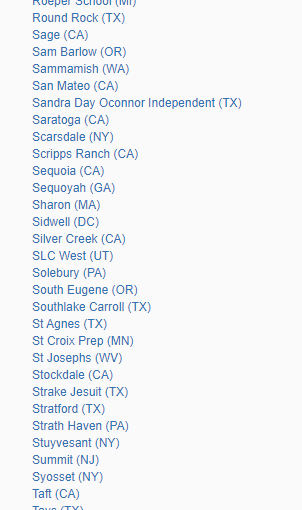
### 1

#### Interpretation: debaters must have contact info disclosed on the wiki under their school name

#### Violation: they don’t

#### Screenshots in the doc –



#### Standards

#### 1 – resource inequities – debaters from lower resourced schools don’t have access to backfiles to contest any aff w/o prep time – means that your model of non disclosure kills fairness bc small school debaters can’t access your method.

#### 2 – ev ethics – we don’t know if you’re miscutting/misrepresenting ev bc we can’t check your research preround. In-round prep doesn’t solve bc there’s no way we can read all of your articles in 5 minutes. Ev ethics controls the internal link to debate & fairness & education. Miscutting ev hurts fair access to the ballot and creates uneducational rounds bc we aren’t learning abt the topic, we’re learning about the ways you choose to misrepresent the topic

#### 3 – accessibility – not all debaters process info the same way – their model of disclosure excludes PWD and debaters who need extra time to process things. Comes as a prior question to any of their offense bc you can’t have debate without debaters, and their model pushes people out

#### Voters:

#### 1 – fairness – necessary for debate – the judge has to determine the better debater, not the better cheater

#### 2 – education – it’s the reason schools fund debate – uq true of the valley soph rr – it’s meant to be an educational experience

#### Paradigm issues:

#### 1 – drop the debater – dta doesn’t make sense bc the shell indicts their entire arg

#### 2 – competing interps – reasonability invites judge intervention

#### 3 – no rvis – a) incentivizes theory baiting, b) detracts from substantive debates, c) sets bad norms that incentivize being as abusive as possible and then winning the theory page

### 2

#### Counterplan Text: The member nations of the World Trade Organization ought to 1] reduce intellectual property protections for medicines except for dual-use biotechnologies and 2] offer a 3 year patent extension on dual use biotechnologies conditioned on accompanying countermeasures.

#### The counterplan incentivizes development into countermeasures and removes terrorist access to biotechnologies.

Million-Perez, H. (2016). Addressing duel-use technology in an age of bioterrorism: Patent extensions to inspire companies making duel use technology to create accompanying countermeasures. AIPLA Quarterly Journal, 44(3), 387-436. Rachael Million-Perez is an associate with Fitzpatrick, Cella, Harper & Scinto and a graduate of the George Washington University Law School. //sid

