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Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic

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From vaccines and therapeutics to delivery robots, intellectual property has played an indispensable role in facilitating development of a range of inventive products that have helped address health care, work, and social challenges brought on by the pandemic.

KEY TAKEAWAYS

- IP provides the incentives that enable innovators across a wide variety of industries to undertake the often risky, difficult, expensive, and time-consuming process of creating new-to-the-world innovations.
- IP is just as important for start-ups as it is for R&D-intensive industries, because it generates capital and revenue, enabling companies large and small to invest in researching, developing, manufacturing, and marketing their products.
- Voluntary licensing agreements enabled by IP have allowed manufacturing of COVID-19 vaccines and therapeutics to scale up globally.
- The pandemic has changed the way the world works and interacts, and technology companies are rising to the new challenges. They are even finding ways to combat health-care concerns ignored during the pandemic.
- Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population, largely thanks to the role IP plays in maintaining the supply chain and ensuring quality control.

INTRODUCTION

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some *pre-existing innovations*, but it would absolutely limit *future innovations*. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, "Well, *this time* we won't take away your IP rights, so go ahead and invest large amounts of time and money." Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.[1] The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.[2] Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.[3]

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:

1. Bharat Biotech: Covaxin
2. Gilead: Remdesivir
3. LumiraDX: SARS-COV-2 Antigen POC Test
4. Teal Bio: Teal Bio Respirator
5. XE Ingeniería Médica: CápsulaXE
6. Surgical Theater: Precision VR
7. Tombot: Jennie
8. Starship Technologies: Autonomous Delivery Robots
9. Triax Technologies: Proximity Trace
10. 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.

1. A FULLY INDIGENOUS VACCINE FOR INDIA

National pride is often overflowing during events such as the Olympic Games and the World Cup, but it is difficult to imagine such pride amid a global pandemic. However, local accomplishments and innovations should be celebrated all the more in the most challenging of times.

There are approximately 7.8 billion people worldwide and an estimated 7.9 million vaccinations against COVID-19 are being given each day.[37] It takes 60–110 days and multiple steps at various facilities to produce one batch of COVID-19 vaccine.[38] New technological demands, factory retrofitting, production bottlenecking, and supply chain issues all add to the wait time.[39] In short, during the early days of vaccine rollout—like most early days for any innovation—the demand for COVID-19 vaccines vastly outweighed the supply.

Strong protection of IP rights is crucial. IP enables R&D-driven innovation, including the vaccines used to fight the pandemic.[40] IP opens doors for innovative collaboration.[41] And, even as scammers attempt to capitalize on pandemic fears by offering fake cures and counterfeit vaccines to a vulnerable, global public, IP offers assurances and bolsters public confidence through quality control and regulation safety approvals.[42]

Like so many pharmaceutical manufacturers around the world, India-based biotechnology company Bharat Biotech started developing a COVID-19 vaccine when the pandemic began in early 2020.[43] In January 2021, Bharat Biotech's Covaxin became one of two COVID-19 vaccines authorized for emergency use in India, the other being AstraZeneca's vaccine, known locally as Covishield.[44] Although both vaccines are manufactured in India—the Serum Institute of India is

producing Covishield—Covaxin was the only fully indigenous COVID-19 vaccine in use as of March 2021.[45]

Working with the Indian Council of Medical Research and the National Institute of Virology, Bharat Biotech developed its vaccine using Whole-Virion Inactivated Vero Cell-derived platform technology, meaning the vaccine contains dead COVID-19 virus incapable of replicating and infecting others "but still able to instruct the immune system to mount a defensive reaction against the infection."[46] By contrast, Covishield uses the viral vector platform wherein a modified version of a different virus, not the virus that causes COVID-19, delivers instructions to the body's cells for creating a harmless spike protein, thereby inducing antibody production and activating immune cells.[47]

Like most other COVID-19 vaccines, Covaxin is given in two doses, 28 days apart. Phase III trials demonstrated 81 percent interim efficacy.[48] Important for transportation and nations without widespread refrigeration, the vaccine does not require sub-zero storage or reconstitution, and, unlike some other vaccines which must be used within hours, a refrigerated vial of Covaxin can be used for up to 28 days after being opened.[49]

India should take pride in its local innovators, such as Bharat Biotech, and further support them through R&D efforts and by strengthening, rather than diminishing, the protection of IP rights.

In addition to aiding the supply of vaccines to India's almost 1.4 billion citizens, Bharat Biotech is looking to export Covaxin to more than 40 other countries.[50] Brazil has already signed an agreement to acquire 20 million doses of Covaxin, and the company began talks with the Ukrainian government in February 2021.[51] U.S.-based Ocugen, Inc. has also teamed up with Bharat Biotech to bring Covaxin to the U.S. market.[52]

Bharat Biotech is a veteran vaccine manufacturer, having previously developed innovative vaccines for rabies, Japanese encephalitis, Zika, and even the world's first typhoid conjugate vaccine, among several others.[53] The company's portfolio boasts more than 16 vaccines and 4 bio-therapeutics, and it has filed at least 433 patents and owns more than 145 active patents worldwide.[54]

The *Global Innovation Index 2020* (*GII 2020*) ranks India 3rd in innovation among lower-middle income countries, 1st in Central and Southern Asia, and 48th overall out of 131 countries.[55] One comment of note from the theme section of the report states:

> India's investment in R&D has decreased over the last decade from 0.85% of GDP in 2008–2009 to remain stagnant at around 0.7% for the last several years. This is significantly lower than the top five R&D spenders globally in 2017—4.3% for the Republic of Korea, 4.2% for Israel, 3.3% for Japan, and 3.2% for both Switzerland and Finland—and lower than the R&D investments of other BRIC countries, which include Brazil, Russia, India, and China.[56]

The *2020 U.S. Chamber International IP Index*, which evaluates the effectiveness of IP rights systems, ranks India 40th out of 53 economies.[57] Although India made progress by joining Patent Prosecution Highway initiatives, the report cites several hinderances for patent owners, especially where biopharmaceuticals are concerned. Among these are:

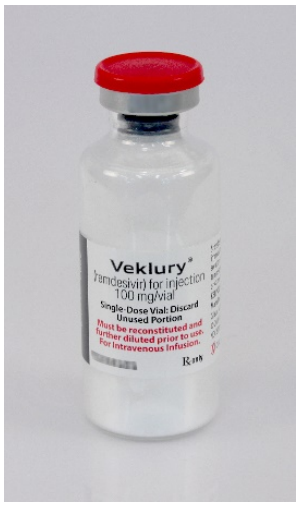
- Compulsory licensing for commercial and non-emergency situations;
- Barriers to licensing and technology transfer, including strict registration requirements;
- Limited framework for the protection of biopharmaceutical IP rights;
- Patentability requirements outside international standards;
- No regulatory data protection available or patent term restoration for biopharmaceuticals;
- Lengthy pre-grant opposition proceedings; and
- Limited participation in international treaties.[58]

The Indian government's frequent use of compulsory licensing is harmful for foreign and domestic innovators alike, especially since the country boasted $20.6 billion in pharmaceutical exports in 2019–2020 and accounts for 50 percent of global vaccine capacity.[59] Rather, India's policymakers should focus on reassuring its population, increasing R&D investment, and enabling collaboration agreements.[60] India should take pride in its local innovators, such as Bharat Biotech, and further support them through R&D efforts and by strengthening, rather than diminishing, the protection of IP rights. India's recent commitment to increase financing for innovation and R&D, especially in the health-care sector, represents an excellent start.[61]

Biopharmaceutical manufacturers are working to rid the world of COVID-19 and other highly infectious diseases, and their innovations are vital for mankind's continued health and survival. Innovative companies, such as Bharat Biotech, can be found in every country and every region around the world, fighting to improve lives locally and globally. Celebrate and support them.

