# T IP Protection

## T Data Exclusivity

#### IP is a specific, definable category which doesn’t include data exclusivity. WTO

“World Trade Organization.” WTO, https://www.wto.org/english/tratop\_e/trips\_e/intel1\_e.htm.

Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. Intellectual property rights are customarily divided into two main areas: (i) Copyright and rights related to copyright.[back to top](https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm#top) The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author. Also protected through copyright and related (sometimes referred to as “neighbouring”) rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work. (ii) Industrial property.[back to top](https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm#top) Industrial property can usefully be divided into two main areas: One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin). The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents). While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users.

# HIF CP

#### Counterplan text: The member nations of the World Trade Organization ought to implement and fund a Health Impact Fund as per the Hollis and Pogge 08 card.

#### Counterplans negate – they are advocating for a plan so any opportunity cost to that plan disproves that the aff is a good idea. They only have to be either textual or functionally competitive – one is enough to prove that it is an opportunity cost – solves for their offense because perms protect against cheaty counterplans

#### The Health Impact Fund would guarantee patent rights and increase profits, while also equalizing the cost of medicines

Hollis & Pogge ’08 - Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008) AT

We propose the Health Impact Fund as the most sensible solution that comprehensively addresses the problems. Financed by governments, the HIF would offer patentees the option to forgo monopoly pricing in exchange for a reward based on the global health impact of their new medicine. By registering a patented medicine with the HIF, a company would agree to sell it globally at cost. In exchange, the company would receive, for a fixed time, payments based on the product’s assessed global health impact. The arrangement would be optional and it wouldn’t diminish patent rights.¶ The HIF has the potential to be an institution that benefits everyone: patients, rich and poor alike, along with their caregivers; pharmaceutical companies and their shareholders; and taxpayers.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PATIENTS¶ The HIF increases the incentives to invest in developing medicines that have high health impact. It directs research toward the medicines that can do the most good. It can also reward the development of new products, and the discovery of new uses for existing products, which the patent system alone can’t stimulate because of inadequate protection from imitation. All patients, rich and poor, would benefit from refocusing the innovation and marketing priorities of pharmaceutical companies toward health impact.¶ Any new medicines and new uses of existing medicines registered for health impact rewards would be available everywhere at marginal cost from the start. Many patients – especially in poor countries, but increasingly in wealthy ones too – are unable to afford the best treatment because it is too expensive. Even if fully insured, patients oft en lack access to medicines because their insurer deems them too expensive to reimburse. The HIF simply and directly solves this problem for registered drugs by setting their prices at marginal cost.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PHARMACEUTICAL COMPANIES¶ Most proposals for increasing access to medicines would reduce the profits of pharmaceutical companies and hence their ability to fund research. The HIF, however, leaves the existing options of pharmaceutical firms untouched. It merely gives them the opportunity to make additional profits by developing new high-impact medicines that would be unprofitable or less profitable under monopoly pricing. Selling such registered medicines at cost, firms won’t be forced to defend a policy of charging high prices to poor people and they won’t be pressured to make charitable donations. With HIF-registered medicines they can instead “do well by doing good”: bring real benefit to patients in a profitable way. Research scientists of these firms will be encouraged to focus on addressing the most important diseases, not merely those that can support high prices.¶ HOW THE HEALTH IMPACT FUND WORKS FOR TAXPAYERS¶ The HIF will be supported mainly by governments, which are supported by the taxes they collect. Taxpayers want value for their money, and the HIF provides exactly that. Because the HIF is a more efficient way of incentivizing the pharmaceutical R&D we all want, total expenditures on medicines need not increase. However, if they do, the reason is that new medicines that would not have existed without the HIF are being developed. The HIF mechanism is designed to ensure that taxpayers always obtain value for money in the sense that any product regis-tered with the HIF will have a lower cost for a given amount of health impact than products outside the HIF. Taxpayers may also benefit from a reduction in risks of pandemics and other health problems that easily cross national borders.

