## 1.

#### Interpretation: The affirmative debater must articulate a distinct ROB in the form of a delineated text in the first affirmative speech.

#### B. Violation: They don’t

#### C. Standards:

#### 1. Strat Skew – Absent a text in the 1AC, they can read multiple pieces of offense under different ROBs and then read a new one in the 1AR that moots 7 minutes of case and allows them to auto-win with specific offense. Shiftiness outweighs since it creates an irreversible skew for the negative that can’t be changed.

#### CX checks fails- A] Not flowed B] skews 6 min of prep during the aff C] They can proactively lie and there’s no way to check D] debaters can be intentionally shady.

#### This spec shell isn’t regressive- it literally determines what the affirmatives framing mechanism is

#### Fairness is a voter because it’s a competitive constraint on both sides

#### Education is a voter because it’s the only reason schools fund debate

#### Competing interps

#### 1] Reasonability is arbritary

#### 2] It’s key to norming

#### 3] It collapses-since you use an offense defense paradigm to evaluate brightlines

#### DTD—DTA doesn’t make sense and it’s key to dettering abuse

#### No RVI

#### 1] Illogical- shouldn’t win for being fair---o/w becuz it’s a litmus test for argumentation

#### 2] Incentivizes theory baiting

#### 3] Chills debaters from going for theory

#### 4] Counter interp-with the brightline of 2 shells solves their offense since it means they don’t have to spend much time on theory

## 2.

#### The role of the ballot is to determine whether the resolution is a true or false statement – anything else moots 7 minutes of the nc – their framing collapses since you must say it is true that a world is better than another before you adopt it.

#### They justify substantive skews since there will always be a more correct side of the issue but we compensate for flaws in the lit.

#### Scalar methods like comparison increases intervention – the persuasion of certain DA or advantages sway decisions – T/F binary is descriptive and technical.

#### Negate because either the aff is true meaning its bad for us to clash w/ it because it turns us into Fake News people OR it’s not meaning it’s a lie that you can’t vote on for ethics

#### a priori's 1st – even worlds framing requires ethics that begin from a priori principles like reason or pleasure so we control the internal link to functional debates.

#### The ballot says vote aff or neg based on a topic – five dictionaries[[1]](#footnote-1) define to negate as to deny the truth of and affirm[[2]](#footnote-2) as to prove true so it's constitutive and jurisdictional. I denied the truth of the resolution by disagreeing with the aff which means I've met my burden.

#### Merriam Webster defines ‘trade’ as: having a larger softcover format than that of a mass-market paperback and usually sold only in bookstores[[3]](#footnote-3)

#### Merriam Webster defines ‘World’ as: a distinctive class of persons or their sphere of interest or activity[[4]](#footnote-4)

#### Merriam Webster defines ‘reduce’ as: to decrease the volume and concentrate the flavor of by boiling[[5]](#footnote-5)

#### Dictionary.com defines ‘intellectual’ as: a person of superior intellect.[[6]](#footnote-6)

#### Dictionary.com defines ‘property’ as: an essential or distinctive attribute or quality of a thing[[7]](#footnote-7)

#### Merriam Webster defines ‘protections’ as: anchoring equipment placed in cracks for safety while rock climbing[[8]](#footnote-8)

#### Dictionary.com defines ‘medicine’ as: any object or practice regarded as having magical powers.[[9]](#footnote-9)

## 3.

#### Util collapses to moral egoism – even if well-being is intrinsically good and motivating, it doesn’t follow that other subjects pleasure is also intrinsically good

#### 1] Non-sequitur – saying that x is good for me doesn’t entail that x is good for everybody.

#### 2] Solipsism – we can’t verify if other humans also are experiential subjects or are just fleshy objects.

#### 3] Dependency – Even if pleasure is good for everyone, they haven’t warranted why one agent has an obligation to any other. Outweighs – none of their metaphysical justifications are actor-specific. Moral egoism means relativism which they can’t solve.

#### Moral egoism means relativism which they can’t solve

#### 1] Schmagency – even if we know what is ethical, there’s no reason that we are bound to ethical behavior.

#### 2] Application – even if we agree on what is ethical, we’ll still disagree on what the best way on how to maximize ethical outcomes.

#### The solution is the sovereign – we must surrender moral judgement.

Williams Williams, Michael C. (Professor in the Graduate School of Public and International Affairs at the University of Ottawa). “Hobbes and International Relations: A Reconsideration.” *International Organization*, Volume 50, Number 2, pgs. 218-220. Spring 1996. [**https://www.jstor.org/stable/2704077**](https://www.jstor.org/stable/2704077). Cho recut from PZ

