# 1NC Nano Nagle Round 2 vs. Harker RM

## 1

**Interp: the aff cannot both specify a member nation of the World Trade Organization and a subset of intellectual property protections. To clarify, either is fine in isolation**

**Violation: they specify both the EU and trade secrets.**

1. **Limits – this topic is already super broad with over 160 member nations and lots of IP laws – the only functional limit is not specing both because at least the other area then becomes a generic I can read – hold the line on limits on this topic because it’s super broad – leads to cherry picking and 0 neg research that destroys the negative and infinitely multiples the small school prep burden**
2. **Ground – specing both allows unique and specific effects of one country’s specific form of IP to make neg offense nonspecific – that’s the basis for any negative response.**
3. **TVA – only spec one--solves pics since you can strategically spec one of them to leverage against pics on the other**

**Fairness and education are voters--debate’s a game that needs rules to evaluate it and teaches portable skills we use life long. Drop the debater--T is a question of the entire aff and pre round prep was already skewed which dropping the arg can’t solve. No rvi’s - forces the NC to go 7 minutes on theory killing substance and chills theory in case you’re baiting infinite abuse then just prepping out the shell. Competing interps-- topicality is a yes/no question so can’t be reasonably topical as it justifies anything beyond the res--brightlines are arbitrary and unpredictable since they aren’t grounded in the res but no race to the top since limited words in the res means limited interps. Neg theory first--NC abuse was reactive so they were the root cause and only 2 months for topic specific shells while we can norm their’s anytime. 1AR theory and independent voters are bad since a] you get 2ar ethos to blow up a 20 second shell b] we’re forced to overcover to match the 3 minute 2ar c] responses will be new in the 2ar so it’s irresolvable. No infinite abuse--a] NC only has a finite amount of time b] pre-empts solve c] it’s a bad way to check infinite abuse. Drop the arg and reasonability to check their 2ar spin advantage--we don’t have a 3nr so small arg’s can easily get blown up**

## 2

**Interpretation: The aff must only defend reducing intellectual property protections for medicines.**

**Three types of IP specific to medicines**

**Wilbur 19** [[Tom Wilbur](https://catalyst.phrma.org/author/tom-wilbur) is Director of Public Affairs at PhRMA focusing on message development and opinion research. Prior to joining PhRMA in 2019, Tom worked on Capitol Hill and on political campaigns for nearly a decade, most recently responsible for communications, campaigns and strategy for U.S. Rep. Fred Upton and the House Energy and Commerce Committee. Masters in Communications from Mich State U.] “IP Explained: Three forms of IP protections for medicines,” PhRMA, August 27, 2019,<https://catalyst.phrma.org/ip-explained-three-forms-of-ip-protections-for-medicines> TG

Intellectual property (IP) protections for the biopharmaceutical sector provide incentives that help to promote the discovery and development of life-saving medicines for patients and foster a competitive market for generic and biosimilar medicines. There are three forms of IP protections critical to biopharmaceutical development, and although they work together in a complementary fashion, each is distinct and governed by different statutory provisions. In today’s IP Explained, we unpack the differences between each protection and consider how they work together to balance innovation and competition. Patents are unique in that they are property rights granted by the United States Patent and Trademark Office and can be issued or expire independent of a drug’s regulatory approval status. Patents provide inventors in all industries the exclusive right to sell an invention for a set period of time before others may copy and sell it. They both foster invention and promote competition by requiring detailed public disclosure of a new technology. However, patents alone do not grant authorization to market new drugs; manufacturers must still seek Food and Drug Administration (FDA) approval to bring a new drug to market. Although patents are important to all technology-intensive industries, [they are particularly vital to the biopharmaceutical industry](https://catalyst.phrma.org/ip-explained-why-patents-are-so-critical-to-biopharmaceutical-innovation), given the lengthy, costly and highly uncertain research and development (R&D) process that leads to new and improved medicines. While patents may prevent a competitor from bringing an exact duplicate of a medicine to market, they do not act as an absolute bar against bringing similar, non-infringing, products to market. And once the patent has expired, the invention can be freely used by anyone. Data exclusivity, also referred to as data protection, prohibits third parties, for a limited time, from using or relying upon an innovator’s valuable clinical data to obtain FDA approval for their product. Data protection does not prevent third parties from conducting their own R&D and clinical trials to seek and obtain regulatory approval for a competing product. In this way, it operates very differently than a “market exclusivity,” which is described below. Market exclusivity is often confused with data exclusivity but they’re actually very different. Market exclusivity prohibits a third party from obtaining FDA approval for a particular pharmaceutical product and entering the market, for a set period of time, even with its own data. This form of IP protection is intended to encourage investment in R&D when market-based incentives are insufficient such as with [orphan drugs](https://catalyst.phrma.org/icymi-orphan-drug-development-brings-unique-challenges). The Orphan Drug Act (ODA) incentivizes the development of new medicines to treat diseases affecting small patient populations, often referred to as rare diseases. Specifically, the ODA blocks third parties from obtaining approval of a product that is the same as an orphan drug, for the same use, for seven years.

