#### Permissibility and Presumption negate: 1 Obligations – the resolution indicates the affirmative has to prove an obligation, and permissibility would deny the existence of an obligation – burden of proof proves 2 Falsity – Statements are more often false than true because proving one part of the statement false disproves the entire statement. Presuming all statements are true creates contradictions which would be ethically bankrupt. 3 Negating is harder – Aff gets last speech to crystallize and shape the debate in a way the favors them with no 3NR

#### 1~ Text – Ought is defined as expressing obligation which means absent a proactive obligation you vote neg since the aff can't prove an obligation. O/W since text is the only thing we have access to prior to the round.

#### 2~ Safety – It's ethically safer to presume the squo since we know what the squo is but we can't know whether the aff will be good or not if ethics are incoherent.

#### 3~ Real world – Policymakers don't pass policies they aren't sure about, they shelve them for later.

## **Innovation DA (evergreening)**

#### Innovation is high and increasing – motivated by monetary incentives

**Swagel 21** Swagel , Philip L. “Research and Development in the Pharmaceutical Industry.” *Congressional Budget Office*, Apr. 2021,

www.cbo.gov/publication/57126. This Congressional Budget Office report was prepared at the request of the Chairman of the Senate Committee on Finance. In accordance with CBO’s mandate to provide objective, impartial analysis, the report makes no recommendations. David Austin and Tamara Hayford prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis. Anna Anderson-Cook (formerly of CBO), Colin Baker, Paul Burnham, Julia Christensen, Michael Falkenheim, Sebastien Gay, Ryan Greenfield, Stuart Hammond, Evan Herrnstadt, Leo Lex, Paul Masi, John McClelland, Lara Robillard, Ellen Werble, Chapin White, and Katherine Young provided useful comments. Pierre Azoulay of the Sloan School of Management at the Massachusetts Institute of Technology, Peter Bach of the Memorial Sloan Kettering Cancer Center, and Craig Garthwaite of the Kellogg School of Management at Northwestern University provided helpful comments on the draft. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.) Jeffrey Kling reviewed the report. The editor was Caitlin Verboon, and R. L. Rebach was the graphics editor and cover illustrator. The report is available on CBO’s website (www.cbo.gov/publication/57025).

The **pharmaceutical industry devoted $83 billion to R&D** expenditures **in 2019**. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. **That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. **Many** specialty drugs **are** biologics (large-molecule drugs based on living cell lines), which are **costly to develop, hard to imitate, and frequently have high prices**. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. Drug companies’ **R&D spending** decisions **depend on** three main factors: **Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs**. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly** **and uncertain process, and** **many potential drugs never make it to market**. **Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally**, the patent system** and certain statutory provisions that delay FDA approval of generic drugs **provide pharmaceutical companies with a period of market exclusivity** when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could**, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular**, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. In real terms, private **investment** in drug R&D **among** member firms of the **Pharma**ceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about **$83 billion in 2019, up** from about **$5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total **R&D spending by all drug companies has trended upward,** small and large firms generally focus on different R&D activities. Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs, many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting post approval testing for safety-monitoring or marketing purposes.

#### The aff’s wholesale attack on secondary patents destroys innovation – prefer contingencies that solve evergreening

**Holman 18** Holman , Christopher M. “Why Follow-on Pharmaceutical Innovations Should

Be Eligible for Patent Protection.” *Intellectual Property Watch*, 21 Sept. 2018, www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/. Chris Holman joined the UMKC faculty in 2005, and his primary research focus lies at the intersection of intellectual property and biotechnology. He has published numerous articles in law reviews and scientific publications such as Science, Cell and Nature Biotechnology, and has authored amicus briefs in a number of important biotechnology patent cases at the Supreme Court and Federal Circuit. In 2008 he was awarded the Daniel L Brenner Faculty Publishing Award for an influential law review article on human gene patent litigation. Professor Holman has taught classes in patent law, copyright law, intellectual property survey, antitrust, biotechnology and pharmaceutical law, and law science and technology. He is a faculty advisor for the law school’s Intellectual Property Emphasis Area, and helps oversee the IP clinic. Prior to becoming a law professor, Holman served as vice-president of intellectual property and patent counsel at several Silicon Valley biotechnology companies and worked as an associate at a major intellectual property law firm. He was also a tenure-track chemistry professor in the California State University system. A native of California, Holman received his Ph.D. in biochemistry and molecular biology from the University of California at Davis, and engaged in post-doctoral drug discovery research at Roche Biosciences in Palo Alto, Calif. He then attended law school at UC Berkeley’s Boalt Hall, during which time he was an associate editor for the Berkeley Technology Law Journal and served as a full-time judicial extern in federal court in the Northern District of California.

