## CP – universal healthcare

#### Text: The member nations of the World Trade Organization ought to implement single payer, universal national health insurance programs

#### Solves the aff - single payer health care stops evergreening, promotes innovation and eliminates financial burdens on consumers

**Narayanan 19**

(Srivats Narayanan, B.A. Biology@UMissouri-Kansas, “Medicare for All and Evergreening”, 8/15/19, <https://medium.com/@srivats.narayanan/medicare-for-all-and-evergreening-cb84c930e0ea)//HW-CC>

This is because pharmaceutical firms are spending their time and money on a technique known as “evergreening.” Evergreening is when drug companies produce redundant drugs that are nothing but minor modifications of old drugs. By making slight alterations to their medicines, biotech companies continue to hold patents for drugs with minimal spending on research and development (R&D). Pharmaceutical companies then use those patents to prevent competitors from selling generic versions of their drugs. Without any competition, these corporations get away with ridiculously high drug pricing and can thus make big profits on their drugs. The companies simultaneously justify their absurd drug prices by pointing to the inflated R&D costs of producing new drugs. This excuse has been used time and again by the profit-hungry pharmaceutical industry, and it’s coming at the expense of patients who struggle to afford their medicines. A well-known example of evergreening pertains to the anticonvulsant medication gabapentin, which was first sold by Pfizer under the brand name Neurontin. When the drug became available as a generic medication over a decade ago, Pfizer created a very similar medicine, pregabalin (Lyrica), that didn’t have any significant benefits over the original drug. As a result, Pfizer has kept a control over the market for anticonvulsant drugs with negligible innovation. The drug industry’s reliance on evergreening is undoubtedly stifling innovation. This is where Medicare for All, which would impose the government as the only health insurer, would be useful. In our current system, there are many insurers and they each have little market power and consequently little negotiating power to reduce treatment prices. Since the government would have consolidated control over healthcare financing under Medicare for All, its stronger bargaining power would force drug companies to charge lower prices for their products. In addition, prescription drugs would be paid for by the government and not by patients under Medicare for All. Medicare for All would prevent evergreening. National healthcare financing would align how much the government pays a drug company with how much patients benefit from the company’s drugs. If a new drug had more clinical benefits than an older version, the government would pay more for it. If a new drug produced the same results as an older version, the government wouldn’t pay more for the new drug. So, Medicare for All would encourage pharmaceutical companies to pursue truly innovative drugs because such drugs would be more profitable. The policy would incentivize companies to invest in R&D for more useful drugs, instead of just producing redundant and expensive medications. A national healthcare plan would prioritize “patient and community needs” and match up pharmaceutical companies’ interests with actually improving public health. Evergreening has become the name of the game for the pharmaceutical industry. A major solution to the evergreening problem is Medicare for All. A single-payer system like Medicare for All would sharply curtail evergreening, since drug companies wouldn’t be able to profit from it. Medicare for All would usher in a new era of medical innovation.

## Pharma DA

#### Biotech strong now — boosted by COVID and it's an inherently stable sector

Cancherini et al. 4-30

[Laura Cancherini, Engagement Manager @ McKinsey & Company. Joseph Lydon, Associate Partner @ McKinsey & Company. Jorge Santos da Silva, Senior Partner @ McKinsey & Company. Alexandra Zemp, Partner @ McKinsey & Company. "What’s ahead for biotech: Another wave or low tide?," McKinsey &amp; Company, 4-30-2021, accessed 8-25-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] HWIC

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 Exhibit 3 We strive to provide individuals with disabilities equal access to our website. If you would like information about this content we will be happy to work with you. Please email us at: [McKinsey\_Website\_Accessibility@mckinsey.com](mailto:McKinsey_Website_Accessibility@mckinsey.com) 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](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), 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](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) 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](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) 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.

**Patent protections are key to the development of industries such as biotech—mountains of economic data proves.**

**Phelps 15**

Marshall Phelps, former chief of global intellectual property operations for IBM and Microsoft, 9-16-2015, "Do Patents Really Promote Innovation? A Response To The Economist," Forbes, <https://www.forbes.com/sites/marshallphelps/2015/09/16/do-patents-really-promote-innovation-a-response-to-the-economist/?sh=7331bbe91921> (MLT)