**Trade secrets are not intellectual property protections--legalities and semantics**

**Gutfleisch 18** Georg Gutfleisch (attorney-at-law in the Corporate Transactions/M&A Department. He advises national and international clients in all areas of corporate and company law, private equity transactions as well as national and international restructurings, reorganizations and M&A transactions. He also has extensive expertise in the areas of intellectual property and IT law) "Employment issues under the European Trade Secrets Directive: Promising opportunity or burden for European companies." European Company Law Journal 15 (2018): 175-181

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 intellectual property 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.1

**The violation is obvious and the counter interp explodes limits to literally any small thing related to the medicine.**

**Farkas ND** Brian Farkas [associate attorney at Goetz Fitzpatrick LLP in New York, focusing his practice on commercial litigation, arbitration and intellectual property. Brian earned his B.A. from Vassar College and J.D. from Cardozo School of Law ] “Trade Secret Basics FAQ” No Date https://www.nolo.com/legal-encyclopedia/trade-secret-basics-faq.html#1743223 SM

What is a trade secret? Trade secrets are a form of intellectual property. According to the law of most U.S. states, a trade secret may consist of any formula, pattern, physical device, idea, process or compilation of information that both: 1. provides the owner of the information with a competitive advantage in the marketplace, and 2. is treated in a way that can reasonably be expected to prevent the public or competitors from learning about it, absent improper acquisition or theft. Some examples of potential trade secrets include: the formula for an energy drink survey methods used by professional political pollsters recipes for cookies a new invention for which a patent application has not yet been filed marketing strategies manufacturing techniques, and computer algorithms. Unlike other forms of intellectual property, such as patents, copyrights, and trademarks, which generally require registration in order to be fully effective, trade secrets are essentially a "do-it-yourself" form of protection. You do not register with the government to secure your trade secret; you most simply keep the information under wraps. Trade secret protection lasts for as long as the secret is kept confidential without any statutory limitations period. However, once a trade secret is made available to the public, trade secret protection ends. What types of information can trade secrets protect? Copyright, patents, and trademarks are fairly well-known forms of intellectual property protection. But trade secrets are another extremely useful form of protection that often protects valuable technical or confidential information. Here's a sampling of what trade secrets can protect: Ideas that offer a business a competitive advantage, thereby enabling a company or individual to get a "head start" on the competition. This might include, for example, an idea for a new type of product or marketing approach. Competitors' knowledge that a product or service is under development and its functional or technical attributes including, for example, the workings of a new software program. Valuable business information such as marketing plans, cost and price information, and customer lists. So-called "negative know-how," meaning information learned during the course of research and development on what not to do or what does not work optimally. Often, this information is almost as valuable as the products or techniques that do work. Virtually any other information that has some value and is not generally known by competitors. This might include, for example, a list of customers ranked by the profitability of their business.

**Standards:**

1. **Precision outweighs - anything outside the res is arbitrary and unpredictable because the topic determines prep, not being bound by it lets them jettison any word. Aff arguments are non-unique since a] it relies on semantics to convey those messages and b] pragmatics can be discussed anytime while we only have 2 months to discuss the wording of this unique topic**
2. **Limits – explodes the topic to anything from random trade secrets to trademark pictures and symbols to copyrights which destroys core generics like counterfeit that obviously don’t link to trade secrets – a big case list with no unifying generics destroy neg prep – disincentivizes in depth topic research and leaves the neg behind and unfair research burdens**

## 3

**CP: The member states of the European Union should:**

* **Provide financial rewards for whistleblowers related to medicines, modelled after the US bounty system established by the Dodd-Frank Act of 2010**
* **Harmonize trade secret law across member states as per Brant and Lohse**

**First plank empirically solves advantage 1 better**

**Maslen 2018** (Caitlin, Research Associate at Transparency International. MA in Corruption and Governance from the University of Sussex. “Whistleblower Reward Programs” (Anti-Corruption Helpdesk, Transparency International, https://knowledgehub.transparency.org/assets/uploads/helpdesk/Whistleblower-Reward-Programmes-2018.pdf 27 September 2018)DR 21

Increasing the quantity of disclosures Whilst protection schemes may negate the severity of personal risks caused by whistleblowing, some research contends that reward programmes are even more effective at counter-balancing the possible dangers. Rewards go further than compensation for damages and instead motivate whistleblowers through awards of funds. Research into the behaviour of managers and employees induced by the U.S. bounty scheme, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act), has demonstrated that employees will perform a costbenefit analysis when considering whistleblowing (Franke, Moser and Simons 2016). In order for incentives to be effective, the rewards must be high enough to compensate for retaliation charges (Franke, Moser and Simons 2016). The study concluded that if rewards outweigh the anticipated costs of retaliation they would support an increase in disclosures (Franke, Moser, and Simons, 2016). In the U.S., increased monetary incentives have led to an 'unprecedented' number of investigations and greater recoveries (Kohn, 2014). Franke, Moser and Simons’ (2016) model does, however, suggest that as rewards increase, so does the risk of false accusations. This is we return to below in the section on false reports. Public awareness Whistleblower rewards are often given media coverage and may help to change wider attitudes on the act of blowing the whistle. According to research by UK-based law-firm RPC, the number of whistleblowers working in financial and professional services rose primarily as a result of greater public awareness of the option of whistleblowing (Craggs 2015). Rewards may then have a two-fold effect on the number of disclosures. Firstly, they garner public attention, which then leads to an increase in the number of whistleblowers coming forward. Secondly, some claim that rewards work towards ending the stigmatisation of whistleblowers. One law firm that works with whistleblowers has praised the U.S. bounty scheme, the Dodd-Frank Act, stating that it both incentivises people to speak up and helps to change the traditional stigmas of whistleblowing (Kasperkevic 2015). They argue that as the government takes greater control over whistleblower protection and reward programmes, this leads to public awareness of the importance of reporting wrongdoing and thus encourages more people to come forward (Kasperkevic 2015). Cost effectiveness Reward programmes may lower public spending, as they are less costly than traditional investigative methods. Police officers and investigators consume real resources, whereas whistleblower rewards are simple wealth transfers (Givati 2016). Research into the theory of whistleblower rewards has shown that - as long as the risk of a false report is low enough - using a whistleblower and a reward programme is more economical than relying upon police officers (Givati 2016). Certain types of allegation are less likely to be prone to false reporting than others; the risk of false reports is likely lower where the reported wrongdoing concerns tax evasion or environmental damage, for instance, as the falsification of evidence would be difficult (Givati 2016). Internal compliance Reward programmes can help to strengthen internal compliance within organisations. Paying whistleblowers could counteract negative social pressures that favour silence (Bradley 2015). This in turn could contribute to the development of organisational norms that inculcate a more compliant, transparent and accountable workplace culture. Cartel deterrence One study of South Korea’s reward system found that a cartel's anti-competitive behaviour is weakened through the introduction of whistleblower rewards. If there are financial incentives for whistleblowing then those who have knowledge of cartel activities must be prevented from exposing misconduct through either threats or bribes (Stephan 2014). This makes existing infringements less stable and encourages distrust between cartel members (Stephan 2014). The efficiency of the cartel is reduced, as trust decreases and the costs of bribery increase in order to match the whistleblower reward (Stephan 2014). It should be noted that this benefit would only occur if the legislation allows co-conspirators to be considered whistleblowers, which is often not the case. The cartel may also choose to reduce the number of people in each firm that are directly involved in the cartel in order to diminish the risks caused by reward programmes.