2. REMDESIVIR HAS HELPED THOUSANDS OF HOSPITALIZED PATIENTS WITH COVID-19 RECOVER

The COVID-19 pandemic took the world by storm at the start of 2020. In the United States, the virus began to break out and steadily worsen in mid-March. By May 1, 2020, the virus had already infected 1 million in the United States, and over 3 million globally, with 57,266 fatalities in America.[62]



The early days of the pandemic were indeed bleak, but there was hope on the horizon: the promise of innovative diagnostics, therapeutics, and vaccines to detect, treat, and ultimately inoculate people from the novel coronavirus. The first ray of hope in this regard arrived on May 1, 2020, when Gilead Sciences received an emergency use authorization (EUA) from the FDA for its investigational antiviral drug, remdesivir, with National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci noting that remdesivir had become the "standard of care" for COVID-19 treatment.[63] However, while remdesivir (branded as Veklury), represented a breakthrough in the COVID-19 response, it would be but the first therapeutic of hopefully many to arrive. In fact, as of late April 2021, biomedical innovations seeking to counter COVID-19 number some 859 unique active compounds actively under development, including 397 treatments, 247 antivirals, and 215 vaccines.[64]

The EUA for remdesivir arrived just 92 days after the World Health Organization (WHO) director general declared the outbreak a Public Health Emergency of International Concern (PHEIC).[65] Gilead was able to innovate so rapidly thanks to its over three decades of experience in developing antiviral medicines.[66] For instance, Gilead's breakthrough drugs in the space have included Truvada and Descovy, antiretroviral therapies that can both treat and prevent HIV, as well as Sovaldi, the backbone for curative regimens for chronic hepatitis C patients.[67]

Gilead's decades of work in developing innovative antiviral medicines means its scientists are constantly working to invent new small molecules, biologics, and cell therapies, and as such it has developed an expansive, research-driven library of small molecules, such as remdesivir, which can be accessed and tested against new pathogens and targets when they emerge. In fact, Gilead's development of remdesivir along its path to ultimately becoming an FDA-approved COVID-19 therapeutic traces its roots back to at least 2009, with research programs investigating the potential of novel molecular compounds for the treatment of patients afflicted with hepatitis C and, later, respiratory syncytial virus. Further investigations, which continued up until the COVID-19 pandemic, have demonstrated that remdesivir exhibits "a broad spectrum of antiviral activity."[68] Remdesivir operates as a nucleoside analog, which works by blocking the ribonucleic acid (RNA) polymerase that coronaviruses and related RNA viruses need to replicate their genomes and proliferate in the human body.[69]

While remdesivir (branded as Veklury), represented a breakthrough in the COVID-19 response, it was but the first therapeutic of hopefully many to arrive.

Over the previous eight years, Gilead's scientists have explored application of remdesivir for multiple potential uses to help address urgent and unmet medical needs around the world, including Ebola, SARS, Marburg, and MERS. For instance, in 2014, when an Ebola outbreak mushroomed across Africa, with the U.S. and African governments desperately looking for solutions, Gilead explored, in partnership with the U.S. government, remdesivir's potential against Ebola. Promising research results demonstrated remdesivir's activity in primates and generated data that could support further investigation of remdesivir as a treatment for humans.[70] The National Institutes of Health (NIH) began two human clinical trials with remdesivir against Ebola disease, and remdesivir was used for the treatment of a small number of patients with infections under a compassionate use protocol. However, while remdesivir showed some promise, ultimately two other investigational treatments in NIH clinical trial were associated with greater survival against Ebola, and so Gilead continued to explore application of its therapeutic against other diseases.[71]

In late 2014, Gilead began to study the activity of remdesivir against the coronaviruses SARS and MERS in *in vitro* and *in mouse* models, which included collaborations with several institutions including the University of North Carolina, Vanderbilt University, and the University of Alabama at Birmingham. The scientific term "coronaviruses" refers to a large family of hundreds of viruses belonging to the family Coronaviridae that consist of a single strand of RNA characteristically featuring club-shaped glycoprotein spikes giving the viruses a crownlike, or coronal, appearance. However, despite promising preclinical data, remdesivir did not advance into clinical development for either SARS or MERS, due in part to a lack of adequate numbers of

potential study participants, and in part because those disease outbreaks at the time also quickly waned.[72]

It should be noted that Gilead, like all life-sciences innovators, undertakes investments to develop and test innovative biologics or small molecules like remdesivir over periods often exceeding a decade "at risk" before even knowing whether any molecule will be an effective potential treatment for a disease and with no guarantee that such investments will ever generate a positive financial return. In fact, according to a study by the U.S. Government Accountability Office (GAO), Gilead has invested approximately $1.3 billion in R&D into remdesivir since 2000.[73] The vast majority of that investment was made before remdesivir received regulatory approval. As noted, IP helps innovators across sectors undertake these types of risky investments secure in the knowledge their potential discoveries may be protected so that they can both recoup their investment costs and earn revenues that can be reinvested into future generations of innovation. The GAO report affirmed how America's effective live-sciences innovation ecosystem supports continued risky investment in R&D despite the precariousness of potential outcomes, noting, "A principal investigator noted that Gilead had dedicated substantial resources and maintained a coronavirus research team for several years prior to the COVID-19 pandemic when few others were interested in studying coronaviruses."[74]

Gilead's decades of R&D investment in antiviral medicines in general, and near-decade of development of remdesivir in particular, meant that when the COVID-19 pandemic hit it had a potential therapeutic to rapidly turn to. So when SARS-CoV-2 (COVID-19) broke out in China in late 2019, Gilead quickly initiated preclinical trials to validate remdesivir's potential efficacy against the virus. In February 2020, Gilead began supporting multiple clinical trials to evaluate the safety and efficacy of remdesivir as a potential treatment for COVID-19, with Phase-III studies beginning the following month.[75] Following positive clinical trial results, by May 2020, as noted, remdesivir would receive EUA from the FDA and become fully approved by October 2020. The drug has since been approved or authorized for temporary (emergency) use in 50 countries.

The final NIH report concluded that in its study of 1,062 randomly assigned, hospitalized COVID-19 patients "the antiviral treatment was beneficial," that "patients who received remdesivir were quicker to recover" by as much as one-third, and that it "also improved mortality rates for those receiving supplemental oxygen."[76] A March 2021 multicenter comparative-effectiveness study of remdesivir's impact found the drug "was associated with faster clinical improvement in hospitalized COVID-19 patients," reporting that, of the 570 matched patients, 82.8 percent of those given remdesivir and 74.7 percent controls clinically improved after a median of five days and seven days, respectively.[77] The authors concluded that their research suggests that "remdesivir was associated with a significant decrease in the time to clinical recovery among patients admitted to the hospital for treatment of COVID-19."[78] By mid-January 2021, remdesivir was being prescribed to approximately half of all U.S. patients hospitalized with COVID-19, increasing from 30 percent in October 2020.[79] Gilead manufactured approximately two million remdesivir treatment courses in 2020, and anticipates producing several million more, in 2021.[80]

U.S. patent law allows inventors to seek patent protection for their invention or discovery of a new chemical compound (or group thereof) as well as for drug formulations, methods of using a drug to treat a particular disease, methods or techniques to administer or manufacture a drug,

and methods or technologies that test for and diagnose diseases.[81] Gilead has secured IP protection for inventions it has made toward development of the drug, which includes patents related to the molecular compound, method of use, synthetic methods, and formulation.

