# Marlborough JYK v Harvard-Westlake KD

## HIF CP

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

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

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

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

## Innovation DA

### Bioterror

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

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

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

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

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

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

#### 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---quick innovation 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.

# Case

#### TRIPS reduces global health inequality

Samir Raheem Alsoodani 15, “"The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) may offered an access to essential pharmaceutical drugs for developing countries,” Journal Of the College of law /Al-Nahrain University 2015, Volume 17, Issue 2, Pages 393-410, <https://www.iasj.net/iasj/article/109180>

To conclude, it is beyond doubt that the TRIPS Agreement and its later, permanent amendment of 2005 attempted in good faith to address an urgent issue faced by many developing countries with regards to accessing essential medicine. To a certain extent in its basic tenets, it has had a profound and positive effect on the system, as it has made permanently possible the opportunity for the poorest countries to obtain medications more cheaply through manufacture in developing countries under a compulsory licensing system. Certain positive outcomes arguably include the fact that disputes have been brought under the jurisdiction of one regulatory body, and the least developed Members have found some redress in the power balance regarding costs paid to the pharmaceutical industries based in the wealthier, developed countries (even if this redress has only been to the extent of facilitating increased bargaining capability). This can be considered a triumph from the perspective of universal human rights.

#### GHI is declining now

Isma Addi Jumbri et al. 19, Faculty of Technology Management and Technopreneurship, University Teknikal, Melaka, Malaysia, Shinya Ikeda, Masayuki Jimichi, Chika Saka & Shunsuke Managi, December 2nd, 2019, “Inequality of health stock and the relation to national wealth,” <https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-019-1096-x>

Overall, in most groups by income countries, inequalities have decreased. Figure 2 shows that the Gini coefficient of health stock declined rapidly from 1990 to 2015, especially for LICs, and declined slowly in lower-middle income countries (LMICs) and upper-middle income countries (UMICs). The Gini coefficient for LICs indicated steadily decline, from 0.69 in 1990 to 0.66 in 2015. From the analysis (see Fig. 3), the working-age population (an increase of 108.6%) and growth in life expectancy at birth (an increase of 19.2%) in LICs were most likely the contributing factors to the decline in inequality. LICs, particularly for SSA, have the world’s highest youth population growth rate (nearly 20% of SSA’s total population) and the highest share of youth in the working-age population [39]. SSA alone is likely to account for nearly two-thirds of the growth in the world’s working-age population between 2015 and 2050 [40].

### Impact D- covid over soon

#### Pandemic will be over in a year

Reuters, 9-23, 21, Moderna chief executive sees pandemic over in a year – newspaper, https://news.trust.org/item/20210923052810-q5d40

ZURICH, Sept 23 (Reuters) **- Moderna** Inc **Chief** Executive **Stéphane Bancel thinks the coronavirus pandemic could be over in a year as increased vaccine production ensures global supplie**s, he told the Swiss newspaper Neue Zuercher Zeitung. "If you look at the industry-wide expansion of production capacities over the past six months, **enough doses should be available by the middle of next year so that everyone on this earth can be vaccinated. Boosters should also be possible to the extent required,"** he told the newspaper in an interview. Vaccinations would soon be available even for infants, he said. **"Those who do not get vaccinated will immunize themselves naturally, because the Delta variant is so contagious. In this way we will end up in a situation similar to that of the flu. You can either get vaccinated and have a good winter. Or you don't do it and risk getting sick and possibly even ending up in hospital**." Asked if that meant a return to normal in the second half of next year, he said: "As of today, in a year, I assume." Bancel said he expected governments to approve booster shots for people already vaccinated because patients at risk who were vaccinated last autumn "undoubtedly" needed a refresher. Its booster shot had half the dose of the original dose, which meant more of them would be available. "The volume of vaccine is the biggest limiting factor. With half the dose, we would have 3 billion doses available worldwide for the coming year instead of just 2 billion," he said. The composition of the booster shot remains the same as the original for this year because Moderna had not had enough time to change it. "We are currently testing Delta-optimized variants in clinical trials. They will form the basis for the booster vaccination for 2022. We are also trying out Delta plus Beta, the next mutation that scientists believe is likely." Moderna can use existing production lines for the new variants as for the original COVID-19 vaccine. The price of vaccination will stay the same, he said. (Reporting by Michael Shields Editing by Robert Birsel)

