# AC

## ADV - pandemics

#### COVID is getting worse, especially in developing countries, while bringing a stronger chance of future pandemics – vaccine inequality is the root cause.

Tharoor 6/2

[The pandemic is getting worse, even when it seems like it’s getting better, <https://www.washingtonpost.com/world/2021/06/02/global-pandemic-worsening/>, Ishaan Tharoor, June 2 2021. Columnist covering foreign affairs, geopolitics and history Education: Yale University, BA, honors in history and ethnicity, race and migration Ishaan Tharoor is a columnist on the foreign desk of The Washington Post, where he authors the Today's WorldView newsletter and column. He previously was a senior editor and correspondent at Time magazine, based first in Hong Kong and later in New York. He also teaches an undergraduate seminar at Georgetown University on digital affairs and the global age.] [SS]

In the United States, life is returning to normal. Restaurants and bars are filling up again, vacations are being booked and flights are selling out. At sporting events, maskless fans are hugging and cheering. Memorial Day weekend, the country’s unofficial start to the summer, was celebrated with much more gusto and many more family barbecues than it was a year ago. That’s all for good reason: A majority of Americans have received at least one dose of a coronavirus vaccine, and daily new infections and deaths are at their lowest levels in almost a year. The pandemic is slowly receding from the daily lives of many Americans as businesses open up and local authorities ease restrictions. Britain, which on Tuesday reported no new coronavirus-related deaths for the first time since March 2020, can also see the sunlit uplands of a post-pandemic future. “Covid-19 won’t end with a bang or a parade,” wrote Devi Sridhar, chair of global public health at the University of Edinburgh. “Throughout history, pandemics have ended when the disease ceases to dominate daily life and retreats into the background like other health challenges.” But the pandemic is hardly in retreat elsewhere. The emergence of more virulent variants of the virus in countries like Brazil and India and the slowness of vaccination efforts in many places outside the West have contributed to deadly new waves. Coronavirus case counts worldwide are already higher in 2021 than they were in 2020. The death toll almost certainly will be. World coronavirus tracker: Cases, deaths and vaccination data from around the world Southeast Asia, once a bastion of resistance to the virus as it ravaged Western countries, is in the grip of a harrowing spike in infections. Cases in Thailand and Vietnam rose dramatically over the past month. Malaysia is now registering more new infections per million people than any medium- or large-size country in Asia, surpassing India, which remains a global hot spot. On Tuesday, the Malaysian government implemented a nationwide lockdown that will last for the next two weeks. “The economy will certainly suffer. The people will suffer even more, those who live. Many are dying and will die,” wrote columnist Munir Majid in the New Straits Times. “We are staring at the abyss.” In Africa, concerns are growing over the possible arrival of a new wave powered by a more transmissible variant of the virus, with the health systems in many countries at risk of being quickly subsumed by a surge of infections. A recent study found that the continent has the world’s highest death rate of patients critically ill with covid-19, 2thanks to limited intensive care facilities and reserves of vital medical supplies like oxygen. In parts of Latin America, the virus rages on, largely unabated. Peru, according to its own government-adjusted data, now has the worst covid-19 mortality rate per capita in the world. The country is slated to stage a closely contested presidential runoff election this weekend. Even in East Asia, where a handful of nations set the gold standard in preventing community spread, the virus is on the march. Taiwan has seen an explosion of cases over the past month. In Japan, which still intends to host the Summer Olympics, numerous areas including Tokyo remain under a state of emergency. It’s a sign, argue some public health experts, that the strict methods that kept places like Taiwan, South Korea and Singapore safer than their counterparts in the West for all of last year may not be sustainable in the long term. For a number of reasons, the vaccine rollouts in these countries have been slow, hampered by a lack of supply. In an interview earlier this year with Today’s WorldView, Koji Tomita, Japan’s ambassador in Washington, described his country and other East Asian states that initially managed to clamp down on community spread — but built up little herd immunity — as “prisoners of their own success.” Public health advocates and international organizations recognize the main problem: The global gap in vaccinations. In the United States, there’s already discussion of booster shots for the general public, while front-line medical workers in some developing countries have yet to even receive a first dose of a vaccine. In a joint statement, the heads of the International Monetary Fund, the World Bank, the World Trade Organization and the World Health Organization laid out a $50 billion plan for collective action that would accelerate vaccine distribution to poor and middle-income countries and expand and diversify production capacity throughout the world. “Inequitable vaccine distribution is leaving millions of people vulnerable to the virus while allowing deadly variants to emerge and ricochet back across the world,” they wrote in an op-ed published in The Washington Post. “As variants spread, even countries with advanced vaccination programs have been forced to reimpose stricter public health measures and travel restrictions. The ongoing pandemic is deepening divergence in economic fortunes, with negative consequences for all.” “It would be a monumental error for any country to think the danger has passed,” WHO Director General Tedros Adhanom Ghebreyesus said Monday at the close of the World Health Assembly. He warned that insufficient global coordination at present means that “we will still face the same vulnerabilities that allowed a small outbreak to become a global pandemic.” Attention now moves to this month’s meeting of the Group of Seven nations, where leaders of these traditional world powers are expected to step up and deliver on the global need for vaccines. The Biden administration also opted to support negotiations at the WTO over a possible waiver of international property protections on coronavirus vaccines, which could lead to more countries being able to produce them. But the waiver is still opposed by major European governments, while advocates contend that these discussions should have taken place at a much earlier stage in the pandemic. Now, time is of the essence, as more transmissible variants appear to be burning rapidly through societies without much immunological protection. “It is, of course, understandable that every nation wants to vaccinate its own first, but a country with high levels of vaccination, especially among its more vulnerable populations, can hold things off, especially if they also had big outbreaks before,” wrote Zeynep Tufekci in the New York Times, arguing that wealthier nations like the United States should be actively prioritizing providing for other countries over its own population. “In addition, excess stockpiles can go where they are needed without even slowing down existing vaccination programs.” Anthony S. Fauci, the leading infectious-disease expert in the United States, appeared to recognize the broader threat. “As long as there is some degree of activity throughout the world, there’s always a danger of variants emerging and diminishing somewhat the effectiveness of our vaccines,” he told the Guardian.