IP rights often only come into existence and meaningful effect after an invention is created and brought forward at significant expense by the innovator. At present, there are likely many untapped biomedical discoveries, including treatment options for debilitating diseases and even for future pandemics. Bringing these innovations forward requires organizations to devote years—if not decades—of R&D, as well as significant costs, in the hopes that one day they will be able to help patients, as Gilead's remdesivir has done. IP rights exist to encourage such innovation.

Nevertheless, some countries have petitioned the World Trade Organization's TRIPS Council to waive all IP associated with COVID-19 products and technologies.[82] The Information Technology and Innovation Foundation (ITIF) has extensively documented the many reasons why this waiver petition is misguided.[83] One of the most important of those reasons is that companies like Gilead—as well as others, such as AstraZeneca and Johnson & Johnson—are partnering with other organizations in order to dramatically scale manufacturing to produce and increase access to the COVID-19 vaccines and therapeutics the world needs, thereby undermining any argument that IP rights are preventing patient access to medicines, when in fact, they are fostering them.[84]

For instance, Gilead has worked with governments and global health authorities worldwide to ensure access to Veklury for patients who need it. Beginning as early as April 2020, Gilead donated its then-existing supply of Veklury—1.5 million doses, or 140,000 treatment courses—for compassionate use, expanded access programs, and clinical trials.[85] Recognizing the need to quickly ramp up production of Veklury, Gilead took multiple steps over the past year—including working on optimizing chemical synthesis processes involved in making the drug—which enabled the company to cut remdesivir's manufacturing lead time in half, from 12 to 6 months.[86] Moreover, Gilead expanded its manufacturing network to include more than 40 contract manufacturers across North America, Europe, and Asia in order to ensure it has sufficient supply of key raw materials and ingredients essential to the drug's manufacture.[87]

Far from being a barrier to, IP has rather been the source of, so many of the innovations shepherding global society through the COVID-19 pandemic.

Internationally, Gilead has signed nonexclusive voluntary licensing agreements with generic pharmaceutical manufacturers based in Egypt, India, and Pakistan to further expand the supply of remdesivir. The agreements allow the companies—Cipla Ltd.; Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, a Biocon company; and Zydus Cadila Healthcare Ltd.—to manufacture remdesivir for distribution in 127 countries, including nearly all low-income and lower-middle-income countries, as well as several upper-middle- and high-income countries that face significant obstacles to health-care access.[88] Since the program's establishment in May 2020, it has enabled access to the drug for more than 2.3 million eligible patients throughout the developing world. Gilead provided these licenses royalty free for the duration of the pandemic.[89] The agreements give the manufacturers the ability to set their own prices and give licensors a right to receive a technology transfer of the Gilead manufacturing process for remdesivir in order to enable them to scale up production more

quickly.[90] This has positioned Gilead to effectively respond to unexpected COVID-19 surges, such as the April 2021 surge in India. To help alleviate this surge, Gilead is providing technical assistance to support the accelerated production of generic remdesivir by its seven Indian voluntary licensees by increasing their batch sizes, adding new manufacturing facilities, and onboarding local manufacturers throughout the country. Gilead has also donated at least 450,000 vials of Veklury to help address the immediate needs of Indian patients.[91] To safeguard against disruption of generic remdesivir supply to other low- and middle-income countries included as part of the voluntary licenses, Gilead will also donate active pharmaceutical ingredients to licensees in Egypt and Pakistan in an effort to accelerate production.

It's also worth noting that Gilead and the European Commission signed a Joint Procurement Agreement (JPA)—a mechanism used by the European Commission that offers faster access to medical countermeasures for appropriate patients in participating countries in times of public health crises. The JPA enables rapid and equitable access to Veklury to participating countries across the European Union, the European Economic Area, and the United Kingdom.[92] Collectively, Gilead's actions to scale up manufacturing and enter into voluntary licensing agreements with contract manufacturers worldwide has allowed the company to ensure that it is providing adequate supply to meet global demand for remdesivir.

In summary, the remdesivir story provides strong evidence showing that far from being a barrier to, IP has rather been the source of, so many of the innovations shepherding global society through the COVID-19 pandemic.

3. POINT-OF-CARE ANTIGEN TEST OFFERS FASTER RESULTS IN THE FIGHT AGAINST COVID-19

The last four decades have brought significant advancements in the technology, digital, and life-sciences fields, and the global COVID-19 pandemic continues to spur this innovation exponentially.[93] In mere months, the waiting period for COVID-19 diagnostic test results went from days to hours to minutes, a much-needed advancement to help prevent further spread of the virus and for frontline workers and others requiring assurances for health care, work, or family purposes.

As Sir John Bell and his colleagues stated, the life-sciences sector fundamentally survives on IP.

In the fight against COVID-19, there are two main types of diagnostic tests: molecular and antigen.[94] According to the U.S. FDA, molecular tests detect an active virus's genetic material and provide more accurate results, while antigen tests provide faster results and detect specific proteins from an active virus.[95] As of December 21, 2020, there were 469 COVID-19 diagnostic innovations in various stages of development around the world, two of which were fully-approved for general use and 203 were authorized for emergency use.[96]

One such innovation was developed by LumiraDx, a point-of-care diagnostic and health care information technology company based in the United Kingdom. The LumiraDx SARS-CoV-2 Ag Test is an antigen diagnostic test used in conjunction with the LumiraDx Instrument and Platform to quickly provide highly accurate results.[97]

Like most COVID-19 diagnostic tests, the LumiraDX SARS-CoV-2 Ag Test starts with collecting a specimen using a nasal swab. In prepping the specimen, the test uses microfluidic immunofluorescence to determine whether a COVID-19 nucleocapsid protein antigen is present in the specimen. A test strip with the prepped specimen is inserted into the LumiraDx Instrument, and results are reported to the LumiraDx Platform within 12 minutes.[98]

In clinical trials, within the first 12 days of symptom onset, the tests produced the same results as molecular tests 97.6 percent of the time for positive results and 96.6 percent of the time for negative results.[99] For tests conducted within the first three days of symptom onset, the results were 100 percent aligned.[100] Subsequent independent tests have shown similar results.[101]

In August 2020, the FDA granted the company EUA for the LumiraDx SARS-CoV-2 Ag Test, and as of January 21, 2021, the test is available in more than 30 countries including Japan, Brazil, and Switzerland.[102] In November 2020, LumiraDx partnered with numerous organizations—including the Africa Centres for Disease Control and Prevention, the Bill and Melinda Gates Foundation, and the COVID-19 Therapeutics Accelerator—to provide 55 African Union member states with portable diagnostic instruments and related COVID-19 antigen tests.

For innovative companies such as LumiraDx, the importance of IP cannot be understated. As Sir John Bell and his colleagues stated, the life-sciences sector fundamentally survives on IP.[103] LumiraDx holds 22 patents associated with the company's platform, diagnostic assays, and smart connectivity, covering nine different jurisdictions.

According to the *2020 U.S. Chamber International IP Index*, the United Kingdom ranks second out of 53 countries in terms of IP system effectiveness.[104] Key factors weakening the country's IP, as noted in the U.S. Chamber's report, include uncertainties surrounding Brexit and the United Kingdom's adherence to European Commission policies concerning patent term restoration for biopharmaceuticals. The *GII 2020* ranks the United Kingdom third in Europe and fourth overall worldwide in innovation policies. Also, the *GII 2020* ranks the United Kingdom sixth out of 49 high-income economies for quality of innovation.

