## CP

#### Counter plan text: The World Health Organization should harmonize its approach to CRISPR patents and the member nations of the World Trade Organization should follow these guidelines. Marlborough reading yellow.

Their own card--Wachowicz 19 [(Jessica, a third-year student at the University of Washington School of Law whose primary area of study is emerging technologies and the legal issues associated therewith.) “The Patentability of Gene Editing Technologies such as CRISPR & the Harmonization of Laws Relating to Germline Editing, “ Intellectual Property Brief, 2019 https://digitalcommons.wcl.american.edu/ipbrief/vol10/iss1/2/] RR

At present, countries take different approaches in applying the ordre public doctrine to cases involving germline editing. In Japan, the patent office examines scientific guidelines pertaining to stem cell research in rendering its decisions.8 1 Others simply look to the values held by that particular country in determining whether the invention would benefit society.82

Looking at the values held by a particular community will lead to varying results. Some countries may value the welfare of individuals over the progression of science.83 Others argue that because these inventions can dramatically improve healthcare, and because healthcare is a human right, this public interest should override any bans on germline editing. 84

A similar dispute arose under TRIPS with respect to pharmaceuticals. As stated previously, some countries, India in particular, argued that patenting pharmaceuticals was immoral because it raised the cost of healthcare. In 2016, the World Health Organization published the "Guidelines for the examination of patent applications relating to pharmaceuticals."86 The purpose of this guideline was to assist legislators in crafting laws that would allow for the patentability of pharmaceuticals generally, while imposing limitations that would prevent healthcare from becoming unaffordable.

One plausible solution is for the World Health Organization to create a set of guidelines for determining the patentability of technologies such as CRISPR. The guideline can look to other international treaties that focus on the preservation of human rights and the improvement of healthcare.87 By encouraging countries to take these agreed upon policy objectives into consideration when examining these controversial patents, results among different patent offices may be slightly less varied. A guideline from the World Health Organization (WHO) or a similar organization may assist countries' legislatures in crafting laws that allow for progression in this field of science while protecting their communities from potential human rights violations, such as the destruction of viable embryos.

Attempts at harmonization have been made in the past. There are currently numerous international instruments that prohibit inventions involving genomes, such as the UNESCO Universal Declaration on Bioethics and Human Rights and the Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biotechnology and Medicine: Convention on Human Rights and Biomedicine. The former states that public welfare should be prioritized over the progress of science, and the latter states that genetic modification techniques should only be allowed if "serious hereditary sexrelated disease[s] [are] to be avoided."89 These agreements make clear that public welfare is of primary importance, and that germline editing techniques should only be applied where serious risks can be avoided. The Oviedo Convention limited the scope of the exception to the avoidance of sex-related diseases, but perhaps with the introduction of CRISPR, countries may need to consider the circumstances under which genome and germline editing may be permissible.

CONCLUSION

In summary, relying on the ordre public doctrine to determine the patentability of CRISPR technology will lead to dramatically varying results around the world. The need for a more harmonized approach is present. Despite countries' general avoidance of genome and germline editing, technology has developed in such a way that these practices may be highly beneficial to public welfare. Countries should reconsider their stances on such practices in light of the potential benefits CRISPR technology can offer and should attempt to reach a general consensus on the proper uses of CRISPR. Given recent events, the WHO should promptly issue guidelines to assist legislatures in crafting laws that promote progress in this area while maintaining consistency with concepts of morality.