**Second plank solves unification – EU protections just have to be consistent, not high or low**

**Brant and Lohse 14** (Jennifer Brant and Sebastian Lohse, [], 2014, ““, No Publication, accessed: 9-18-2021, https://iccwbo.org/content/uploads/sites/3/2017/02/ICC-Research-Trade-Secrets-english.pdf) ajs

In addition to its own actions, a firm’s ability to retain control over its confidential data, and to recover without exposing itself to further risk, will depend in large part on the legal frameworks in relevant jurisdictions. The fragmentation of trade secret protection frameworks creates major challenges, given the globalized nature of doing business and the prevalence of open innovation. Convergence of trade secret legislation across jurisdictions could provide legal certainty and enable owners of trade secrets to more effectively address misappropriation, wherever initiated. This in turn could enhance knowledge flows and cross-border investments in R&D. Policymakers should address trade secrets systematically in free trade agreements, such as the Trans-Pacific Partnership Agreement and the Trans-Atlantic Trade and Investment Partnership Agreement. In particular, policymakers should work to establish common rules to address cross-border misappropriation cases. Action at the domestic level will be an important complement to such international efforts. Policymakers should enact clear provisions on trade secret protection, whether in a stand-alone law or as part of legislation providing for the protection of other types of IPRs. Trade secret laws should include a clear definition of trade secrets based at least on Article 39.2 of the TRIPS Agreement. They should define and criminalize conduct amounting to a serious trade secret violation, including third party misappropriation, while providing for both individual and corporate liability. Trade secret protection frameworks should contain a comprehensive set of interim and final remedies. They should include effective tools to preserve, facilitate, and secure the gathering of evidence, including disclosure orders and ex parte search orders for premises and IT systems. Criminal and civil remedies, including damages, must be structured so as to constitute a deterrent to trade secret misappropriation. Policymakers should also ensure confidentiality of trade secrets during legal and administrative proceedings, so that recovery does not lead to further disclosure and losses for the trade secret owner. Finally, trade secret and related laws should adopt a balanced approach to employee mobility, providing for the protection of confidential information without unduly restricting individuals’ opportunities for professional development. Policymakers and industry groups may consider providing training for SMEs, to guide them in using trade secrets as part of their intellectual asset management strategies. Compared to larger firms, SMEs have relatively lower levels of experience with and fewer resources to dedicate to IP management. Innovative SMEs are likely to benefit from training on the appropriate actions they must take to protect confidential business information, in order to be able to enforce their rights before the courts in the event of misappropriation. They could also benefit from insights into how to institute effective processes for managing confidential information internally and vis-à-vis partners.

**Trade secrets create incentive for collaboration and drive innovation through profit motives – that turns the aff because companies will increase secrecy.**

**ICC 14** “TRADE SECRETS: TOOLS FOR INNOVATION AND COLLABORATION” 2014 International Chamber of Commerce (ICC)<https://iccwbo.org/content/uploads/sites/3/2017/02/ICC-Research-Trade-Secrets-english.pdf> SM

