# Meadows R3 vs. Marlborough ML

## Off

### EU CP

#### CP: Member nations of the World Trade Organization should adopt the European Union’s proposal to:

#### Ensure that COVID-19 vaccines, treatments and their components can cross borders freely

#### Encourage producers to expand their production, while ensuring that those countries most in need of vaccines receive them at an affordable price

#### Facilitate the use of compulsory licensing within the WTO's existing Agreement on Trade-Related Aspects of Intellectual Property Rights

#### Solves vaccine access but avoids innovation

Brachmann 6/8 [(Steve, contributor to IPWatchdog.com, Research on Point, and Main Street Host writing about technology and innovation) “EU Offers Alternative to COVID-19 IP Waiver That Supports Innovation and Addresses Supply Chain Problems,” IP Watchdog, 6/8/2021] JL

The EU’s proposal to the WTO regarding COVID-19 vaccine access focuses on three key elements. The first element focuses on international supply chain issues, advocating for countries producing vaccines to increase international exports and to avoid any trade restrictions on vaccines or their raw materials that could hinder the supply chain either for countries in need or the global COVAX Facility initiative. Supply chain issues have a real and devastating effect on unvaccinated communities, as evidenced by the recent news that Thailand government officials acknowledged delays and reductions for a promised shipment of 17 million doses of Thai-produced AstraZeneca vaccines to the Philippines. One of the biggest supply chain issues facing the unvaccinated world right now is the decision of India’s government, which along with South Africa proposed the patent waiver at the WTO, to stop exporting vaccines manufactured by the Serum Institute of India, the world’s largest vaccine manufacturer, in order to address India’s own exploding COVID-19 infection rates. For its part, the United States under President Joe Biden recently announced an increase of 20 million doses to the country’s planned COVID-19 vaccine exports.

The second key element in the EU’s proposal requests that governments support vaccine manufacturers and developers to ensure affordable vaccine supplies. This portion of the EU’s proposal acknowledges the beneficial impacts of licensing, which ensures that developers and manufacturers enter into agreements that those companies are incentivized to uphold because they promote business interests. The EU’s proposal notes that the vaccine developers Pfizer, BioNTech, Johnson & Johnson and Moderna have all committed to agreements to deliver a combined 1.3 billion doses through 2021 at no profit to low-income countries and at low cost to middle-income countries.

The final key element in the EU’s alternative focuses on intellectual property and recognizes that “voluntary licenses are the most effective instrument to facilitate the expansion of production and sharing of expertise.” While compulsory licensing could be available without voluntary licensing due to the extraordinary nature of the COVID-19 pandemic, the EU advocates for using existing mechanisms for compulsory licensing under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While the EU is currently drafting a communication dedicated to intellectual property rights which it plans to submit to all WTO members, the governmental body was clear on its thoughts regarding the India-South Africa proposal backed by many governments, including the Biden Administration:

As regards the broad waiver proposed by a number of WTO members, the European Commission, while ready to discuss any option that helps end the pandemic as soon as possible, is not convinced that this would provide the best immediate response to reach the objective of the widest and timely distribution of COVID-19 vaccines that the world urgently needs.

The forces urging the world towards waiving international patent rights under TRIPS for COVID-19 vaccines are about as legion as they are misguided. On June 7, the WTO announced that it had received a petition signed by 2.7 million people around the world calling for the suspension of patent rights on COVID-19 vaccines. Currently more than 60 nations have publicly supported the India-South Africa proposal to waive patent rights under TRIPS for COVID-19 vaccines. However, as the EU’s proposal indicates, developing effective responses to international supply chain issues regarding vaccines do not have to stoop to dismantling the system for encouraging the investment in pharmaceutical R&D that produced the vaccine in the first place. In fact, the EU’s proposal recognizes that properly respecting IP rights and encouraging voluntary licensing, while making some allowances for Article 31 of TRIPS, will be a much more effective answer than a political stance that creates more problems than it solves by reducing medical innovation at exactly the time that the world needs it the most.

In supporting the waiver, the Biden Administration has arguably abdicated one of its first promises: that it would be an administration guided by science and truth. There is no science that exists to show that patents are barriers to vaccine access. That is a fact that has been acknowledged by the World Intellectual Property Organization, the UN’s agency for intellectual property rights, since the beginning of the COVID-19 pandemic. The sentimentality driving those supporting the TRIPS waiver for COVID-19 vaccines won’t solve supply chain issues in manufacturing capacity, which the EU’s alternative does address, but it will do a great job at decreasing investment into medical R&D because weak patent rights decrease economic productivity. Decreased investment in medical R&D will slow down the research needed to cure new COVID-19 variants that continue to appear across the world, and needless human death will continue.

