# 1NC

### 1– T-Ought

#### 1] Interpretation – The Affirmative must defend a definite reduction of IP protections for Medicines.

#### “Ought” means a particular obligation.

American Heritage Dictionary 16 5th Edition by Editors of the American Heritage Dictionaries //Elmer

**Used to indicate obligation** or duty.

#### Obligation means a binding requirement – it denies an option.

Black’s Law 90 Black’s Law Dictionary 2ND ED. “Obligation” https://thelawdictionary.org/obligation/

//Elmer

An **obligation is a legal duty**, by which a person is **bound to do or not to do a certain thing**. Civ. Code Cal.

#### 2] Violation – The Aff does not definitely reduce IP Protections – there’s a world where the Courts don’t agree w/ the Plaintiffs.

#### 3] Standards –

#### a] Limits – Allowing Conditions Affs explodes the Topic – there’s an infinite number of other conditions that become Topical if this Aff does - companies could be forced to go through a third-party audit to check if their IP protections were beneficial or not, public citizens could be asked to take a poll as to whether a certain IP patent should go through or not, etc.

#### b] Neg Ground – Conditions Affs allow the Aff to spike out of every Neg Arg – generics like Innovation don’t link if the Aff can say the Aff only applies if it is proven to not harm innovation or Biotech Heg since they can say “only if it doesn’t violate National Security”. No Neg Link arguments assume every condition since they’re all Patents Good/Bad meaning they either force us to research infinite conditions or we simply lose since the 1AR will no link everything. Proven in this instance, since the 1AR will always say “every Neg Arg will just be proven to be against the Public Good” making negating impossible.

#### 4] TVA – unconditionally enforce the Plan regardless of plaintiff justifications.

#### 5] Paradigm Issues –

#### a] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### b] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation.

#### c] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

#### d] Topicality outweighs 1AR Theory – 1] Outweighs on scope cause 1AC abuse effects every speech – we had to be abusive since the 1AC was abusive first and 2] Better for norming since we have more speeches to discuss what’s the best norm for debate.

### 2– T-Reduce

#### 1] Interpretation – “Reduce” means to annul.

Black’s Law 90 Black’s Law Dictionary 2ND ED. “Reduce” <https://dictionary.thelaw.com/reduce/> //Elmer

In Scotch law. **To rescind or annul**.

#### That means the Aff has to cancel IP protections in their entirety, they can’t just modify it.

Black’s Law 90 Black’s Law Dictionary 2ND ED. “Annul” <https://thelawdictionary.org/annul/>

//Elmer

**To cancel**; **make void ; destroy.** To annul a judgment or judicial proceeding is to **deprive it of all force and operation**, either a6 initio or prospectively as to future transactions. Wait v. Wait, 4 Barb. (N. Y.) 205; Woodson v. Skinner, 22 Mo. 24; In re Morrow’s Estate, 204 Pa. 484, 54 Atl. 342.

#### 2] Violation – They don’t remove the IP, the Trade Secret still has the same protection under law, it cannot be disclosed unless disclosure is in the public interest – the Aff only shifts who has to prove that NOT the actual protection.

#### 3] Standards –

#### a] Limits – Allowing the Aff’s to deal with the enforcement of IP rather than the actual protection explodes the Topic – Affs can modify court proceedings, specify which courts hear the cases, how long those proceedings last, which agencies pursue legal action, etc. – it eviscerates a predictable stasis by shifting it away from IPP good/bad.

#### b] Neg Ground – Shifting the topic to enforcement means DAs like Innovation, Biotech Heg, Politics no longer apply since the Aff doesn’t have to reduce anything related to the IPP itself – proven by the fact we can’t read Trade Secrets Good vs this Aff since the 1AR will shift to the IP itself doesn’t change and if they were good, the Aff wouldn’t be enforced proving modifications are infinitely abusive.

#### 4] TVA – eliminate Trade Secret protection of Pharma to eliminate deterrent litigation against whistle-blowers since there’s no longer a legal basis for enforcement.

#### 5] C/A Paradigm Issues.

### 3 – Innovation DA

#### Strong current IP guarantees causes massive Pharma innovation.

* Answers Evergreening/Me-Too Drugs

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### Trade Secrets are key to incentivize competitive Innovation – specifically key to protect start-ups.