Trade secrets are often the “crown jewels” of a firm’s intellectual capital, developed over many years through myriad interactions and projects (Jorda 2007). According to recent estimates, trade secrets encompass some 70 per cent of the value of companies’ intellectual assets (Bird & Jain 2008; Forrester 2010; Schwarts & Weil 2010). In one survey, respondents rated proprietary technology highly as a key source of competitive advantage, and a large majority of respondents (88 per cent) cited skills and knowledge as the most important intellectual assets (IPOA 2003). The economic rationale for trade secret protection is two-fold: first, it enables firms to avoid overinvesting in secrecy and thus to use their resources more cost-effectively, and, second, it facilitates the diffusion of knowledge by creating a safe environment for firms to share information that, for whatever reason, they have not patented (Friedman et al 1991; Arrasvuori et al. 2014). In relation to this last point, trade secret protection is particularly well suited to current approaches to innovation, which emphasize incremental change and collaboration. As empirical evidence shows, over-investment in secrecy implies not only wasted resources, but also lost opportunities for collaboration when information cannot be safely shared externally. Over-investment in secrecy may be specific, in the form of over-protection of a particular idea, or it can be general, in the sense that a company may impose too many restrictions on employees and business partners, or may over-spend on physical infrastructure to protect confidential information. The legal protections provided under trade secret laws serve as a substitute for physical and also contractual secrecy (Chally 2008; Lemley 2008). For instance, when hiring and assigning employees, an employer can focus on candidates’ skills and appropriateness for particular roles, rather than choosing people exclusively from within a trusted inner circle (Risch 2007). On the other hand, companies’ actions to prevent leakage of trade secrets sometimes appear to be at odds with employee mobility and the use by an employee of learned skills in subsequent employment (Rowe 2005). Trade secret protection laws that provide appropriate disincentives for misappropriation help to strike a balance between employee mobility and personal development, on the one hand, and the legitimate interests of companies in securing confidentiality of their proprietary information, on the other hand. Trade secret laws also facilitate flows of knowledge by making it less risky for firms to share knowledge. Like patents, trade secrets provide a partial solution to Arrow’s Information Paradox (Lemley 2008). This paradox relates to the difficulties an inventor faces if he or she needs to share a potentially valuable but secret idea in order to exploit it commercially. Without appropriate safeguards, once knowledge is exchanged between parties, there are few disincentives against using that knowledge for commercial benefit. Thus, potential partners may withhold information because they fear creating a new competitor. However, external cooperation is an increasingly important feature of firms’ innovation strategies, enabling them to combine expertise and resources, and thus to accelerate technology development as well as commercialization. By providing additional security, trade secret protection enables the sharing of knowledge between parties (Arrasvuori et al. 2014). The protection afforded by trade secrets matches the needs of contemporary modes of innovation. Today, innovation is increasingly characterized by a high degree of collaboration and also by emphasis on incremental progress. Adaptation of existing solutions to local environments, one form of incremental innovation, is especially relevant in developing countries. Trade secrets help to establish secure channels for exchanges of know-how, helping to build absorptive capacity, which is defined as the ability to identify, assimilate, and apply new knowledge. They also provide an alternative tool for protecting gradual advancements for which patents may not be available or financially practical (Maskus 2012). Finally, given their relative affordability, trade secrets can provide a resource-effective line of defence to SMEs in countries at all levels of development. To summarize, trade secrets are directly implicated in the dissemination of proprietary skills and knowledge, stimulating broader disclosure and use of information. As patent protection encourages the sharing of proprietary technology, trade secret protection facilitates the sharing of proprietary know-how and expertise (Box 3). The combined deployment of trade secrets and patents provides exclusivity to the innovator, while furthering technology transfer through licensing and other transactions (Jorda 2007). Licensing agreements that include conveyances for both forms of protection are credited with stimulating the most value creation (Cummings 2008).

**EU’s key**

**EPM Scientific 19** (202, [], 4-1-2019, “Why US Biotech Companies Should Consider Launching in Europe Directly“, No Publication, accessed: 9-18-2021, https://www.epmscientific.com/blog/2019/04/why-us-biotech-companies-should-consider-launching-in-europe-directly) ajs

​In the past, biotech startups have sought to partner with big pharmaceutical companies. However, the market is changing — in 2019 it may be better to license directly in Europe. For a US-based pharmaceutical company, the prospect of taking a new drug to market in Europe can be daunting. Many young biotech companies decide to [out-license for royalty](https://www.researchgate.net/publication/327407817_Factors_Affecting_Pricing_in_Patent_Licensing_Contracts_in_the_Biopharmaceutical_Industry) or milestone payments instead of navigating the tricky path to commercializing their own product. However, this strategy may be a mistake. Let’s examine why... Drug licensing in Europe vs. the US Europe and the US dominate the [global biotech market](https://www.thebalance.com/ranking-the-top-biotech-countries-3973287) (although China and Japan are important growth markets of their own). This trend is not likely to change, a [2019 iQvia report](https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023) predicted that global pharmaceutical spending will exceed $1.5 trillion by 2023 with market leaders in the US ($625-665 billion, up 4-7%) and Europe ($195-225 billion, up 1-4%). However, the US and Europe have very [different requirements](https://www.fool.com/investing/2018/05/19/how-drug-approvals-in-europe-are-different-than-in.aspx) for clinical trials and new drug applications. Historically, the [US Food and Drug Administration (FDA)](https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/default.htm)  has been seen as a [centralized consumer protection agency](https://www.sciencedirect.com/science/article/pii/S2452302X16300638) — with the critique that it slows approval with safety considerations. In contrast, the [EU European Medicines Agency (EMA)](https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pre-authorisation-guidance) was designed to [standardize commercial rules](https://www.sciencedirect.com/science/article/pii/S2452302X16300638) — with the critique that it primarily preserves commercial interests. There is a debate as to which system approves drugs quicker, a [2015 analysis](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6091770/) indicates that the US is likely the faster of the two approval processes (304 days as compared to 478 in Europe). Small companies may not want to invest in two very-different approval processes. Traditionally, licensing has been regarded as a good exit strategy for biotech and small pharmaceutical companies to help [manage risk](https://www.researchgate.net/publication/327407817_Factors_Affecting_Pricing_in_Patent_Licensing_Contracts_in_the_Biopharmaceutical_Industry), which is why licensing, royalties, mergers and acquisitions are such major drivers of the biotech and pharma industries. But is European licensing really the best exit strategy for US companies in 2019? Data Supporting European Launch over License A [2013 analysis](http://bionest.com/wp-content/uploads/2015/10/In_Vivo_Article_Bionest_web_final_IV1312.pdf) published in the Business and Medicine Report examined companies facing the launch-vs-license dilemma. Using public data from the [EMA database](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/eudra_gmp_database.jsp&mid=WC0b01ac058006e06e) the study examined US-based companies who had chosen to market their primary drug in the US, but were then facing the European launch-or-license decision. From 2003-2013 the study identified 25 companies fitting this criterion, 9 of whom chose to launch directly in Europe and 16 of whom chose to license for royalty and/or milestone payments. The study found that the “launch companies significantly outperformed their licensing peers” and that “launching a drug alone may lead to significant financial reward and success”. To put numbers behind this claim, in a two-year window (one year prior to EMA approval to one year post-approval) the median share price of the launch companies increased by 46%, as compared to 2% for the out-licensing companies. Now this study had small numbers and a wide range of variation in the companies performances. But it gives an important insight into the benefits of navigating European regulatory structures. While there are likely many factors contributing to this data, it's possible that we’re simply seeing a direct result of the EU's new centralization. Before 1995 there were [15 different national bodies](https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246776.htm) regulating drugs in the European Union. Since the formation of the EU, what used to be a country-specific launch in Europe has become a centralized review leading to efficient access to Europe’s population of [741 million people](https://www.google.com/search?q=europe+population&rlz=1C5CHFA_enCA730CA732&oq=europe+population&aqs=chrome..69i57j0l5.2374j0j4&sourceid=chrome&ie=UTF-8). Regardless, the data suggests that the conventional wisdom is no longer true. Biotech companies should strongly consider launching directly in Europe. In conclusion Traditionally biotech companies have sought to be acquired by, or partner with large pharmaceutical companies. However, this model is changing. Now companies may have more success going straight to market in Europe.