Economists have repeatedly demonstrated that inventors are driven primarily by the expectation of profiting from owning the rights to their inventions. Zorina Khan of [Bowdoin College](http://www.forbes.com/colleges/bowdoin-college/), whose 2005 classic The Democratization of Invention: Patents and Copyrights in American Economic Development was awarded the prestigious Alice Hanson Jones Prize for outstanding work in economic history, observed that “Ordinary people [are] stimulated by higher perceived returns or demand-side incentives to make long-term commitments to inventive activity.” She also found that “their patterns of patenting were procyclical [and] responded to expected profit opportunities.” Along with her colleague the late Kenneth Sokoloff of UCLA, Professor Khan then [summarized the role of patents](http://www.nber.org/papers/h0042.pdf?new_window=1) in helping U.S. startup businesses grow the economy from an agrarian backwater into the most powerful industrial economy on the face of the earth: The U.S. patent system had a powerful impact on the patterns of inventive activity. Its provision of broad access to property rights on new inventions, coupled with the requirement of public disclosure, was extremely effective at stimulating the growth of a market for technology and promoting technological change [emphasis added]. Then, as now, the American formula for success was simple: **Startups + patents = jobs and economic growth**! Over the last 50 years, economists have found that patents continue to foster ex ante innovation — meaning, they induce people to invent because of the prospect of profiting from those inventions. The work of economists such as Arrow (1962), Griliches (1963), Schmookler (1966), Kitch (1977), Reinganum (1981), Klemperer (1990), Romer (1990), Giulbert and Shapiro (1990), Grossman and Helpman (1991), Scotchmer (1999), and Gallini (2002) on this issue is mostly available for free online at the [Social](http://www.ssrn.com/en/)[Science](http://www.forbes.com/science/) Research Network. One especially interesting 2007 study by Arora, Ceccagnoli, and Cowen entitled ["R&D and the Patent Premium"](https://www.scheller.gatech.edu/directory/faculty/ceccagnoli/pubs/ceccagnoli_ijio.pdf) found that "the patent premium for innovations that were patented is substantial. Firms earn on average a 50% premium over the no patenting case, ranging from 60% in the health related industries to about 40% in electronics.” Sure, one should be cautious about academic research, especially given the old joke about how an economist opens a can of soup. (Answer: assume a can opener.) But real-world economics clearly confirms the research findings. Consider, for example, that the biggest job-creating new industries of the last 60 years — semiconductors (consumer electronics), PCs, software, biotech, mobile telephony, and Internet e-commerce — were all launched and grew strong on the basis of patented inventions created by startup businesses. As the CEO of Juno Therapeutics, Hans Bishop, and ARCH Venture Partners co-founder Bob Nelson [recently wrote in Forbes](http://www.forbes.com/sites/matthewherper/2015/03/24/new-patent-law-would-trash-disease-cures/): “Let us be clear: **investments in the biotech industry are based entirely on patents. Without strong patents, we cannot raise money to find cures for disease.”** Moreover, the evidence that patents foster innovation is not confined to the U.S., nor is it limited only to developed countries. In 2008,[a study](http://nw08.american.edu/~wgp/park_lippoldt08.pdf) by the Organization for Economic Co-operation and Development (OECD) found that “stronger levels of patent protection are positively and significantly associated with inflows of high-tech product [and] expenditures on R&D.” And in [another study](http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=0ACC6C3B3E81D0484614C3293871858C?doi=10.1.1.199.6247&rep=rep1&type=pdf)that attracted wide attention, Shih-Tse Lo of Concordia University in Montreal found that the 1986 reforms strengthening the Taiwanese patent system “stimulated additional inventive activity, especially in industries where patent protection is generally regarded as an effective strategy for extracting returns, and in industries which are more R&D intensive. The reforms also seemed to induce additional foreign direct investment in Taiwan.” Interestingly, the evidence also shows that rather than hindering knowledge sharing, as the Economist claims, patents actually promote it. [Acemoglu, Bimpikis, and Ozdaglar (2008)](http://economics.mit.edu/files/6780)observed that “patents improve the allocation of resources by encouraging rapid experimentation and efficient ex-post transfer of knowledge across firms.” Indeed, it turns out that the patent system is one of the most effective tools for knowledge-sharing and technology transfer ever devised. [A 2006 study](http://www.microeconomix.fr/sites/default/files/import2/FL-YM-PatentsInnovationJanuary07.pdf) by French economists Francois Leveque and Yann Meniere found that 88 percent of U.S., European, and Japanese businesses said they actually rely upon the information disclosed in patents to keep up with technology advances and direct their own R&D efforts. This is hardly a new phenomenon. The 19th century inventor Elias E. Reis [reported](http://www.nber.org/chapters/c10229.pdf) that when he read about an 1886 patent issued to Elihu Thomson for a new method of electric welding, “there immediately opened up to my mind a field of new applications to which I saw I could apply my system of producing heat in large quantities.” Thomas Edison was known to frequent the patent office in order to study other inventors’ patents and hopefully spark ideas of his own. As for Edison himself, [a 2013 study](http://works.bepress.com/cgi/viewcontent.cgi?article=1073&context=rkatznelson) found that rather than blocking further invention, his seminal 1880 incandescent lamp patent (No. 223,898) actually “stimulated downstream development work” that resulted in “new technologies of commercial significance [including] the Tesla coil, hermetically sealed connectors, chemical vapor deposition process, tungsten lamp filaments and phosphorescent lighting that led to today’s fluorescent lamps.” A simple thought experiment suggests why this is so. As UCLA’s Sokoloff and Yale’s Naomi Lamoreaux [observed in a 1997 paper,](http://www.nber.org/papers/h0098.pdf?new_window=1) “The very act of establishing exclusive property rights in invention not only protected patentees but also promoted the diffusion of information about technology. To see why, imagine a world in which there was no patent system to guarantee inventors property rights to their discoveries. In such a world, inventors would have every incentive to be secretive and guard jealously their discoveries from competitors [because those discoveries] could, of course, be copied with impunity. This is the world of trade secrets. “By contrast,” the authors noted, “in a world where property rights in invention were protected, the situation would be very different. Inventors would now feel free to promote their discoveries as widely as possible so as to maximize returns either from commercializing their ideas themselves or from [licensing] rights to the idea to others. The protections offered by the patent system would thus be an important stimulus to the exchange of technological information in and of themselves. Moreover, it is likely that the cross-fertilization that resulted from these information flows would be a potent stimulus to technological change.” In the real world, one need only look at the smartphone industry to see the truth in that thought experiment. Does anyone believe that global smartphone use would have experienced such extraordinarily rapid growth under a trade secret regime? Impossible. Only a strong patent system enabling the licensing and cross-licensing of proprietary technology across four very disparate industries —telephony, electronics, computing and software — could have produced the hugely successful smartphone industry that we enjoy today. The response of some critics to all this evidence is, “Yes, but you can’t prove causation.” And it’s true, one cannot prove theoretically that the patent system by itself causes higher rates of innovation and economic growth. That’s because the exogenous factors — the dynamism of markets, the efficacy of legal and governmental institutions, the availability of capital, and the role of countless other factors — are far too complex and interdependent to isolate causation to patents alone. It’s like trying to pinpoint ultimate causation in the weather. It can’t be done. But by the same token, one also cannot prove that free market capitalism — isolated from all the legal, educational, economic, governmental and cultural institutions that surround it in any country — causes more economic growth than a government-run socialist economy. Yet we all know without a doubt from real-world experience — including the fact that 74 years of socialism in the Soviet Union failed to produce even a decent refrigerator — that free markets are strongly correlated with greater economic prosperity. The same is true of the patent system: on balance and over the long term, **patents are strongly correlated with increased innovation,** knowledge sharing, and economic growth. I’m all for stopping the patent trolls who pillage innocent businesses rather than create anything useful. But if we want America to keep inventing the future, we’d better keep patenting.

#### With a lack of new procedures and medicines due to the innovation drought, thousands to millions could die of potentially treatable diseases.