Although previous congressional proposals, Acts, and committees aimed to fund and incentivize countermeasures, each failed to target dual-use technology countermeasure development. This article proposes, therefore, that the USPTO offer a patent-term extension for patents directed to dual-use technology on the condition that the patent owner creates an accompanying countermeasure. This article argues for an extension of three years 251 for patent owners who meet this condition in addition to any patent-term adjustments afforded to the patent owner pursuant to Title 35 of the U.S. Code or legislative acts. A. Patent Extension for Dual-Use Technologies in Exchange for an Accompanying Countermeasure is an Appropriate and Realistic Incentive that Could Yield Significant Benefit The conditional patent-term extension proposed here provides an incentive that will: (1) reduce unbridled accessibility to dual-use technologies, (2) make countermeasure development an attractive and cost-effective business investment, and (3) take advantage of companies and individuals who currently specialize in the dual-use technology field, and who possess the necessary resources to create accompanying counter-measures. The conditional patent-term extension proposed here provides an incentive that will reduce unbridled accessibility to dual-use technologies. Although accessibility to dual-use technology is essentially ungovernable in the Internet age, providing a three-year patent-term extension to a dual-use technology will motivate companies to collaborate with the U.S. Government to identify and enjoin individuals infringing their patented dual-use technology. As a result, biohackers and terrorist organizations will have diminished access to these technologies. Dissimilar to previous and current countermeasure incentives, the conditional patent-term extension proposed here will make countermeasure development an attractive and cost-effective business investment, because it will be easily applicable, lower the financial risk of countermeasure development, and potentially lead to profits. Unlike previous incentives, a patent-term extension on a dual-use technology in exchange for creating a countermeasure to that technology presents a simple and easily-applicable business model. Private companies need not contort themselves to meet the demands of legislation, like Project BioShield. Rather, a patent-term extension on the dual-use technology will be granted when the company identifies a dual-use quality of one of its innovations and opts to develop a countermeasure to the dual use of that specific innovation. Upon successful development of a countermeasure, the USPTO will then extend the company's dual use technology patent. Because the company likely has already received approval of the dual-use technology, it need not worry about whether the extension is affected by the countermeasure's approval time. The simplicity of this proposed regime would attract companies and individuals frustrated with other complicated or inapplicable incentives. In addition, the length and specificity of this proposed extension renders it a strong incentive that will lower the financial risk of countermeasure investment. The length of patent-term extension incentive must be able to generate participation by virtually guaranteeing a return on the company's investment in countermeasure production. As discussed above, the risk of countermeasure development is incredibly high, and thus the promise that a company may recoup or even profit from developing a countermeasure will entice companies who had previously avoided countermeasure investment.253 For these reasons, this article proposes a three-year patent term extension. Recent studies showed an increase in domestic R&D investment and new pharmaceutical product development when the patent-term extension changed from seventeen years to twenty years in both the United States and Canada.254 A similar surge may occur for dual-use technology countermeasure investment under the proposed extension. Over the additional three years of the patent term, companies are likely to receive the benefit of extending their monopoly on a profitable dual-use technology such that the company will likely recoup countermeasure development costs and, potentially, profit. As a result, dual-use technology countermeasure production is likely to increase. Additionally, proponents of patent extension, like Dr. Josh Bloom, Director of Chemical and Pharmaceutical Sciences at the American Council on Science and Health, contend that three-year patent extensions are likely appropriate for patents related to the company's portfolio.255 Unlike previous and current countermeasure incentives, the extension proposed here would neither under- nor over-compensate companies. For example, the six-month to two-year extension- offered in S. 975 and S. 3-are too short in length to ensure both that small and large companies find the incentive desirable.25 6 A three-year extension, however, would further assure that any size company would recoup its investment. Furthermore, unlike a wild card patent extension, which would permit a company to extend the life of any blockbuster product and thus accrue arguably unwarranted financial gain, under this proposal a company can only extend the life of a narrowly defined dual-use technology. A dual-use technology may or may not be a blockbuster. The chances that a dual-use technology has blockbuster status, however, are slim, considering only around 30 percent of newly-introduced pharmaceutical drugs have profits that exceed average R&D costs.257 As a result, large companies do not have an unfair advantage, nor do small companies have an unfair disadvantage. Rather, if a dual-use technology is not a blockbuster, both smaller biotechnology companies, with less than $500 million in annual revenue, and large companies will need a patent extension lengthy enough to guarantee cost recoup.258 Therefore, unlike the previously proposed extensions, three-year extensions to a dual-use technology patent will afford companies a considerable, yet fair, return on their investment in countermeasure development. A conditional patent-term extension like the one proposed here will also leverage companies' expertise and resources. Because a countermeasure to a dual-use technology will likely require the same expertise and resources used to develop the dual-use technology, a company may avoid some R&D costs when it develops both. Furthermore, tapping into a company's foundation of expertise and resources may expedite production of countermeasures to dual-use technology. Unlike acquiring separate countermeasures via mergers or acquisitions, using this expertise and resources springboard for countermeasure 259 The Monsanto herbicide, Roundup@, and the Roundup Ready@ crops genetically modified to be resistant to Roundup illustrates when a patent owner could be taking advantage of her expertise and resources. In the 1970s, Monsanto created the Roundup herbicide farmers use today.260 By the mid-90's, Monsanto neared the expiration date on its patent of Roundup and faced the possibility of losing the production rights of the blockbuster.261Yet Monsanto was able to use genetic engineering to create Roundup-Ready crops resistant to Roundup in 1996.262 In particular, Monsanto was able to create these plants after working on its herbicide when one of its scientists accidentally discovered Roundup-resistant bacteria. 263 Exploiting this discovery, the company worked diligently to splice the 26 resistant gene into a working plant model. 4 Because these crops were resistant to Roundup, a farmer used the herbicide in the fields to eliminate unwanted foliage while not harming the main crop. 265 Notably, Monsanto did not make a countermeasure to its herbicide, but similar to Monsanto's ability to create two technologies from a single concept, companies producing dual-use technologies can exploit discoveries made in their pursuit of creating a dual-use technology to eventually create an accompanying countermeasure. In sum, unlike previous countermeasure incentives, the conditional patent-term extension proposed here provides an incentive that reduces terrorist or biohacker accessibility to dual-use technologies, makes countermeasure development an attractive investment, and takes advantage of companies' resources and expertise.