Given the country's sustained success in innovation, and for the sake of patients and innovators alike, the United Kingdom must ensure that robust IP systems remain and improve throughout the future.[105] Due to government restrictions and market access barriers, UK patients often lack access to the latest medical innovations.[106] These policies and restrictions must be reviewed and addressed in a more market-friendly manner moving forward. As the country settles into this new era, policymakers should also ensure strong IP provisions are included in all trade agreements.[107] Continued consistency between the UK and European Union systems will ensure certainty and continuity for innovative businesses such as LumiraDx. UK policymakers should also adopt and implement the proposed policy changes set forth in Sir John Bell's 2017 *Life Sciences Industrial Strategy* report.[108]

If policymakers in the United Kingdom maintain providing robust IP systems for their innovators, they will continue to be among the world's innovation leaders. When these provisions are in place and implemented properly, citizens of the United Kingdom—and the world—will continue to benefit from innovations such as the LumiraDx SARS-CoV-2 Ag Test.

4. HEALTH-CARE WORKERS CAN SHARE A SMILE AGAIN THROUGH A REUSABLE SILICONE MASK

Smiling, a seemingly simple and everyday action, can have a significant impact. From the mysterious smile of Leonardo da Vinci's Mona Lisa to the mischievous grin of Lewis Carrol's Cheshire Cat, smiling can communicate a vast array of emotions. Studies have shown smiling boosts mood and reduces stress both for the individual who is smiling and those perceiving the smile.[109] Many have experienced love from a friend or family member or comfort and peace from a health-care worker through the simple act of smiling.

As the COVID-19 pandemic gripped the world, society found itself hidden behind masks, struggling to balance safety with personal connections. On top of this, supply could not keep up with the global demand for medical-grade PPE, such as the N95 mask.[110] In response, certain innovators are finding ways to safely sanitize and reuse certain single-use PPE without excessive degradation.[111] Meanwhile, others are working to upgrade PPE.[112]

One research team from the Massachusetts Institute of Technology (MIT) and Brigham and Women's Hospital (BWH) led by Giovanni Traverso, an assistant professor of mechanical engineering at MIT and a gastroenterologist at BWH, began developing a reusable mask early during the pandemic to improve the availability of N95 respirators and reduce landfill waste.[113] The designs from the first-generation mask developed by Traverso's lab—known as iMASC (Injection Molded Autoclavable, Scalable, Conformable)—were published online and made freely available for use, and the clinical feasibility study was published in the *British Medical Journal*'s open access journal, *BMJ Open*, in July 2020.[114]

Jason Troutner, Teal Bio's founder, observed, "What we've noticed is that the IP that exists within Teal Bio has been critical to our path to getting the product into the hands of healthcare workers."

Molded from durable, liquid silicone rubber, the mask can withstand several sterilization methods, including using an autoclave and soaking them in isopropyl alcohol, without damage.[115] The mask has space for one or two small filter cartridges that pop into place and can be thrown away after each use. Smaller filters mean less wasted material and hospital storage rooms can stock more filters. Using moldable silicone allows for a more comfortable and improved seal between the mask and the wearer's face, while the transparent design allows for better communication. Studies conducted during the pandemic have shown clear masks greatly improve physician-patient relationships and are thus meeting the needs of both health-care workers and patients in multiple ways.[116]

Subsequent generations of the innovation have improved upon the iMASC, including features such as alerts for when filters need to be replaced and sensors to let the users know whether the mask is fitting properly.[117] By November 2020, the latest generation of the iMASC came to be called the TEAL (transparent, elastomeric, adaptable, long-lasting) Respirator, and at the end of 2020, the start-up Teal Bio was founded to bring its Teal Bio Respirator out of the lab and into the hands of health-care workers.[118] Jason Troutner, a health-care entrepreneur who previously cofounded the start-up Cast21, is president and cofounder of Teal Bio.[119]

Since the company was only a few months old as of April 7, 2021, Teal Bio's IP is still in the early stages. The company is filing for utility and design patent protection on a number of additional innovations developed since its inception, and it filed a trademark application on March 1, 2021.[120] "What we've noticed is that the IP that exists within Teal Bio has been critical to our path to getting the product into the hands of healthcare workers," Troutner said during an interview. "It's a pretty expensive process to start manufacturing these types of products." Between manufacturing tooling and regulatory work, significant investments are required long before the innovation can reach the health-care workers who need it.

According to a recent study, intangible assets such as IP rights comprise approximately 84 percent of the company value for most major businesses.[121] Since 1985, business portfolios have exponentially shifted toward intangible assets, and, in 2018, intangible assets accounted for $21 trillion worth of S&P 500 companies, compared with $4 trillion in tangible assets.[122] This shift is abundantly apparent for start-ups looking for investors.

Troutner emphasized that IP has been a major component of proving to potential investors the business is on solid ground and worth investing in. "IP to us is not important because we intend to go around suing people who might be doing similar things. IP is important to us because we need capital to bring the product to the end users, and the way we secure that capital is through investors who, in order to be in a good position with their investments, need to see that there is sustainable value in the intellectual property in the company."[123]

The value of IP for COVID-19 innovations, such as the Teal Bio Respirator, cannot be overstated. Companies such as Teal Bio are relying on the protection of these rights to bring these vital innovations to market and into widespread use. According to Troutner, "The most important thing as it relates to technology and the fight against COVID-19 is reducing friction to getting the product to the people who need it. It may seem to some people that IP can cause friction, but more often than not, especially in medical devices, IP is a path to the funding that's required to get the product to the patients." Troutner also noted that IP can "be used to increase the speed and the reach of the product to market," especially for medical devices. IP "has really allowed us to take this from the lab closer and closer to being in the hands of healthcare workers," Troutner said.[124] Faster and greater access to PPE is critical during this pandemic, and—despite the claim that IP is a barrier—in reality, IP can open doors.

When asked what he would like policymakers to know about the role of IP in innovation, Troutner commented, "It's important to take a holistic view of what does it take to get a product to

market. If, for example, you're worried about IP abuses, what's the best path to get a product to market in the absence of strong IP? If you just [take away] IP, you're interrupting a process that exists that can get a product to market and likely not giving an alternate path to the market. Any actions that reduce IP coverage, whether taken by governments or other organizations should consider what that means for the actual path to get a product to the market. Because otherwise you may be introducing more friction to that process than you're actually removing."[125]

Innovations such as the Teal Bio Respirator are still desperately needed in the fight against COVID-19, and they will continue to improve the future of health care. With every reassuring smile a patient sees, the level of care improves. When health-care workers are guaranteed a strong, quality seal on their facial PPE, lives are saved. As waste is reduced, the future becomes brighter. And innovations such as this are made possible because of IP.

5. MEXICAN PARAMEDIC AND ENGINEER DEVELOPS CAPSULE TO REDUCE RISK OF EXPOSURE WHILE TRANSPORTING COVID-19 PATIENTS

For paramedics and health-care workers worldwide, exposure to patients infected with COVID-19 is almost guaranteed, with frontline providers at nearly 12-times greater risk of testing positive than the general population.[126] The transportation of infected patients through hospital corridors and elevators or other populated areas is also a global concern. In overflowing health-care facilities and places where hospitals do not have large isolation rooms, it is even more difficult to reduce the risk of exposure.