**Twist 17**

(Twist Bioscience, What Would Our World be Like Without Modern Medicines? December 12th, 2017. https://www.twistbioscience.com/blog/perspectives/what-would-our-world-be-without-medicines) LAM

It’s easy to be cynical about the effects of pharmaceuticals on our society, given the rates of abuse of some prescription drugs, as well as the high profits of the pharmaceutical industry. But have you ever imagined what the world would be like without prescription and over-the-counter drugs? Despite the issues raised by the modern pharmaceutical industry, a world without medicine would be very different from the world we live in today. For starters, would all of us even be here if it weren’t for modern drugs? **Humans were afflicted with smallpox for thousands of years, with** [**death**](http://www.historyofvaccines.org/content/timelines/smallpox) **being the end result in 30% of cases. However, modern vaccines** [**eradicated smallpox**](http://www.who.int/csr/disease/smallpox/faq/en/) **in 1979**, as declared by the World Health Organization. **There are millions of people who would not be alive today if they or their ancestors had not been inoculated against the disease. Modern medicine has directly affected our longevity as well. In the US, life expectancy for men** [**rose nearly 11**](http://www.phrma.org/sites/default/files/pdf/chartpack-2015.pdf?__hstc=110588826.03f7e4f7b8462293d3f092f0ca3d6f4d.1430323119866.1430918649144.1431103046901.4&__hssc=110588826.33.1431103046901&__hsfp=1985457564www.who.int/csr/disease/smallpox/faq/en/) **years to 76.2 years between 1950 and 2011. Meanwhile, women’s life expectancy rose similarly, from 71.1 to 81.2 years over the same time period**. To quote the President’s Council of Advisors on Science and Technology, “…**innovative medicines have also played a profound role in this progress**”. This increase in longevity was due in part to the drop in the death rate by heart disease, one of the major killers in the US. Between 1999 and 2011 alone, the risk of death within a year of hospitalization for heart disease [decreased 20%](http://www.webmd.com/heart/news/20140818/big-drop-in-us-heart-related-hospitalizations-and-deaths-study-finds). This significant decrease was due partly to the [availability of heart medications](http://content.healthaffairs.org/content/26/1/25.full.html). **We have less chance of dying from diseases, and we now live longer thanks in part to modern drugs. At the same time, our quality of life is improving.** High blood pressure is one of the most prevalent maladies in modern society. An astounding [one of every three](http://www.heart.org/idc/groups/heart-public/@wcm/@sop/@smd/documents/downloadable/ucm_319587.pdf) US adults suffers from high blood pressure. [Left untreated](http://www.mayoclinic.org/diseases-conditions/high-blood-pressure/basics/complications/con-20019580), as was the case before blood pressure medications, it can lead to kidney damage, vision loss, stroke, and loss of memory and understanding. High blood pressure also plays a role in the group of disorders known as metabolic syndrome, which includes diabetes. Modern blood pressure (anti-hypertensive) drugs have been in use for more than 50 years. **They enable many people to live happy and healthy lives with a** [**reduced risk**](http://www.shen-nong.com/eng/lifestyles/hypertension_treatment_facts_and_myths.html) **of stroke, kidney damage and vision problems.** There are many other examples of how modern drugs affect our quality of life on a daily basis, such as aspirin for headaches, topical antibiotics for annoying cuts and scrapes, and allergy and cold medications that help us counteract the symptoms of these common maladies. While modern pharmaceuticals have the potential for abuse and harmful side effects, there can be no doubt that their development and use have decreased mortality rates, while improving lifespan and quality of life. **With the new tools that are available for efficacious and rapid drug development, such as** [**synthetic biology**](http://sybhel.org/?p=730) **and synthetic DNA, these positive trends should continue and accelerate.**

## Safety DA

#### Covid-19 vaccines are safe and effective right now.

Moline ‘21

(Heidi L. Moline, MD; Michael Whitaker, MPH; Li Deng, PhD; Julia C. Rhodes, PhD; Jennifer Milucky, MSPH; Huong Pham, MPH; Kadam Patel, MPH; Onika Anglin, MPH; Arthur Reingold, MD Shua J. Chai, MD; Nisha B. Alden, MPH; Breanna Kawasaki, “Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years” <https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e3.htm> , August 13)

Clinical trials of COVID-19 vaccines currently authorized for emergency use in the United States (Pfizer-BioNTech, Moderna, and Janssen [Johnson & Johnson]) indicate that these vaccines have high efficacy against symptomatic disease, including moderate to severe illness (1–3). In addition to clinical trials, real-world assessments of COVID-19 vaccine effectiveness are critical in guiding vaccine policy and building vaccine confidence, particularly among populations at higher risk for more severe illness from COVID-19, including older adults. To determine the real-world effectiveness of the three currently authorized COVID-19 vaccines among persons aged ≥65 years during February 1–April 30, 2021, data on 7,280 patients from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) were analyzed with vaccination coverage data from state immunization information systems (IISs) for the COVID-NET catchment area (approximately 4.8 million persons). Among adults aged 65–74 years, effectiveness of full vaccination in preventing COVID-19–associated hospitalization was 96% (95% confidence interval [CI] = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Effectiveness of full vaccination in preventing COVID-19–associated hospitalization among adults aged ≥75 years was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products. COVID-19 vaccines currently authorized in the United States are highly effective in preventing COVID-19–associated hospitalizations in older adults. In light of real-world data demonstrating high effectiveness of COVID-19 vaccines among older adults, efforts to increase vaccination coverage in this age group are critical to reducing the risk for COVID-19–related hospitalization. COVID-NET includes data on laboratory-confirmed COVID-19–associated hospitalizations in 99 U.S. counties in 14 states, representing approximately 10% of the U.S. population.† COVID-NET cases were hospitalizations that occurred in residents of a designated COVID-NET catchment area who were admitted within 14 days of a positive SARS-CoV-2 test result. COVID-NET program personnel collected information on COVID-19 vaccination status (vaccine product received, number of doses, and administration dates) from state IISs for all sampled COVID-NET cases.§ Some sites expanded collection of information on vaccination status to all reported COVID-NET cases, not only sampled cases, which were included for analysis if all cases in a single month had vaccination status available. Data from 13 sites were included for analysis; one site (Iowa) does not have access to the state IIS and cannot collect vaccination data.¶ Population-level vaccination coverage was determined using deidentified person-level COVID-19 vaccination data reported to CDC by jurisdictions, pharmacies, and federal entities through the IISs,\*\* Vaccine Administration Management System,†† or direct data submission.§§ The study was restricted to adults aged ≥65 years and included the period February 1–April 30, 2021. The Janssen vaccine was authorized for use during the study period beginning March 15, 2021.¶¶ Patients were classified as 1) unvaccinated (no IIS record of vaccination), 2) partially vaccinated (1 dose of Moderna or Pfizer-BioNTech received ≥14 days before hospitalization or 2 doses, with the second dose received <14 days before hospitalization), or 3) fully vaccinated (receipt of both doses of Moderna or Pfizer-BioNTech with second dose received ≥14 days before hospitalization or receipt of a single dose of Janssen ≥14 days before hospitalization). Patients with only 1 dose of any COVID-19 vaccine received <14 days before hospitalization were excluded. Daily county-level coverage data for adults aged 65–74 and ≥75 years in the COVID-NET catchment area were estimated using population denominators from the U.S. Census Bureau; vaccination status was classified as described for hospitalized cases.\*\*\* For vaccine records missing county of residence, county of vaccine administration was used. To estimate vaccine effectiveness and corresponding 95% CIs, methods were adapted based on previously published literature (4). Poisson regression was used to compare case counts by vaccination status (outcome) and the proportion of the population vaccinated and unvaccinated (offset).††† Data were stratified by age group because of the potential for confounding by age, and adjusted for COVID-NET site, time (number of weeks since the start of the study period as a categorical covariate), and monthly site-specific sampling frequency.§§§ Vaccine effectiveness was calculated as one minus the exponent of the estimated coefficient of the exposure (vaccination status) variable. For estimating effectiveness of full vaccination, partially vaccinated persons were excluded; for estimating effectiveness of partial vaccination, fully vaccinated persons were excluded. Vaccine product–specific estimates excluded persons who had received other COVID-19 vaccines. To account for the interval between infection and hospitalization, sensitivity analyses were conducted using a reference date 1 week and 2 weeks before admission, rather than admission date, for classification of vaccination status for cases (i.e., adding 7 and 14 days, respectively between last vaccine dose and hospital admission date); the same adjustment was included for population vaccination coverage. Statistical analyses were conducted using SAS software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶¶ During February 1–April 30, 2021, among 7,280 eligible COVID-NET patients, 5,451 (75%) were unvaccinated, 867 (12%) were partially vaccinated, and 394 (5%) were fully vaccinated; 568 (8%) who received a single vaccine dose <14 days before hospitalization were excluded from the analysis (Table). Vaccination coverage in the population increased rapidly during this period among persons aged ≥65 years and varied by age and vaccine product (Figure 1). Among adults aged ≥65 years in the COVID-NET catchment area, full vaccination coverage from any of the three authorized vaccines ranged from 0.7% on February 1, 2021, to 72% on April 30, 2021. Effectiveness of full vaccination in preventing hospitalization among adults aged 65–74 years was estimated at 96% (95% CI = 94%–98%) for Pfizer-BioNTech, 96% (95% CI = 95%–98%) for Moderna, and 84% (95% CI = 64%–93%) for Janssen vaccine products. Among adults aged ≥75 years, effectiveness of full vaccination was 91% (95% CI = 87%–94%) for Pfizer-BioNTech, 96% (95% CI = 93%–98%) for Moderna, and 85% (95% CI = 72%–92%) for Janssen vaccine products (Figure 2). Effectiveness of partial vaccination among adults aged 65–74 years was 84% (95% CI = 76%–89%) for Pfizer-BioNTech and 91% (95% CI = 87%–93%) for Moderna vaccine products. Among those aged ≥75 years, effectiveness of partial vaccination was 66% (95% CI = 48%–77%) for Pfizer-BioNTech and 82% (95% CI = 76%–86%) for Moderna vaccine products. Sensitivity analyses accounting for interval between infection and hospitalization did not yield notably different vaccine effectiveness estimates, with point estimates varying by <1% for Pfizer-BioNTech and Moderna vaccine models. Point estimates for Janssen COVID-19 vaccine models varied by <10%, with few cases eligible for inclusion and wide CIs.

