

NC Innovation DA

BioPharm- Bioterror

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 turns case. Macdole and Ezell 4-29:

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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 concurs **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**.

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

Marjanovic and Feijao '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 quantitative 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 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. 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.**

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 COVID-19; 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.³⁴ Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential

therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.^{35,6} **The primary purpose of such innovation is to benefit patients and wider population health.**

Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are 'commercial' winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world's poorest countries.⁷ Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.^{8,9} Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.¹⁰ Pharma is mobilising

substantial efforts to rise to the COVID-19 challenge at hand. However, **we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term.**

The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.¹¹ However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, **levels of activity in response to the threat of antimicrobial resistance are still low.**¹² There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

Bioterror causes extinction---early response key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders”

<http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/>)

Bioterrorists could one day **kill hundreds of millions** of people **in an attack more deadly than nuclear war**. Bill Gates will warn world leaders. **Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons**. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, **they are overlooking the threat of biological warfare.** Mr Gates, whose charitable foundation is funding research into **quickly spotting outbreaks and speeding up vaccine production**, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With **nuclear weapons** you’d think you **would** probably **stop** after **killing** 100million. **Smallpox won’t stop.** Because the population is naïve and **there are no real preparations**. That, if it got out and spread, would be a larger number.” He said **developments in genetic engineering** were **proceeding at a “mind-blowing rate”.** **Biological warfare ambitions** once limited to a handful of nation states are **now open to small groups with limited resources and skills**. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The **increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy.** Technologies which have made it easy to **read DNA sequences and** **tinker with** them to rewrite **or tweak genes** have many legitimate uses. He said: “It’s not like when someone says, “Hey I’d like some Plutonium” and you start saying “Hmmm.. I wonder why he wants Plutonium?”” Mr Gates said **the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war.** He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. **With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.** ” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at **bio-defence is worth increasing**. ” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same **biotechnology can prevent epidemics spreading out of control.** Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. **Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques**. **Being able to develop a vaccine as soon as possible against a new outbreak is particularly important** and could save huge numbers of lives, scientists working at his foundation believe.

Health Impact Fund CP

Counterplan text: (the member nations of the World Trade Organization) should implement and fund a Health Impact Fund as per the Hollis and Pogge 10 card

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 often 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