The solution for these problems, and more, lies with innovation. Continuous innovation is enabled by IP rights, such as patents.[127] When revenue from IP is re-invested into R&D, it creates a virtuous cycle of innovation.[128] This innovation cycle enables many innovators worldwide that are providing the solutions needed to combat the global pandemic, providing them the means to expand upon their work. Therefore, it's vital for policymakers around the world to adopt strong policies that protect IP and enable innovation.

When the pandemic broke out, biomedical engineer and paramedic Fernando Avilés was already working on a solution to protect emergency responders during the transport of patients with infectious diseases.[129] He adapted this innovation, the CápsulaXE, in response to the COVID-19 crisis.[130] Avilés is the founder of XE Ingeniería Médica, a Mexico-based medical equipment and services company, whose CápsulaXE is only one of the ways XE Ingeniería Médica is providing innovative solutions in response to the pandemic.[131] By March 2020, state and national governments as well as private institutions across Mexico, such as the Mexican Red Cross, the Secretaría de Marina, and the Instituto Nacional de Enfermedades Respiratorias, had all purchased a CápsulaXE.[132] The company also donated a device to the State of Mexico to aid in early relief efforts.[133]

When the pandemic broke out, biomedical engineer and paramedic Fernando Avilés was already working on a solution to protect emergency responders during the transport of patients with infectious diseases. He adapted this innovation, the CápsulaXE, in response to the COVID-19 crisis.

Inspired by neonatal chambers, the CápsulaXE is a hermetically sealed isolation chamber with an inflated, flexible, lightweight, and transparent dome offering three access ports for care providers

to insert their arms or connect ventilation machines, infusion pumps, patient monitors, or other medical devices.[134] Airflow for the capsule is channeled through a HEPA-grade filter, and the plastic dome utilizes the Venturi effect to create a vacuum around the capsule, ensuring the contagions are drawn into the chamber, thereby reducing the risk of exposure for those on the outside. In addition to isolating patients with infectious diseases, the capsule's airflow can be reversed to protect immunosuppressed patients within the chamber.

With a base akin to that of a stretcher, the CápsulaXE is capable of being fixed or portable, making it useful for hospitals and clinics as well as transporting patients via land or air. This innovative device is also highly durable—utilizing the same type of tape used to seal airplane vents—and reusable. Applying the techniques used to clean operating rooms, XE Ingeniería Médica's ambulatory services have subjected their CápsulaXE devices to up to 30 washes with little to no additional wear and tear.

According to XE Ingeniería Médica's website, more than 1,200 CápsulaXE devices are in use throughout 12 different countries, including Mexico. As of February 4, 2021, the capsule costs less than 24,500 MXN ($1,200), making it as affordable as a traditional stretcher.[135]

Like so many of XE Ingeniería Médica's innovative solutions in the global fight against COVID-19, the CápsulaXE is protected and supported by IP. The registration process before the Mexican Institute of Industrial Property (IMPI) to patent this device began in early 2020.[136] XE Ingeniería Médica is saving lives through services and innovations, and IP ensures the company can continue the innovation cycle and create the next generation of life-saving medical advancements.

Ultimately, the innovation cycle is only as effective as the policies supporting it. The *2020 U.S. Chamber International IP Index*, which evaluates the effectiveness of IP systems, ranks Mexico 23rd out of 53 economies.[137] The *GII 2020* ranks Mexico as 55th overall and 2nd in Latin America and the Caribbean in innovation policies.[138] These statistics reflect significant improvements for the country, but Mexico must not stop here.[139] For instance, Mexico could further stimulate innovation by introducing stronger IP protections (especially with regard to countering counterfeiting), creating incentives for domestic innovation, increasing investment in education, and ensuring its trade agreements include substantive IP provisions.[140]

Amidst the chaos and uncertainties of the COVID-19 pandemic, there is hope and progress because of innovations such as XE Ingeniería Médica's CápsulaXE. Innovations that would not be possible without IP. Worldwide, there are boundless possibilities and an enduring capacity to innovate. Therefore, policymakers must enable innovators, such as Fernando Avilés, through robust IP policies if the global society is going to recover and local communities are going to thrive in the post-pandemic world. Otherwise, innovation could stagnate, thus exposing nations to further economic hardship.

6. FORMER ISRAELI AIR FORCE OFFICERS GIVE HEALTH-CARE WORKERS AN INSIDE VIEW IN THE FIGHT AGAINST COVID-19

With new diseases come new challenges, and adaptation is key to survival. In the midst of the COVID-19 pandemic, health-care professionals are discovering new and lingering effects as they combat the disease. Yet, technological innovations and adaptations of proven methods can offer a new perspective in the fight against COVID-19.

Flight simulators have been used to train pilots since the earliest days of aviation.[141] With the technological advancements of the late 20th century, fighter pilots and astronauts began benefitting from virtual reality (VR) training.[142] In 2010, two former Israeli Air Force officers and flight simulator experts began a mission to bring the benefits of VR-simulated training to surgeons.[143]

The company Surgical Theater provides surgeons, surgical teams, and residents with an immersive environment for surgical planning and education. Using patient-specific data from conventional 2D scans, such as CTs and MRIs, Precision VR—Surgical Theater's medical visualization platform—reconstructs the images in a VR setting.[144] This platform can be used for patient engagement and education as well, offering the patient and their family interactive and immersive views to better understand their condition and the pending procedure.[145] The company also provides 360˚ VR video fly-throughs on their website, courtesy of the Precision VR Platform, for conditions such as synovial sarcoma and arteriovenous malformation.[146]

SuRgical Planner (SRP), another aspect of Surgical Theater's system, allows surgeons to pre-plan surgeries with fewer surprises since the VR platform allows them to study patient-specific scans from every angle through a touchscreen or VR headset, much like a fighter pilot studying and pre-flying a mission.[147] Surgical Theater's innovations afford surgeons greater situational awareness and precision, provide safe opportunities to test surgical approaches, and improve surgical efficiency.[148] The company's Surgical Navigation Advanced Platform (SNAP) is also being used during delicate and highly complex surgeries to easily review surgical plans and see what comes next, optimizing outcomes and patient recovery times.[149]

Surgical Theater's interactive inside look at the effects of COVID-19 on a patient's lungs has afforded researchers and health-care workers the opportunity to adapt and potentially increase survival rates in a difficult time.

The VR Studio, yet another aspect of Surgical Theater's training platform, is an interactive, collaborative environment providing surgeons and professors the chance to walk residents and students through procedures and cases.[150] Instructors can either allow students to "walk" around and interact with the VR environment or they can control a student's view, ensuring students see precisely what is intended during a demonstration.[151] In the future, Surgical Theater plans to utilize VR Studio for telemedicine enhancement.[152]

In March 2020, the company released a 360˚ VR video fly-through showing the real-life effects of COVID-19 on a patient's lungs.[153] Then in June, it was announced that Surgical Theater would make its VR technology available free of charge to any hospital worldwide "seeking to navigate inside a COVID-19 patient's lungs."[154] This technology allows medical teams to identify and differentiate between COVID-19-specific lesions and other pre-existing or subsequent conditions, such as COPD (chronic obstructive pulmonary disease) and pneumonia, respectively. Understanding and seeing the difference between COVID-19 lesions and lesions from pneumonia could mean faster, better treatment and fewer deaths. Adapting this technology for the pandemic also provides opportunities to study the virus and various treatments, as well as enhance algorithms being used in the fight against COVID-19.