#### The counter plan entails that the European Union would comply with the same patent rules as the rest of the WTO which solves the second advantage

## Innovation DA

#### 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:

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

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

#### CRISPR has especially high prices. Irvine 19

Alison Irvine [science writer], 19 - ("Paying for CRISPR Cures: The Economics of Genetic Therapies," Innovative Genomics Institute (IGI), 12-16-2019, accessed 9-4-2021, https://innovativegenomics.org/blog/paying-for-crispr-cures/)//ML

Developing a gene therapy can cost an [estimated $5 billion](https://gskkr.files.wordpress.com/2015/01/biotechnology.pdf). This is more than five times the average cost of developing [traditional drugs](https://www.sciencedirect.com/science/article/pii/S2452302X1600036X). In addition to the costs of research, manufacturing and distribution, these biological therapeutics are subjected to multiple regulatory structures, which result in a long and expensive route to approval. When you factor in the limited number of eligible patients (customers), the motivation behind pricing becomes clear.¶ According to a base-case analysis conducted by the Institute for Clinical and Economic Review (ICER), Zolgensma’s subjective value to their patients has been estimated to be around $900,000 per treatment. Still, nothing is stopping Novartis from inflating the price. Zolgensma’s only other competition is Spinraza, which, in comparison, requires a procedure every few months and can cost a total of $30 million over a lifetime.

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

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### 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 foundationis 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.

#### If gene mutation leads to extinction, we better access these arguments because we provide a way for CRISPR to be used in response to bioterror which would be a deliberate manipulation of pathogens – they concede in CX that this is the only way to solve maliciously enhanced pandemics

Wachowicz says laws would be sufficient to prevent gene manipulation for the wrong purposes, but that’s not sufficient – we need to actually be able to counter that with CRISPR technology

#### Turns the innovation advantage – funding is a prereq to innovation – and accesses a stronger link to extinction

## Case

### Advantage 1

#### No solvency—their plan does not increase uniformity in IP protections for CRISPR because it just reduces patents protections for CRISPR, and does not create a uniform set of reductions

#### Their only solvency card does not advocate their plan so there is no ev that they can solve the harms in their aff

#### Voluntary licensing solves—Pfizer Biotech licensed each other’s tech to create the covid vaccine which proves that this is real world

1. Their Reader card says research comes from scientists with a stake in the intellectual property - that’s proof that scientists are incentivized by IP to make new discoveries AND THAT IP INCENTIVES OVERCOME FEAR OF LITIGATION because this is taking place in the context of a card that says litigation drives innovation down

#### Patents facilitate piggybacking because it makes transparent what technology exists and enables voluntary licensing

#### Weakening patents is worse – eliminates funds for R&D and halts pharma innovations that prevents an effective development of a right to health.

Sarah Joseph 11, Professor of Human Rights Law, and the Director of the Castan Centre for Human Rights Law at Monash University, Sarah, “Blame it on the WTO?” http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8#acprof-9780199565894-note-1350

IP protection restricts trade and competition, so IP clauses are somewhat anomalous in trade agreements, which are normally designed to decrease trade barriers. What is the justification for IP protection?44 Due to their relevance to this chapter, I will concentrate on arguments in favour of patents.45 Patents reward people for their inventions, thus encouraging creativity and innovation. Patents operate on the assumption that people are not inherently altruistic, and expect rewards for their endeavours, especially when those endeavours are risky as they may, and often do, result in costly failure.46 Furthermore, the money raised from patent protection is said to be necessary to fund the considerable costs of research and development (R&D).47 Therefore, without patents, innovation in the pharmaceutical field (or any industrial field) might grind to a standstill. While it is true that the high prices generated by patent protection may render access to drugs selective, (p.221) it is nevertheless better that a drug is available to some rather than non-existent and available to no one. The global extension of patent law mandated by TRIPS helps to ensure that patents are not undermined by the sale of competing pirated copies. Furthermore, global IP regimes should theoretically encourage greater technology transfer between countries, greater foreign direct investment, and greater local innovation within compliant states.48 All of these outcomes should accelerate the economic development of poor countries, with positive knock-on effects for human rights. Thus, perhaps it is arguable that pharmaceutical patents are justifiable under international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health. Furthermore, to the extent that they are held by natural persons, they are one way of protecting that person’s rights under Article 15(1)(c) of the ICESCR.