The **attack on secondary pharmaceutical patents is based** in part **on the flawed premise that follow-on innovation is of marginal value at bes**t, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient**. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients.** A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as **the “first breakthrough in AIDS therapy**.” AZT **began** its life as **a failed attempt at a cancer drug**, and it was only **years later** that its potential application in the fight against AIDS was realized. **Follow-on research resulted in a** method-of-use **patent** directed towards the use of AZT in the treatment of AIDS, and it was this patent **that incentivized the investment necessary** **to bridge the gap between a promising** drug **candidate** **and a safe, effective,** and FDA-approved **pharmaceutical**. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate**. Other examples** of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent **include Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), **and** an orally-administrable formulation of the **antibiotic cefuroxime**. Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation**. Critics of secondary patents downplay the significance of extended-release formulations,** claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate). “**Evergreening” – an Incoherent Concept Drug innovators are often accused of** using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this **is a false assumption** — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. **Once the patents covering the original formulation have expired, generic companies are free to market a generic version** of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, **if a drug company is found to have engaged in some anticompetitive activity to block generic competition** in the market for the original product once it has gone off patent, then antitrust and competition **laws** should be **invoked to address that problem.** If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that **misuse of the patent system** which **should be addressed directly**, **rather** **than** through what amounts to **an attack on the patent system itself**. Compatibility with TRIPS The heightened requirements of patentability proposed in the Guidelines not only pose a threat to important follow-on pharmaceutical innovation, but if they were to be adopted could constitute noncompliance with certain international treaties, including in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), which the 164 Members of the World Trade Organization (WTO) have agreed to abide by. The TRIPS Agreement requires WTO Members to provide certain minimum levels of protection for patentable inventions, thus placing substantive limitations on the ability of WTO Members to raise the bar for patentability. The TRIPS Agreement in no way sanctions subject matter-specific heightened requirements of patentability; to the contrary, the antidiscrimination provision in the TRIPS Agreement affirmatively precludes such measures. Unfortunately, this point is all too often lost in discussions of international and domestic patent policy.

## Incentives CP

#### CP text: The member nations of the World Trade Organization ought to raise the inventiveness standard for granting secondary patents for medicines.

#### The “inventiveness” standard outlines how much a drug must improve to be re-patented. Increasing the standard allows for generic drug competition while maintaining innovation.

Christensen 20 [Connor Christensen, "The Evergreen Forests of Insulin Patents", Awakenwfu, The Creative Journal of Contemporary Bioethics, 9-14-2020, https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/, accessed: 9-7-2021.] //CHSTM and Lex VM

A potential solution to prevent patent evergreening would be to modify the “inventiveness” standard required to obtain a new patent on drugs.[[27]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn27) By modifying this standard, the goal would be to stop non-inventive and commonly practiced pharmaceutical techniques from receiving patent protection.[[28]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn28) Moreover, each incremental improvement must be worth the burden on the consumer, especially in a country where the price of insulin has reached unconscionable levels.[[29]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn29) Therefore, to be considered inventive, the newer formula or methodology should be demonstratively safer or clearly more efficacious.[[30]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn30) Increasing the scrutiny would help control drug companies receiving patents on non-inventive, incremental improvements on insulin while still rewarding them for making sizable leaps forward.[31] Further, increasing the “inventiveness” standard would also encourage generic drug companies to enter the market. Previously, generic companies were precluded from producing generic insulins because patents protected the original formulas for such long periods of time that they were obsolete when it became possible to make a generic version.[[32]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn32) These obsolete versions of insulin were not viewed as a worthwhile investment to generic drug companies, so the market has been mostly devoid of generic versions.[[33]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn33) However, generic drug companies have shown some interest in creating generic versions of the next-generation of insulin. Reducing evergreening by raising the inventiveness standard required for new insulin patents could be enough to make manufacturing generics a worthwhile investment.[[34]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn34) Affording greater scrutiny to the issue of whether an incremental improvement is truly “inventive” is just one piece of the solution to reducing the price of insulin to affordable levels. Evergreens are a symbol of vitality; the irony is tangible that something of the same name can be depriving people of life.

#### It’s competitive – the cp modifies IPR, it’s not a net decrease –

#### Reduce is defined as an annulment of IPR.

#### Black’s Law 90 [Black’s Law Dictionary 2ND ED. “Reduce” <https://dictionary.thelaw.com/reduce/> Elmer In Scotch law.] To rescind or annul. Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide>] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues. Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6 What about SPACs? The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story. Fundamentals continue strong When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances. In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development. Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries. Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising. For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic. More innovation on the horizon The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science. Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### IPR key to innovation.

Bacchus 20 [(James, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland) "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, 12-16-2020, https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines] TDI

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16) This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor[to innovation] is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19) As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (

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#### COVID accelerated biopharma R&D

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The COVID-19 pandemic has had a significant disruptive effect on clinical trial operations, with biopharma companies, clinical research organizations (CROs), and other research organizations being forced to shut down trials, suspend enrollment, or delay planned study startups or completions (an estimated 1,210 trials have been negatively affected across the industry). However, the pandemic has also accelerated the adoption of new approaches to R&D with the development of a number of novel COVID-19 vaccines and therapies in record time through extraordinary collaboration and partnerships, as well as a wider use of transformative approaches such as master protocols and adaptive trial design and the use of real-world data (RWD). The positive learnings arising from the COVID-19 pandemic have sown the seeds of change for a more productive future for biopharma R&D. Moreover, the accelerated development of COVID-19 therapies and vaccines is expected to have a positive impact on the internal rate of return (IRR) over the coming years.