Gutfleisch 18, Georg. "Employment issues under the European Trade Secrets Directive: Promising opportunity or burden for European companies." European Company Law Journal 15 (2018): 175-181. (working as an Associate with Brandl & Talos Rechtsanwälte GmbH in Vienna, Austria, and recently studied in the LL.M. (International and European Business Law) program at Trinity College Dublin, Ireland.)//Elmer

The **protection of trade secrets** can be **considered** as a **prerequisite for the continuous growth and success of European companies as well as the** general (**technological) advancement and competitiveness of the European economy**.7 Trade secrets can basically be described as secret information that is of value for its owner because of its secrecy. Trade secrets must be differentiated from other (registered) intellectual property rights, such as patents, designs or trademarks. They are not publicly registered and do not grant the trade secret owner an exclusive right against third parties. Most legal systems rank trade secret protection as part of unfair-competition law rather than intellectual property law.8 However, trade secrets are nevertheless related to intellectual property rights. In particular, they could be considered as a **preliminary** step or by-product **to** the **i**ntellectual **p**roperty rights **creation**. Further, trade secrets could also be maintained as permanent alternative to (registered) intellectual property rights. They do not involve costs for the application or subsequent prolongations with the competent authorities and do not impose risks of disclosure during such proceedings.9 Especially **small- and medium-sized enterprises** and start-ups **in** the **research and engineering** business often **rely on the confidentiality of sensitive information as basis of their existence**.10 The **importance** **of** effective **trade secret protection** has been **acknowledged by lawmakers globally.** Back in 1994, the member states of the World Trade Organisation (WTO) entered into the international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),11 which mandates the WTO member states to ensure the protection of undisclosed information without consent in a manner contrary to honest commercial practices. In addition, the Paris Convention on the protection of industrial property of 20 March 1883 (CUP Agreement)12 provides another international legal framework, which some scholars argue does afford protection to trade secrets.13 However, the rather vague minimum requirements of the TRIPS Agreement and the CUP Agreement resulted in significant differences in the national levels of trade secret protection, especially within the member states of the European Union (EU).14 The European Commission acknowledged this situation and started to actively engage with the issue of trade secret protection in the EU. In November 2013, the European Commission introduced its proposal for the TSD (together with an impact assessment and implementation plan).15 The TSD was then enacted in June 2016 after further input from the European Economic and Social Committee16 and the European Parliament Committee on Legal Affairs.17 The TSD has been based on two main reasons.18 On the one hand, it has been argued that the different levels of protection in Europe caused companies to refrain from exchanging confidential information across borders and hindered the proper development of research and innovation. On the other hand, **European companies** regularly **faced** **competitive disadvantages when their trade secrets are misappropriated**.

#### Yes Link – the thesis of the Aff is mean to help ease burden of whistleblowers in winning suits to expose Trade Secrets – the mere threat of a weakening IPR and Secret Protection deters investment.

Ezell et al. ’19 (Stephen; vice president of global innovation policy at the Information Technology and Innovation Foundation; 4-25-2019; “The Way Forward for Intellectual Property Internationally”; Information Technology and Innovation Foundation; <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally>; Accessed: 8-31-2021; AU)

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

#### Pharma innovation solves Pandemics, ABR, and Bioterrorism – only Private Firms have the ability for preparedness and reaction.

Marjanovic and Feijao 20 Sonja Marjanovic and Carolina Feijao May 2020 "Pharmaceutical Innovation for Infectious Disease Management" <https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND_PEA407-1.pdf> (directs RAND Europe's portfolio of research in the field of healthcare innovation, industry and policy)//Re-cut by Elmer

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, 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 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.

#### Bioterrorism and future pandemics cause extinction.

de Bretton-Gordon 20, Hamish. "Biosecurity in the wake of COVID-19: the urgent action needed." (2020). (Director at DBG Defense)//C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The **world may be confronted with** other **viruses** in the future **whose combination of virulence** (the harm a pathogen does to its host), **transmissibility, and other characteristics pose much greater danger**. While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the **advances in synthetic biology** and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 **mean** there is also the very **real possibility** **that** in the future, **bad actors will** try to **engineer or steal**/obtain **a** **highly transmissible and** highly **virulent** **virus** **and unleash it onto the world**. **Another risk is accidental releases** from such biocontainment facilities. COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, **we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science**. It should also be noted that the fear and panic that **even a medium-scale bioterror attack** **could create** could have **dangerous implications** that may rival or even surpass the immediate loss of life. The Need to Rethink Likelihood Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the **interconnectedness** of a world in which millions of people fly each day6 **means** they can **spread** very **rapidly**. There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the **number of people with** access to potentially dangerous ‘**dual use’ technology** has greatly **expanded** and continues to expand, making malevolent use of such technology ever more likely. In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that: The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm. The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7 As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9 Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, **there should no higher priority** for the international community **than biosecurity**.