#### But, waiving patent rights does not guarantee vaccine safety

Smith Spark ‘21

(Laura,- Former Senior Broadcast Journalist for the BBC, and Newsweek editor of CNN,,“Right Countries Urged to Share Vaccine Knowledge as WTO Debates Waving Patents” <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>, May 05)

If the proposed waiver were to be approved, then **technological know-how** must be transferred to new production sites as well as the intellectual property rights, Rockwell said. Countries must also ensure that they have a strict but transparent regulatory infrastructure in place, he added. The proposed waiver has previously been obstructed by a ["small number" of wealthier nations](https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations), according to Doctors Without Borders. When it was blocked at the WTO in March, aid organization [Oxfam](https://reliefweb.int/report/world/oxfam-response-wto-trips-waiver-covid-19-vaccines-being-blocked-again-rich-countries) slammed the decision as a "massive missed opportunity" to speed up worldwide vaccine production, and accused rich countries of "siding with a handful of pharmaceutical corporations in protecting their monopolies against the needs of the majority of developing countries who are struggling to administer a single dose."**Gross Failure of Leadership** Rights group Amnesty International and the People's Vaccine Alliance urged G7 leaders Wednesday to listen to their people and ensure vaccine knowledge is shared. "G7 governments have clear human rights obligations to put the lives of millions of people across the world ahead of the interests of the pharmaceutical companies that they have funded," said Steve Cockburn, head of economic and social justice at Amnesty International, [in a news release](https://www.amnesty.org/en/latest/news/2021/05/an-average-of-7-in-10-across-g7-countries-think-their-governments-should-force-big-pharma-to-share-vaccine-know-how/). "It would be a gross failure of leadership to continue blocking the sharing of life-saving technologies, and would only serve to prolong the immense pain and suffering caused by this pandemic." Wednesday's WTO meeting comes a day after the chief of Pfizer said the company was expecting approximately $26 billion in revenue from its Covid-19 vaccine in 2021.More than 300 public health experts [signed a letter](https://www.publichealth.columbia.edu/sites/default/files/trips_sign_on_letter_4-30-21.pdf) Friday arguing that the United States should join an effort to force vaccine makers to waive intellectual property rights to coronavirus vaccines and treatments so more countries can start making them. The group, led by Columbia University professors Terry McGovern and Chelsea Clinton, said the so-called TRIPS waiver would allow local manufacture of vaccines, treatments and diagnostics. "Allowing countries to manufacture locally will speed access to vaccines and treatment, prevent unnecessary deaths, and facilitate a stronger, faster economic recovery," they wrote. "Until vaccines, testing, and treatments are accessible to everyone everywhere we risk recurring new variants, drug resistance, and greater loss of life and suffering at home and globally." That appeal came a fortnight after more than 170 former world leaders and Nobel laureates, including former UK Prime Minister Gordon Brown, former President of Liberia Ellen Johnson Sirleaf and former French President François Hollande sent an [open letter to the White House](https://peoplesvaccinealliance.medium.com/open-letter-former-heads-of-state-and-nobel-laureates-call-on-president-biden-to-waive-e0589edd5704) urging President Joe Biden to support the temporary waiver on IP rights for Covid-19 vaccines at the WTO. **Legal Battles** But even as public pressure grows, some experts argue that handing over the IP rights for Covid-19 vaccines won't necessarily mean that more can be rapidly produced worldwide at large scale. US infectious diseases chief Anthony Fauci [told the UK's Financial Times](https://www.ft.com/content/2f41b122-5738-4707-a822-0d79276710c5) on Monday that he was not convinced that forcing companies to share their intellectual property was the most effective approach, warning that legal battles could slow the process."Going back and forth, consuming time and lawyers in a legal argument about waivers -- that is not the endgame. People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible," he said. Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the **transfer of know-how,**" he said. "I **don't think there's clear evidence** that a waiver of an intellectual property is going to be the best way for that technology transfer to occur."Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. It's **very different for vaccines**, where it's really a **biological process** as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "**It requires a lot of knowledge that's not part of the IP."** The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said.

