that winning an ideological war against drug companies more important than winning the war against bioterrorism and global disease. If we stay the present course, they'll get their

## Innovation

**Biotech strong now -- boosted by COVID and it's an inherently stable sector**

**Cancherini et al. 4-30** [Laura Cancherini, Engagement Manager @ McKinsey & Company. Joseph Lydon, Associate Partner @ McKinsey & Company. Jorge Santos da Silva, Senior Partner @ McKinsey & Company. Alexandra Zemp, Partner @ McKinsey & Company. "What’s ahead for biotech: Another wave or low tide?," McKinsey &amp; Company, 4-30-2021, accessed 8-25-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] HWIC

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6 Exhibit 3 We strive to provide individuals with disabilities equal access to our website. If you would like information about this content we will be happy to work with you. Please email us at: McKinsey\_Website\_Accessibility@mckinsey.com What about SPACs? The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story. Fundamentals continue strong When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances. In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development. Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries. Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising. For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic. More innovation on the horizon The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science. Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### Patent protection is especially important to the pharmaceutical industry and biodefense.

Petruzzi, JD Candidate, 5

(Heather, 3L at George Washington University Law School, THE MISSING LINK: THE NEED FOR PATENT PROTECTION IN THE DEVELOPMENT OF BIODEFENSE VACCINES, Public Contract Law Journal, 37(1), Fall)

Although most private companies consider patent rights their most valuable asset,28 they play a special role in the pharmaceutical industry for two reasons. First, drug research is time consuming, expensive, and risky.29 For example, it takes more than a decade and an average of over $200 million to develop a drug in the United States.30 Second, the pharmaceutical industry has unique concerns given the nature of medical research. Oftentimes new drug discoveries build from existing technology and not completely original ideas.31 As a result, old and new drugs intersect and overlap during many phases of discovery.32 Private pharmaceutical companies fear that if the Government owns the rights to a biodefense drug, this may hinder future development based on similar technology or reduce the value of existing patents that served as a guide to the new vaccine.33 Thus, patent rights have greater importance in the pharmaceutical industry because they can affect the value of the company's prior blockbuster drug or inhibit its future research and development in areas unrelated to the Government and bioterrorism.

**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. 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. 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.”

**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

### No Solvency

#### The aff’s scenario is nonsense and they don’t solve because of bioweapon development – all of their impact evidence says that bioterrorism is about engineering NEW pathogens which means that current vaccines and medicine are irrelevant in minimizing damage from an attack. Either terrorists use an existing virus and the attack is easily treatable and not an existential threat or the entire world is screwed and the aff can’t solve. Vote neg on presumption to encourage better research.

### Vaccines

#### COVID and vaccines flow negative – it took almost a full year to develop a COVID vaccine which isn’t feasible against ultra-deadly bioweapon and patent protection was what encouraged the expensive vaccine race and rapid production by so many medical companies.

### Squo Solves

#### Frame aff solvency through an incremental lens. They only get offense for the amount they make more effective current bioterror prevention and treatment mechanisms and they certainty don’t “solve” bioterror.

#### The squo solves – compulsory licensing already exists globally and there’s an emergency exception to ensure speed.

Mullowney and Harris, JDs, 13

(Jared, Texas Tech, Neil, Texas Tech, Patent Protectability or Public Health?—An Examination of the Patent Compulsory License and Bioterrorism, Journal of Biosecurity, Biosafety, and Biodefense Law, 4(1))

One potential benefit in the event of a bioterrorism attack and the major focus of this Article is the compulsory license scheme found in the American patent system.61 A compulsory license is a license granted to a non-patent holder to make, use, sell, offer to sell, or import a patented product.62 What makes the compulsory license interesting is that, unlike the copyright compulsory licenses,63 the patent compulsory license is a license granted by the United States Government.64 What also makes the compulsory license scheme interesting is that the patent holder is not able to bring suit against the compulsory licensee for patent infringement.65 Instead of flat payment from the licensee to the patent holder and instead of total reimbursement of profits made off of the license, the patent holder’s remedy is against the United States Government “for the recovery of his reasonable and entire compensation for such use and manufacture.”66 The compulsory license is not unique to the American patent system. In fact, the TRIPS Agreement also lays out a groundwork for a compulsory license system.67 Article 31 of the TRIPS Agreement lays forth guidelines for determining when another entity may use or make a product protected by a patent without the patent holder’s permission.68 The major provisions set forth in TRIPS focus on the necessity and the effort of the government to obtain a voluntary license first. Specifically, TRIPS provides that compulsory license authorization shall be considered on a case-by-case basis,69 shall be permitted only after efforts are made to obtain a voluntary license,70 the duration and scope of the compulsory license shall be limited,71 the licensee shall not be able to assign the license to another entity,72 manufacturing of a patent product under a compulsory license shall be for domestic use,73 the license shall terminate if and when the circumstances giving rise to the license cease to exist,74 and the patent holder shall be reimbursed adequately, as determined on a case-by-case basis.75 One major exception to section (b) requiring voluntary license negotiation is in the event of a national emergency or “other circumstances of extreme urgency.”76