### Whisteblowing

#### Top-Level – this Advantage is missing uniqueness – they have card zero that whistleblowers are high now – they just don’t want to due to Trade Secrets – threats of getting fired, being paid off, etc. are all huge alt causes to the Aff that thump this to zero.

#### DA turn this Advantage – 1] 1AC Dreyfus and Galizzi cite protective equipment or supplies – Innovation is key to making better, more effective medical tools to fight pandemics and 2] 1AC Mooney proves our arg – we need new Vaccine Preparedness

Mooney 21 — (Tom Mooney, Senior Communications & Advocacy Manager for the Coalition for Epidemic Preparedness Innovations, “Preparing for the next “Disease X””, CEPI, 2-1-21, Available Online at <https://cepi.net/news_cepi/preparing-for-the-next-disease-x/>, accessed 9-10-21, HKR-AM)//Re-cut by Elmer

We cannot develop vaccines against all potential viral threats, but **we could produce a library of prototype vaccines** **and other biological interventions** against representative pathogens **from each** of these 25 **viral families**. **Having such a library** of prototype vaccines, which **could be ‘pulled** off the shelf’, **and advanced** into clinical testing **as soon as** a related **threat emerges** would dramatically accelerate the development of vaccines. We also know that beta coronaviruses that cause SARS and MERS are associated with case fatality rates of 10-35% (25-88 times worse than COVID-19) and that coronaviruses circulate widely in animal reservoirs. The emergence of a coronavirus variant combining the transmissibility of COVID-19 with the lethality of SARS or MERS would be utterly devastating. **We must minimise** **this threat** as a matter of urgency. One **way to do this** in the long-term **would be to develop a vaccine that provides broad protection** against coronaviruses in general. If we can produce vaccines against Disease X in a matter of months instead of a year or more, we could revolutionise the world’s ability to respond to epidemic and pandemic diseases. Disease X and other emerging infectious diseases pose an existential threat to humanity. But for the first time in history, with the right level of financial commitment and political will, we could credibly aim to eliminate the risk of epidemics and pandemics.

#### Zero Inherency or Uniqueness – the EU passed a Whistleblower Directive in 2019 – note they have card zero more recent – only card is 1AC HAI et Al 14 which doesn’t assume recent changes.

Sandeen and Mylly 20 Sharon K. Sandeen & Ulla-Maija Mylly 20, Trade Secrets and the Right to Information: A Comparative Analysis of E.U. and U.S. Approaches to Freedom of Expression and Whistleblowing, 21 N.C. J.L. & TECH. 1 (2020). Available at: https://scholarship.law.unc.edu/ncjolt/vol21/iss3/2 //sid