#### The alternative to a patent system is trade secrecy which chills innovation

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What would our innovation system look like without patents? It’s hard to imagine that it would be much to look at given that the primary alternative would be trade secrecy. But the high cost of seeking patent protection overseas, among other reasons, is elevating the status of trade secrecy as an IP tool of choice, despite its chief shortcoming. As the NIH points out, “trade secret protection lasts for as long as the secret is kept confidential. If the secret is never publicly disclosed, it will never lose its protection. If the secret is uncovered by means of industrial espionage, disloyal employees, theft, or the like, the owner of the secret has legal recourse against those who misappropriated the secret, or anyone who procured it through such impropriety.”35 Protection is not afforded, however, “in the event that someone managed to successfully duplicate the recipe by legitimate means.”36 A trend toward greater trade secrecy to avoid the pitfall of an insufficient patent regime poses two significant problems. For companies, it’s unsustainable because today’s technology makes inimitability exceedingly difficult to maintain. For society, it’s undesirable because secrecy deeply undermines the scientific process that feeds on the kind of transparency and collaboration that the patent system was conceived to deliver. Opting for trade secrecy over patent protection will have a chilling effect on innovation and threatens to undermine broad-ranging scientific advancement. The quality of innovation touches our lives and enterprises in so many ways. Thus, we are all stakeholders in the patent debate and, in particular, the life science patent debate.

#### The aff mandates tech transfer, which decks the lively and collaborative environment of competition that has always existed between the faculty who actually conduct studies – their author, Marlborough reads yellow

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University-against-university patent disputes, like CRISPR, complicate interinstitutional research agreements on several levels. First, they have the potential to chill formal interinstitutional research collaborations among universities if the institutions cannot agree on intellectual property issues beforehand.25 Universities may simply be unwilling to enter into such agreements in the first instance, or, perhaps more perniciously, discourage their faculty from informally developing such networks.26 While the empirical evidence for such a diminishment in collaborative efforts is slight—difficult to demonstrate, in part, because it requires the proof of opportunities not taken by universities—some recent survey data have found that ‘institutionally mandated [materials transfer agreements] put sand in the wheels of a lively system of intra-disciplinary exchanges of research tools’.27 Aside from this, there is substantial anecdotal evidence of institutional difficulties in creating such agreements.28 It stands to reason that, at least in some instances, these difficulties have ended some collaborations before they could begin. More immediately, this is a current issue with the CRISPR patent dispute given some internal dissention between Doudna and Charpentier's respective institutions concerning the intellectual property involved. Although Doudna and Charpentier filed their joint patent application in 2012, their institutions did not formally assent to a cross-licensing agreement until December 2016.29 If assenting to a cross-licensing agreement for a single piece of technology has proved difficult, it is unclear how the two institutions will deal with one another on future collaborations.

### Advantage 2

#### No collapse from EU—the whole point of the WTO is that it is a forum for negotiating trade disputes, so EU governments can work within the WTO to fix its agreement.

#### No economic decline does not cause nuclear war---the 2008 financial crisis and the covid pandemic prove

#### No brink—their Menz et al 20 card says that the EU has gone against WTO rules since 2018 and their **Horton and Hopewell 8/3 card says that the EU has a lot of cred in the WTO now.**

#### Covid waiver thumper—the EU currently refuses to pass a waver for covid medicines which is at odds with the majority of the members of the WTO. Baschuk 7/26

Bryce Baschuk [Reporter, Bloomberg Economics], 21 - ("WTO Holiday From Vaccine Equity Talks Draws Calls for Action," Bloomberg, 7-26-2021, accessed 8-18-2021, https://www.bloomberg.com/news/articles/2021-07-26/wto-s-holiday-from-vaccine-equity-talks-draws-calls-for-action)//ML