#### Vulnerabilities exposed by COVID have invigorated availability and interest in bioterror, but technical challenges remain as barriers to acquisition.

Koblentz and Kiesel 7/14 [Gregory D. Koblentz (Deputy Director of the Biodefense Graduate Program and Assistant Professor of Government and Politics in the Department of Public and International Affairs at George Mason University) and Stevie Kiesel (Biodefense PhD Student, Schar School of Policy and Government, George Mason University). “The COVID-19 Pandemic: Catalyst or Complication for Bioterrorism?”. Studies in Conflict & Terrorism. Published online 14 Jul 2021. Accessed 7/22/21. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2021.1944023?journalCode=uter20> //Xu]

Since COVID-19 was declared a pandemic in March 2020, there has been no major bioterrorist incident that challenges or validates the core beliefs of the optimists, pessimists, or pragmatists. Extremists with violent apocalyptic or accelerationist ideologies—chiefly jihadists and far-right extremists—have sought to capitalize on the pandemic, but they still rely on conventional weapons. Based on available open-source information, terrorist interest in weaponizing SARS-CoV-2 seems limited. While some individuals and groups who subscribe to violent apocalyptic or accelerationist ideologies have shown some interest in crudely spreading the virus, most terrorists have sought to exploit the conditions the pandemic created rather than the virus itself. An increase in the risk of bioterrorism cannot be completely discounted as the equipment, knowledge, and expertise to work with high-risk pathogens is increasingly available and there are a small number of groups with the ideologies and objectives consistent with the use of biological weapons. Still, important technical barriers to acquiring and using a biological weapon capable of causing mass casualties, even far below the effects of a pandemic pathogen, will remain even after the pandemic is contained. While COVID-19 graphically demonstrated the vulnerability of modern societies to infectious diseases, the lessons learned from this experience, if properly implemented, should significantly improve the capability of governments around the world to detect and respond to future pandemics as well as deliberate disease outbreaks. Counterterrorism and biodefense efforts should not be dictated by the latest “‘risk of the month’ policies crafted in the wake of visible or highly publicized events.”117 Instead, strategies for reducing the likelihood and consequences of bioterrorism in the wake of the COVID-19 pandemic should be based on a realistic appraisal of the risk and investments should be optimized to strengthen preparedness against the full spectrum of biological threats.

#### IP protections are the only limit on proliferating dual-use biotech – losing patents puts financial pressure on companies to outsource R&D, which skyrockets bioterror acquisition.

Finlay 10 [Brian Finlay (President and Chief Executive Officer of the Stimson Center, M.A. from the Norman Patterson School of International Affairs at Carleton University, a graduate diploma from the School of Advanced International Studies, the Johns Hopkins University and an honors B.A. from Western University in Canada). “The Bioterror Pipeline: Big Pharma, Patent Expirations, and New Challenges to Global Security”. The Fletcher Forum of World Affairs. Vol. 34, No. 2 (Summer 2010), pp. 51-64. <https://www.jstor.org/stable/45289504?seq=1#metadata_info_tab_contents> //Xu]

