#### Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

## DA 1- Pandemic

#### The pharmaceutical industry is booming.

The Economist 21 (“American biotechnology is booming” Aug 11th 2021, The Economist, <https://www.economist.com/business/american-biotechnology-is-booming/21803495>)

In 1908 ashton valve company built a factory on the corner of Binney Street and First Street in Cambridge, Massachusetts. In what was a high-tech industry of the day, it made gauges, valves, whistles, clocks and other gadgets that helped make steam boilers less susceptible to blowing up and killing people. Just over 100 years later, in 2010, another purveyor of a life-saving technology moved into Ashton’s long-abandoned premises: Moderna. In the past year the biotech darling has become synonymous with the fight against covid-19. Its ingenious [mrna](https://www.economist.com/briefing/2021/03/27/covid-19-vaccines-have-alerted-the-world-to-the-power-of-rna-therapies) vaccine has, like a similar one developed by Pfizer, an American drug giant, and BioNTech, a German startup, saved millions of lives. Moderna’s success has also brought attention to America’s biotechnology industry, a lot of it centred on Cambridge. Home to Harvard University and the Massachusetts Institute of Technology, it is the closest that the biotech business currently has to a Silicon Valley. And the industry is booming. Since 2010 an index of biotech firms listed on the Nasdaq exchange has quintupled in value (see chart), and the number of companies in it has more than doubled, to 269. Between 2011 and 2020 the money that biotech startups raised in American initial public offerings (ipos) ballooned from $4bn to $65bn. So far this year venture capitalists have poured more than $20bn into pharmaceutical and biotech firms, not far from last year’s record tally of $27bn. Cambridge is filled with cranes and new buildings, dull on the outside but bursting with exciting science within. In next-door Boston new laboratories are going up around the revamped Seaport. Prices for lab space reportedly reach $160 a square foot, perhaps the costliest commercial real estate in America not at street level. The pace of the industry’s expansion would have been inconceivable 10-15 years ago, marvels Jean-François Formela of Atlas Venture, a venture-capital (vc) firm. Businesses are popping up everywhere, including down the hall from Mr Formela’s office. Flagship Pioneering, a vc firm which guides entrepreneurs from a promising idea to a business that can attract outside investors, has spun out 26 companies since 2013. Its founder, Noubar Afeyan (who is also Moderna’s chairman), hopes to spin out up to ten a year from now on. The boom has several causes. Tim Haines, chairman of Abingworth, a London-based asset manager focused on life sciences, notes that many investors have been swept up in the notion of “philanthropic capitalism”: making money from products that could benefit society. Other reasons are more hard-headed. According to Mr Haines’s estimates, 64% of drugs in late-stage development are being concocted by youngish biotech companies built around a novel technology rather than by big pharma firms such as Pfizer (which often team up with smaller biotechs like BioNTech, or acquire them, to juice up development pipelines). Many of these technologies are themselves the result of recent advances in cell and gene therapies, in ways of delivering them, and in identifying which patients they are likely to benefit most. New money is flowing into firms developing treatments for cancer, illnesses of the immune system or the brain, and even infectious diseases. Everyone is vying to be the next Moderna, whose market capitalisation has jumped from $5bn when it went public in late 2018 to $156bn. Many are hoping to emulate it by expanding from developing therapies to manufacturing them. Walking past Moderna’s headquarters just off bustling Binney Street it is easy to overlook the risks. People with both a phd in life sciences and managerial nous are a rare breed. Unlike brainstorming the next app, life science cannot be done on Zoom. Many clever ideas never come to fruition. Those that do become therapies often cost a lot, which increasingly angers both Democrats and Republicans in Congress and has led to calls for price controls. The greatest danger is a common one for startups: can they make money? Only one in six firms in the Nasdaq biotech index did so in 2020. The remaining five-sixths lost a combined $33bn. Vertex, a star graduate of Binney Street that has relocated to Seaport, lost money from its founding in 1989 until 2017. Moderna turned a profit last quarter for the first time in a decade and its share price has slid. Still, its wannabe imitators can take comfort that biotech investors are a patient lot.