### Innovation DA

#### Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### IP protections are key to innovation – recouping startup costs and high risk of failure

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.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 competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.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 accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2\

## Case

### Framing

1. **Moral uncertainty means preventing extinction should be our highest priority.  
   Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
   These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.
2. **Reducing the risk of extinction is always priority number one.   
   Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. [http://www.existenti...org/concept.pdf](http://www.existential-risk.org/concept.pdf)Even if we use the most conservative of these estimates, which entirely ignores the   possibility of space colonization and software minds, **we find that the expected loss of an existential   catastrophe is greater than the value of 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  lives of ordinary length) makes the same point even   more starkly.  Even if we give this allegedly lower bound on the cumulative output potential of a   technologically mature civilization a mere 1% chance of being correct, we find that the expected   value of reducing existential risk by a mere one billionth of one billionth of one percentage point is worth   a hundred billion times as much as a billion human lives. **One might consequently argue that even the tiniest reduction of existential risk has an   expected value greater than that of the definite provision of any ordinary good, such as the direct   benefit of saving 1 billion lives.**  And, further, that the absolute value of the indirect effect of saving 1  billion lives on the total cumulative amount of existential riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.

### Answers

#### Waivers don’t improve vaccine supply or distribution, but do allow for poorly made vaccines that undermine vaccine confidence

Delgado 5/25 [(Carla, health & culture journalist who’s written for Insider, Architectural Digest, Elemental, Observer, and Mental Floss) “Experts Say Patent Waivers Aren't Enough To Increase Global Vaccination,” Verywell Health, 5/25/2021] JL

“Waiving intellectual property rights for COVID-19 vaccines is likely to only have a modest impact on global vaccine supply,” William Moss, MD, executive director of the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health, tells Verywell. “A vaccine IP waiver is not in itself likely to lead to increased vaccine production in less developed countries because much more needs to be in place to increase the global vaccine supply.”

For several countries outside of the U.S. that have the necessary equipment to produce mRNA vaccines effectively and safely, the IP waiver can be of great help. However, many more countries lack this capacity, and this move still leaves them behind.

“The majority of the world’s countries lack the capacity to produce and distribute COVID-19 vaccines, and especially at the scale required to get this pandemic under control,” Richard Marlink, MD, director of the Rutgers Global Health Institute, tells Verywell. “They need funding, manufacturing facilities, raw materials, and laboratory staff with the technological expertise required.”

We've already seen what can go wrong with substandard vaccine manufacturing. In April, the Food and Drug Administration (FDA) inspected the Emergent BioSolutions factory in Baltimore and consequently shut down their production after concerning observations, which include:3

The factory was not maintained in a clean and sanitary condition.

Waste handling was found to be inadequate because generated waste was transported through the warehouse before disposal, which can potentially contaminate other areas.

Employees were seen dragging unsealed bags of medical waste from the manufacturing area across the warehouse.

Peeling paint, paint flecks, loose particles/debris were observed. There were also damaged floors and rough surfaces that cannot be properly cleaned and sanitized.

Employees were seen removing their protective garments where raw materials were staged for manufacturing.

They reportedly spoiled about 15 million doses of the Johnson and Johnson COVID-19 vaccine, and more than 100 million doses are on hold as regulators inspect them for possible contamination.4

“Vaccines are complex biological products, much more complex than drugs, and need to be produced by manufacturers and in facilities with the highest quality control standards,” Moss says. “Adverse events associated with a poorly made or contaminated batch of vaccines would have a devastating impact on vaccine confidence.”

In a statement last October, Moderna announced that they will not enforce their COVID-19-related patents against those who will make vaccines during this pandemic.5 While waiving some vaccine patents may allow third-party manufacturers to make and sell COVID-19 vaccines, the transfer of skills and technology that will allow them to manage production isn't very simple.

For instance, a spokesperson for Pfizer said that the Pfizer-BioNTech vaccine required 280 different components sourced from 86 suppliers across various countries. Manufacturing the vaccine would require highly specialized equipment and complex technology transfers.6

“Technology transfer also would need to be a critical component to expand vaccine manufacturing by other companies as an IP waiver is insufficient to provide the ‘know how’ needed to manufacture mRNA or adenovirus-vectored COVID-19 vaccines,” Moss says. “And supply chains for the reagents, supplies, and equipment would be needed.”

Interested manufacturers would need to have the proper equipment to test the quality and consistency of their manufacturing. At present, the World Health Organization (WHO) has plans to facilitate the establishment of technology hubs to transfer "a comprehensive technology package and provide appropriate training" to manufacturers from lower- and middle-income countries.7

While waiving vaccine patents is necessary, it's likely not enough. Additionally, negotiations about it are still ongoing. Even though the U.S. supports the waiver of COVID-19 vaccine patents, other countries like the United Kingdom, Japan, and Germany oppose it.8

It's also important to remember that manufacturing vaccines is only one step of the process of vaccinating the global population—distributing it is yet another hurdle.