By themselves, the laws of nature are not enough, not because rational actors cannot trust each other enough to enter into a social contract but because in the condition of epistemological indeterminacy that Hobbes portrays as natural, this universality is at best a partial step. For even if all were to agree on the right to self-preservation, all need not necessarily agree on what comprised threats to that preservation, how to react to them, or how best to secure themselves against them. Conflict is not simply intrinsic to humanity's potential for aggression; nor can it be resolved directly through the utilitarian calcula- tions of competing and conflicting interests. On the contrary, Hobbes believes that the answer lies in recognizing the problem: namely, the inability to resolve objectively the problem of knowing facts and morals in any straightforward manner. Once this is recognized, the stage is set for Hobbes's solution, a solution that lies not-as Donald Hanson has argued-in a flight from politics but rather in an appeal to politics.19 Or, put another way, Hobbes tries to show how rational certainty and skepticism can be paradoxically combined into a solution for politics and a solution by politics. To escape the state of nature, individuals do not simply alienate their "right to everything" to a political authority.20 More fundamentally, what is granted to that authority is the right to decide among irresolvably contested truths: to provide the authoritative criteria for what is and thus to remove people from the state of epistemic and ethical anarchy that form the basis of the state of nature. Hobbes uses his skepticism both to show the necessity of his solution and to destroy (what he views as dogmatic) counterclaims to political authority based upon unsupportable (individual) claims to truth. In arguing against what he views as seditious individual claims against the authority of the sovereign in De Cive, Hobbes puts it in the following way: "the knowledge of good and evil belongs to each single man. In the state of nature indeed, where every man lives by equal right, and has not by any mutual pacts submitted to the command of others, we have granted this to be true; nay, [proved it] ... [But in the civil state it is false. For it was shown. . .] that the civil laws were the rules of good and evil, just and unjust, honest and dishonest; that therefore what the legislator commands, must be held for good, and what he forbids for evil. "21 Earlier in the same work, he phrased the argument even more unequivocally, noting that since "the opinions of men differ concerning meum and tuum, just and unjust, profitable and unprofitable, good and evil, honest and dishonest, and the like; which every man esteems according to his own judgment: 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 evel; that is summarily, what is to be done, what to be avoided in our common course of life." It follows that for Hobbes: "All judgment therefore, in a city, belongs to him who hath the swords; that is, to him who hath the supreme authority."22 These are the fundamental reasons why the sovereign must be unchallenge- able; to rebel is to return to the subjectively relative claim to know and the conflict that this inevitably entails. They also explain why the sovereign ultimately must control language (which defines what is) and clarify Hobbes's repeated stress on the importance of education rather than coercion as the essential element in a successful sovereign's rule.23 Interpretive dissent leads to political dissension and to conflict. In the words of Hobbes's patron, the Earl of Newcastle, "controversy Is a Civil Warr with the Pen which pulls out the sorde soon afterwards. "24

#### Outweighs util

#### 1] Solves skep

#### A] Relativism – the sovereign can arbitrate their truths as objective which secures moral certainty

#### B] Linguistic – obligations are always up to interpretation which means we can never follow them, like how the bible or constitution are heavily debated on. Surrendering judgement solves by declaring the sovereign’s interpretation as objectively true.

#### 2] Solves state of nature – infinite violence occurs over attempts to be the creator of meaning, the sovereign solves by eliminating all disagreements Outweighs under util – the state of nature is definitionally the epitome of pain.

#### That outweighs:

#### A] Abduction – even if util is true and motivating, they can’t explain why we don’t follow it. Answering this negates – If we were actually motivated by utilitarian obligations then the squo would be the best state of affairs.

#### B] hijacks lexical pre-req – even if util is true we can’t ever use it because we fear for our bodily security.

#### Negate

#### 1] Many Sovereigns oppose the aff --

#### 2] IP rights are crucial to sovereign arbitration.

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.

#### My offense o/ws on specificity because only our fw answers the question of government obligations. Their framework can’t solve skep which results impossible calculus and moral permissibility.

## 4.

#### The standard is *intending to maximize expected well-being*. Morality must be binding else it can’t be enforced so there’s no reason to follow moral codes and it can’t be called an obligation nor guide action.

#### Next, util relies on intentions to be coherent –

#### 1] Util relies on choosing between predictions, which presupposes the intention to make the world a better place. Proves its inescapable – ignoring it justifies rolling dices to decide actions by flattening the value of predictions.

#### 2] Consequentialist frameworks are contingent on events that are ever-changing, so they can’t be the basis of consistent duty. Outweighs – (a) butterfly effect means unforeseen consequences are inevitable (b) utility monster – you wouldn’t be culpable for making the world a better place if a satanic creature derived infinite pleasure from human suffering (c) Endpoints – Consequences cause infinite other consequences – the decision to stop calculating at some point is an intention.

#### 3] Solipsism paradox – pleasure can only be binding for the person experiencing it – aggregation requires that we care for others which is an intention. Else states only care about themselves so the aff will get rolled back since otherwise self-interested states would’ve already passed the aff, so negate on presumption.

#### Negate – they say states don’t have intentions which triggers permissibility as it makes util incoherent.

## 5.

#### 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.

#### **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.**

1. <http://dictionary.reference.com/browse/negate>, <http://www.merriam-webster.com/dictionary/negate>, <http://www.thefreedictionary.com/negate>, <http://www.vocabulary.com/dictionary/negate>, <http://www.oxforddictionaries.com/definition/english/negate> [↑](#footnote-ref-1)
2. *Dictionary.com – maintain as true, Merriam Webster – to say that something is true, Vocabulary.com – to affirm something is to confirm that it is true, Oxford dictionaries – accept the validity of, Thefreedictionary – assert to be true* [↑](#footnote-ref-2)
3. https://www.merriam-webster.com/dictionary/trade [↑](#footnote-ref-3)
4. https://www.merriam-webster.com/dictionary/world [↑](#footnote-ref-4)
5. https://www.merriam-webster.com/dictionary/reduce [↑](#footnote-ref-5)
6. https://www.dictionary.com/browse/intellectual [↑](#footnote-ref-6)
7. https://www.dictionary.com/browse/property [↑](#footnote-ref-7)
8. https://www.merriam-webster.com/dictionary/protection [↑](#footnote-ref-8)
9. https://www.dictionary.com/browse/medicine [↑](#footnote-ref-9)