The E.U. adopted a Directive for the protection of whistleblowers (“Whistleblower Directive”) in April 2019.199 The objective of the Directive is to give further protection to whistleblowers to prevent breaches of law which are harmful to the public interest (Recital 1). The material scope of the Whistleblower Directive covers among others the following areas of E.U. law: food and feed safety, transport safety, consumer protection, nuclear safety, public health, environmental protection, public procurement, financial services and protection of privacy (Article 2). Thus, even though the Whistleblower Directive covers many areas of E.U. law, the approach is still sector specific, which is similar to the U.S. approach albeit in the U.S. there are different laws for different situations and sectors. Before the introduction of the Whistleblower Directive, some urged a need for a horizontal approach. But the E.U. does not have a power to legislate in all areas of law, which ruled out a horizontal approach.200 Moreover, the material scope of the Whistleblower Directive does not cover all breaches of Union law, but only breaches in the areas of Union law which are explicitly mentioned under Article 2. From the recitals of the Whistleblower Directive, one can learn that areas selected are the ones where breaches may cause serious harm to public interest and welfare of society.201 However, E.U. Member States are allowed to extend the application of the Directive to other areas of law. Moreover, the Whistleblower Directive does not have an impact on legislation already at place in the Member States for reporting wrongdoings in some specific areas of law. Under Article 21(7) of the Whistleblower Directive, if there is a need to disclose trade secrets, when reporting or disclosing information, which falls within the scope of the Whistleblower Directive, such disclosures are considered to be lawful disclosures under Article 3(2) of the Trade Secret Directive. Consequently, the Whistleblower Directive is a lex specialis within the scope of the Whistleblower Directive. However, these two Directives are understood as complementing each other and it is clearly highlighted that when cases do not belong to the scope of the Whistleblower Directive, the exceptions provided in the Trade Secret Directive remain applicable (Recital 100); for instance, freedom of expression exceptions may apply. However, the introduction of the Whistleblower Directive may have an impact on interpretations of the Trade Secret Directive. For example, the material scope of the Whistleblower Directive can provide some guidance when analyzing when there is a public interest in disclosing misconduct, wrongdoing or illegal activity under the Trade Secret Directive. But the interpretation of the exceptions in the Trade Secret Directive should not become more limited, even though there might be less need to rely on provisions of the Trade Secret Directive, as the material and the personal scopes of the Whistleblower Directive are very broad. The personal scope of the Whistleblower Directive is quite all- encompassing. Even though the provision refers to the persons who learn the information in work-related situations, the definitions applied also cover job-applicants, trainees, freelancers, sub-contractors and different type of collaborators who could face some harmful consequences due to disclosures. In addition, it is applicable both to public and private sectors (Article 4). Also, in the Trade Secret Directive the personal scope of the whistleblowing provision is wide, but it has been reached through defining the exception to cover the disclosure activity without making any reference to the personal scope of the exception. In accordance with the Whistleblower Directive, Member States are obligated to set up procedures for internal and external reporting. The Whistleblower Directive clearly refers to and draws upon the ECtHR’s practice on this issue (Recital 32). Under the Trade Secret Directive, the recitals only referred to the Charter provisions, but in the Whistleblower Directive there is a direct reference also to the ECHR. Moreover, one can see the impact of the ECtHR’s case law in the structuring of the internal and external reporting channels. How an entity’s internal reporting channels and relevant public authorities should be preferred before disclosing the wrongdoing to the general public seems to stem from the case law of the ECtHR. This preference is also illustrated in the cases discussed above. The disclosure to the public should always be the last resort. However, the Directive also provides some flexibility for cases when these preferred reporting channels are deemed to be impractical. In such cases the wrongdoings could be reported directly to the public. Article 15 sets up specific conditions when public disclosures are allowed. First, one is allowed to disclose information to the public, if they first have used internal and/or external reporting channels, but there has been no action taken within the timeframes set in the Whistleblower Directive. Moreover, one is allowed to disclose information to the public when one has reasonable grounds to believe that there is an imminent or manifest danger to the public interest. Likewise, public disclosure is allowed in cases of external reporting if one believes that because of the specific circumstances of the case there is a risk of retaliation or low prospect of the case being addressed, such as that evidence may be concealed or destroyed or that an authority is in collusion with the perpetrator of the breach or involved in the breach. This provision defines the conditions in a quite detailed manner.

#### This means zero Aff – their arg will be that there’s a risk that Abusive Litigation Lawsuits exist – the Aff doesn’t solve that – their change is on the burden structure BUT if status quo protections that explicitly ban intimidation suits don’t work, then burden shifts definitely doesn’t work either.

#### No EU spill-over warrant for Pandemics – your 1AC only effects the EU – 1AC Dreyfus and Galizzi are about China and Global Whistleblower Protection – means Pandemics starting is inevitable if the Aff’s Internal Link and Uniqueness is true.

#### Can’t solve 1AC Dreyfus and Galizzi – it’s about health workers who lack proper protective equipment or supply chains or medical supplies, which isn’t medicine – that means Trade Secret Protections for those aren’t affected since the Plan only affects medicines – independently the 1AC I/L is about Hospitals NOT Pharmaceutical Companies.

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

### Uniformity

#### DA turns this Advantage – Two Warrants:

#### 1] Trade Secret confidentiality is key for European Tech Competitiveness – that’s 1NC Gutfleisch.

#### Top-Level – They don’t solve any of this Advantage –

#### 1] ZERO Medicine Key Warrant – 1AC Junge is about Trade Secrets writ large – they have no reason Medicine is a totalizing issue nor a spill-over argument – that zaps the Advantage to literally zero since both pieces of 1AC Junge evidence says total uniform consistency matters which trade secret protection over non-medicines still causes gaps in consistency

#### 2] The Plan doesn’t uniform all Trade Secrets – they reform one issue but it doesn’t affect all other Trade Secret Exemptions since their 1AC Junge evidence takes issue with the floor not a ceiling approach that the Aff doesn’t resolve –ton of alt causes