Until recently, these investment risks were frequently mitigated by income generated from past drug development successes. In most markets, that income was guaranteed by strict patent protections that closed the window to outside competition for a set period of time. More recently, however, the uncertainty of R&D investments has been complicated not only by the global economic downturn, but more importantly by looming patent expirations that will open many of big pharma's patent-protected drugs to generic competition. Between 2007 and 2012, more than three dozen drugs will lose patent protection, removing an estimated $67 billion from big pharma's annual sales.33 With existing drug development pipelines unable to fill the gaps, biopharmaceutical companies are under intense pressure not only to cut costs - which would provide only temporary relief to the bottom line - but also to rapidly replenish their development pipelines. Some industry analysts have described this "perfect storm" as an "existential" moment for big pharma.34 Many pharmaceutical companies have approached this challenge by accelerating and widening the outsourcing and off-shoring of both R&D and manufacturing, and by aggressively buying promising assets from small biotech companies through acquisitions and strategic alliances. Interestingly, these partnerships are less frequently linked with American or even Western-owned and-operated companies than in the past. Many pharmaceutical giants like Indiana-based Eli Lilly are turning to alliances with firms in Asia and elsewhere around the world, outsourcing key technical operations. Instead of functioning as fully integrated firms, big pharma companies have found value in networked relationships with independent small to large firms, universities, and non-profit biotechnology laboratories around the globe.35 The net result has accelerated technology proliferation - for both beneficial and nefarious uses - far beyond the traditional hubs for biotech innovation. Pharma's increasingly desperate search to seed and ultimately acquire innovative new biotechnologies means that foreign (non- Western) markets are pulling ahead in biotech innovation. Indeed, the quantity of biotech companies outside the United States has grown remarkably in recent years: in Israel, the number grew from 30 in 1990 to about 160 in 2000; in Brazil, from 76 in 1993 to 354 in 2001; and remarkably, in South Korea, from one in 2000 to 23 in 2003. 36 More generally, the Asia-Pacific region has emerged as one of the world s fastest-growing biotechnology hubs, with the growth of publicly traded companies handily outpacing growth in the United States and Europe over recent years.37 As fruitful partnerships lead big pharma to increasingly generate resources, technologies, and knowledge, these capacities spin off new competitor firms in a self-executing multiplier effect. With the number of facilities and highly trained individuals increasing, the likelihood of a serious biological accident or nefarious incident will similarly rise, which will be particularly risky when dual-use technologies are introduced into insufficiently regulated markets. CONCLUSIONs In statements, U.S. officials continue to cite several countries believed to have or to be pursuing a biological weapons capability.38 But globalization exports the challenge of bioproliferation far beyond these geographic boundaries and transcends multiple societal layers well beyond government actors. As a result, it is increasingly clear that states no longer have a monopoly on dual-use biological R&D. Recent evidence suggests a growing threat of terrorist acquisition of biological weapons. As technological advancement in the life sciences is progressively pushed into countries of the Global South, some of which are also potential hotbeds for terrorist activity, the nexus of science and terrorism becomes especially acute. While far from perfect, the current system of stringent controls levied by Western governments over the biopharmaceutical sector has proven remarkably effective, especially given the diffusion of technologies and the ease of their redirection for hostile purposes. As the biotech revolution continues to widen, however, advanced industrialized governments are increasingly playing catch-up with changing technological realities. As these technologies proliferate, security analysts have become uneasy with the lack of controls in many states. The dearth of legal controls, the lack of rigor in their enforcement, and the growth in private-actor involvement in dual-use activities has sobering implications for global security.

#### Bioterrorism causes Extinction – overcomes any conventional defense.

Walsh 19, Bryan. End Times: A Brief Guide to the End of the World. Hachette Books, 2019. (Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University)//Elmer

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public again and again. It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

### 3

#### Innovation is doing great now – answers all your warrants.

Lisa Jarvis, 1-17-2020, (Based in Chicago, Lisa has been covering the biotech and pharmaceutical industries at C&EN since 2006. She writes feature articles that weave together the business and science of developing drugs, while also serving as pharmaceuticals editor for the magazine. She has a particular interest in rare diseases, innovative models for drug discovery, and emerging technologies.) "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the past 3 years of approvals represent drug companies’ most productive period in more than 2 decades. Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of new molecular entities (NMEs), making up 67% of overall approvals in 2019, the list also includes several antibody-drug conjugates, an antisense oligonucleotide therapy, and a therapy based on RNA interference (RNAi). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

#### 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

#### Cannabis wipes out superbugs and kills developing mutations, but further research and investments are required.

Sample ’20 [Ian; journalist at New Scientist and worked at the Institute of Physics as a journal editor, PhD in biomedical materials; 1-19-2020; "Cannabis compound could be weapon in fight against superbugs", Guardian; https://www.theguardian.com/society/2020/jan/19/cannabis-compound-could-be-weapon-in-fight-against-superbugs, accessed 4-16-2021]