Surgical Theater's VR systems are being used in hospitals, universities, and treatment centers around the world, including the Mayo Clinic, Stanford School of Medicine, Fondazione I.R.C.C.S. Istituto Neurologico Carlo Besta, and St. Joseph's Children's Hospital in Tampa, Florida.[155] This U.S.-based company's innovative technology is also backed by at least seven U.S. patents.[156]

Adaptation and innovation are vital for survival in any situation, and even more so during a global pandemic. Surgical Theater's interactive inside look at the effects of COVID-19 on patients' lungs has afforded researchers and health-care workers the opportunity to adapt and potentially increase survival rates in a difficult time. IP-supported innovations, such as Surgical Theater's VR system, are leading the fight against the COVID-19 pandemic.

7. ROBOTIC PUPPY OFFERS COMPANIONSHIP IN A SOCIALLY DISTANCED WORLD

Scientific research has long documented the health benefits of having a dog.[157] In a pandemic marked by extended periods of isolation and an increase in both physical and mental health concerns, the benefits of socialization and reduced loneliness can be appreciated by all. Yet, practical implications such as costs, caregiving requirements, and allergies have prevented many—especially seniors who could benefit the most—from owning a dog.

Therapy dogs have been officially used since World War II, and U.S. courts began using emotional support dogs to aid vulnerable witnesses in the mid-1990s.[158] However, bridging the gap for seniors and others with degenerative diseases who would greatly benefit from continuous animal companionship yet are unable to care for a live animal remains a problem. Tom Stevens, cofounder of U.S.-based Tombot, Inc., developed a solution.

Stevens's mother was diagnosed with Alzheimer's in 2011, and Stevens was ultimately forced to give away her best friend and companion, a golden doodle puppy named "Golden Bear."[159] Having spent 35 years in the technology industry, Stevens began looking toward advanced technology for a substitute companion for his mother and others like her.[160] However, none of the existing products could adequately fulfill her needs.[161]

It's estimated that more than 90 percent of those with dementia experience behavioral and psychotic symptoms associated with the disease, including anxiety, loneliness, sundowners syndrome, and depression.[162] Studies have shown the simple act of petting animals helps lower anxiety, reduces loneliness, increases mental stimulation, reduces the need for some medications, and releases hormones known to elevate mood.[163] Emotional attachments, such as those formed with baby dolls or companion animals, also provide these benefits.[164] However, unrealistic mechanical toys rarely elicit such attachments.

In 2017, Tombot, Inc. launched to serve the millions "facing health adversities [who] cannot safely or practically care for a live animal companion."[165] Working with animatronics experts from Jim Henson's Creature Shop, Stevens set about creating an affordable and realistic robot dog powered by advanced technology.[166] The result was "Jennie," a barking, tail-wagging, autonomous, fully interactive, robotic Labrador puppy.

Recordings from a 12-week-old puppy were used to ensure Jennie sounds realistic.[167] The furry innovation includes interactive touch sensors, allowing Jennie to react based on how and where it is touched.[168] Jennie's innovative, upgradable software includes voice activation technology so the puppy reacts to a user's commands as a real dog would.[169] The smartphone app also allows users to customize their robotic companion's functionality, rename the puppy, and even track daily interactions to provide caregivers greater insight.[170] Among the planned updates to the technology are medical-alert capabilities.[171]

Jennie prototypes underwent several rounds of consumer testing with Alzheimer's and dementia patients before its release.[172] One concern was the ethical dilemma of "fooling the person," but studies showed even patients with moderate to severe dementia understood they were dealing with a robot. Stevens said, "They actually prefer that it's a robot," because it's less overwhelming and does not threaten memories or attachments to previous pets.[173]

Studies have shown petting animals helps lower anxiety, reduce loneliness, increase mental stimulation, reduce the need for some medications, and release hormones known to elevate mood.

In April 2019, Tombot, Inc. began a 30-day Kickstarter campaign, taking pre-orders for the robotic puppies with an expected release date of May 2020.[174] By chance, 100 percent of the company's initial investors had been impacted by Alzheimer's disease in some way, and 20 percent of pre-orders were intended for children with autism or who were too young to have a pet.[175] The initial "litter," as the company calls it, quickly sold out at $450 per puppy, before the pandemic slowed production.[176] According to an article from November 2020, Tombot, Inc. already had a 5,000-person pre-order list for its 2022 shipment.[177]

Currently, the company holds two U.S. patents and has one pending international patent for its robotic puppy.[178] These patents cover the design and "method and system for operating a robotic device." The innovation was also named one of The Best Inventions of 2020 by *Time Magazine*.[179] From Alzheimer's to autism and depression to isolation, Tombot, Inc.'s Jennie could have a significant, positive effect on all aspects of health care. For every person worldwide, proper mental health care is as important as proper physical health care, as the two are not mutually exclusive.

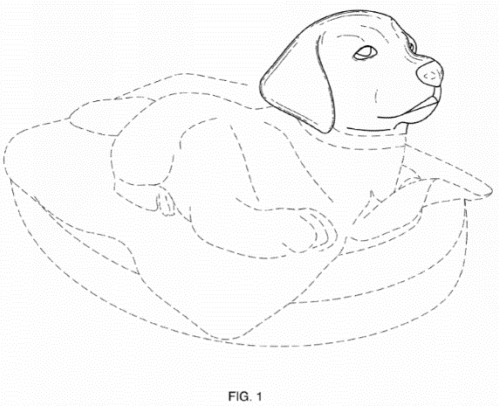


FIG. 1

During this global pandemic, the need for companionship and innovations such as Tombot, Inc.'s Jennie is abundantly clear. Although the technology was not designed specifically with COVID-19 in mind, the applications and benefits throughout such a pandemic are apparent. Like its predecessors, the first therapy dogs, Jennie will continue to aid in health-care solutions throughout the pandemic and beyond.

8. STARSHIP TECHNOLOGIES' AUTONOMOUS DELIVERY ROBOTS ROLLED IN AT JUST THE RIGHT TIME DURING THE PANDEMIC

COVID-19 rolled around the world with astonishing speed, but as this report has demonstrated, it has accelerated or spawned a tremendous amount of innovation in its wake, including a new generation of autonomous sidewalk delivery robots that rolled in at just the right time. With people asked to not only not leave their homes but actually, in many cases, on physical lockdown within their domicile, sidewalk delivery robots have played a crucial role in facilitating safe, rapid, contactless delivery of take-out food, groceries, and beverages to hungry, isolated individuals. While the sector is rapidly growing, with at least 20 autonomous delivery robot services of note, including Amazon Scout, Kiwi, and Uber's Postmates Serve, probably the highest-profile competitor, as *Robotics & Automation News* noted, is Starship Technologies.[180]

Founded in Tallinn, Estonia, in 2014 by Skype cofounders Janus Friis and Ahti Heinla, by 2018, when it started commercial operations, Starship was "heralded as one of the most promising European tech startups" for its vision of developing last-mile delivery robots that would revolutionize inner city and neighborhood deliveries. The company "started with the observation that last mile delivery is one of the least efficient and most wasteful industries on a global scale."[181]

In addition to being convenient for people, including individuals with disabilities who can't easily walk or drive to stores, delivery robots are likely to prove to be beneficial for the environment as well.

