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

First, Permissibility and presumption negate – Statements are more often false than true because any part can be false – outweighs on probability. This means you negate if there is no offense because the resolution is probably false.

Ethics must begin a priori:

[A] Naturalistic fallacy

– Experience only tells us what is since we can only perceive what is, not what ought to be. But it's impossible to derive an ought from descriptive premises, so there needs to be additional a priori premises to make a moral theory.

[B] Empirical uncertainty

Evil demon could deceive us, dreaming, simulation, and inability to know others' experience make empiricism an unreliable basis for universal ethics. Outweighs since it would be escapable since people could say they don't experience the same.

[C] Action theory

Only evaluating action through reason solves since reason is key to evaluate intent, otherwise we could infinitely divide actions. For example: If I was brewing tea, I could break up that one big action into multiple small actions. Only our intention, to brew tea unifies these actions if we were never able to unify action, we could never classify certain actions as moral or immoral since those actions would be infinitely divisible

[D] Constitutive Authority

Practical reason is the only inescapable authority because to ask for why we should be reasoners concedes its authority since it uses reason – anything else is nonbinding and arbitrary.

Next, the relevant feature of reason is universality – any non-universalizable norm justifies someone's ability to impede on your ends i.e. if I want to eat ice cream, I must recognize that others may affect my pursuit of that end and demand the value of my end be recognized by others which also means universalizability acts as a side constraint on all other frameworks. It's impossible to will a violation of freedom since deciding to do would will incompatible ends since it logically entails willing a violation of your own freedom

Next, practical reason means we all have a unified perspective: What can be justified to me can be justified to everyone who is a practical reasoner. Ethics must be universalizable:

A) absent universal ethics, morality becomes arbitrary and fails to guide action, which means that ethics is rendered useless,

B) otherwise it creates a contradiction in which you justify your freedom while limiting others'

Thus the standard is consistentcy with the categorical imperative.

Prefer additionally:

1] Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place

a)All frameworks assume liberty to be coherent – for example, if someone holds a gun to my head and makes me steal someone's apple, I am not truly culpable because I wasn't free.

b) Freedom is a necessary prerequisite to moral action – we must have the capacity to set and maintain ends, else we cannot achieve ends even if it were feasible. Freedom is consistent with practical reason because we must have the freedom to reason.

c) Making and presenting arguments concedes the authority of freedom – without setting and pursuing our own ends, we wouldn't be able to debate.

2] Consequentialism fails - a] induction fails: the logic of looking into the past to predict the future is predicated on past experiences, meaning it's circular, b] butterfly effect: every consequence is infinitely cascading so we don't know the true extent of our actions, meaning we cannot predict consequences

Contention 1: The aff violates Kant's philosophies in countless ways.

A) The aff violates the categorical imperative and is <u>non-universalizable</u>- governments have a <u>binding obligation</u> to protect creations.

Van Dyke 18 Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/ SJ//DA recut SJKS

As we shall see, applying **<u>Kantian logic entails first acknowledging some basic principles; that the people have a right to express themselves, that that expression (the fruits of their labor) has value and is theirs (unless consent is given otherwise), and that government is obligated to protect people and their property. Thus, an inventor or creator has a right in their own creation, which cannot be taken from them without their consent.</u>** So, employing this canon, **<u>a proposed Categorical Imperative (CI) is the following Statement: creators should be protected against the unlawful taking of their creation by others. Applying this Statement to everyone, i.e., does the Statement hold water if everyone does this, leads to a yes determination. Whether a child, a book or a prototype, creations of all sorts should be protected, and this CI stands.</u>** This result also dovetails with the purpose of government: to protect the people and their possessions by providing laws to that effect, whether for the protection of tangible or intangible things. **<u>However, a contrary proposal can be postulated: everyone should be able to use the creations of another without charge. Can this Statement rise</u>**

to the level of a CI? This proposal, upon analysis would also lead to chaos. Hollywood, for example, unable to protect their films, television shows or any content, would either be out of business or have robust encryption and other trade secret protections, which would seriously undermine content distribution and consumer enjoyment. Likewise, inventors, unable to license or sell their innovations or make any money to cover R&D, would not bother to invent or also resort to strong trade secret. Why even create? This approach thus undermines and greatly hinders the distribution of ideas in a free society, which is contrary to the paradigm of the U.S. patent and copyright systems, which promotes dissemination. By allowing freeriding, innovation and creativity would be thwarted (or at least not encouraged) and trade secret protection would become the mainstay for society with the heightened distrust.