A compound made by cannabis plants has been found to wipe out drug-resistant bacteria, raising hopes of a new weapon in the fight against superbugs. Scientists screened five cannabis compounds for their antibiotic properties and found that one, cannabigerol (CBG), was particularly potent at killing methicillin-resistant Staphylococcus aureus (MRSA), one of the most common hospital superbugs. Tests in the lab showed that CBG, which is not psychoactive, killed common MRSA microbes and “persister” cells that are especially resistant to antibiotics and that often drive repeat infections. The compound also cleared up hard-to-shift “biofilms” of MRSA that can form on the skin and on medical implants. Having seen how effective the substance was against bacteria in the lab, the researchers decided to test CBG’s ability to treat infections in animals. In a study that has not yet been published, they found that CBG cured mice of MRSA infections as effectively as vancomycin, a drug widely considered to be the last line of defence against drug-resistant microbes. The study is under review at the ACS Infectious Diseases journal. Eric Brown, a microbiologist who led the work at McMaster University in Hamilton, Ontario, said cannabinoids were “clearly great drug-like compounds”, but noted it was early days in assessing the compounds for use in the clinic. “There is much work to do to explore the potential of the cannabinoids as antibiotics from the safety standpoint,” he said. Antibiotic resistance has become a major threat to public health. England’s former chief medical officer Dame Sally Davies has said the loss of effective antibiotics would lead to “apocalyptic scenarios”, with patients dying from routine infections and many operations becoming too risky to perform. In the study, the researchers describe how the rapid global spread of drug resistance, caused by microbes developing mutations that protect them against antibiotics, has driven an urgent need to explore new sources of drugs. Among antibiotics in use today, the newest date back to discoveries made more than 30 years ago.

#### Only CBD solves superbugs.

Stevens ’21 [Kylie; reporter covering medical breakthrough by Researchers at University of Queensland’s Institute for Molecular Bioscience and the peer-reviewed Communications Biology journal; 1-19-2021; Mail Online; https://www.dailymail.co.uk/news/article-9165415/Medical-breakthrough-revealed-cannabis-kill-superbugs-save-10million-lives-year.html, accessed 4-16-2021; RG]

Laboratory studies have shown synthetic cannabidiol, the main nonpsychoactive component of cannabis better known as CBD can kill bacteria in diseases such as gonorrhea, a sexually transmissible infection. The research has been hailed as a potential world medical breakthrough, amid predictions drug-resistant infections could result in 10 million deaths worldwide a year by 2050 unless an alternate treatment is found. The research, recently published in the Communications Biology journal is part of a collaboration between Queensland researchers and Botanix Pharmaceuticals, which lead to the first new class of antibiotics for resistant bacteria in 60 years. 'This is the first time CBD has been shown to kill some types of Gram-negative bacteria. These bacteria have an extra outer membrane, an additional line of defence that makes it harder for antibiotics to penetrate,' Institute for Molecular Bioscience director Dr Mark Blaskovich said in a statement. Researchers also discovered cannabidiol is effective in killing off superbug MRSA found in golden staph bacteria. It may also be used to treat infected diabetic ulcers and wounds. 'Cannabidiol showed a low tendency to cause resistance in bacteria even when we sped up potential development by increasing concentrations of the antibiotic during 'treatment,' Dr Blaskovich added. 'We think that cannabidiol kills bacteria by bursting their outer cell membranes, but we don't know yet exactly how it does that, and need to do further research.'

### 4

#### The standard is maximizing expected wellbeing.

#### 1] Death is bad and outweighs – a] agents can’t act if they fear for their bodily security which constrains every ethical theory, b] it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life

#### 2] Pleasure and pain are the starting point for moral reasoning—they’re our most baseline desires and the only things that explain the intrinsic value of objects or actions

Moen 16, Ole Martin (PhD, Research Fellow in Philosophy at University of Oslo). "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267.