**Key to solve disease and bioterror--turns case**

**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, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

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.

## 4

**CP: The United Nations General Assembly should request an advisory opinion with binding force stating that the member states of the European Union’s trade secrets for medicines violate international law, and pass a concurrent resolution that non-compliance with the International Court of Justice’s opinion constitutes an enforceable violation of Charter obligations. The United Nations International Court of Justice should convene and, if a dispute is present, issue a binding advisory opinion that not reducing trade secrets for medicines is in violation of United Nations Charter obligations.**

**The ICJ has jurisdiction over IPR – international treaties prove**

**Venkatachalam 21** [Manasa, B.A. LL.B. (law degree) at Gujarat National Law University in India] “No Rocket Science!: Outer Space, Intellectual Property Rights, and the International Court of Justice,” Volkerrechtsblog, April 15, 2021,<https://voelkerrechtsblog.org/no-rocket-science/> TG

The next question that arises is what forum can states approach for claiming violations of IPR in connection to the OST mechanism. Given that the rights protecting a state’s IPR are derived from multilateral treaties like the OST, and even the ISS Intergovernmental Agreement, the forum of adjudication would naturally be the International Court of Justice (ICJ). This results from Article 38 (1) of the ICJ Statute, which allows the ICJ to assume jurisdiction over matters referred to it by parties for disputes regarding treaties and conventions in place. While issues of space law are yet to be adjudicated by the ICJ, such an issue arising in relation to IPR would not be entirely surprising, given that treaties related to IPR like the Paris Convention cite the ICJ to be the appropriate forum for disputes arising out of such treaties. However, the practicality of approaching the ICJ for every IPR violation in outer space is questionable.

**It’s key to harmonizing international IPR – solves the aff**

**Askew 2k** [Lee Ann, JD May 2000] “ECJ, the ICJ and Intellectual Property: Is Harmonization the Key,” Tulsa Journal of Comparative and International Law, Vol 7 Iss 2, 3-1-2000,<https://core.ac.uk/download/pdf/232678481.pdf> TG

An important hurdle that must be jumped is compulsory jurisdiction to the ICJ without any reservations. But if governments sincerely wish to promote further development of inventions and ideas, they will need to be more open to letting the ICJ handle the intellectual property issues and then abiding by and enforcing its judgments. Also, because the ICJ does not follow precedent, it is difficult to predict the outcome of a case. To date, the ICJ has not rendered a decision on intellectual property issues, thus increasing the difficulty of gaining protection for intellectual property owners. VI. CONCLUSION With the EU becoming members of some of the more important and significant international organizations, it has shown the ability to work through conflicting issues with other nation-states. As a result, it has gained increasing support from its Member States and continues to thrive throughout Europe. Even though the UN was created mainly to maintain international peace and security, and the ICJ is its judicial organ to enforce that, the ICJ has jurisdiction over any Member States international issue that is brought before it. Therefore, if a State (or individual if the ICJ would open its jurisdiction for individuals) wished to bring an intellectual property issue before the ICJ, the Court could look to what the EU, the ECJ and specifically the EPC has done with intellectual property as a model and guide for harmonizing intellectual property law throughout UN States. There is no easy solution for preventing piracy and adequately protecting intellectual property rights on an international level; however, the EU and ECJ have shown how commitment towards harmonizing intellectual property throughout its Member States - a model which organizations, agencies and courts can follow in the future. ICJ legitimacy is key to global multilateralism and cooperation Korneliou 18 [Kornelios, Permanent Representative of Cyprus and Vice-President of the 73rd Session of the UN General assembly], "Report of the International Court of Justice," United Nations, 10-25-2018 https://www.un.org/pga/73/2018/10/25/report-of-the-international-court-of-justice/ In the face of the headwinds against the multilateral system and global institutions, including direct attacks on their legitimacy, the International Court of Justice stands as testament to the principles of peace and justice in a multilateral world. Today’s debate builds on fifty years of exchange between the Court and the General Assembly, allowing Member States the opportunity to debate the work of the Court. This historic exchange is particularly pertinent to the 73rd Session of the General Assembly, which aims to ‘make the UN relevant to all’. The court system serves as a bulwark against arbitrariness and provides the mechanism for peaceful settlement of disputes, guaranteeing the stability so necessary for international cooperation. For the peoples of the world, the court may be far away but its impact is real. Excellencies, I am encouraged by the continued and enhanced confidence in the International Court of Justice. Not only has the Court’s workload increased over the last 20-years but this trend has continued into the period under review, demonstrating unequivocally that there remains a need and desire for a multilateral mechanism to address legal challenges of international concern. The variety of cases addressed by the court, and the fact that these cases stem from four continents, is also testament to the universality of the Court. In fact, as of today a total of 73 Member States have accepted, as compulsory, the jurisdiction of the Court. In addition to the Court’s role in advancing multilateralism, its judgements and advisory opinion directly influence the development and strengthening of the rule of law in countries the world over. As stated by the report: “everything the court does is aimed at promoting and reinforcing the rule of law, through its judgement and advisory opinions, it contributes to developing and clarifying international law.” Finally, at a time when human rights abuses and conflict devastate the lives of millions, and when tensions simmer in regions throughout the world, the adjudication of disputes between states remains an essential role of the Court in preserving peace and security. We welcome the continued readiness by the Court to intervene when other diplomatic or political means have proven unsuccessful. For Member States, respect for the decisions, judgements, advice, and orders of the Court remains critical for the efficacy and longevity of the international Justice System. The General Assembly has thus called upon States that have not yet done so to consider accepting the jurisdiction of the Court in accordance with its Statute. In closing, allow me to reiterate: if we are to preserve the international multilateral system, then adherence and respect for international law remains key.