# Innovation DA

The link cards can probably also be used as turns on case

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### Data exclusivity is uniquely key to innovation. Lybecker ‘14

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Biologic medicines are fundamentally different from traditional “small molecule” therapies, presenting a host of new challenges in the design and enforcement of the intellectual property (IP) architecture that will protect them.[2] Protecting the intellectual property of biologics is complicated, difficult, and essential to the future of medicine. This new frontier is also one of the remaining hurdles in the Trans-Pacific Partnership (TPP) Trade Agreement negotiations. The debate over protecting biologics focuses on a proposed twelve years of data exclusivity and the consequences this will have for international trade, global public health, and access to medicines. The nuances of producing biologics greatly complicate the logistics of protecting their intellectual property, making patents alone inadequate for safeguarding their IP. Data exclusivity protection allows for a period of time following marketing approval during which competing firms may not use the innovative firm’s safety and efficacy data, from proprietary preclinical and clinical trial results, to obtain marketing authorization for a generic version of the drug. From the moment when the compound first shows medicinal promise, data is generated and compiled, a process that is both expensive and time consuming. Data exclusivity provides the innovative firm with a period of protection for their investment in clinical trials and data collection, regardless of the length of time required to bring the drug to market. Although complementary, patents and data exclusivity protection incentivize innovation in different ways and serve distinct purposes. Patents provide protection for innovations that meet the standards of patentability and are novel, nonobvious, and useful. In the context of biopharmaceuticals, patents protect both breakthrough discoveries as well as incremental improvements. Due to the length of the drug-development and patent-approval processes, effective patent terms rarely correspond to FDA approval. Accordingly, in some cases innovative therapies may experience patent expiry shortly after making it to market. In contrast, data exclusivity protects the tremendous investments of time, talent, and financial resources required to establish a new therapy as safe and effective. This is accomplished by requiring competing firms seeking regulatory approval of the same or a similar product to independently generate the comprehensive preclinical and clinical trial data rather than rely on or use the innovator’s data to establish safety and efficacy of their competing product. Alternatively, the competing firm may wait a set period of time after which they are able to utilize the innovator’s prior approval in an abbreviated regulatory approval, eliminating the need for independently generated data. Data exclusivity is not an extension of patent rights, and it does not preclude a third party from introducing a generic version of the innovator’s therapy during the data exclusivity period, provided that the innovator’s data is not used to secure marketing approval. Fundamentally, data exclusivity protection incentivizes biopharmaceutical firms to invest the necessary time and financial resources in establishing the safety and efficacy of their product and prevents competitors from free riding on these efforts for a limited period of time. [Kristina] The Hatch-Waxman Act of 1984 provided innovative drug firms with a period of patent extension as well as a period of data exclusivity, in the hopes of providing a return on their investment and an incentive for future innovation.[3] These protections have been crucial to the development of the innovative drugs and therapies that currently enhance and extend life. They are even more critical to the future of the biopharmaceutical industry and the development of biologic medicines that are more targeted and more complex. In an analysis of the appropriate length of data exclusivity, a financial model was utilized to determine how long the exclusivity period must be to provide a typical pioneer biologic a positive return on investment. Drawing on a representative portfolio of pioneer biologics, the break-even period ranges from thirteen to sixteen years.[4] An appropriate period of protection is essential if the promise of biologics is to come to fruition. Beyond the importance of biologics to public health and longevity, innovation is crucial to trade and economic prosperity. As evidence of the importance of these sectors, in 2011 IP-intensive industries exported more than $1 trillion in goods and services, which accounts for approximately seventy-four percent of total 2011 U.S. exports.[5] Moreover, the biopharmaceutical industry is a significant contributor. The biopharmaceutical industry of the United States is the fourth-largest U.S. exporter among IP-intensive industries, with exports valued at $49.4 billion in 2010.[6] Accordingly, the TPP Trade Agreement should include the proposed twelve years of data exclusivity and provide innovative firms with the incentives needed to continue to invest in the breakthrough therapies that will extend and enhance life for years to come. Technology inevitably evolves faster than the legal architecture that surrounds it. The provision of data exclusivity protections is a straightforward legal step to catch up to the science that brings us biologic medicines. Biologic medicines are critical to the healthcare advances of the future, and data exclusivity is vital to innovative biologics. The period of data exclusivity provides innovators with an incentive to invest in the testing data necessary to prove a drug’s safety and efficacy by granting them a measure of certainty that they will enjoy a fixed amount of time during which they maintain proprietary control of the test data that resulted in the approval of its drug before requiring that data be made available to generic imitators. As technology changes to enable the development of new biologic vaccines and therapies, intellectual property protection must also evolve to ensure protection for these products. If we believe in the importance of biologic medicines for the future of healthcare, we must protect them.