An urgent global effort to rebalance the inequity between rich, vaccinated nations and poor nations sliding further into pandemic misery is colliding with an immovable calendar conflict: the European summer holiday. Next week World Trade Organization delegates are planning to depart Geneva for their August break and, in doing so, pause their fractious debate over a proposal to waive intellectual-property protections for Covid-19 shots until the second week of September.¶ Before they leave, members will adopt a report that acknowledges they’ve made scant headway on the proposal aimed at making doses more widely available, which the world’s top health expert says is critical to ending a “moral failure.”¶ “With so many lives on the line, profits and patents must come second,” World Health Organization Director-General Tedros Adhanom Ghebreyesus [said](https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-wto---who-high-level-dialogue-expanding-covid-19-vaccine-manufacture-to-promote-equitable-access) during a virtual summit last week.¶ WTO Director-General Ngozi Okonjo-Iweala previously urged ambassadors to shorten their usual six-week summer holiday to focus on pressing issues like the waiver. Nevertheless, members aren’t planning to reconsider the matter until the week of Sept. 6, according to officials familiar with the planning.¶ “August doesn’t matter in Geneva; it doesn’t matter if people are dying around the world,” said Shailly Gupta, a spokesperson at Médecins Sans Frontières. “We hope members will move at a faster pace.”¶ Disagreement persists on the fundamental question of whether a waiver is the “appropriate and most effective way” to address the shortage of vaccines, according to a draft status report produced by Dagfinn Sørli, the chairman of WTO council on Trade-Related Aspects of Intellectual Property Rights, or TRIPS.¶ That split could sink prospects for an ambitious vaccine waiver because WTO decisions must be taken on the basis of consensus -- which means any of the 164 members can veto a final agreement for any reason.¶ ”The WTO’s response to Covid is the most critical issue before our organization right now,” WTO spokesman Keith Rockwell said a phone interview. “Millions have died and lives are at stake. Finding a pragmatic outcome by December is essential.”¶ Proponents of the waiver had hoped to conclude their negotiations by the [end of July](https://pmindiaun.gov.in/public_files/assets/pdf/Statement_as_delivered_on_Waiver_Proposal.pdf) and are now criticizing the European Union and other developed nations for sandbagging the talks.¶ EU ‘Not Interested’¶ The European Commission, which [opposes a WTO TRIPS waiver](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_2361), has proposed a [series of measures](https://www.bloomberg.com/news/articles/2021-06-03/eu-s-trade-response-to-pandemic-stops-short-of-vaccine-ip-waiver) that it argues will create greater legal certainty for nations to leverage existing trade tools in order to expand their production capacities.¶ “The EU is not interested,” Gupta said. “Switzerland, Norway and the United Kingdom are not engaging. They’re saying: ‘This or that won’t work; the waiver won’t work.’ There is no intention of engaging.”¶ A spokesman for the EU mission in Geneva declined to comment.§ Critics counter that the proposal from Brussels is a distraction to redirect focus from India and South Africa’s earlier waiver proposal and to prevent members from engaging in more detailed negotiations.¶ “The EU’s actions are incredibly cynical and dangerous,” said Lori Wallach, the founder of Public Citizen’s Global Trade Watch. “They have submitted a paper that basically conflicts with the text-based negotiations by saying ‘We don’t want a waiver.’”¶ The U.S., meanwhile, has taken a back seat in the process and enthusiasm about Washington’s engagement on the issue has begun to wane in the three months since Trade Representative Katherine Tai announced American [support for a waiver](https://twitter.com/AmbassadorTai/status/1390021205974003720?s=20).¶ Though Tai’s surprise announcement briefly knocked shares of [Moderna Inc.](https://www.bloomberg.com/quote/MRNA:US), [Pfizer Inc.](https://www.bloomberg.com/quote/PFE:US), and [BioNTech SE](https://www.bloomberg.com/quote/BNTX:US), the stocks quickly rebounded and all are now trading at or near their highest levels of the year.¶ “People feel that message from Ambassador Tai is not playing out on the ground or being implemented in a meaningful way,” said Thiru Balasubramaniam a managing director at [Knowledge Ecology International](https://www.bloomberg.com/quote/0746610D:US) in Europe.

#### The delegates who support increasing access to CRIPSR are not the WTO as a whole body—only 10/164 members signed the petition according to their Menz et al 20 card

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