#### Patents fail during pandemics only direct government support can solve – put away advantage counterplans, it’s just a world without patents aka the aff.

Lindsey 6/3

[Why intellectual property and pandemics don’t mix, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>, Brink Lindsey, June 3 2021] [SS]

On May 5 the Biden administration announced that it would support waiving intellectual property protections for COVID-19 vaccines under the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS). Predictably, the move drew fiery condemnation from drug companies. In addition, many disinterested observers criticized the support for a TRIPS waiver as empty symbolism, arguing that vaccine patents are not the major obstacle hindering the currently flagging drive to make vaccines available around the world. Waiving patent protections is certainly no panacea. What is needed most urgently is a massive drive of technology transfer, capacity expansion, and supply line coordination to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this effort. Brink Lindsey Brink Lindsey Vice President - Niskanen Center lindsey\_brink Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPlS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference. Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. THE NATURE OF THE PATENT BARGAIN When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, the U.S. patent system at present is out of balance. Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: the number of patents granted annually has skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, a law that is supposed to encourage innovation has turned into a legal minefield for many would-be innovators. In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant “innovations” that allow them to extend their monopolies and keep raising prices long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support. PUBLIC HEALTH EMERGENCIES AND DIRECT GOVERNMENT SUPPORT For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response. The basic patent bargain, even when well struck, is to pay for more innovation down the road with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction. What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments by the government to buy large numbers of doses at set prices, and other, related payouts. And when we pay drug makers, we should not hesitate to pay generously, even extravagantly: we want to offer drug companies big profits so that they prioritize this work above everything else, and so that they are ready and eager to come to the rescue again the next time there’s a crisis. It was direct support via Operation Warp Speed that made possible the astonishingly rapid development of COVID-19 vaccines and then facilitated a relatively rapid rollout of vaccine distribution (relative, that is, to most of the rest of the world). And it’s worth noti2ng that a major reason for the faster rollout here and in the United Kingdom compared to the European Union was the latter’s misguided penny-pinching. The EU bargained hard with firms to keep vaccine prices low, and as a result their citizens ended up in the back of the queue as various supply line kinks were being ironed out. This is particularly ironic since the Pfizer-BioNTech vaccine was developed in Germany. As this fact underscores, the chief advantage of direct support isn’t to “get tough” with drug firms and keep a lid on their profits. Instead, it is to accelerate the end of the public health emergency by making sure drug makers profit handsomely from doing the right thing. Patent law and direct support should be seen not as either-or alternatives but as complements that apply different incentives to different circumstances and time horizons. Patent law provides a decentralized system for encouraging innovation. The government doesn’t presume to tell the industry which new drugs are needed; it simply incentivizes the development of whatever new drugs that pharmaceutical firms can come up with by offering them a temporary monopoly. It is important to note that patent law’s incentives offer no commercial guarantees. Yes, you can block other competitors for a number of years, but that still doesn’t ensure enough consumer demand for the new product to make it profitable. DIRECT SUPPORT MAKES PATENTS REDUNDANT The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus. Under these circumstances, the decentralized approach isn’t good enough. There is no time to sit back and let drug makers take the initiative on their own timeline. Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return. For the pharmaceutical industry, it is useful to conceive of patent law as the default regime for innovation promotion. It improves pharmaceutical companies’ incentives to develop new drugs while leaving them free to decide which new drugs to pursue – and also leaving them to bear all commercial risk. In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease. In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. It should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading. That said, it is a serious mistake to try to cast the current crisis as a morality play in which drug makers wear the black hats and the choice at hand is between private profits and public health. We would have no chance of beating this virus without the formidable organizational capabilities of the pharmaceutical industry, and providing the appropriate incentives is essential to ensure that the industry plays its necessary and vital role. It is misguided to lament that private companies are profiting in the current crisis: those profits are a drop in the bucket compared to the staggering cost of this pandemic in lives and economic damage. RELATED CONTENT Hellen Nanez, who lost 13 relatives to the coronavirus disease (COVID-19) and whose father is being treated for COVID-19 in the Intensive Care Unit, shops ingredients to make handmade soap for sale, in Pisco, Peru, May 8, 2021. Picture taken May 8, 2021. REUTERS/Alessandro Cinque FUTURE DEVELOPMENT COVID-19 is a developing country pandemic Indermit Gill and Philip SchellekensThursday, May 27, 2021 San Salvador, El Salvador.- In the photos taken on March 23, 2021, it shows a vaccination center against the coronavirus. El Salvador began with the immunization of non-health personnel who are more exposed to the virus through their work, including members of the Armed Forces, Civil Protection and teachers. The doses used will be those of the pharmaceutical company Pfizer, whose shipment arrived on Monday. FUTURE DEVELOPMENT How big of a vaccine surplus will the US have? Simon J. EvenettTuesday, May 4, 2021 FILE PHOTO: A health official draws a dose of the AstraZeneca's COVID-19 vaccine manufactured by the Serum Institute of India, at Infectious Diseases Hospital in Colombo, Sri Lanka January 29, 2021. REUTERS/Dinuka Liyanawatte ORDER FROM CHAOS Biden’s misstep in India Thomas WrightFriday, April 30, 2021 What matters isn’t the existence or size of the profits, but how they are earned. We have good reason to want drug makers to profit from vaccinating the world: the comparative price is minuscule, and the incentive effects are a vital safeguard of public health in the event of future crises. What we want to avoid at all costs is putting drug makers in the position where drug companies can profit from standing in the way of rapid global vaccination. That is why intellectual property rights need to be taken out of the equation. Vaccinating the world in any kind of reasonable time frame will require large-scale technology transfer to drug firms in other countries and rapid expansion of their production capacity. And looking beyond the current pandemic to the longer term, we need ample, redundant global vaccine production capacity that is widely distributed around the planet. To achieve these goals as rapidly as possible will require the active cooperation of the U.S. pharmaceutical industry, which is why the direct support model now needs to be extended. What is needed now is an Operation Warp Speed for the world, in which we make it worth current vaccine producers’ while to share their know-how broadly and ramp up global capacity. Here again, we must recognize that the choice isn’t between people on the one hand and profits on the other. Rather, the key to good pandemic response policy is ensuring that incentives are structured so that drug company profit-seeking and global public health are well aligned. That means opting out of the default, decentralized patent bargain in favor of generous but well-focused direct government support.