#### **The industry is made up of companies, who without profit, stop producing products.**

CHAN 17 (https://apps.who.int/iris/bitstream/handle/10665/255355/9789241512442-eng.pdf?sequence=1 BY DR MARGARET CHAN, DIRECTOR-GENERAL, WORLD HEALTH ORGANIZATION World Health Organization 2017 “TEN YEARS IN PUBLIC HEALTH 2007-2017”)

In recent years, the need for uninterrupted supplies of medicines has become more urgent. The importance of preventing stockouts has been underscored by the advent of antiretroviral therapy for HIV, the long duration of treatment for multidrug-resistant tuberculosis, the ability of artemisinin-combination therapies to prevent malaria deaths if administered quickly, and the need for life-long treatment of chronic conditions such as hepatitis B infection and diabetes. Lack of access to medicines is one of the most complex – and vexing – problems that stand in the way of better health. The agenda for improving access is exceptionally broad. Affordability is the cornerstone of access, but many other factors also determine whether people get the medicines they need. Gaps in local health systems and infrastructures hamper the delivery of medicines to millions of people. Access also depends on procurement practices, tax and tariff policies, mark-ups along the supply chain, and the strength of national drug regulatory authorities. Apart from being affordable and of good quality, medicines must also be safe; a system for pharmacovigilance needs to be in place. Secure supply chain management is likewise needed to protect populations from substandard or falsified medical products. International conventions for the control of narcotic drugs can be another barrier to access. They place a dual obligation on governments: to prevent abuse, diversion and trafficking, but also to ensure the availability of controlled substances for medical and scientific purposes. Many controlled substances play a critical role in medical care, for the relief of pain, for example, or use in anaesthesia, surgery, and the treatment of mental disorders. Unfortunately, the obligation to prevent abuse has received far more attention than the obligation to ensure availability for medical care. WHO estimates that 80% of the world’s population lives in countries with zero or very little access to controlled medicines for relieving moderate to severe pain. Efforts to improve access are complicated by a number of economic issues. Affordability matters for households and health budgets. WHO estimates that up to 90% of the population in low- and middle-income countries purchases medicines through out-of-pocket payments. If a household is forced to sell an asset, like the family cow, or take its children out of school, this payment can be the final nail in the coffin that buries the family in intergenerational poverty. This is the pathology of poverty when no forms of social protection, such as those provided by universal health coverage, are available and even low-cost generic products are a heavy financial burden. For health budgets, staff costs usually absorb the biggest share of resources, with the costs of drug procurement following closely behind. The part of the budget devoted to medicines varies significantly according to a country’s level of economic development. Medicines account for 20% to 60% of health spending in low- and middle-income countries, compared with 18% in countries belonging to the Organization for Economic Co-operation and Development. One of the most daunting economic issues comes from the fact that the research-based pharmaceutical industry is a business, and a big one. Multinational pharmaceutical companies, concentrated in North America, Europe and Japan, are powerful economic operators. Economic power readily translates into political power. When ways to improve access are negotiated at WHO, a familiar polarizing tension surfaces. Which side should be given primacy, economic interests or public health concerns? As many have argued, letting commercial interests override health interests would lead to even greater inequalities in access to medicines, with disastrous life-and-death consequences. At the same time, the pharmaceutical industry is a business, not a charity. When prices are so low they preclude profits, companies leave the market – and leave a hole in the availability of quality products, as happened with anti-snakebite venom. Economic factors shape another pressing public health concern. Many diseases mainly prevalent in poor populations have no medical countermeasures whatsoever, or only old and ineffective ones. In other cases, access suffers from the lack of products adapted to perform well in resource-constrained settings with a tropical climate. The patent system, with its market-driven R&D incentives, has historically failed to invest in new products for poor populations with virtually no purchasing power, resulting in a paucity of R&D driven by the unique health needs of the poor. Apart from having few new products that address their priority diseases, the poor are punished in a second way: the common practice of recouping the costs of R&D through high prices protected by patents means that those who cannot pay high prices do without. Recent shifts in the poverty map introduces another set of problems. An estimated 70% of the world’s poor now live in middle-income countries which are losing their eligibility for support from mechanisms like the Global Fund to Fight AIDS, Tuberculosis and Malaria and Gavi, the Vaccine Alliance. Will governments step in to make up for the shortfall in access to medicines and vaccines? If not, vast numbers of poor people living in countries that are rapidly getting rich will be left to fend for themselves.