1. Their climate excalation impacts were supposed to come within the year, after the first post-COVID grain harvest – it was written in april 2020 – this should’ve already happened
2. The Kitfield Card
   1. This person evidently has reason to believe both that the LIO is good and that China is always looking to destroy it with nuclear weapons – remember what happened last time we listened to these people and this ideology
   2. The card is pessimistic securitization– the facts say COVID is bringing countries closer together, but the rhetoric says they’re primed for war
   3. Xi was being more provocative in response to Trump blaming him for COVID, not COVID himself – Biden isn’t Trump
   4. The EU are the people that don’t support the vaccine waiver, but France is mad at us for deploying nuclear submarines against China – these alliances and grievances between countries don’t neatly match up across issues, so solving COVID won’t increase international cooperation
3. **We rehighlighted their OWN CARD whose tagline is “no alt cause” – that’s a lie – the US is mad at the WTO to the point of forcing its leadership to run aground AND barely participates anyway – the WTO is dying and useless, especially in the context of China and the US, and the EU doesn’t like it either so it’s already illegitimate and we’re still standing**

**Meyer 6-18-21**

(David, Senior Writer, https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/)

The World Trade Organization **knows all about crises**. Former U.S. President Donald Trump threw a wrench into its core function of resolving trade disputes—a blocker that President Joe Biden has not yet removed—and there is widespread dissatisfaction over the **fairness of the global trade rulebook**. The 164-country organization, under the fresh leadership of Nigeria's Ngozi Okonjo-Iweala, has a lot to fix. However, **one crisis is more pressing than the others**: **the battle over COVID-19 vaccines**, and whether the protection of their patents and other intellectual property should be temporarily lifted to boost production and end the pandemic sooner rather than later. According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—the WTO's future rests on what happens next. "The credibility of the WTO will depend on its ability to find a meaningful outcome on this issue that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "Final nail in the coffin" The Geneva-based WTO isn't an organization with power, as such—it's a framework within which countries make big decisions about trade, generally by consensus. It's supposed to be the forum where disputes get settled, because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's founding agreement allows for rules to be waived in exceptional circumstances, and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) Consensus is the key here. Although the failure to reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an **unprecedented and seismic event**. In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union, and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. It's a dispute between countries, but the result will be on the WTO as a whole, say waiver advocates. "If, in the face of one of humanity's greatest challenges in a century, the WTO functionally becomes an obstacle as in contrast to part of the solution, I think it could be the final nail in the coffin" for the organization, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. "If the TRIPS waiver is successful, and people see the WTO as being **part of the solution**—saving lives and livelihoods—it could **create** **goodwill and momentum to address what are still daunting structural problems**." Those problems are legion. Reform needs Top of the list is the WTO's Appellate Body, which hears appeals in members' trade disputes. It's a pivotal part of the international trade system, but Trump—incensed at decisions taken against the U.S. —blocked appointments to its seven-strong panel as judges retired. The body became completely paralyzed at the end of 2019, when two judges' terms ended and the panel no longer had the three-judge quorum it needs to rule on appeals. Anyone who hoped the advent of the Biden administration would change matters was disappointed earlier this year when the U.S. rejected a European proposal to fill the vacancies. "The United States continues to have systemic concerns with the appellate body," it said. "As members know, the United States has raised and explained its systemic concerns for more than 16 years and across multiple U.S. administrations." At her confirmation hearing in February, current U.S. Trade Representative Katherine Tai reiterated those concerns—she said the appellate body had "overstepped its authority and erred in interpreting WTO agreements in a number of cases, to the detriment of the United States and other WTO members," and accused it of dragging its heels in settling disputes. "Reforms are needed to ensure that