#### Removing IP would cause ineffective and unsafe vaccines

Brougher MPH 3/30/21

Joanna T. Brougher, Esq., Mph &amp; Andrew Kingsbury, 3-30-2021, "Calls for Compulsory Licensing and IP Waivers of COVID-19 Vaccines Ignore Technical Complexities," IPWatchdog, <https://www.ipwatchdog.com/2021/03/30/calls-compulsory-licensing-ip-waivers-covid-19-vaccines-ignore-technical-complexities/id=131617/> // AW

While seeking compulsory licensing or IP waivers may seem an attractive solution to address technological disparities across human populations, these mechanisms ignore some of the more technical hurdles to increasing accessibility to vaccination. This post will first briefly explain what compulsory licensing and IP waivers are and then examine three possible causes for why compulsory licenses and IP waiver are not a feasible solution to the current COVID-19 pandemic. Compulsory Licensing One of the agreements that countries must ratify upon joining the World Trade Organization (WTO) is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was negotiated in 1994 to harmonize intellectual property laws across different countries and to establish minimum standards for protecting and enforcing intellectual property rights for all WTO member countries. There are several provisions under TRIPS that allow governments to provide for limitations to intellectual property rights. In [Article 31](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf), for instance, TRIPS allows governments to order domestic manufacturers to make a patented product without permission from the patent holder. This practice is known as compulsory licensing. Article 31 permits countries to engage in compulsory licensing if there is a “case of a national emergency or other circumstances of extreme urgency,” or in cases of “public non-commercial use.” Under these circumstances, the country is first required to negotiate with, or seek approval from, the patent holder of the drug, but if the negotiations fail, is ultimately just permitted to manufacture patented products, such as essential medicines, for its domestic market. For countries that cannot manufacture drugs themselves, and who would thus not be able to issue compulsory licenses under Article 31, Article 31bis was created to permit a developed country to export a generic drug under a compulsory license to a less developed country. IP Waivers Contrary to compulsory licensing, IP waivers simply ask that countries be exempt from the provisions of TRIPS that require countries to protect and enforce patent rights to COVID-19 treatments and vaccines. In October 2020, [India and South Africa petitioned the WTO](https://www.ipwatchdog.com/2021/01/02/india-south-africas-covid-vaccine-proposal-wto-patent-waiver-must-considered-compulsory-licensing/id=128652/) for a temporary waiver from specific provisions of the TRIPS Agreement that could essentially put entire realms of existing intellectual property law on hold at the international level until widespread vaccination has become globally implemented. Perhaps unsurprisingly, this proposal was met with strong resistance from developed nations while developing and less developed nations were more welcoming towards it. In March 2021, the proposal failed to pass resolution at the WTO. Covid-19 Vaccines are New What these proposals fail to take into account is the nature of the Pfizer and Moderna vaccines. The efficacy of both of these proposals turns on a country’s internal technological capabilities to recreate and administer the vaccine. The Pfizer and Moderna vaccines, however, are not typical vaccines. Whereas traditional vaccines functioned by introducing parts of a virus — or a weakened form of a virus — Pfizer’s and Moderna’s vaccines use messenger RNA to cause host cells to produce the protein themselves. These are the [first vaccines to utilize this type of technology](https://www.abc27.com/news/health/coronavirus/vaccination-frustration/digital-original-how-do-covid-19-vaccines-compare-to-other-vaccinations/). The novelty of these vaccines potentially degrades the utility of a compulsory license or IP waiver. For instance, remdesivir received a great deal of focus early in the pandemic. Bangladesh managed to recreate the drug without Gilead Science’s approval because it is exempt from Article 31 of TRIPS, and Bangladesh [was able to produce a sufficient supply for the country by the summer of 2020](https://patentlyo.com/patent/2021/01/shortages-compulsory-licensing.html) because information about the drug was available. Given the fact that Pfizer’s and Moderna’s vaccines represent a new form of vaccine, lacking technical information on how to make this new form of vaccine could lead the countries to create entirely ineffective vaccine replicas. These issues may be compounded by the fact that many vaccine manufactures [rely on trade secret protection more heavily](https://www.jdsupra.com/legalnews/trade-secret-protection-the-covid-19-37383/) following the [Ass’n for Molecular Pathology v. Myriad Genetics, Inc](https://www.leagle.com/decision/insco20130613e08). decision. These trade secrets can withhold critical scientific know-how that might be necessary for replicating a vaccine. Thus, the new technology behind these messenger RNA vaccines and the lack of accessibility to the related know-how might deter countries from attempting to manufacture them. Lack of Information Yet another more fundamental problem exists for replicating these vaccines. Not only do these vaccines represent a new form of vaccine, but information about these particular vaccines is simply unavailable. Even if the Pfizer and Moderna vaccines do not utilize any trade secrets, the discovery of these vaccines is fundamentally different than remdesivir’s timeline, which resulted in Bangladesh’s recreation of the drug. [A patent for remdesivir was filed as early as 2015](https://patents.google.com/patent/US20170071964A1/en), and thus the information had been publicly available for years. While the technology underlying mRNA vaccines has been in development for decades, there are likely specific technological hurdles associated with, for instance, the coronavirus, mass production and scale up, and delivery mechanisms that needed to be developed for this specific application of the legacy technology. This additional information will not be found in scientific journals or magazine articles, nor can it be found in any patent application, yet. Patents, moreover, can take up to 18 months from filing to be published. BioNTech made an [F-1 filing with the SEC](https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm) on July 21, 2020, in which it acknowledged its partnership with Pfizer to develop the vaccine. If this filling is at all indicative of when a patent could have been filed, then this would mean the patent may not be available to the public until late-2021–mid-2022. With Novelty Comes Difficulty The newness of these vaccines also creates problems due to the complexity in how these types of vaccines function and how to produce them. According to a [Wall Street Journal report](https://www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401), manufactures say that vaccine production is difficult both “because some steps are difficult to scale up quickly or because they simply haven’t been done before.” Even Pfizer is [having difficulty obtaining](https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787) the necessary materials for vaccine production. Here, the complexity of these vaccines demonstrates the potential futility of a compulsory license or IP waivers. Even if other countries could compel manufactures to license the underlying intellectual property and provided them with the information about how to do so, the complexity of manufacturing these types of vaccines could be a particularly high barrier to overcome. It’s Complicated Countries face roadblocks for producing a viable vaccine candidate based on Pfizer’s and Moderna’s vaccines. The new technology that utilizes messenger RNA vaccines, coupled with the lack of public information about these vaccines and the vaccines’ complicated nature, present significant hurdles to seeking compulsory licenses or IP waivers.