#### IP serves as barriers to mass production to key parts of solving diseases – only the aff solves

WTO 1/15 [World Trade Organization. “WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19 – RESPONSES TO QUESTIONS”. Council for Trade-Related Aspects of Intellectual Property Rights. 15 January 2021. Accessed 8/2/21. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W672.pdf&Open=True> //duongie]

36. Cases involving potential intellectual property infringements emerged early on in the pandemic revealing the complex legal implications of producing copies of life-saving medical products or parts thereof as well as impact on access. Therapeutics 37. A number of therapeutics are under investigation. Some of the therapeutics are presently off-patent but as its use is explored for COVID-19 treatment, the filing of new patent applications extending to secondary uses of these therapeutics can be expected. Several other therapeutics under examination are patented in multiple jurisdictions. Attached please refer to a selected patent landscape of priority therapeutics. Some of the candidate have patents filed and/or granted in nearly 50 developing and least developed countries. 38. The case of Remdesivir best sums up the how patents can block access to therapeutics. The primary patent on the base compound of Remdesivir has been granted to Gilead in more than 70 low-and middle-income countries, hence potentially blocking access to generic alternatives until 2031. Civil society called for non-enforcement of Gilead's patents, but this call went unheeded. Instead Gilead signed secretive voluntary licenses with a few generic manufacturers of its choosing to supply countries as determined by Gilead. As a result, other manufacturers in countries with patents were excluded from manufacturing and nearly half of the world's population were prevented from being supplied by the licensee and hence denied from accessing more affordable generics. While more recently WHO has declared Remdesivir to be ineffective in the treatment of COVID-19 , this case study is a striking example of inequities that will replay should the international community fail to take steps to address intellectual property barriers. Such inadequacy of supply also allowed Gilead to bid up the price of the treatment for those countries that were excluded from a voluntary license agreement, and to use the lack of supply to persuade some countries, such as the 27 Member States of the European Union, to spend more than one billion euros on the drug even though the WHO was about to disclose that through its own trials the drug was not effective. 39. In therapeutics, monoclonal antibodies (mAbs) holds promise for curbing COVID-19. Many mAbs are currently in development for treatment and prevention of COVID-19. Even prior to the spread of COVID-19, access to mAbs was highly unbalanced, with Europe, US and Canada accounting for 80% of global sales. Prices also remain prohibitively expensive. 40. Many of the monoclonal antibody candidate therapeutics such as tocilizumab, sarilumab, bevacizumab are under patent protection in many developing countries. Secondary patents on new uses or formulations of an existing mAb product could further strengthen the patent holder's market monopoly, also the primary reason for delayed introduction of biosimilars in some markets including in the US. 41. Disparity in access is certain unless concrete steps are taken to address intellectual property barriers. Competition to lock up existing capacity is already intense. For instance, it is reported that Regeneron signed a USD 450 million deal in July to sell to the US enough doses of its antibody treatment, REGN-COV2, to treat around 300,000 people. Similarly Eli Lily has announced an IP/C/W/672 - 8 - agreement with the U.S. government for USD 375 million to supply 300,000 vials of bamlanivimab (LY-CoV555) 700 mg, an investigational neutralizing antibody, granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). Diagnostics 42. In March 2020, it came to light that Netherlands was not able to do mass testing for COVID-19 as most Dutch testing laboratories work with Roche equipment and depend on Roche for supplies of the liquid buffer needed to run the tests, and there was a shortage of this buffer. Initially, Roche refused to provide the recipe for the buffer. With the recipe, labs would be able to quickly make their own solution and ramp up their testing capability. Eventually however as public pressure mounted and the European Commission considered investigating Roche for possible abuse of its market position, Roche agreed to release the recipe to the Dutch authorities. 43. Shortages of testing materials in developing countries have also been widely reported as most supplies are destined for the US or Europe. In May 2020, South Africa, my home country, faced similar challenges as its diagnostic infrastructure also depends on the use of proprietary test materials – including reagents, consumables and cartridges. A virologist with the South African National Health Laboratory Service explained "that commercial diagnostic manufacturers develop their own tests, containing proprietary reagents and unique consumables and packing. As a result, the tests cannot be interchanged between different diagnostic systems" adding that "even we don't know what is in the proprietary reagents", as the specific formulations are protected as trade secrets". This situation prevents laboratories from making their own test materials or procuring test materials from sources other than the diagnostic machine's manufacturer. 44. MSF in its analysis has found that "major diagnostics companies hold a considerable number of patents, often bundled into thickets for various instrumentation, assays, methods and software, related to different aspects of the technologies, methodologies and devices", concluding that "the overall business model for diagnostics results in multiple dominant closed diagnostics systems (since each major diagnostics company develops both the device and the consumable parts – for example the reagent kits or reagent-loaded integrated cartridges – specifically tailored to that device), making competition extremely difficult. The high cost and burden of switching between systems results in a "locked-in" effect for end users since they have no choice but to buy both the device and the assays from the same company". 