the underlying causes of such problems do not resurface," Tai said. "While the U.S. [has] been engaging [with the WTO] it hasn't indicated it would move quickly on allowing appointments to the Appellate Body," says Bryan Mercurio, an economic-law professor at the Chinese University of Hong Kong, who opposes the vaccine waiver. "This is not a good sign. In terms of WTO governance, it's a much more important step than supporting negotiations on an [intellectual property] waiver." It's not just the U.S. that wants to see reform at the WTO. In a major policy document published in February, the EU said negotiations had failed to modernize the organization's rules, the dispute-resolution system was broken, the monitoring of countries' trade policies was ineffective, and—crucially—"the trade relationship between the U.S. and China, two of the three largest WTO members, is currently largely managed outside WTO disciplines." China is one of the key problems here. It became a WTO member in 2001 but, although this entailed significant liberalization of the Chinese economy, it did not become a full market economy. As the European Commission put it in February: "The level at which China has opened its markets does not correspond to its weight in the global economy, and the state continues to exert a decisive influence on China's economic environment with consequent competitive distortions that cannot be sufficiently addressed by current WTO rules." "China is operating from what it sees as a position of strength, so it will not be bullied into agreeing to changes which it sees as not in its interests," says Mercurio. China is at loggerheads with the U.S., the EU and others over numerous trade-related issues. Its rivals don't like its policy of demanding that Chinese citizens' data is stored on Chinese soil, nor do they approve of how foreign investors often have to partner with Chinese firms to access the country's market, in a way that leads to the transfer of technological knowhow. They also oppose China's industrial subsidies. Mercurio thinks China may agree to reforms on some of these issues, particularly regarding subsidies, but "only if it is offered something in return." All these problems won't go away if the WTO manages to come up with a TRIPS waiver for COVID-19 vaccines and medical supplies, Wallach concedes. "But," she adds, "**the will and the good faith** to tackle these challenges is **increased enormously** if the WTO has the **experience of being part of the solution, not just an obstacle."** Wallach points to a statement released earlier this month by Asia Pacific Economic Cooperation (APEC) trade ministers, which called for urgent discussions on the waiver. "The WTO must **demonstrate that global trade rules can help address the human catastrophe** of the COVID-19 pandemic and facilitate the recovery," the statement read in its section about WTO reform. Okonjo-Iweala's role The WTO's new director general, whose route to the top was unblocked in early 2021 with the demise of the Trump administration, is certainly keen to fix the problems that contributed to the early departure of her predecessor, Brazil's Robert Azevedo. "We must act now to get all our ambassadors to the table to negotiate a text" on the issue of an IP waiver for COVID vaccines, Ngozi Okonjo-Iweala, director general of the World Trade Organization, has said. Dursun Aydemir—Anadolu/Bloomberg/Getty Images Earlier this week, when the U.S. and EU agreed a five-year ceasefire in a long-running dispute over Boeing and Airbus aircraft subsidies, Okonjo-Iweala tweeted: "With political will, we can solve even the most intractable problems." However, Mercurio is skeptical about her stewardship having much of an effect on the WTO's reform process. "Upon taking [over she] stated it was time for delegations to speak to each other and not simply past each other, but at the recent General Counsel meeting delegations simply read prepared statements in what some have described as the worst meeting ever," he says. "On the other hand, Ngozi is very much someone who will actively seek solutions to problems, and in this way different to her predecessor. If the role of mediator is welcomed, she could have an impact not in starting discussions but in getting deals over the finish line." A spokesperson for the WTO Secretariat declined to offer comment on Mlumbi-Peter and Wallach's suggestions that the organization's credibility rests on the vaccine patent waiver issue, but pointed to a May speech in which Okonjo-Iweala said the WTO could help tackle vaccine supply chain monitoring and transparency, helping manufacturers scale up production, and creating a more geographically diversified manufacturing base. In her speech, the WTO chief also said members "must address issues related to technology transfer, knowhow and intellectual property," including the waiver proposal. "We must act now to get all our ambassadors to the table to negotiate a text," she said.