#### Any imperfection in LIC implementation leads to vaccine skepticism – low bar for offense and turns case

Trogen et al 20

Brit Trogen (Md, Ms1), David Oshinsky ( PhD), Arthur Kaplan (PhD) 1-28-2020, "Rushing a SARS-CoV-2 Vaccine: Potential for Harm," JAMA, <https://jamanetwork.com/journals/jama/fullarticle/2766651%20> // AW

As the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic persists across the US and the world, the spotlight on vaccine science has never been more intense. Researchers across the globe are working rapidly to produce a potential vaccine, and 7 candidates are already in clinical trials.[1](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r1) Operation Warp Speed, the vaccine development project announced by President Trump, has advocated for a vaccine to be made available in the US by the beginning of 2021.[1](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r1) But for scientists and physicians, the term “warp speed” should trigger concern. Good science requires rigor, discipline, and deliberate caution. Any medical therapy approved for public use in the absence of extensive safeguards has the potential to cause harm, not only for COVID-19 prevention efforts and vaccine recipients, but also for public trust in vaccination efforts worldwide. Long before coronavirus disease 2019 (COVID-19), vaccine hesitancy and refusal were increasing.[2](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r2) In 2019, the World Health Organization listed vaccine refusal as one of the top 10 global health threats.[3](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r3) Pediatricians, in particular, frequently encounter resistance to childhood vaccinations, and as a result, outbreaks of measles and other vaccine-preventable illnesses, such as pertussis and influenza, have increased in recent decades.[4](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r4) Much of the distrust of vaccines (and, by extension, the physicians and scientists who promote them) is driven by widespread misinformation from both online sources and skeptical communities.[2](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r2),[4](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r4) The belief that vaccines cause harmful adverse effects like autism has persisted despite carefully designed research studies that have refuted such claims. When physicians promote vaccines, they do so knowing that the benefits far outweigh the minimal risks, and that each vaccine has been studied extensively to establish its safety profile. Yet vaccine opponents frequently accuse physicians and researchers of failing in this respect, citing financial or political interests as the motivation for promoting vaccines. As the search for a SARS-CoV-2 vaccine accelerates, physicians and **scientists who wish to maintain the public’s trust must not promote a vaccine that has either bypassed established safety standards or is open to a serious charge of having done so. There is grim historical precedent** for allowing expediency to rule vaccine development. In 1955, the inactivated polio vaccine developed by Jonas Salk was declared “safe, potent, and effective” following the largest public health experiment in the nation’s history, involving more than a million schoolchildren.[5](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r5) Within weeks, however, the miracle vaccine intended to end the scourge of polio stood accused of causing it. Years in development, the Salk vaccine had been rigorously tested in preparation for the massive trials. But the very success of these trials led to an understandable outcry for the immediate, but premature, public release of the vaccine. Five pharmaceutical companies were given Salk’s formula and left to produce the vaccine without significant oversight. As speed took precedence over caution, serious mistakes went unreported.[5](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r5) One company, Cutter Laboratories, distributed a vaccine so contaminated with live poliovirus that 70 000 children who received that vaccine developed muscle weakness, 164 were permanently paralyzed, and 10 died.[6](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r6) Not surprisingly, that incident forced the federal government to directly intervene. The legacy of this event is a regulatory landscape in which vaccines undergo thousands of tests to ensure their safety and effectiveness.[6](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r6) Yet on rare occasions, this vital evidence-based process of vaccine development and testing has still been ignored. In 1976, concerns about the emergence of a new swine flu strain reminiscent of the lethal 1918 version led President Gerald Ford to convene a panel that recommended a government-backed mass vaccination program.[7](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r7) Poorly conceived, the attempt to vaccinate the US population at breakneck speed failed in virtually every respect. Safety standards deteriorated as one manufacturer produced the incorrect strain. The vaccine tested poorly on children who, depending on the form of vaccine tested, either developed adverse reactions with high fevers and sore arms or did not mount an immune response at all. Reports emerged that the vaccine appeared to cause Guillain-Barré syndrome in a very small number of cases, a finding that remains controversial, but added to the early momentum of the antivaccine movement.[7](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r7) Once again, the pressure to rapidly distribute a vaccine undermined the scientific integrity of the process and damaged public trust. COVID-19 has created intense concern and uncertainty in the US and throughout the world. There are immense public and political pressures to develop a new vaccine, a process that typically takes years, not months. But as history warns, these pressures must not supplant rigorous scientific practice. Proceeding stepwise through the phases of clinical trials is the ethical standard for investigations involving human research participants. Adherence to the scientific method is the only way to safeguard against a SARS-CoV-2 vaccine that is ineffective, or worse, carries unacceptable adverse effects. Failing to abide by standards of safety and scientific rigor during the COVID-19 crisis will fuel the argument that physicians and scientists cannot be trusted. Vaccination rates, which are declining due to widespread concern about visiting clinicians’ offices, could further decrease. The US could see resurgences of many vaccine-preventable illnesses, and inevitably, massive increases in avoidable deaths and irreversible outcomes. There are, however, reasons to hope that these scenarios will not come to pass. In response to past failures, vaccine development in the US is subject to increased regulatory oversight designed to protect against substandard practices. Technological advances permit the rapid communication of adverse events in clinical trials, and the understanding of the genetic factors influencing immunologic responses has increased. To proactively address safety concerns, these and other safeguards should be clearly communicated to the public during the vaccine development process. Both the public and the scientific community want an effective and safe intervention to prevent COVID-19. The morbidity, mortality, and societal and financial devastation that SARS-CoV-2 has caused throughout the world will have wide-reaching consequences for almost every aspect of life for years to come. Nothing should dampen the ardor of researchers worldwide in the aggressive search for effective treatments. In this unprecedented crisis, novel trial designs, such as those that include challenge studies, should be carefully considered.[8](https://jamanetwork.com/journals/jama/fullarticle/2766651%20#jvp200112r8) But what cannot and must not be allowed is for desperation to result in the suspension of scientific principles and ethical research values. Physicians should not administer inadequately vetted vaccines; researchers should not endorse them without sufficient data. The scientific community has only one chance at winning public acceptance of a SARS-CoV-2 vaccine. The likelihood of achieving that goal will depend on convincing evidence of vaccine safety and efficacy.