Starship Technologies' boxy-wheeled delivery robot weighs 44 pounds, operates at 4 mph, delivers orders from vendors to customers within 15–30 minutes, and has been designed to be 99 percent autonomous (with rare difficult situations handled by a human operator).[182] As Heinla, also the company's CEO, explained, "The robots will cross the streets very much like the humans do: stop, look both ways, and wait until it is safe to cross. They can recognize

approaching cars with its sensor suite from 100–200 meters and will cross the streets only in locations with great visibility."[183] Starship robots make 55,000 road crossings a day.[184]

Starship, which is now headquartered in San Francisco, operates more than 20 service areas globally in 5 countries—Denmark, Estonia, Germany, United Kingdom, and the United States—and has seen demand skyrocket during the pandemic. Up until April 2019, the company's robots had made only 50,000 deliveries (well beyond any other robot delivery service), but this exploded after COVID-19 hit, with the company's deliveries growing to 500,000 by June 2020 and then doubling in just six months to 1 million by January 2021, with the company reporting it expects another doubling of deliveries by 1 million in mere months.[185] (That's in line with growth in overall remote delivery food services, such as DoorDash, Uber Eats, Grubhub, and Postmates, in the United States during the pandemic, with those companies collectively seeing their volumes double in Q2 and Q3 2020 compared with the year prior.)[186] Starship Technologies estimates that demand has increased fivefold in the neighborhoods it serves since the beginning of the pandemic and reports that its robots are "doing deliveries every minute" with "thousands of deliveries per day" and "millions of miles [traversed] per year."[187] According to one analyst, Starship's 600,000 hours of fully autonomous operations make it the "#2 autonomous transport company" in the world, after Waymo.[188] In terms of particular foodstuffs, Starship's most popular deliveries are milk, pizza, coffee, and bananas. Starship also provides deliveries on some U.S. college campuses, and, since some in-person classes resumed, the company notes it's continuing to break its own delivery records with the high volume of orders.

In addition to being convenient for people, including individuals with disabilities who can't easily walk or drive to stores, delivery robots are likely to prove to be beneficial for the environment as well. Indeed, each such robot trip takes a car off the road (replacing it with a robot not on the road), thereby reducing road use, energy consumption, congestion, and safety risks on the road.[189] According to the Logistics Research Centre at Heriot-Watt University, the last mile—the final stage of delivery from a transportation hub to the customer's home—contributes an average of 181 grams of carbon dioxide (CO_2) into the air per delivery.[190] With the volume of urban freight increasing by as much as 40 percent by 2050, battery-operated delivery robots could bring both efficiencies and environmental benefits.[191] For instance, Starship estimates its service has saved 403 tons of CO_2.[192]

As ITIF vice president Daniel Castro noted, "While much of [Starship's] growth has been driven by the COVID-19 pandemic and the resulting desire for safe, contactless delivery, it also reflects the rapid evolution of technologies like robotics, computer vision, and machine learning that are creating new opportunities for innovation in the use of autonomous robots for last-mile delivery."[193] Indeed, to function, autonomous delivery robots need precise, accurate sensors; fast connection systems analogous to the human nervous system; and rapid data processing, often enabled by artificial intelligence.[194] In other words, these aren't just cute little robots, but quite sophisticated platforms that leverage wireless communications networks and integrate a wide range of technologies and systems to facilitate autonomous navigation and operation.

For these reasons, IP represents a critical component of Starship's business strategy, with the company seeking patent protection for dozens of novel inventions across both Europe and the United States. As Lauri Vain, VP of Engineering at Starship Technologies, explained, "Intellectual property is a key enabler of innovation. At Starship, we've devoted a lot of resources to making our delivery robots a viable commercial product so it's important that we safeguard our competitive advantages. We've applied for and received several patents and we expect to continue doing so as we continue to advance Starship's technology and service."[195]

For instance, on April 6, 2021, Starship Technologies received a grant for Patent No. 10967926, "Obstacle traversing mobile robot," which discloses a mobile robot adapted to traverse vertical obstacles with a series of tilting levers that "can be turned around a lever bearing located between the respective axial centers of rotation of each pair of wheels."[196] Patent No. 10930015 was awarded to the company on February 23, 2021, for a "method and system for calibrating multiple cameras." Other patents the company has received include Patent No. 10625926 for a "Device and system for insulating items during delivery by a mobile robot" and Patent No. 10343286 for "Storage system, use and method with robotic parcel retrieval and loading onto a delivery vehicle."[197] On April 6, 2020, Starship applied for a patent for a "mobile robot having [an] insulated bag for food delivery."

Thus, there's little question IP rights are stimulating innovation in the sector, but if autonomous delivery robots are going to flourish to their full extent, policymakers need to put out the welcome mat for them.[198] Unfortunately, in 2017, the city of San Francisco enacted an effective ban on the devices, prohibiting them in many parts of the city.[199] However, in part spurred by the pandemic, in 2020, a number of states and jurisdictions, including Pennsylvania and Virginia, updated their laws to permit sidewalk delivery robots—the latter state's legislation noting that delivery robots "operating on a sidewalk or crosswalk shall have all the rights and responsibilities applicable to a pedestrian."[200] The COVID-19 pandemic will eventually abate, but hopefully autonomous delivery robots will keep rolling long after.

9. CONTACT TRACING AND SOCIAL DISTANCING SYSTEM ALLOWS FOR SAFER WORKPLACES

Although the term "social distancing" was coined in 2003, it was relatively obscure until the rise of the COVID-19 pandemic in 2020.[201] Since then, the term has become ubiquitous, permeating everything from general conversations and social media posts to health-care updates and store policies. The six-foot rule has proven difficult for most workplace situations—with many office jobs transitioning to fully remote operations—and especially so for those in the construction and other labor-intensive industries.

Triax Technologies is an information technology company based in the United States that supports the construction, oil, gas, energy, and industrials sectors. The company designs, engineers, and services an IoT platform offering real-time data collection for "the most challenging work environments."[202] One of these IoT systems, Proximity Trace, is used to curb the spread of COVID-19 through contact tracing and social distancing alerts. Like so many innovations utilized in response to the COVID-19 pandemic, Proximity Trace is supported by IP protection. Triax Technologies owns patents and trademarks associated with Proximity Trace and the company's other IoT platforms and devices.[203]

Founded in 2012, Triax Technologies began by developing the Spot-r system.[204] A heavy-duty device worn by workers, known as the Spot-r Clip, automatically logs time and attendance, is capable of detecting free falls, identifies zone-based worker location for faster emergency response, sounds an evacuation alarm in case of emergencies, and features a push button for on-site emergency communication.[205] The devices automatically sync with the communication hub, providing leaders and their teams with greater on-site visibility and safety.[206]

Proximity Trace's IoT-based systems, supported by IP rights, are being used to curb the spread of COVID-19 through contact tracing and social distancing alerts.

Responding to urgent needs spurred by the pandemic, Triax Technologies launched the Proximity Trace system in April 2020, building upon the innovations of the Spot-r system.[207] A device known as TraceTag is fixed to the body or a hardhat, providing both active feedback and passive data collection to assist in reducing the spread of COVID-19.[208] TraceTag alerts the wearer audibly and visually whenever social distancing protocols are breached.[209] If a task requires workers to maintain close proximity, a button may be pressed, silencing the alert for up to five minutes.[210] The system also collects data on worker interactions, including duration, which can be used in contact tracing should a worker test positive for COVID-19.