#### Seriously, countries can already unilaterally override patent privileges to protect public health.

Okediji, JD Harvard, 14

(Ruth, Professor @ Harvard Law School, “The Role of WIPO in Access to Medicines” in Balancing Wealth and Health, Chapter 13, 312-313)

The right of countries to adopt measures to protect public health is one of the grounds explicitly mentioned as part of the principles of the TRIPS Agreement,20 and the Doha Declaration subsequently established elements of this right, including the residual power of countries to unilaterally determine the conditions in which public health needs can override patent privileges.21 Access to medicines is an integral part of the human right to health in many countries (Lee and Hunt 2012). WIPO, however, has been far less embracing of human rights approaches to IP as a basis for access to medicines despite robust scholarly examination and affirmation of a positive effect of the IP-human rights link on access to medicines (Land, this volume; Land and Pakenham-Walsh 2012; Helfer and Austin 2011). To the extent patent grants circumscribe the terms of access, human rights norms provide countervailing arguments of equal or, arguably, greater moral force. These normative strategies of resistance to maximalist patent rights have had a measurable impact on access to medicines campaigns across Brazil, Latin America, South Africa, and East Africa. At a minimum, human rights arguments, because they so easily galvanize global public concern, can exert significant bottom-up pressure that eventually affects the scope and direction of the exercise of IP rights.22 Even when formally marginalized within politically agile organizations such as WIPO or the WTO, human rights arguments constitute a centripetal force compelling normative reconsideration of global patent norms. This overlapping regime complex, which frames the access to medicine challenge, requires shared competence across international organizations in addressing public health and access to medicines.

### Alt Cause

#### Weak public health infrastructure is an alt-cause and dooms solvency.

NTI 15

(Nuclear Threat Initiative, 12-30, https://www.nti.org/learn/biological/)

The 2014 Ebola outbreak in West Africa showed how vulnerable we are to infectious disease, how quickly it spreads, and how weak public health systems are in some of the poorest countries in the world. The world saw firsthand how access to trained medical professionals, sterile equipment and basic medical facilities are a rare commodity in the developing world, enabling diseases to expand beyond what modern medical advances might suggest. Global travel makes the biological threat even more serious and highlights the need for a global approach to improve public health. Spurred by the Ebola crisis, many countries took steps to improve global health security in order to monitor and respond to disease threats, but there is much more work to do.

### AT: Cipro

#### Cipro is a bad example – their evidence is politicized lobbying material from the generic drug industry.

Goldberg, PhD, 5

(Robert, Politics @ Brandeis, “Terrorising Patents”, Expert Opinion on Therapeutic Patents, 3)

The notion that patents denied Americans access to CiproTm (ciprofloxacin hydrochloride) came from the activists seeking to weaken patent protection in developing countries at the recent trade-related aspects of intellectual property rights negotiations. In the recent round of trade talks in Doha, Qatar, designed to encourage free trade around the world, AIDS activists, African countries, (who have the highest levels of HIV infected people, 33 million), and antiglobalisation groups pushed to revise international patent-protection rules to allow any country to seize any patent, or import any generic drug, so long as it claimed it had a public health crisis. That could not then be challenged in any forum. They succeeded in getting the US and Europe, which wanted a deal to protect Western-nation farm subsidies that block developing world competition and needed African and Indian complicity to get it, to concede to just that, all in the name of helping to solve the HIV crisis. But in fact, in all of Africa, there were an average of only three drugs patented out of a total of 15 used to treat the disease. If winning the war against patent protection won't help fight AIDS, then what can it achieve? James Love of the Consumer Project on Technology, which is help-ing to lead this war, wants to apply the declaration made in Qatar; that less devel-oped countries can make generic versions of drugs; to any medicine and for any disease. He is also requesting that the language of the trade agreement to become public policy in every country. The policy of governments seizing patents and importing for a public-health crisis goes beyond AIDS, malaria and tuberculosis. Any healthcare item could be included. We want to use this in the United States, in Germany and in Switzerland m.' Love and his colleagues succeeded at doing just that with CiproTM. They first found a politician willing to assert that the price of CiproTM was denying Americans access to an essential medicine during a public-health crisis and that only patent seizure could solve the problem. To be sure, price was never a barrier to public access and government stockpiling of CiproTM alone was never essential to public health. But the attack on the CiproTM patent, led by Sen. Charles Schumer, with help from Love and the generic drug industry, was never about public health, any more than the fight about HIV patents is about ensuring access to AIDS drugs. The ultimate goal of the activists is to use patent seizure of all drugs as a tool for encroaching the perceived economic and political power of pharmaceutical companies worldwide. It is for this reason that activists maintain that drug development should be cheap, easy and largely funded by the National Institutes of Health. This claim is highly suspect. The dearth of new vaccines produced by modern methods in genetic engineering is not a failure of the technology. On the contrary, vaccine technology has entered a golden age. By rights, the number of diseases targeted by vaccines should be in the dozens. During this time, the number of vaccine targets funded by government agencies throughout the world grew considerably. Generic companies never paid the nominal licensing fees to claim what critics of the patent system say are lucrative returns. In addition, limits on patents imposed by the NIH as a condition for using government-funded biotech research all but drove the private sector away completely.