45. Testing is a crucial aspect of containing the spread of COVID-19 especially in the absence of effective therapeutics and vaccines, and some countries are now moving to a model of mass testing of the entire population, either at once or on a regular basis, as a route out of the pandemic. 46. And yet, the disparity in testing between developed country Members and other countries is vast. As of 11th November, reported tests for everyone million population, was approximately 342000 in developed countries, 81000 in developing countries and 9700 in LDCs. In other words, high income countries are testing its population at nearly 35 times the rate of the world's poorest countries. When new tests come onto the market, only a few countries rapidly purchase all of the existing supply or put forward large sums of capital to claim all supply. More supply is needed, and such supply requires multiple manufacturers unhindered by any barriers to production. Intellectual property has proven to be a barrier in the scaling up of testing for COVID-19. Existing manufacturers are unable to keep up the needed global supply, hence negatively impacting a country's ability to screen samples for COVID-19 – an essential part of controlling the pandemic. Vaccines 47. 45 vaccine candidates are in human trial, while about ten are in or entering phase III trials. The candidate vaccines are of various types – virus vaccines using live attenuated virus, viral vector vaccines, protein- based vaccines, and nucleic acid or RNA and DNA vaccines, which are completely new platforms. 48. The effects of patents in hindering the introduction of affordable vaccines in developing countries have been published by MSF. While the focus is on pneumococcal conjugate vaccines (PCV) and the human papillomavirus (HPV) vaccine, the paper reveals the expansive patent claims applied for or granted across the entire spectrum of vaccine development, production and use including on IP/C/W/672 - 9 - vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; vaccination age groups; methods of using vaccines; and vaccine schedules and presentations. These patents increased uncertainty, costs, delayed competition, leading to high prices in developing countries and hindering access. In 2016-2017, MSF filed a patent opposition and later a writ petition to challenge Pfizer's vaccine composition patent that blocked development of alternative versions of Pfizer's PCV13 vaccine. Equivalent patent granted in South Korea, compelled a Korean vaccine developer to close their production of PCV13. The patent invalidation proceeding launched by MSF towards Pfizer remains open in India concerning PCV13. 49. A similar situation will materialise with COVID-19 vaccines unless concrete steps are taken to address the intellectual property barriers. Research already discloses many patent filings and grants such as more than 100 patents on mRNA platform technologies that are used for COVID-19 vaccines. Other Medical Products 50. In March 2020 in the Lombardy region in Northern Italy, one of the areas which was hit hardest by the pandemic an Italian hospital ran out of ventilator valves (which cost USD 11,000 each), and their regular supplier could not produce them on time. Two local engineers reverse engineered and 3D printed replacement valves for the cost of about USD 1. It is reported that the original manufacturer declined to share the blueprints and even threatened patent infringement and that potential legal implications stopped the engineers from distributing the digital design file more widely, despite receiving hundreds of requests for the 3D-printed valves". 51. Following this case, a law firm warned "[m]anufacturers should be aware of the complex intellectual property issues concerned with this 3D printing technology. Parts such as valves or other medical devices and equipment are capable of protection by patent and/or registered design. Unregistered design rights and copyright will also apply to the part itself and/or the digital model or CAD file. Some or all of these rights might apply in respect of a single component". The firm cautioned "In scanning a component such as a valve, and manufacturing a part using 3D printing equipment, there is a risk that this action will infringe an existing patent, design or copyright which protects the component, leading to an injunction or claim from the rights holder for damages or other remedies (such as delivery up of infringing parts)". Notably in In March 2020, WHO noted a shortage of ventilators around the world. 52. In another case, the Governor of Kentucky has called on multinational company 3M to release its patent for the N95 respirator — a desperately needed type of protective gear that's difficult to get during the coronavirus pandemic — so that more manufacturers can start making it. The N95 is considered top-of-the-line face protection for the professionals on the front lines of this pandemic. The Governor is reported as saying "The procurement is incredibly difficult, as is the manufacture because it's under patent. I'd like to see the people with that patent, which is 3M, provide that to the nation under a license for this period of time," adding that "I believe it's their patriotic duty, and they should put it out there so everybody else can manufacture it," he said of 3M. "That hasn't happened." Intellectual Property Disputes 53. Emerging intellectual property disputes already threaten the development and supply of COVID-19 medical products. In one dispute Regeneron and vaccine developers Pfizer and BioNTech are facing a lawsuit from Allele Biotechnology and Pharmaceuticals alleging that their coronavirus products were developed using Allele's mNeonGreen fluorescent protein without the company's permission.