#### TRIPS IP rights are key for innovation

James Bacchus 20, adjunct scholar at CATO, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

#### Only pharma innovation solves global pandemics that risk extinction (same card as my opponents’)

Jeffrey Sachs 14, Professor of Sustainable Development, Health Policy and Management @ Columbia University, Director of the Earth Institute @ Columbia University and Special adviser to the United Nations Secretary-General on the Millennium Development Goals) “Important lessons from Ebola outbreak,” Business World Online, August 17, 2014, http://tinyurl.com/kjgvyro

Ebola is the latest of many recent epidemics, also including AIDS, SARS, H1N1 flu, H7N9 flu, and others. AIDS is the deadliest of these killers, claiming nearly 36 million lives since 1981. Of course, even larger and more sudden epidemics are possible, such as the 1918 influenza during World War I, which claimed 50-100 million lives (far more than the war itself). And, though the 2003 SARS outbreak was contained, causing fewer than 1,000 deaths, the disease was on the verge of deeply disrupting several East Asian economies including China’s. There are four crucial facts to understand about Ebola and the other epidemics. First, most emerging infectious diseases are zoonoses, meaning that they start in animal populations, sometimes with a genetic mutation that enables the jump to humans. Ebola may have been transmitted from bats; HIV/AIDS emerged from chimpanzees; SARS most likely came from civets traded in animal markets in southern China; and influenza strains such as H1N1 and H7N9 arose from genetic re-combinations of viruses among wild and farm animals. New zoonotic diseases are inevitable as humanity pushes into new ecosystems (such as formerly remote forest regions); the food industry creates more conditions for genetic recombination; and climate change scrambles natural habitats and species interactions. Second, once a new infectious disease appears, its spread through airlines, ships, megacities, and trade in animal products is likely to be extremely rapid. These epidemic diseases are new markers of globalization, revealing through their chain of death how vulnerable the world has become from the pervasive movement of people and goods. Third, the poor are the first to suffer and the worst affected. The rural poor live closest to the infected animals that first transmit the disease. They often hunt and eat bushmeat, leaving them vulnerable to infection. Poor, often illiterate, individuals are generally unaware of how infectious diseases -- especially unfamiliar diseases -- are transmitted, making them much more likely to become infected and to infect others. Moreover, given poor nutrition and lack of access to basic health services, their weakened immune systems are easily overcome by infections that better nourished and treated individuals can survive. And “de-medicalized” conditions -- with few if any professional health workers to ensure an appropriate public-health response to an epidemic (such as isolation of infected individuals, tracing of contacts, surveillance, and so forth) -- make initial outbreaks more severe. Finally, the required medical responses, including diagnostic tools and effective medications and vaccines, inevitably lag behind the emerging diseases. In any event, such tools must be continually replenished. This requires cutting-edge biotechnology, immunology, and ultimately bioengineering to create large-scale industrial responses (such as millions of doses of vaccines or medicines in the case of large epidemics). The AIDS crisis, for example, called forth tens of billions of dollars for research and development -- and similarly substantial commitments by the pharmaceutical industry -- to produce lifesaving antiretroviral drugs at global scale. Yet each breakthrough inevitably leads to the pathogen’s mutation, rendering previous treatments less effective. There is no ultimate victory, only a constant arms race between humanity and disease-causing agents.

## COVID-19 DA

#### Eliminating patents will actually slow down the process of getting the vaccine out to everyone.

Kappos and Michel 21 (“Waiving Covid-19 vaccine patents won't get shots in arms faster. It slows down new vaccines.” May 25, 2021, 5:24 AM PDT By David J. Kappos, partner, Cravath, Swaine & Moore LLP and Paul R. Michel David J. Kappos, a partner at Cravath, Swaine & Moore LLP, served as the under secretary of commerce for intellectual property and director of the United States Patent and Trademark Office from 2009 to 2013. Paul R. Michel served on the United States Court of Appeals for the federal circuit for 22 years, and as its chief judge from 2004 until his retirement in 2010. THINK https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099)