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative. 2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good. 3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value. Although pleasure and pain thus seem to be good candidates for intrinsic value and disvalue, several objections have been raised against this suggestion: (1) that pleasure and pain have instrumental but not intrinsic value/disvalue; (2) that pleasure and pain gain their value/disvalue derivatively, in virtue of satisfying/frustrating our desires; (3) that there is a subset of pleasures that are not intrinsically valuable (so-called “evil pleasures”) and a subset of pains that are not intrinsically disvaluable (so-called “noble pains”), and (4) that pain asymbolia, masochism, and practices such as wiggling a loose tooth render it implausible that pain is intrinsically disvaluable. I shall argue that these objections fail. Though it is, of course, an open question whether other objections to P1 might be more successful, I shall assume that if (1)–(4) fail, we are justified in believing that P1 is true itself a paragon of freedom—there will always be some agents able to interfere substantially with one’s choices. The effective level of protection one enjoys, and hence one’s actual degree of freedom, will vary according to multiple factors: how powerful one is, how powerful individuals in one’s vicinity are, how frequent police patrols are, and so on. Now, we saw above that what makes a slave unfree on Pettit’s view is the fact that his master has the power to interfere arbitrarily with his choices; in other words, what makes the slave unfree is the power relation that obtains between his master and him. The difﬁculty is that, in light of the facts I just mentioned, there is no reason to think that this power relation will be unique. A similar relation could obtain between the master and someone other than the slave: absent perfect state control, the master may very well have enough power to interfere in the lives of countless individuals. Yet it would be wrong to infer that these individuals lack freedom in the way the slave does; if they lack anything, it seems to be security. A problematic power relation can also obtain between the slave and someone other than the master, since there may be citizens who are more powerful than the master and who can therefore interfere with the slave’s choices at their discretion. Once again, it would be wrong to infer that these individuals make the slave unfree in the same way that the master does. Something appears to be missing from Pettit’s view. If I live in a particularly nasty part of town, then it may turn out that, when all the relevant factors are taken into account, I am just as vulnerable to outside interference as are the slaves in the royal palace, yet it does not follow that our conditions are equivalent from the point of view of freedom. As a matter of fact, we may be equally vulnerable to outside interference, but as a matter of right, our standings could not be more different. I have legal recourse against anyone who interferes with my freedom; the recourse may not be very effective—presumably it is not, if my overall vulnerability to outside interference is comparable to that of a slave— but I still have full legal standing.68 By contrast, the slave lacks legal recourse against the interventions of one speciﬁc individual: his master. It is that fact, on a Kantian view—a fact about the legal relation in which a slave stands to his master—that sets slaves apart from freemen. The point may appear trivial, but it does get something right: whereas one cannot identify a power relation that obtains uniquely between a slave and his master, the legal relation between them is undeniably unique. A master’s right to interfere with respect to his slave does not extend to freemen, regardless of how vulnerable they might be as a matter of fact, and citizens other than the master do not have the right to order the slave around, regardless of how powerful they might be. This suggests that Kant is correct in thinking that the ideal of freedom is essentially linked to a person’s having full legal standing. More speciﬁcally, he is correct in holding that the importance of rights is not exhausted by their contribution to the level of protection that an individual enjoys, as it must be on an instrumental view like Pettit’s. Although it does matter that rights be enforced with reasonable effectiveness, the sheer fact that one has adequate legal rights is essential to one’s standing as a free citizen. In this respect, Kant stays faithful to the idea that freedom is primarily a matter of standing—a standing that the freeman has and that the slave lacks. Pettit himself frequently insists on the idea, but he fails to do it justice when he claims that freedom is simply a matter of being adequately (and reliably) shielded against the strength of others. As Kant recognizes, the standing of a free citizen is a more complex matter than that. One could perhaps worry that the idea of legal standing is something of a red herring here—that it must ultimately be reducible to a complex network of power relations and, hence, that the position I attribute to Kant differs only nominally from Pettit’s. That seems to me doubtful. Viewing legal standing as essential to freedom makes sense only if our conception of the former includes conceptions of what constitutes a fully adequate scheme of legal rights, appropriate legal recourse, justiﬁed punishment, and so on. Only if one believes that these notions all boil down to power relations will Kant’s position appear similar to Pettit’s. On any other view—and certainly that includes most views recently defended by philosophers—the notion of legal standing will outstrip the power relations that ground Pettit’s theory.