TraceTag does not, however, utilize Wi-Fi, GPS, or location data, making it more user-friendly for sites where Internet access is limited.[211] In July 2020, Triax Technologies launched Intrinsically Safe variants of Spot-r and Proximity Trace, providing additional measures to ensure the devices

are safe even for extremely hazardous worksites such as oil refineries, mines, and chemical plants.[212]

As of December 2020, more than 200 worksites across the United States and Canada use Proximity Trace, spanning the construction, manufacturing, mining, oil and gas, bioscience, entertainment and hospitality, food processing, supply chain and logistics, utilities, and education industries.[213]

Many of the technological breakthroughs and innovations making work, health care, and everyday life possible—especially during the pandemic—such as Triax would not be feasible without IP protection.[214] According to the U.S. Patent and Trademark Office, Triax Technologies owns three trademarks associated with the Spot-r system and filed two more trademarks in 2020 for the Proximity Trace system.[215] The company also owns at least eight patents in connection with the two systems.[216] The IP associated with these unique systems affords Triax Technologies opportunities to develop further innovative solutions to workforce problems.

One way U.S. policymakers could further support innovators in this important IoT field is by adopting a national strategy for IoT focusing on funding, convening and planning, agency action, regulatory action, and trade.[217] The 2015 Smart Cities Initiative was an excellent start, but policymakers must not rest there.[218]

As policymakers look to the future, they must ensure U.S. policies adequately support the progress of innovators such as Triax Technologies. IoT-enabled systems such as Proximity Trace are meeting needs, solving challenges, and continuously driving the world through the COVID-19 pandemic and into the future.

10. ZOOM BECAME THE GLOBAL MEETING POINT DURING THE PANDEMIC

Video conferencing has long been recognized as a mobility-, productivity-, and efficiency-enhancing tool in the workplace and a way to bridge personal connections over long distances.[219] But with the outbreak of COVID-19, video conferencing services—and especially Zoom, which is easy to use and readily accessible to regular citizens and large companies alike—almost overnight became the focal point of personal and professional life. During the pandemic, Zoom enabled both virtual work through office meetings and social engagement through happy hours, trivia nights, birthday parties, weddings, baby showers, cooking and yoga classes, music lessons, religious and community events, and innumerable other uses. As Rani Molla, then of *Recode* (now a part of Vox) wrote, "Zoom became an indispensable lifeline to the outside world [during the pandemic]."[220]

Zoom's growth through the pandemic serves as testament to the critical role it has played in helping global society through the crisis. Overall, daily downloads of the Zoom mobile app have increased 30 times year over year.[221] Zoom was the most downloaded Apple app of 2020.[222] And while in December 2019 Zoom attracted on average of 10 million daily meeting participants, by

December 2020, it had 350 million.[223] Financially, Zoom finished 2020 with a profit of $671.5 million on $2.65 billion in revenue, compared with $21.8 million in profit and $622.7 million in revenue a year earlier.[224] As *Wired's* Victoria Turk put it, "Zoom is the pandemic's success story."[225]

The ability to work from home during the pandemic saved an estimated 2.28 million U.S. jobs and $832 billion of U.S. GDP.

Yet, Zoom's importance during the COVID-19 crisis wasn't just about facilitating the social connections so many craved throughout the pandemic-induced isolation and social distancing. The company ended the year with approximately 467,100 business customers with more than 10 employees, a nearly sixfold increase from a year earlier.[226] Zoom—alongside other video-conferencing and collaboration services such as Microsoft Teams, Cisco Webex, BlueJeans, and GoToMeeting—kept the American (and global) economy afloat. For instance, Stanford University's Nick Bloom estimates that two-thirds of American GDP in May 2020 was produced from within peoples' houses, a phenomenon *The Economist* called "a shift in production techniques unmatched in peacetime."[227]

A Boston Consulting Group report (commissioned by Zoom), "The Impact of Video Communications During COVID-19," found that the ability to work remotely during the crisis saved $832 billion in U.S. GDP (equivalent to 4 percent of the U.S. economy); $171 billion in British GDP; $105 billion for German GDP; and $86 billion in French GDP.[228] In terms of jobs spared, the ability to work remotely saved 2.28 million American jobs; 550,000 British ones; 372,000 Germany ones; and 250,000 French ones.[229]

To be sure, many will go back to the office once the pandemic abates, but the experience will make hybrid work environments much more prevalent.[230] Loup Ventures' analyst Gene Munster estimates that 100 million Americans are working remotely now, and that at least 20 percent will continue to do so full time after the pandemic.[231] And even a pre-pandemic study found that 77 percent of remote workers report they are more productive when working from home, while 74 percent of employees say they are less likely to leave a company if it offers remote work.[232]

The massive migration to video conferencing during the course of the pandemic has led to a surge of innovation in the sector, making "the competitive battleground for videoconferencing software all about new features," as Molla wrote. [233] For instance, both Microsoft Teams and Cisco's Webex have added at least 100 new features since the pandemic began. Likewise, Zoom has released a number of new products and features including Zoom Rooms; Zoom Phone; OnZoom, a video events platform that allows people to sell tickets; and Zoom Apps, which lets people navigate to other workplace apps such as Dropbox and Slack within Zoom.[234] As Jeetu Patel, senior vice president of security and apps at Webex, explained, "A direct outcome of the pandemic was, hey, our innovation velocity has to increase because this has become a far more strategic technology today than it was five years ago."[235]

IP appears to be an important part of Zoom's efforts to innovate, as it seeks to keep pace with competitors. Zoom protects its IP through a variety of measures including patents, copyrights, trademarks, domain names, and trade secrets.[236] Zoom has applied for at least 13 patents and been granted 9.[237] The patents Zoom currently owns fall into two primary U.S. patent

classifications: H04N, which is for pictorial communications, and H04L for the transmission of digital information.[238]

For instance, Zoom created a feature for combining the individual thumbnails of participants on a Zoom and automatically taking a group photograph on a video conference call. The feature is unique to Zoom, as it's protected by U.S. Patent No. US10523900B1for a novel "Method and apparatus for capturing a group photograph during a video conferencing session."[239] Another example pertains to Zoom's efforts to protect copyrights for users of its service. For instance, if a presenter is sharing a proprietary image or video, given that Zoom calls can be recorded, or screen shots taken of them, this creates a situation wherein the presenter's copyright could be violated. As Arjun Bala noted, "To prevent this, Zoom has a feature to embed a watermark into an image or a video to enable detection of the source when someone distributes content that was captured from a Zoom call," a feature Zoom has patented with U.S. Patent No US10419511B1 titled "Unique watermark generation and detection during a conference."[240]

Zoom has filed for trademark protection with the USPTO for several word marks, including the stylized version of the company's name and the image containing a white camera on a blue background.[241] Currently, the company owns registered trademarks for "Zoomtopia" and "Meet Happy."[242] Zoom has also secured copyright protection for some of its computer files, including Zoom Client for Meetings (Version 5.2.0).[243]

Zoom, alongside other video conferencing services, has played a critical role in shepherding global society through the pandemic. IP rights have played an important role in supporting the company's innovations and will certainly play a role in shaping the future landscape of competition in the sector.

CONCLUSION

IP has enabled the creation of the innovations highlighted in this report and many others used in the fight against COVID-19.

Without the assurance of knowing that other entrepreneurs or companies cannot simply copy their innovation or tarnish their reputation through counterfeit products, innovators will be much less likely to take the risks involved in innovating, and start-ups will be unable to generate capital to bring innovations to market. Whatever supposed benefits are reaped from waiving IP would be very short lived, and consumers would wind up missing out on potential future innovations as entrepreneurs and companies would be significantly challenged to make the investments needed. Strong IP rights have enabled innovators around the world to meet the unique challenges brought on by the COVID-19 pandemic. From start-ups and small enterprises to multinationals, innovators are fighting to end the pandemic and move society forward, and they are able to do this because of IP protection.

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