#### Comprehensive studies prove that data exclusivity is the best way to ensure innovative future medicines. This turns case. Goldman et al ‘13

Dana P Goldman (Dean of the USC Sol Price School of Public Policy, C. Erwin and Ione L. Piper Chair Leonard D. Schaeffer Director’s Chair, Schaeffer Center for Health Policy & Economics Distinguished Professor of Public Policy, Pharmacy, and Economics) et al., 10-21-2013, "The Benefits From Giving Makers Of Conventional `Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data," PubMed Central (PMC), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334 //Accessed 10/6/2021](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334%20//Accessed%2010/6/2021) //JH

Data exclusivity refers to the period of time after approval of a new drug and before a generic manufacturer can access the clinical trial data that was submitted by the drug's originator during the approval process. Given the high cost of conducting clinical trials, data exclusivity provides strong intellectual property protection to pharmaceutical innovators. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, establishes the process by which generic drug manufacturers can seek approval from the Food and Drug Administration (FDA) to manufacture and market conventional drugs. Conventional drugs are created through chemistry, whereas the term biologics refers to drugs created from living organisms. ¶The Hatch-Waxman Act provides originators of new conventional drugs with five initial years of data exclusivity, and three extra years for supplemental applications, for uses other than the one[s] for which the drug was originally approved. In addition, the Food and Drug Administration Modernization Act of 1997 provides a six-month extension for previously approved drugs when such drugs are subsequently approved for use in pediatric populations. By comparison, the data exclusivity period in Europe is ten years for both conventional drugs and biologics, plus an additional year if a new indication is added for which the drug provides significant clinical benefits compared to existing therapies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) In the United States, biologic drugs were granted a 12-year exclusivity period under the Affordable Care Act. We are not aware of any pending legislation to lengthen data exclusivity for conventional drugs in the US. ¶In 2007, the National Academies of Science and Engineering called for the United States to “adopt the European [data exclusivity] period” of 10–11 years and recommended that research be conducted to determine whether even that period of time is adequate, “given the complexity and length of drug development today.”[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R2) The pharmaceutical company GlaxoSmithKline has proposed fourteen years of data exclusivity for conventional drugs.[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R3) Unfortunately, the health policy literature contains no information about the effects such a policy would have on innovation, longevity, and social welfare. We believe our study is the first to address these issues. ¶Data exclusivity provides intellectual property protection that is distinct from patent protection. In the United States, a patent becomes effective at the date of filing—typically long before clinical trials start—whereas data exclusivity begins on the date a drug is approved for marketing by the FDA. ¶In addition, a patent is subject to challenge. The Hatch-Waxman Act allows a would-be generic competitor to contest the validity of a patent in court. Such litigation now occurs for the vast majority of new drugs, and typically commences shortly after FDA approval.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) Data exclusivity, by contrast, cannot be legally challenged. ¶The duration of the data exclusivity period entails a trade-off between current and future generations. A longer period delays competition from generic drug companies, effectively extending the originator's exclusive position in the marketplace. The prospect of higher profits gives drug companies a stronger incentive to innovate—both to create new drugs and to find new indications for existing products. An increase in innovation, in turn, benefits future generations of consumers. At the same time, however, a delay in generic competition imposes a greater spending burden on current consumers. So an increase in the length of data exclusivity benefits future generations, but at the expense of today's drug consumers. ¶Although some have questioned whether profits drive innovation, empirical evidence strongly supports this relationship. The Orphan Drug Act of 1983, which provides pharmaceutical companies with incentives to develop drugs for treating rare diseases or conditions for which there are small patient populations, was followed by a sharp increase in the number of drugs approved for this market.[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R4) Higher profits from vaccines have been associated with a significant increase in the number of clinical trials to develop new vaccines.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R5) There is also evidence that manufacturers have delayed new drug launches rather than accept a lower anticipated price.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R6) ¶Daron Acemoglu and Joshua Linn[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) concluded that a 1 percent increase in the potential market size for a drug class leads to a 3–4 percent growth in the entry of new drugs.