#### 3] Extinction outweighs

MacAskill 14 [William, Oxford Philosopher and youngest tenured philosopher in the world, Normative Uncertainty, 2014]

The human race might go extinct from a number of causes: asteroids, supervolcanoes, runaway climate change, pandemics, nuclear war, and the development and use of dangerous new technologies such as synthetic biology, all pose risks (even if very small) to the continued survival of the human race.184 And different moral views give opposing answers to question of whether this would be a good or a bad thing. It might seem obvious that human extinction would be a very bad thing, both because of the loss of potential future lives, and because of the loss of the scientific and artistic progress that we would make in the future. But the issue is at least unclear. The continuation of the human race would be a mixed bag: inevitably, it would involve both upsides and downsides. And if one regards it as much more important to avoid bad things happening than to promote good things happening then one could plausibly regard human extinction as a good thing.For example, one might regard the prevention of bads as being in general more important that the promotion of goods, as defended historically by G. E. Moore,185 and more recently by Thomas Hurka.186 One could weight the prevention of suffering as being much more important that the promotion of happiness. Or one could weight the prevention of objective bads, such as war and genocide, as being much more important than the promotion of objective goods, such as scientific and artistic progress. If the human race continues its future will inevitably involve suffering as well as happiness, and objective bads as well as objective goods. So, if one weights the bads sufficiently heavily against the goods, or if one is sufficiently pessimistic about humanity’s ability to achieve good outcomes, then one will regard human extinction as a good thing.187 However, even if we believe in a moral view according to which human extinction would be a good thing, we still have strong reason to prevent near-term human extinction. To see this, we must note three points. First, we should note that the extinction of the human race is an extremely high stakes moral issue. Humanity could be around for a very long time: if humans survive as long as the median mammal species, we will last another two million years. On this estimate, the number of humans in existence in the The future, given that we don’t go extinct any time soon, would be 2×10^14. So if it is good to bring new people into existence, then it’s very good to prevent human extinction. Second, human extinction is by its nature an irreversible scenario. If we continue to exist, then we always have the option of letting ourselves go extinct in the future (or, perhaps more realistically, of considerably reducing population size). But if we go extinct, then we can’t magically bring ourselves back into existence at a later date. Third, we should expect ourselves to progress, morally, over the next few centuries, as we have progressed in the past. So we should expect that in a few centuries’ time we will have better evidence about how to evaluate human extinction than we currently have. Given these three factors, it would be better to prevent the near-term extinction of the human race, even if we thought that the extinction of the human race would actually be a very good thing. To make this concrete, I’ll give the following simple but illustrative model. Suppose that we have 0.8 credence that it is a bad thing to produce new people, and 0.2 certain that it’s a good thing to produce new people; and the degree to which it is good to produce new people, if it is good, is the same as the degree to which it is bad to produce new people, if it is bad. That is, I’m supposing, for simplicity, that we know that one new life has one unit of value; we just don’t know whether that unit is positive or negative. And let’s use our estimate of 2×10^14 people who would exist in the future, if we avoid near-term human extinction. Given our stipulated credences, the expected benefit of letting the human race go extinct now would be (.8-.2)×(2×10^14) = 1.2×(10^14). Suppose that, if we let the human race continue and did research for 300 years, we would know for certain whether or not additional people are of positive or negative value. If so, then with the credences above we should think it 80% likely that we will find out that it is a bad thing to produce new people, and 20% likely that we will find out that it’s a good thing to produce new people. So there’s an 80% chance of a loss of 3×(10^10) (because of the delay of letting the human race go extinct), the expected value of which is 2.4×(10^10). But there’s also a 20% chance of a gain of 2×(10^14), the expected value of which is 4×(10^13). That is, in expected value terms, the cost of waiting for a few hundred years is vanishingly small compared with the benefit of keeping one’s options open while one gains new information.

### Case

#### AT SV First -

#### 1---Prefer util---even if its flawed, alternatives are worse because they justify the same ends but create decision paralysis, and requires saying some lives are more valuable than others, which turns all their impacts

#### IP laws are key to prevent the development and spread of counterfeit drugs.

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The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation of fraudulent and dangerous goods. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses, as this is the most responsible way to bring their technologies to the world and safeguard global health. In addition, as the COVID-19 pandemic continues there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups have been producing fake drugs and medical products and selling them for lucrative profits in developing countries.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected**, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness and death for the individual and the retardation of herd immunity for the population at large. Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and reducing trust in vaccines.