### Medicines Not Key

**The aff is non-unique – tons of innovation now and medicines aren’t key.**

Taeyjuana **Curry**, 3-10-20**16**, [phd in physics@umich] "Nanoparticles – 5 Ways These “Little Fighters” Are Making a Big Impact in the War on Terrorism," Sustainable Nano, <http://sustainable-nano.com/2016/03/10/nanoparticles-war-on-terrorism/> RE

The term “terrorism” is becoming quite ubiquitous in our everyday lives. It seems that you can hardly watch a news report, browse the internet, listen to a podcast, or tune into your favorite radio station without being made aware of the most recent terrorist attack that has happened here or abroad. **The prevalence of these acts is quite disheartening. However, as a scientist in the field of nanotechnology, I can tell you that there is a bright side, or a silver lining to this particular societal cloud. In essence, “necessity is the mother of invention!” The unfortunate rise in the number of terrorist attacks around the world has resulted in many scientists in the field of nanotechnology devoting effort toward the use of nanoparticles in the fight against terrorism.**

The Merriam-Webster dictionary gives the simple definition of terrorism as “the use of violent acts to frighten the people in an area as a way of trying to achieve a political goal” and the full definition as “the systematic use of terror especially as a means of coercion.”1 You can find more detailed definitions used by the Department of State and the Federal Bureau of Investigation (FBI).2 For the sake of clarity, in this post I will refer to the simpler definition, with a specific emphasis on toxic chemicals used as form of warfare agents against innocent targets.

Nanotechnology, and nanoparticles specifically, are likely not the first thing that comes to mind when most people consider the fight against terrorism. However, nanoparticles have some particularly advantageous properties that can be exploited for this very use:

Nanoparticles are very, very, very small and can have many shapes. The ability to change the size and shape of nanoparticles makes them extremely versatile, which means they can be adapted to address many types of threats associated with terrorism (more details on this later).

Nanoparticles have a high surface to volume ratio, which means they are very efficient attaching themselves to targets such as toxic chemicals meant to harm innocent people, animals, or crops, etc.

Nanoparticles can also be made to be porous (filled with holes). Porous nanoparticles can be filled with sensing and neutralization agents that make them excellent at alerting authorities to a terrorist threat, even when the threat is only present at low levels.

Nanoparticles can be packaged in different forms like solids, gels, and aerosols. This makes them potentially useful in a range of contexts for law enforcement, military, and research scenarios.

Lastly, many nanoparticle-based technologies that are focused on aiding in the fight against terrorism have the added benefit of easy disposal. For example, some solid nanoparticle-based materials that are designed to neutralize a threat substance can then simply be thrown away without needing any extra steps to make the materials safe. Moreover, in many cases there have been efforts to make all of the byproducts “green” or nontoxic to the environment.

**Nanoparticle-based applications are particularly suited for two aspects of the fight against terrorism: rapid detection and neutralization of a terrorist threat. Rapid detection is the ability to accurately detect the presence of a terrorist threat, for example a chemical warfare agent, in a short time span. Neutralization is the ability to transform a toxic agent into a nontoxic form. Here are a few exciting and innovative examples from the last five years that illustrate how scientists all over the world are using the advantageous characteristics of nanoparticles to ensure that nanotechnology plays a key role in the fight against terrorism.**

**Rapid Detection of Threat**

**⇒ In 2013, Scientists from the Institute of Biophysics at the Chinese Academy of Sciences developed a system for the rapid detection of a nerve agent, Sarin. The system is based on iron oxide metal nanoparticles. It can sense the presence of the highly toxic nerve agent in a matter of minutes** and the results of the test are easily read out via a color change of the test solution.3 This application is particularly cool because it provides a quick read-out that is easily interpreted.