## Case

#### The plan diffuses, but does not diminish, the power of intellectual monopolization under capitalism – without strict IP regimes, companies move to secrecy in business practices along with either complete outsourcing or completely in-house production – both dispossess global south economies.

Durand and Milberg, 18

[Cédric, Associate Prof. Political Economy @ U-Geneva, member @ Paris Nord Economics Center; and William, Dean @ The New School for Social Research: “Intellectual Monopoly in Global Value Chains,” published in 2018, https://hal.archives-ouvertes.fr/hal-01850438]//AD

\*GVCs=Global Value Chains

The late 20th century internationalization of IPRs and the expansion of GVC trade have each been driven by a separate set of factors, but there is a link and we see it in the growing role of intangible assets in international trade. GVC trade is qualitatively different from the traditional exchange of final goods or primary products. It requires intense information flows to coordinate the labor process in parts across countries (see section 2.2). Moreover, the density of these information flows entails a risk of appropriation by would-be competitors, even more than in traditional trade of finished products, where a costly process of reverse engineering is required prior to any imitation (Mansfield et al., 1981). In GVCs, lead firms thus have to weigh the advantages of disaggregating the production process and the cost reduction this can bring against the risk of losing control over some of their proprietary intangible assets. 21 Management studies and transaction costs economists have stressed the importance of the IP institutional context for business decisions when there are international alliances, investment and sourcing due to the risk of so called “appropriability hazards” (Oxley, 1997; Teece, 1986). This risk seems to have expanded since the 1990s, although there are some early testimonies from chemical and information industries reporting a reluctance to transfer advanced technology in countries with weak intellectual property regimes (Mansfield, 1994, pp. 26–29). From the perspective of transaction cost economics, considering the case of a relation with a foreign supplier or buyer, the risk of IP leakage due to a weak IP environment will tend to raise the cost of relying on contract-based alliances relative to equity joint venture (Oxley, 1999, pp. 287–288; Williamson, 2008, p. 12). From the perspective of management research, careful management of the flow of technology along GVCs is imperative and necessitates strict control over information flows in countries with weak IPRs (Prasad & Sounderpandian, 2003, p. 246). Adequate governance arrangements, secrecy or restraint to outsource offshore were thus considered as the main way to deal with the risk of IP leaks in GVCs: Companies can mitigate intellectual property risk by bringing, or keeping, some production in-house, or at least under direct company control. That is a major reason why Motorola owns some of the testing equipment at supplier locations. Managers also can decrease risk by limiting the flow of new intellectual property into countries with weak legal protections. Companies like Cisco, which outsources all manufacturing, also lower risk by creating business processes that cannot be easily replicated by a single manufacturer. Electronics manufacturer Sharp Corp. even repairs equipment itself, thus preventing any possibility, accidental or otherwise, that its vendors will share proprietary information with Sharp's competitors. The company goes so far as to reprogram various computer-aided machines used by its vendors without sharing the information. (Chopra & Sodhi, 2004, p. 57) In the 2010s, a new field of business research and consulting emerged around the management of IP in global value chains. Its purpose is to circumvent the difficulty of using formal IP protection channels and to find other ways to enforce IPRs without limiting the scope of GVC activity. A first issue is supplier selection to minimize the risk of IP leaks (Wu, Li, Chu, & Sculli, 2013). There is also an attempt to move beyond legal procedure and use the reporting procedures created for the implementation of Corporate Social Responsibility to enforce stricter IPRs standards along the chains (Gillai, Rammohan, & Lee, 2014). The Center for Responsible Enterprise And Trade (CREATe.org) was founded in 2011 with the support of start-up grants from the Microsoft Corporation with this objective of fostering “a culture of IP protection and compliance” throughout the global supply chain. This agenda is becoming mainstream, as it was endorsed by the World Intellectual Property Organization in its annual report dedicated to Intangible Capital in Global Value chains (WIPO, 2017).

#### Huge firms circumvent the plan – they stop trading with companies that don’t abide by their interpretations of IP – Apple proves.

Durand and Milberg, 18

[Cédric, Associate Prof. Political Economy @ U-Geneva, member @ Paris Nord Economics Center; and William, Dean @ The New School for Social Research: “Intellectual Monopoly in Global Value Chains,” published in 2018, https://hal.archives-ouvertes.fr/hal-01850438]//AD

Apple is an even more radical case due to the complexity of its products and industrial processes. The firm abandoned its factories of Fountain in Colorado Springs and Elk Grove in Sacramento in 1996 and 2004 (Barlett & Steele, 2011) and generated a veritable industrial renaissance based on value chains management capabilities, becoming the most renown factory-less goods producer in the world (Bernard & Fort, 2015). Apple makes none of its products itself. All manufacturing is performed by other firms in China and elsewhere. Nonetheless, the firm built “a closed ecosystem where it exerts control over nearly every piece of the supply chain, from design to retail store.” (Satariano & Burrows, 2011). Apple innovation capabilities goes beyond design, development, marketing and the creation of the software to include the technical features of the parts of its products but also the improvement of the means of producing these products. While manufacturing subcontractors do the actual production, manufacturing equipment design and capability are a distinctive competitive advantage of the company. Suppliers who provide some intellectual property to the process face a risk that Apple can abruptly sever its purchases in order to take control of what it considers to be strategic technologies, as the GPU chip designer Imagination Technologies learned at its expense when it was abruptly sidelined by Apple in 2017 (Barrett, 2017; Bradshaw, 2017). According to industry specialists, what is at stake is the ability of the Apple to optimize the design of the processors for the specific function of its products and to allow customization in order to differentiate its devices and keep competitors at bay. To be effective, these manufacturing capabilities without direct ownership of manufacturing operations rely on a distinctive ability to integrate the operations, i.e. an organizational and information system that coordinates and monitors the dispersed productive operations processes in a coherent labor process. This is a key asset of Apple and an obligatory passage for its suppliers to get access to their enormous consumer end market.