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) To our knowledge, this is the only study that estimates this relationship for the entire drug market. As Darius Lakdawalla and colleagues observe,[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8) the relationship identified by Acemoglu and Linn presumes that increases in the number or share of the aged population (60+ years old) driven by past baby booms or busts also increase innovation in drug classes targeted toward the aged. Moreover, it presumes that pharmaceutical innovation does not drive historical trends such as baby booms of busts; there is no evidence that contradicts this presumption. Applying this relationship between market size and innovation to average sales within a drug class, innovators produce one additional drug for every additional $97.5 million of annual potential revenue. Because the cost of a new conventional drug is estimated to be $800 million,[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R9) innovators require a 12 percent annual return on their investment—within accepted boundaries for the return on capital in the drug industry. ¶In this paper we analyze the effect of a longer period of data exclusivity for conventional drugs on both current and future generations. We do not consider the effects of a change in the data exclusivity period for biologics. We focus on a twelve-year duration because, as noted above, this is data exclusivity period recently approved by Congress for biologics. As such, it serves as a natural benchmark for extended data exclusivity for conventional drugs. ¶We address three specific policy questions: How would extending the initial five years of data exclusivity for new conventional drugs in the United States affect innovation? How would a longer period of data exclusivity affect the health of current and future generations? What is the dollar value of a longer period of data exclusivity to US society?¶ STUDY DATA AND METHODS ¶Our analysis has two main components. First, we estimated the effect of a longer period of data exclusivity on revenues to pharmaceutical companies. We used retrospective data from the drugs@FDA database[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R10) and the FDA Electronic Orange Book[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R11) of approved drug products to construct a representative profile of protection from generic competition during a drug's life cycle. ¶Second, we feed that result into our global pharmaceutical policy model[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8) to determine the effect of increased pharmaceutical revenues on drug innovation and consumers' longevity. The model is a set of dynamic interactions that link present health and innovation to their future values. For example, next year's health status depends on today's health, on the drug treatments that are available, and on a set of random health “shocks” that vary with an individuals' own risk-factors such as age, health behaviors, and current disease conditions. An example of a shock would be exposure to an infection. ¶Following Joseph Lipscomb and colleagues,[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R12) we assume a real (inflation-adjusted) “social” discount rate of 3 percent in our baseline analysis. This discount rate captures the manner in which society discounts benefits in the future compared to benefits today. It is distinct from companies' cost of capital – the amount of interest they need to pay to borrow money – which is typically higher than 3 percent.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R9) ¶For our baseline analysis, we assume an innovation elasticity of 3.0, meaning that a 1 percent increase in expected drug revenue leads to a 3 percent increase in the number of drugs approved within the class each year. This assumption is slightly conservative and understates changes in innovation, longevity, and welfare, relative to the findings of Acemoglu and Linn.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) ¶Increased innovation in turn affects population health. The global pharmaceutical policy model uses the health benefits documented in the clinical literature as a result of recent drugs for seven major conditions (heart disease, hypertension, diabetes, cancer, lung disease, stroke and mental illness). The model also accounts for the increased likelihood of treatment associated with drug innovation. As innovation expands because of greater data exclusivity, the life expectancy of older Americans improves; this improvement results mainly from the increased likelihood of treatment, not the health benefits of new drugs. With longer life expectancy, the population of potential drug users grows, further increasing revenues and stimulating innovation over time. We model innovation and health through 2060. ¶The monetary value of increased longevity, that is, the amount consumers are willing to pay for longer life spans, has long been a subject of debate. An analysis by Richard Hirth and colleagues of attitudes and behavior related to mortality risk showed that the median value of a life-year ranges from $110,200 to $505,400 (in 2004 US dollars).[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R13) Research by Kip Viscusi and Joseph Aldy implies that the value of a life-year ranges from $150,000 to $360,000.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8),[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R14) ¶In our baseline analysis, we assign a monetary value for increased longevity of $200,000 per life-year, though in sensitivity analyses we consider a range of values for this and other parameters. Additional details about our methods, data, and assumptions are provided in a technical appendix.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R15) ¶Limitations ¶Simulations of this sort have certain limitations. Because laws, regulations, science, and medicine are likely to change in unforeseen ways, the retrospective data we relied on may not characterize the future. Some plausible changes, for example, an increase in the number of successful challenges to patent validity,[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) may cause us to understate the effects of longer data exclusivity. Other changes such as government price controls, which would reduce potential profits available to drug companies, may cause us to overstate effects. Still other changes, such as advances or setbacks in science and medicine that are impossible to anticipate, could lead to either understated or overstated effects. ¶We do not model behavioral responses to a longer period of data exclusivity due to the technical complexity and lack of good evidence. For example, a generic drug company might attempt to bypass lengthier data exclusivity periods in the United States by conducting clinical trials of a generic version of an already-approved drug. If drug developers believe that generic manufacturers would behave in this way, our results