WTO director-general Ngozi Okonjo-Iweala [said on Friday](https://www.reuters.com/business/healthcare-pharmaceuticals/vaccine-patent-waiver-will-not-be-enough-wto-chief-2021-05-20/) that a full waiver of companies' Covid-19 vaccine patents under the World Trade Organization's auspices — sought by many developing countries and supported by President Joe Biden to combat disproportionate access to the therapies — will not be enough to speed up the provision of vaccines to countries where it is lagging. On that small point, at least, we agree: The nations that spearheaded the petition to waive the patent rights at the WTO, India and South Africa, have been unable to provide any evidence that the international system of respecting intellectual property rights under the law have impeded the development, production or distribution of Covid-19 vaccines and treatments. And it is hard to imagine that any such evidence will be forthcoming, as intellectual property is facilitating — not inhibiting — the pharmaceutical industry's pandemic response. Normally fierce rival companies have been able to cooperate on vaccine production precisely because inventors know their property rights are — and will remain — secure. For instance, Johnson & Johnson invited Merck to help manufacture its viral-vector vaccine, while Pfizer and BioNTech, which jointly developed their revolutionary mRNA vaccine, are similarly working with French drug giant Sanofi to boost its production. And generics manufacturers are already working around the clock on a contract basis with innovator firms to produce vaccines. For instance, India's largest generics manufacturer, the Serum Institute, is producing billions of doses of the AstraZeneca vaccine for low-income countries, while South Africa's largest generics firm, Aspen Pharmacare, is producing hundreds of millions of doses of Johnson & Johnson's vaccine. India and South Africa's petition to nullify intellectual property protections, were it to have been in effect, would have made those collaborations impossible. Suspending intellectual property rights will not get shots in arms any faster at this point and would, in fact, undermine efforts to scale up vaccine production. As Okonjo-Iweala herself pointed out last week, though it will take time to negotiate a wholesale change to WTO treaties, the capacity to manufacture Covid-19 vaccines already exists in Pakistan, Bangladesh, Indonesia, Thailand, Senegal and South Africa but is currently sitting idle despite existing frameworks giving manufacturers in those places the right to start. The EU, in the meantime, has [offered a counterproposal](https://www.reuters.com/world/europe/eu-present-wto-plan-boost-vaccine-production-2021-05-19/) to waive or minimize export restrictions on vaccines and vaccine components, to pledge to supply vaccines to countries with shortages at cost and to allow more countries to take advantage of existing WTO rules that allow countries to license intellectual property without the consent of the patent holders, essentially allowing for an increasing production capacity without waiving the patent rights altogether. So while the appeal of an intellectual property waiver is tempting in the short-run, doing so imperils our ability to develop new medicines and combat future pandemics. The Biden administration, however, announced its support for such a petition earlier in May and progressive groups cheered, contending that the intellectual property suspension would hasten and make more equitable the global vaccine rollout by enabling more manufacturers to produce the vaccines developed by Western firms. And, certainly, the rapid and equitable distribution of Covid-19 vaccines is absolutely critical to ending this pandemic. But sacrificing the innovation ecosystem in order to achieve this end would be myopic policy. There are already very real challenges to inoculating the world, including a widespread lack of proper refrigeration (let alone the ultracold storage required for some vaccines), a shortage of trained professionals to administer them and conduct follow-up evaluations, and a lack of patient compliance with the two-dose regimen for the Pfizer-BioNTech and Moderna jabs. Plus, there have already been issues with fakes and a lack of trust in the government that have come into play. In Mexico and Poland, [authorities have identified](https://urldefense.com/v3/__https:/www.wsj.com/articles/pfizer-identifies-fake-covid-19-shots-abroad-as-criminals-exploit-vaccine-demand-11619006403__;!!PIZeeW5wscynRQ!5im4XdWEGVpKy_ctvTTJNvidGqa0qNpMLCmOYVDuZgi0OzUdPpczT-h4tNU-_CdcL6-x$) counterfeit versions of the Pfizer-BioNTech vaccine. In Malawi, [the New York Times reported](https://urldefense.com/v3/__https:/www.nytimes.com/2021/04/14/world/europe/western-vaccines-africa-hesitancy.html__;!!PIZeeW5wscynRQ!5im4XdWEGVpKy_ctvTTJNvidGqa0qNpMLCmOYVDuZgi0OzUdPpczT-h4tNU-_JTNQHUw$) that "people are asking doctors how to flush the AstraZeneca vaccine from their bodies." Suspending intellectual property rights will not remove any of these roadblocks and would likely exacerbate them. Without certain quality controls implemented by original patent holders, especially in places with existing levels of government or industrial corruption, we could see ineffective vaccines manufactured using substandard processes, and then administered without adequate refrigeration, professional handling or required counseling and follow up.