**Extinction---cooperation key to solve existential risk.**

Yuval Noah **Harari 18**. Professor of History at Hebrew University of Jerusalem. “We need a post-liberal order now.” The Economist. 9/26/2018. <https://www.economist.com/open-future/2018/09/26/we-need-a-post-liberal-order-now>

The second thing to note about this vision of friendly fortresses is that it has been tried—and it failed spectacularly. All attempts to divide the world into clear-cut nations have so far resulted in war and genocide. When the heirs of Garibaldi, Mazzini and Mickiewicz managed to overthrow the multi-ethnic Habsburg Empire, it proved impossible to find a clear line dividing Italians from Slovenes or Poles from Ukrainians. This had set the stage for the second world war. The key problem with the network of fortresses is that each national fortress wants a bit more land, security and prosperity for itself at the expense of the neighbors, and without the help of universal values and global organisations, rival fortresses cannot agree on any common rules. Walled fortresses are seldom friendly. But if you happen to live inside a particularly strong fortress, such as America or Russia, why should you care? Some nationalists indeed adopt a more extreme isolationist position. They don’t believe in either a global empire or in a global network of fortresses. Instead, they deny the necessity of any global order whatsoever. “Our fortress should just raise the drawbridges,” they say, “and the rest of the world can go to hell. We should refuse entry to foreign people, foreign ideas and foreign goods, and as long as our walls are stout and the guards are loyal, who cares what happens to the foreigners?” Such extreme isolationism, however, is completely divorced from economic realities. Without a global trade network, all existing national economies will collapse—including that of North Korea. Many countries will not be able even to feed themselves without imports, and prices of almost all products will skyrocket. The made-in-China shirt I am wearing cost me about $5. If it had been produced by Israeli workers from Israeli-grown cotton using Israeli-made machines powered by non-existing Israeli oil, it may well have cost ten times as much. Nationalist leaders from Donald Trump to Vladimir Putin may therefore heap abuse on the global trade network, but none thinks seriously of taking their country completely out of that network. And we cannot have a global trade network without some global order that sets the rules of the game. Even more importantly, whether people like it or not, humankind today faces three common problems that make a mockery of all national borders, and that can only be solved through global cooperation. These are nuclear war, climate change and technological disruption. You cannot build a wall against nuclear winter or against global warming, and no nation can regulate artificial intelligence (AI) or bioengineering single-handedly. It won’t be enough if only the European Union forbids producing killer robots or only America bans genetically-engineering human babies. Due to the immense potential of such disruptive technologies, if even one country decides to pursue these high-risk high-gain paths, other countries will be forced to follow its dangerous lead for fear of being left behind. An AI arms race or a biotechnological arms race almost guarantees the worst outcome. Whoever wins the arms race, the loser will likely be humanity itself. For in an arms race, all regulations will collapse. Consider, for example, conducting genetic-engineering experiments on human babies. Every country will say: “We don’t want to conduct such experiments—we are the good guys. But how do we know our rivals are not doing it? We cannot afford to remain behind. So we must do it before them.” Similarly, consider developing autonomous-weapon systems, that can decide for themselves whether to shoot and kill people. Again, every country will say: “This is a very dangerous technology, and it should be regulated carefully. But we don’t trust our rivals to regulate it, so we must develop it first”. The only thing that can prevent such destructive arms races is greater trust between countries. This is not an impossible mission. If today the Germans promise the French: “Trust us, we aren’t developing killer robots in a secret laboratory under the Bavarian Alps,” the French are likely to believe the Germans, despite the terrible history of these two countries. We need to build such trust globally. We need to reach a point when Americans and Chinese can trust one another like the French and Germans. Similarly, we need to create a global safety-net to protect humans against the economic shocks that AI is likely to cause. Automation will create immense new wealth in high-tech hubs such as Silicon Valley, while the worst effects will be felt in developing countries whose economies depend on cheap manual labor. There will be more jobs to software engineers in California, but fewer jobs to Mexican factory workers and truck drivers. We now have a global economy, but politics is still very national. Unless we find solutions on a global level to the disruptions caused by AI, entire countries might collapse, and the resulting chaos, violence and waves of immigration will destabilise the entire world. This is the proper perspective to look at recent developments such as Brexit. In itself, Brexit isn’t necessarily a bad idea. But is this what Britain and the EU should be dealing with right now? How does Brexit help prevent nuclear war? How does Brexit help prevent climate change? How does Brexit help regulate artificial intelligence and bioengineering? Instead of helping, Brexit makes it harder to solve all of these problems. Every minute that Britain and the EU spend on Brexit is one less minute they spend on preventing climate change and on regulating AI. In order to survive and flourish in the 21st century, humankind needs effective global cooperation, and so far the only viable blueprint for such cooperation is offered by liberalism. Nevertheless, governments all over the world are undermining the foundations of the liberal order, and the world is turning into a network of fortresses. The first to feel the impact are the weakest members of humanity, who find themselves without any fortress willing to protect them: refugees, illegal migrants, persecuted minorities. But if the walls keep rising, eventually the whole of humankind will feel the squeeze.