#### Future pandemics lead to extinction.

Supriya 4/19

[Humans versus viruses - Can we avoid extinction in near future?, <https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx>, Lakshmi Supriya, 4/19/21] [SS]

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown. Scientists identify natural SARS-CoV-2 super immunity against 23 variants New estimate of total immunity to SARS-CoV-2 in Texas SARS-CoV-2 Iota variant increases mortality risk among older adults Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains. An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors. The brain There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease. Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision. Pandemics can cause other diseases that can threaten humanity’s entire existence. The COVID-19 pandemic brought this possibility to the forefront. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and the next pandemic could lead us to extinction.

#### Continued COVID is a threat magnifier and causes nuclear war.

Kampf 20 David Kampf 6-16-2020 “How COVID-19 Could Increase the Risk of War” <https://www.worldpoliticsreview.com/articles/28843/how-covid-19-could-increase-the-risk-of-war> (Senior PhD Fellow at the Center for Strategic Studies at The Fletcher School)//Elmer

To make matters worse, most of the global trends that explained why interstate war had decreased in recent decades are now reversing. The theories that democracy, prosperity, cooperation and other factors kept the peace have been much debated—but if there was any truth to them, their reversals are likely to increase the chance of war, irrespective of how long the coronavirus pandemic lasts. Democracy is often considered a prophylactic for war. Fully democratic countries are less likely to experience civil war and rarely, if ever, go to war with other democracies—though, of course, they do still go to war against non-democracies. While this would be great news if democracy and pluralism were spreading, there have now been 14 consecutive years of global democratic decline, and there have been signs of additional authoritarian power grabs in countries like Hungary and Serbia during the pandemic. If democracy backslides far enough, internal conflicts and foreign aggression will become more likely. Wars between states have declined, but civil wars never disappeared—and these internal conflicts could easily escalate into regional or global wars. Other theories posit that economic bonds between countries have limited wars in recent decades. Dale Copeland, a professor of international relations at the University of Virginia, has argued that countries work to preserve ties when there are high expectations for future trade, but war becomes increasingly possible when trade is predicted to fall. If globalization brought peace, the recent wave of far-right nationalism and populism around the world may increase the chances of war, as tariffs and other trade barriers go up—mostly from the United States under President Donald Trump, who has launched trade wars with allies and adversaries alike. The coronavirus pandemic immediately elicited further calls to reduce dependence on other countries, with Trump using the opportunity to pressure U.S. companies to reconfigure their supply chains away from China. For its part, China made sure that it had the homemade supplies it needed to fight the virus before exporting extras, while countries like France and Germany barred the export of face masks, even to friendly nations. And widening economic inequalities, a consequence of the pandemic, are not likely to enhance support for free trade. This assault on open trade and globalization is just one aspect of a decaying liberal international order, which, its proponents argue, has largely helped to preserve peace between nations since World War II. But that old order is almost gone, and in all likelihood isn’t coming back. The U.N. Security Council appears increasingly fragmented and dysfunctional. Even before Trump, the world’s most powerful country ratified fewer treaties per year under the Obama administration than at any time since 1945. Trump’s presidency only harms multilateral cooperation further. He has backed out of the Paris Agreement on climate change, reneged on the Iran nuclear deal, picked fights with allies, questioned the value of NATO and defunded the World Health Organization in the middle of a global health crisis. Hyper-nationalism, rather than international collaboration, was the