“Many countries are counting on COVAX, a global collaboration to distribute COVID-19 vaccines more equitably around the world,” Marlink says. “The single largest supplier to COVAX is in India, where exports have been suspended since March due to the country’s COVID-19 crisis.”

#### TRIPs waiver is a symbolic gesture that prevents vaccine production and distribution

Ikenson 6/25 [(Dan, former director of the Cato Institute's Herbert A. Stiefel Center for Trade Policy Studies, MA in economics from George Washington University) “Stop Blaming Patents For The World’s Low Vaccination Rates,” Forbes, 6/25/2021] JL

The premise of the need for a TRIPS waiver is simply absurd. It serves to divert attention from the failures of governments to protect their citizens with smart public health policies and, importantly, to demonize intellectual property protections more broadly. Governments are already free to waive IP protections and to engage in compulsory licensing in times of health crises but have not done so because patents are not the bottleneck. The bottlenecks result from limited global expertise in the highly technical process of producing the vaccine, the dearth of production facilities and capacity to ramp up production at existing facilities, the tight supply of crucial pharmaceutical ingredients (including vials, bags, and other components), and the limited distribution channels through which the proper handling of vaccines at proper temperatures can be assured.

To be sure, global health officials and biopharmaceutical companies have been working to resolve these real bottlenecks—a process that has benefited significantly from the fact that U.S. officials have more bandwidth to devote more attention and other resources to these matters precisely because U.S. vaccination efforts have been successful. And why have they been successful? In large measure, they have been successful because intellectual property protections have bred expectations of future intellectual property protections, which has invited and enabled an accumulation of R&D investment, infrastructure, and expertise in the United States.

The effort to surmount these real impediments to producing, distributing, and injecting vaccines is not made any easier by a symbolic waiver of IP protections—and may be made more difficult. The volume of vaccines necessary to ending the pandemic requires governments and public health officials to coordinate and focus on ramping up the capacity to produce and distribute, and to safeguard against the squandering of pharmaceutical ingredients by ensuring those inputs are channeled to producers with expertise in manufacturing and distribution. On the contrary, suspending IP protection might encourage novice firms with no expertise to end up wasting limited, essential ingredients.

#### Waivers antagonize drug-makers and manufacturers which reduces vaccine production

Furlong 4/21 [(Ashleigh, health care reporter for POLITICO, based in London, former reporter at the science policy publication Research Fortnight who covered biomedical research policy) “Why waiving patents might not boost global access to coronavirus vaccines,” Politico EU, 4/21/2021] JL

Lifting IP rules may make it pretty straightforward to make some types of drugs where technology transfer isn’t important, said ‘t Hoen. For example, during the pandemic, both Hungary and Russia have issued compulsory licenses for remdesivir, with both countries then producing the drug. But that’s not true for vaccines.

A vaccine patent prevents another company from producing the same product. But even without a patent in the way, the company that produced the vaccine holds an enormous amount of relevant know-how that it's not going to turn over for free. So when drugmakers make deals with other manufacturers to produce their vaccine, they transfer this knowledge along under strict agreements. For example, AstraZeneca reached a licensing agreement with the Serum Institute of India last June that ensured that SII treats AstraZeneca as a priority customer in return for access to the technology behind the Oxford/AstraZeneca vaccine.

Compulsory licensing may also be an over-hyped solution, aside from removing the possibility of being sued for patent infringement, says Guilherme Cintra, director of innovation policy at the International Federation of Pharmaceutical Manufacturers and Associations, a pharma lobby. It could actually be "an antagonistic move," he added. "In a way it removes trust, and undermines the possibility of engaging in good faith to build up manufacturing."

#### The plan alienates pharma companies and doesn’t solve lack of vaccine purchasing

Glassman 5/6 [(Amanda, executive vice president and senior fellow at the Center for Global Development, research focuses on priority-setting, resource allocation and value for money in global health, former director for global health policy at the Center from 2010 to 2016, former deputy director of the Global Health Financing Initiative at Brookings and carried out policy research on aid effectiveness and domestic financing issues in the health sector in low-income countries, MSc from the Harvard School of Public Health) “Big Pharma Is Not the Tobacco Industry,” Barrons, 5/6/2021] JL

In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen.

But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita.

It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize preventable disease and deaths, address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started.

What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could?

No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

The big problem is that countries have not bought enough vaccine to inoculate most of their populations. Covax, buying on behalf of 91 lower-income countries, is only collecting enough funding to cover 20% of their population. In many parts of the world, such as the Middle East, sub-Saharan Africa and some countries in Latin America, we see very low levels of vaccine prepurchasing. We have seen this week that the government of India had not ordered enough vaccine to cover its own population, for example, resulting in export bans on its domestic vaccine manufacturers; nor has it approved the Pfizer vaccine. Our collective focus instead must be to make the market: to set up advance purchase agreements to establish demand via country cooperation, Covax, and the multilateral development banks.