## 5

**Permissibility and presumption negate—the aff has the burden of proof to show the normative claim of the resolution is true, so the neg gets anything that denies that. Ought implies a moral obligation to do something but permissibility denies the existence of said obligation**

**Ethics are not a universal truth but rather mere categories of languages created by us**

**Parrish 1** (Rick Parrish. "Derrida's Economy of Violence in Hobbes' Social Contract." Theory & Event 7, no. 4 (2005) <https://muse.jhu.edu/>)

Perhaps the single most telling quote from Hobbes on this point comes from The Philosophical Rudiments Concerning Government and Society (usually known by its Latin name, De Cive), in which he states that "to know truth, is the same thing as to remember that it was made by ourselves by the very usurpation of the words." 24 "For Hobbes truth is a function of logic and language, not of the relation between language and some extralinguistic reality," 25 so the "connections between names and objects are not natural." 26 They are artificially constructed by persons, based on individual psychologies and desires. These individual desires are for Hobbes the only measure of good and bad, because value terms "are ever used with relation to the person that useth them, there being nothing simply and absolutely so, nor any common rule of good and evil to be taken from the nature of the objects themselves." 27 Since "there are no authentical doctrines concerning right and wrong, good and evil," 28 these labels are placed upon things by humans in acts of creation rather than discovered as extrinsic facts. Elaborating on this, Hobbes writes that "the nature, disposition, and interest of the speaker, such as are the names of virtu es and vices; for one man calleth wisdom, what another calleth fear; and one cruelty what another justice." 29 A more simplistic understanding of the brutality of the state of nature, which David Gauthier calls the "simple rationality account," 30 has it that mere materialistic competition for goods is the cause of the war of all against all, but such rivalry is a secondary manifestation of the more fundamental competition among all persons to be the dominant creator of meaning. Certainly, Hobbes writes that persons most frequently "desire to hurt each other" because "many men at the same time have an appetite to the same thing; which yet very often they can neither enjoy in common, nor yet divide it; whence it follows that the strongest must have it, and who is strongest must be decided by the sword." 31 But this competition for goods only arises as the result of the more primary struggle that is inherent in the nature of persons of meaning creators. In the state of nature, "where every man is his own judge," 32 persons will "mete good and evil by diverse measures," creating labels for things as they see fit, based on individual appetites. 17. One of the most significant objects that receives diverse labels in the state of nature is 'threat'. Even if most people happen to construe threat similarly, there will be serious disagreement regarding whether or not a specific situation fits a commonly held definition. This is of course the key to the famous Security Dilemma that internationalrelations theorists spend so much time trying to overcome34 -- certain perfectly innocent actions by one person (or state) can easily be construed, and rationally must be construed, as a threat. Furthermore, any attempt by one person to allay another's fears about the threatening nature of actions must be taken as strategic disinformation, rather than as genuine explanation. Even if "I agree with you in principle about your right to preserve yourself," this agreement is useless "if I disagree about whether this is the moment for you to implement that right." 35 Given that persons "are individual in experience, they are individual in their conceptions and in their speech. Their power of reasoning with words . . . dissociates them and provokes violent competition" 36 specifically because concepts that seem simple invoke very different interpretations. If there were some universally objective and knowable set of circumstances that constituted Threat as such, the rationally self-interested persons of the state of nature would not have to seek control over all things for their own protection. All persons could both avoid actions that would be defined as threat and shed the overbearing suspicion that, taken together, make the Hobbesian state of nature so unbearably brutish.