#### 1. No inherency – governments and the WTO are already reducing IP protections for medicines related to COVID-19. WTO No Date

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TRIPS, the intellectual property system and COVID-19 ¶The way in which an intellectual property (IP) system is designed at national or regional levels – and how effectively it is put to work - can be a significant factor in facilitating access to existing technologies and in supporting the creation, manufacturing and dissemination of new technologies, such as medicines, vaccines and medical devices, in response to the COVID-19 pandemic. This question – the relationship of IP to the pandemic response – has sparked a vigorous debate within and beyond the WTO, and is a high priority for technical assistance and policy support for WTO members. This page gives access to background information and current WTO documents (including members’ proposals) on this urgent question. ¶Introduction ¶From the beginning of the pandemic, the pressing need was clear for both the development of new vaccines and treatments, and access to these medicines for all – a global challenge unprecedented in both scope and urgency. ¶Governments and other stakeholders have therefore focused on how innovation mechanisms and tools for enhancing access to medical technologies can contribute to the pandemic response, well beyond a reliance on “business as usual”. This has led to a range of initiatives by international organizations, governments and private actors for the voluntary sharing, pooling or non-assertion of IP rights (IPRs), responding to the spirit of collaboration that dominates the global effort to tackle the pandemic. ¶A range of pro-health policy options and interventions are also available for WTO members under the TRIPS Agreement, as implemented in domestic law. ¶Transparency and the availability of up-to-date information on IP and COVID-19 respond to an immediate and critical need. They contribute to the empirical basis that is essential for policy-making in a rapidly evolving trade landscape in the mutual interest of all stakeholders, including governments and economic operators. ¶In furtherance of this objective, the following sections provide access to useful WTO and other resources that specifically address the interface between IPRs and COVID-19, as well as to the work of the TRIPS Council ¶Work of the [TRIPS Council](https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm) ¶Members have exchanged information and experiences relating to IP measures taken in the context of COVID-19 at the TRIPS Council, and have considered members’ proposals. 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It also provides an overview of measures taken by members. **¶**[Information Note: How WTO members have used trade measures to expedite access to COVID-19 critical medical goods and services](https://www.wto.org/english/tratop_e/covid19_e/services_report_16092020_e.pdf) ¶This note on access to COVID-19 critical medical goods and services includes information on using IPRs and policy tools to facilitate innovation in and access to COVID-19-related technologies. **¶**[Information Note: Developing and delivering COVID-19 vaccines around the world](https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf) ¶This note looks at issues with trade impact and discusses trade policy choices, including in the area of intellectual property rights, that may be considered along the vaccine value chain to support access to COVID-19 vaccines. **¶**[An integrated health, trade and IP approach to respond to the COVID-19 pandemic](https://www.wto.org/english/res_e/booksp_e/extract_who-wipo-wto_2020_e.pdf) **¶**A standalone section on COVID-19 in the 2020 study jointly published by the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and WTO, [Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition)](https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm), maps the multiple challenges posed by the pandemic in relation to the integrated health, trade and IP policy frameworks set out in the study. **¶**[Working Paper: Patent-related actions taken in WTO members in response to the COVID-19 pandemic](https://www.wto.org/english/res_e/reser_e/ersd202012_e.htm)**¶**This working paper provides an overview of the patent landscape of medical treatments and technologies related to COVID-19, and of the patent status of two investigational medical treatments: remdesivir and lopinavir/ritonavir. 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# A2 Solvency

#### in unsafe or ineffective medicines. Turns solvency because too many people will be afraid of the vaccine to achieve herd immunity.

Crosby et al. 21Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jeffrey Telep, Brian White; Crosby specializes in international trade, investment and matters related to public international law. Diamond is a partner on our Intellectual Property, Patent, Trademark and Copyright Litigation team.; 3-5-2021; "Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products"; https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/, JD Supra, accessed 7-21-2021; JPark

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.” At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

ongoing quality assurance support.