**Schematic**

Schematic of a magnetic nanoparticle-based tool for the detection of toxic chemicals including the nerve agent Sarin and some toxic pesticides. The amount of the toxic chemicals present is indicated by a color change that is easily seen by the naked eye (from clear to blue, far right). (image from Liang et al., 20123)

⇒ **MIT Scientists have developed protein coated carbon nanotubes for the detection of very small traces of explosives.** Carbon nanotubes are very small, cylindrical tubes made out of carbon that have ultrathin walls. In this project, **coating carbon nanotubes with various types of proteins from bee venom made them useful for detecting different types of explosives at the single molecule level** (much more sensitive than typical methods).4,5

⇒ **Scientists from Georgia Tech developed a wireless sensor prototype based on carbon nanotubes that can be used to detect the presence of improvised explosive devices or IEDs. This is extra cool because the carbon nanotubes are printed directly on paper using a common inkjet printing technology This sensor is very promising as it is low cost and can be used anywhere.**6

Neutralization of Threat

⇒ **FAST-ACT®, which stands for First Applied Sorbent Treatment-Against Chemical Threats**, is a product offered by Timilon Technology Acquisitions LLC. The company uses NanoActive® metal oxides “for the destruction of toxic and noxious materials, including air and water pollutants, hazardous chemicals, biological organisms, odors and chemical warfare agents.” Specifically, **FAST-ACT is non-flammable, non-corrosive, and can be used to significantly reduce both liquid and vapor hazards.**7 It comes in many different forms (liquid, vapor, or on mitts) and can be safely used in a variety of environments. **This product has been shown to be highly effective in neutralizing the chemical warfare nerve agents VX, Soman, and mustard gas. It is also very versatile as it can be safely used by the military, first responders, and scientists.**8

⇒ **Silica nanoparticles filled with special reactive chemicals have been successfully used in the removal of several chemical nerve and blister warfare agents including Sarin.** The nanoparticles were able to absorb the toxic chemicals and neutralize them by changing them into nontoxic chemicals in only a few minutes.9 **This application is an example of how scientists can take advantage of the porosity of certain kinds of nanoparticles to target them toward specific toxic chemical agents used in terrorist attacks.**

⇒ **Scientists from the Department of Nanoengineering at the University of California, San Diego developed self-propelled “micro-motors” for use in neutralizing an anthrax threat in natural water.** The so called “micro-motors” are made of magnesium microparticles, coated with a titanium oxide shell that has gold nanoparticles embedded in it. **As if self-propulsion and anthrax eradication aren’t impressive enough, the environmentally friendly micro-motors convert toxic agents into environmentally safe products, making them an especially “green” solution that can be applied to a chemical or biological warfare agent.**10

Nanotechnology is quickly becoming a part of our everyday lives. More specifically, nanoparticles are now included in many consumer products including electronics, cosmetics, and medicine. **The fight against terrorism, another familiar topic in many of our lives, has also been influenced by nanotechnology. Nanotechnology can make use of the best qualities of nanoparticles in a variety of ways, especially enabling rapid detection and neutralization of toxic chemical agents in various environments. I’m proud to know that some of the research done on a daily basis in scientific labs across the world is being used to positively impact global society by helping in the fight to keep innocent people safe from certain types of terrorist attacks. GO NANOSCIENCE!!!**

**AT: Pharma = Biased**

**Relying on pharma company evidence is fine – they’re not universally bad and know the field**

**McArdle 9** – The Atlantic  
Megan, Just Say No to . . . Drug Companies?, 8/4/2009, https://www.theatlantic.com/business/archive/2009/08/just-say-no-to-drug-companies/22739/

Speaking of Ezra Klein's obsession with experts, I'd like to suggest another class of experts he may not have considered: people who run companies. I know, I know--it feels too much like conceding to the kind of annoying right wing ideologues who think that the market is so perfect that if anything good is possible, a company will do it--indeed, will already have done it. Believe it or not, those people annoy me too. But while it is certainly true that companies don't know everything . . . that they are merely a part of the vibrant web of different institutions that makes up this America of ours . . . you do not have to be a lunatic free-marketer to acknowledge that companies might be good at a few things that other institutions don't do so well. You just have to visit the former Soviet Union and ask around.

Our turns aren’t from pharma, their from independent sources