**To escape the state of nature, people unite to imbue a sovereign with absolute authority to define ethics and enforce them at will. The sovereign is the only binding ethical force - absent it, ethics fail since everyone has competing conceptions of the good**

**Parrish 2** (Rick Parrish. "Derrida's Economy of Violence in Hobbes' Social Contract." Theory & Event 7, no. 4 (2005) <https://muse.jhu.edu/>)

All of the foregoing points to the conclusion that in the commonwealth the sovereign's first and most fundamental job is to be the ultimate definer. Several other commentators have also reached this conclusion. By way of elaborating upon the importance of the moderation of individuality in Hobbes' theory of government, Richard Flathman claims that peace "is possible only if the ambiguity and disagreement that pervade general thinking and acting are eliminated by the stipulations of a sovereign. Pursuant to debunking the perennial misinterpretation of Hobbes' mention of people as wolves, PaulJohnson argues that "one of the primary functions of the sovereign is to provide the necessary unity of meaning and reference for the primary terms in which men try to conduct their social lives." 58 "The whole raison d'être of sovereign helmsmanship lies squarely in the chronic defusing of interpretive clashes," 59 without which humans would "fly off in all directions" 60 and fall inevitably into the violence of the natural condition. 26. It is not surprising that so many noted students of Hobbes have reached this conclusion, given how prominently he himself makes this claim. According to Hobbes, "in the state of nature, where every man is his own judge, and differeth from others concerning the names and appellations of things, and from those differences arise quarrels and breach of peace, it was necessary there should be a common measure of all things, that might fall in controversy." 61 The main categories of the sovereign's tasks are "to make and abrogate laws, to determine war and peace, [and] to know and judge of all controversies," 62 but each of these duties is a subspecies of its ultimate duty to be the sole and ultimate definer in matters of public importance. It is only through the sovereign's effective continued accomplishment of this duty that the people of a commonwealth avoid the definitional problems that typify the state of nature. 27. Judging controversies, which Hobbes lists as the third main task of the sovereign, is the duty most obviously about being the ultimate definer. In fact, Hobbes declares it a law of nature that "in every controversy, the parties thereto ought mutually to agree upon an arbitrator, whom they both trust; and mutually to covenant to stand to the sentence he shall give therein." 63 As I repeatedly alluded to above, this agreement to abide by the decision of a third party arbitrator, a sovereign in the commonwealth, is necessary because of the fundamentally perspectival and relative nature of persons' imputations of meaning and value into the situations they construct. Hobbes understands this problem, as evidenced by his claim that "seeing right reason is not existent, the reason ofsome man or men must supply the place thereof; and that man or men, is he or they, that have the sovereign power" 64 to dictate meanings that will be followed by all. The sovereign is even protected from potential democratic impulses, by which a 'true' meaning would be that agreed upon by the greatest number of people. Because "no one man's reason, nor the reason of any one number of men, makes the certainty," they willstill "come to blows . . . for want of a right reason constituted by nature" 65 unless both the majority and the minority agree to abide by the meanings promulgated by the sovereign. 28. These meanings are usually created and promulgated by the sovereign in the form of laws, another of the tasks with which 7/29/13 RickParrish | Derrida's Economyof Violence in Hobbes' Social Contract | Theory& Event 7:4 https://muse.jhu.edu/journals/theory\_and\_event/v007/7.4parrish.html 13/42 Hobbes charges it. In one of his clearest explanations of the law, Hobbes writes that "it belongs to the same chief power to make some common rules for all men, and to declare them publicly, by which every man may know what may be called his, what another's, what just, what unjust, what honest, what dishonest, what good, what evil; that is summarily, what is to be done, what to be avoided in our common course of life." 66 The civil law is the set of the sovereign's definitions for ownership, justice, good, evil, and all other concepts that are important for the maintenance of peace in the commonwealth. When everyone follows the law (that is, when everyone follows the sovereign's definitions) there are far fewer conflicts among persons because everyone appeals to the same meanings. This means that people know what meanings others will use to evaluate the actions of themselves and others, so the state of nature's security dilemmas and attempts to force one's own meanings upon others are overcome.

**Turns the aff fw at the highest layer - absent a sovereign we live in a state of nature where individuals can just force their own moral vision onto another which destroys any chance of productive ethics since no one can guarantee they achieve their ends in a chaotic state justifying infinite violations of their fw**

**Thus, the standard is consistency with the Hobbesian Social Contract. Not consequentialist but concerned on if an action procedurally violates the rules of a contract**

**I’ll defend the lack of a universal obligation to the aff. Negate –**

**1] Sequencing – a sovereign can’t be obligated to do anything because they are the ones who choose what ethics and truth – the rez tries to coerce the sovereign to do something which challenges its authority**

**2] IP is implicit in the creation of a sovereign in expressing creativity**

**Ghosh 04** [Shubha Ghosh (B.A., Amherst College; Ph.D., University of Michigan; J.D., Stanford Law School; Professor of Law, University at Buffalo, SUNY, Law School; Visiting Professor, SMU Dedman School of Law). “PATENTS AND THE REGULATORY STATE: RETHINKING THE PATENT BARGAIN METAPHOR AFTER ELDRED”. BERKELEY TECHNOLOGY LAW JOURNAL. 2004. Accessed 9/3/21. https://lawcat.berkeley.edu/record/1119327/files/fulltext.pdf //Xu]

As illustration of the limits of social contract theory,46 particularly the malleability of the notions of consent and promise, consider a social contract theory of intellectual property based on the thoughts of Thomas Hobbes rather than that of John Locke. No scholar has expressly developed a Hobbesian theory of patent or of copyright, but as a challenge to social contract theory, it may be useful to imagine what such a theory would look like.47 For Hobbes, humans created the leviathan-the sovereign state-to protect themselves from each other in the state of nature. 48 Without the leviathan, the state of nature was not an idyllic paradise but a condition of savagery and brutality. In the state of nature, to the extent that any creative activity occurred, the objects of creation would be cannibalized, thoughtlessly copied, adapted, distributed, and performed or used, sold, offered to sell, and made by others. Thus, intellectual property law under the leviathan would protect individuals from this state of nature by making them absolute, immutable, bountiful, and unlimited. Humans would consent to these terms if they were enforced equally for all creations, and each author and inventor would promise to all others to abide by this form of the intellectual property social contract.