overstate the long-term effects of longer data exclusivity. ¶We do not model non-mortality benefits, for example, treatments for mental health conditions, pain, and rheumatoid arthritis. Such benefits account for much of the value of many drugs, yet there was insufficient evidence on the non-mortality benefits of new drugs. If these benefits are important, our estimates of the benefits of longer data exclusivity are conservative. ¶Finally, we do not calculate the potential benefits of a data exclusivity period shorter than the current Hatch-Waxman provisions. ¶STUDY RESULTS ¶Applying our findings about increased revenues over a drug's life cycle, we found that extending data exclusivity to twelve years would increase lifetime drug revenues by 5.0 percent on average. ¶[Exhibit 1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F1/) explains how we reached this result. The exhibit shows the proportion of conventional drugs that had protection against generic competition under existing law—arising from either patents or data exclusivity—and the proportion of such drugs that would have had protection if data exclusivity had lasted twelve years. The drugs in our sample began facing generic competition eight years after launch. With a twelve-year period of data exclusivity, by contrast, all the drugs would have faced no generic competition for at least twelve years after launch. ¶We also determined that expanding data exclusivity to twelve years would result in 228 extra drug approvals between 2020 and 2060, relative to the number of approvals that we project under the current Hatch-Waxman data exclusivity provisions. We lay out these data in [Exhibit 2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F2/), which illustrates the impact of increasing the period of data exclusivity to twelve years on the number of conventional drug approvals in the United States. ¶We found that a twelve-year data exclusivity period has little beneficial effect on longevity at age fifty-five. Americans in the early 2020s will bear the cost of increased drug spending with relatively little increased innovation and therefore relatively little benefit in terms of longevity. However, people turning fifty-five in the year 2060 can expect increased life expectancy of 1.44 years as opposed to 1.30 years under the status quo ([Exhibit 3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F3/)). The difference—1.7 months—is a result of innovation in the interceding years—that is, the new drugs brought to market because of lengthier data exclusivity. As a point of comparison, the elimination of obesity in the United States could increase life expectancy at birth by 2.5 to 13.0 months. ¶By 2060, these Americans would spend $3,400 per capita (in 2009 US dollars) over their remaining lives on drugs developed as a result of longer data exclusivity ([Exhibit 4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F4/)). Given the substantial value of a life-year, the benefit of increased longevity would be $13,800, or $10,400 when you calculate benefits minus costs. The increase in “welfare” or well-being is smaller, but still positive, between 2020 and 2060. ¶Sensitivity Analyses ¶The baseline model implies that a longer period of data exclusivity would be of value to future generations of Americans. How sensitive are these results to our assumptions? To answer this question, we varied the value of a life-year ($50,000 to $300,000), the innovation elasticity (0.5 to 4.0), the social discount rate (2 percent to 4 percent), and the revenue impact of a twelve-year period of data exclusivity (base case plus or minus 25 percent). ¶In most of these scenarios, the net benefit of a twelve-year period of data exclusivity to people age fifty-five was positive from 2020 through 2060. The costs exceeded the benefits—and so longer data exclusivity was harmful—only for the lowest levels of the innovation elasticity (0.5–1.0) and the value of a life-year ($50,000). These parameter levels are much smaller than the best available evidence (described earlier). Hence, even though there is uncertainty about model parameters, a lengthier data exclusivity period would likely be beneficial overall. ¶DISCUSSION AND POLICY IMPLICATIONS ¶Recent discussions about the appropriate length of data exclusivity for new drugs have focused on biologics,[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) but as noted above, the National Academies Committee on Science, Engineering, and Public Policy[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R2) and the pharmaceutical company GlaxoSmithKline[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R3) have proposed increasing the data exclusivity period for conventional drugs, as several European countries have done. ¶Unfortunately, there has been no quantitative analysis of the effects of a longer data exclusivity period on innovation, longevity, and societal welfare. To our knowledge, this is the first study to provide such estimates. Our analysis suggests that Americans would benefit in the long term from a longer period of data exclusivity. ¶This finding is robust with respect to plausible assumptions about the effect of revenues on innovation and other factors. Nevertheless, there is uncertainty regarding potential changes in regulations, science, and medicine that were not incorporated into our model. ¶The idea of extending data exclusivity for conventional drugs has not garnered much political support. It appears that elected officials are unlikely to embrace legislation that would result in higher drug prices. Our research suggests such legislation would spur innovation that would benefit future generations.

#### Data exclusivity is necessary to ensure effective clinical research

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Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences 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 con-text**.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 compe-tition 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 pharmaceu-tical 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 sec-tor.2 It is therefore unsurprising that we are seeing indus-try-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 com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.