#### Aff doesn’t attack all of the root causes of disease spread- lack of materials, equipment, and facilities when faced with skyrocketed demands means solving IP protections alone isnt enough

Brant & Burns 7-29 [Jennifer Brant, CEO and Founder of Innovation Insights, and Thaddeus Burns, Head of Life Science Government & Public Affairs at Merck and served in senior positions at the US Department of Commerce and the White House Office of the US Trade Representative, served as a member of the National Academy of Sciences Committee charged with preparing a report on the science and technology capabilities of the U.S. Department of State. “Trade restrictions are delaying the COVID response. The WTO must act.” July 29, 2021. <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>] AL

The COVID-19 pandemic hit at a time when bio-manufacturing was undergoing a process of democratization. Technological progress had enabled growing capacity in many countries including Brazil, Indonesia, South Africa, Tunisia, Argentina, and Egypt. By 2020, the business model for bio-manufacturing had fundamentally changed and it was becoming the norm for companies to distribute research, development and manufacturing across geographies and work with partners. As recently as 15 years ago, building a facility to produce biologics such as monoclonal antibodies or vaccines could require an investment of as much as €500m, and it would take up to 3 years to bring that facility online. New manufacturing technologies have made it cheaper and easier to build new facilities and to scale up existing ones. Today, an investment of €20m can get a bio-manufacturing plant up and running. Such changes are part of the reason the global community was able to launch production of new COVID-19 vaccines so quickly. The urgency of COVID-19 accelerated further innovations in bio-manufacturing equipment and processes, and compressed production time in a way that will have positive impacts in the future. But the pandemic also revealed major weaknesses in global value chains. It was difficult for manufacturers to keep up with the sudden surge for demand for raw materials and equipment, as many new research and development and manufacturing partnerships rapidly took off. To extend capacity, new employees, intensive training and collaboration, and more infrastructure were needed. The global community was faced with the reality that facilities cannot be built everywhere in an instant, and that there are bottlenecks in the supply chain. Government action in some cases made things worse. Some countries enacted export restrictions on COVID-related products, which made it extremely difficult to run a global supply chain. Another difficult issue has been the tariffs applied on biologics and the products needed for their manufacture. Eighteen months into the pandemic, biologics manufacturers are still trying to cope with a range of challenges. There is still surging demand for equipment and raw materials. In some cases, they have expanded manufacturing capacity to produce more equipment such as filters and bioreactors. This continues to require time and significant investments.

#### IP protections incentivize innovation – our pandemic response would be hindered without innovation through strong IP systems

Van Etten 07-15

(Megan Van Etten; senior director of public affairs at PhRMA, responsible for leading the association’s public affairs efforts on international issues, including trade, intellectual property and access to medicines, was director of media and external communications at the U.S. Chamber of Commerce; (07-15-21) Promoting global vaccine equity while protecting innovation; Pharma; <https://catalyst.phrma.org/promoting-global-vaccine-equity-while-protecting-innovation>; CKD)

America’s biopharmaceutical companies have successfully researched, developed and distributed billions of doses of multiple vaccines and therapeutics to halt the spread of COVID-19. The availability of COVID-19 vaccines has shifted the trajectory of the pandemic and is undoubtedly saving lives. Further, the approval of the first ever mRNA vaccines has the potential to usher in an era of groundbreaking mRNA applications beyond COVID-19. But the transformative promise of these vaccines only extends as far as patients’ ability to access them. [Equitable distribution worldwide](https://www.phrma.org/Press-Release/Five-Steps-to-Urgently-Advance-COVID-19-Vaccine-Equity) is critical. Despite significant cross-sector and multi-stakeholder efforts like COVAX, we are still seeing vaccine access and distribution challenges across many regions of the world due to complex barriers. Unfortunately, [some have focused](https://catalyst.phrma.org/the-biden-administration-allows-politics-to-upend-a-pragmatic-pandemic-response) their attention on a short-sighted and misguided “solution” that seeks to waive international commitments to honor intellectual property (IP) rights for COVID-19 vaccines under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The approach fails to examine and address the real barriers to equitable vaccine distribution and could undermine the global pandemic response. Biopharmaceutical manufacturers, governments and non-governmental organizations must work together to take urgent steps to further address this inequity by: Stepping Up Dose Sharing A handful of countries secured contracts for COVID-19 vaccines during the early research and development phases, and as a result, have a larger supply of vaccines than needed. Manufacturers and governments in these countries must continue to work together to urgently and responsibly redirect meaningful proportions of these doses to low- and middle-income countries through COVAX and other established mechanisms. Continuing to Optimize Production The vaccine manufacturing process depends on a complex global network of suppliers of raw materials and equipment. The scale and speed at which these vaccines must be produced to keep up with the current demand is unprecedented. To address this challenge, vaccine manufacturers must work with governments and suppliers to undertake all practicable efforts to maximize COVID-19 vaccine output without compromising safety and quality. Calling out Trade Barriers To ensure supply chains are globally integrated, and for distribution systems to work efficiently, officials must remove trade barriers. It is critical that governments, in coordination with the WTO, work to eliminate all trade and regulatory barriers standing in the way of vaccine distribution and the procurement of the raw materials and components needed for the manufacturing process. Supporting Country Readiness Serious gaps in readiness across a significant number of countries need to be swiftly addressed to ensure that supplied doses are used and not destroyed. We urgently need cross-stakeholder collaboration—particularly in low- and middle-income countries—that supports vaccine roll-out and ensures countries are ready and able to deploy vaccines as efficiently as possible. Driving Further Innovation While the development of COVID-19 vaccines has been a remarkable feat, stakeholders must continue to prioritize policies and legal mechanisms that foster a strong innovation ecosystem, supported by IP incentives. Without this commitment to continuous innovation, our ability to swiftly address emerging COVID-19 variants and future pandemics is hindered. The COVID-19 innovations available today would not have been possible without strong IP systems that encourage innovation, protect novel ideas, enable critical partnerships and incentivize continued progress against deadly diseases. To ensure that patients around the world can access and realize the benefits of this astonishing progress, governments, the biopharmaceutical industry and non-governmental organizations must invest in solutions that comprehensively address the real issues driving inequities in vaccine distribution. America’s biopharmaceutical companies are focused on saving lives. Right now, that means more vaccines in more arms in countries around the world – without sacrificing safety or endangering production supply chains.

#### Squo solves--cost and bureaucracy are barriers to patent protection and other countries violate IP laws without punishment now.

Chao and Mody 15 (Tiffany Chao [Editor in Chief of Journal of Medical Insight, adjunct professor at Stanford Med School] and Gita Mody [MPH Harvard, assistant professor at UNC Chapel Hill Med School], The impact of intellectual property regulation on global medical technology innovation, BMJ Innovations, 3/5/2015, https://innovations.bmj.com/content/1/2/49) hwof

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.[i](https://innovations.bmj.com/content/1/2/49#fn-4) High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.[4](https://innovations.bmj.com/content/1/2/49#ref-4) This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.[5](https://innovations.bmj.com/content/1/2/49#ref-5) As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.