## Circumvention

#### Companies will continue applying for patents after it expires.

Amin 18 (“The problem with high drug prices isn't 'foreign freeloading,' it's the patent system,” 9:08 AM ET Wed, 27 June 2018, Tahir Amin is the co-founder and co-executive director of I-MAK.org, a non-profit organization comprised of senior attorneys, scientists and health experts who have worked to lower drug prices for 15 years.)

Americans continue to suffer the highest prescription drug costs of anyone in the world. One in four are unable to fill prescriptions due to high prices, according to a recent poll. And even though drug prices tripled over the last decade, analysts predict they will double again in the next ten years. We have a runaway problem on our hands, and while new proposals from Congress and the president seek to improve the drug pricing system, we will fail to reach lasting solutions unless we address a root factor in this national crisis: patents. Contrary to the Trump administration’s recent claims, the source of our prescription drug problems is not “foreign freeloading” governments creating unfair pricing schemes—it’s the unfair pricing systems created right here in the U.S. Today’s drug patent monopolies are deeper, longer and stronger than at any point in the last century—and it’s costing Americans and people around the world. Before a prescription drug even enters the market—before pricing negotiations occur between payers, government agencies, insurers, and so on—the U.S. patent office awards exclusivity to drug makers for intellectual property claims that have a huge impact on the market. And unfortunately, while patenting is an important mechanism for incentivizing and rewarding invention, pharmaceutical companies have figured out how to game the system—prolonging monopolies, claiming newness where there often is none, and taking patients on a ride they can barely afford. In a recent study of every drug on the market between 2005 and 2015, a University of California School of Law professor found a “startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals.” Instead of going to new medicines, the study finds that 74 percent of new patents during the decade went to drugs that already existed. It found that 80 percent of the nearly 100 best-selling drugs extended their exclusivity protections at least once, and 50 percent extended their patents more than once—with the effect of prolonging the time before generics could reach the market as drug prices continued to rise. The strategy is called “evergreening”: drug makers add on new patents to prolong a drug’s exclusivity, even when the additions aren’t fundamentally new, non-obvious, and useful as the law requires. One of the most expensive cancer drugs on the market, Revlimid®, is a case in point: priced at over $125,000 per year of treatment, Celgene has sought 105 patents on Revlimid®, many of which have been granted, extending its monopoly until the end of 2036. That gives the Revlimid® patent portfolio a lifespan of 40 years, which is being used to block or deter generic competitors from entering the market. But a recent I-MAK analysis finds that several of Celgene’s patents are mere add-ons—not fundamentally new to deserve a patent. And because of the thicket of patents around Revlimid®, payers are projected to spend $45 billion in excess costs on that drug alone as compared to what they could be paying if generic competitors were to enter when the first patent expires in 2019. Meanwhile, Celgene is also among the pharmaceuticals that have been recently scolded by the FDA for refusing to share samples with generic makers so they can test their own products against the brands in order to attain FDA approval. In the absence of genuine competition in the U.S. prescription drug market, monopolies are yielding reckless pricing schemes and prohibitively expensive drugs for Americans (and people around the world) who need them. In 2015, for example, U.S. Senators Wyden and Grassley found after an 18-month bipartisan investigation that the notorious $84,000 price tag for the hepatitis C drug made by Gilead was based on “a pricing and marketing strategy designed to maximize revenue with little concern for access or affordability.” Gilead’s subsequent hepatitis C drug Harvoni® was introduced to the market at a still higher cost of $94,500. Who benefits when drugs are priced so high? Not the 85 percent of Americans with hepatitis C who are still not able to afford treatment. “Since the early 2000s, very few new drugs or indications have provided a tangible advance for patients,” the French medical journal Prescrire wrote in 2014. This is the problem with drug pricing today. Plenty of top-dollar drugs armored in patents, but too few solutions for patients that are genuinely affordable and helpful. Until our patent system is reformed, the pharmaceutical industry will continue to abuse it—denying real competition, blocking incentives for actual new drug discoveries and using clever marketing strategies around “new” products that do not improve health outcomes. For a free and competitive market that will actually help America’s patients, what we really need is to restore fairness to the patent system in the U.S. It may be convenient to blame foreign countries or insurance companies or any number of culprits for our high drug prices, but until we look at the heart of the problem and stop deflecting, patients in the U.S. and around the world will continue to lack treatments they can access and afford.