B) The aff encourages free riding- that treats people as means to an end and takes advantage of their efforts which violates the principle of humanity

Van Dyke 18 Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/ SJ//DA recut SJKS

Also, **allowing the free taking of ideas, content and valuable data, i.e., the fruits of individual intellectual endeavor**, would disrupt capitalism in a radical way. **The resulting more secretive approach in support of the above free-riding Statement** would be akin to a Communist environment **where the State owned everything and the citizen owned nothing, i.e., the people "consented" to this. It is, accordingly, manifestly clear that no reasonable and supportable Categorical Imperative can be made for the unwarranted theft of property, whether tangible or intangible,** apart from legitimate exigencies.

Rebuttal cards:

Reuters, '21 5-28-2021, "Patents are needed to develop medicines for future pandemics," https://www.reuters.com/business/healthcare-pharmaceuticals/patents-are-needed-develop-medicines-future-pandemics-merkel-2021-05-28/ BERLIN, May 28 (Reuters) - German Chancellor Angela Merkel urged G20 countries to fund the COVAX initiative to provide COVID-19 vaccines to the world's poorer countries but stressed that patent protection was vital to the development of medicines to deal with future pandemics.

Addressing a conference held on Friday in connection with Italy's chairmanship of the G20 group of large economies, Merkel said **the world needed to apply the lessons of the coronavirus crisis in preparing for future pandemics**

"**This includes not weakening the incentives for research and development but developing them further if necessary," she said. "Patent protection plays an important role here.**"

Reducing IP protections chills future investment – even the perception of wavering commitment scares off companies.

Grabowski et al. '15 (Harry; Professor Emeritus of Economics at Duke, and a specialist in the intersection of the pharmaceutical industry and government regulation of business; February 2015; "The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation"; Health Affairs; https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047; Accessed: 8-31-2021; AU)

Patents and other forms of **intellectual property protection** play **essential roles** in encouraging innovation in biopharmaceuticals. As part of the "21st Century Cures" initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand. We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting. We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances.

Technological innovation is widely recognized as a key determinant of economic and public health progress. 1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is **long, costly, and risky**, and the costs of imitation are low. After a new drug has been approved and is being marketed, its **patents protect it** from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. **For firms** to have an **incentive** to **continue to invest** in innovative development efforts, they must have an **expectation** that they can **charge enough** during this period to **recoup** costs and make a profit. After a drug's patent or patents expire, **generic rivals** can enter the market at **greatly reduced development cost** and prices, providing added consumer benefit but **eroding** the **innovator drug** company's revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug's marketing exclusivity while providing a regulatory framework for generic drug approval. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases. Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the "21st Century Cures" initiative, 3 following earlier recommendations by the President's Council of Advisors on Science and Technology on responding to challenges in "propelling innovation in drug discovery, development, and evaluation." 4 In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. We also review the R&D incentives that complement patents in certain circumstances. Finally, we consider the pros and cons of selected voluntary ("opt-in") or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition. The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection **particularly important** to **innovation incentives** for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a **billion** dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the **few successful, on-market**

products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug's patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. **Absent intellectual property protections** that allow marketing exclusivity, innovative firms would be **unlikely** to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, **they do not guarantee demand**, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians' choices for patient treatment. Patents play an **essential role** in the economic "ecosystem" of **discovery and investment** that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the **strength of intellectual property protection** plays a **key role** in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer
through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

R&D's key to innovation – otherwise, future pandemics.

Marjanovic et al. '20 (Sonja; Ph.D. at the University of Cambridge; May 2020; "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis"; RAND; https://www.rand.org/pubs/perspectives/PEA407-1.html; Accessed: 8-31-2021; AU)

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**.