default response to the coronavirus outbreak in the U.S. and many other countries around the world. A refugee camp in the eastern Lebanese border town of Arsal, Lebanon, June 16, 2019 (AP photo by Bilal Hussein). It’s hard to see the U.S. reluctance to lead as anything other than a sign of its inevitable, if slow, decline. The country’s institutionalized inequalities and systemic racism have been laid bare in recent months, and it no longer looks like a beacon for others to follow. The global balance of power is changing. **China is** both keen to assert a greater leadership role within traditionally Western-led institutions and to **challenge** the existing regional **order** in Asia. Between a rising China, **revanchist Russia** and new global actors, including non-state groups, we may be heading toward an increasingly multipolar or nonpolar world, **which could prove destabilizing i**n its own right. Finally, the pacifying effect of nuclear weapons could be waning. While vast nuclear arsenals once compelled the United States and the Soviet Union to reach arms control agreements, old treaties are expiring and new talks are breaking down. Mistrust is growing, and the **chance of an unwanted U.S.-Russia nuclear confrontation** is arguably as high **as it has been since the Cuban missile crisis**. The theory of nuclear peace may no longer hold if more countries are tempted to obtain their own nuclear deterrent. Trump’s decision to abandon the Iran nuclear deal, for one thing, has only increased the chance that Tehran will acquire nuclear weapons. It’s almost easy to forget that, just a few short months ago, the United States and Iran were one **miscalculation or dumb mistake away from waging all-out war**. And despite Trump’s efforts to negotiate nuclear disarmament with Kim Jong Un’s regime in Pyongyang, it is wishful thinking to believe North Korea will give up its nuclear weapons. At this point, negotiators can only realistically try to ensure that North Korea’s nuclear menace doesn’t get even more potent. In other words, by turning inward, the United States is choosing to leave other countries to fend for themselves. The end result may be a less stable world with more nuclear actors. If only one of these theories for peace were worsening, concerns would be easier to dismiss. But together, they are unsettling. While the world is not yet on the brink of World War III and no two countries are destined for war, the odds of avoiding future conflicts don’t look good. **The pandemic is already degrading democracies, harming economies and curtailing international cooperation, and it also seems to be fostering internal instability within states**. Rachel Brown, Heather Hurlburt and Alexandra Stark argue that the coronavirus could in fact sow more **civil conflict**. If this proves accurate, the increase in civil wars is likely to lead to more external meddling, and these next proxy wars could soon precipitate all-out international conflicts if outsiders aren’t careful. With the usual deterrents to conflict declining around the world, major wars could soon return. Preventing the Next Major War Regardless of what happens whenever the pandemic is resolved, it will be tempting to point to the coronavirus as the cause. But the shape of the post-pandemic world was forming long before the virus began to spread. The risk of war was already rising. If leaders are smart, they will take seriously the warning signs exposed by this global emergency and work to reverse the drift toward war. Countries, particularly the United States, need to fight the urge to turn inward and increase defense spending at any sign of trouble. Further militarizing foreign engagements will only enflame tensions and make matters worse. No country can shoot its way out of worsening circumstances. Instead, the United States should take the lead, reducing its military commitments and avoiding any ill-advised military interventions. Foreign relations should be characterized by diplomacy and development, not defense. The United States will need to make up with its friends and reengage in multilateral efforts to tackle global problems and resolve ongoing civil wars. International institutions should be consolidated and modernized to better respond to an unstable world with gathering threats like infectious diseases, climate change, growing inequality and demographic shifts. With the international order slowly crumbling and the United States retreating to focus on its own internal problems, the tendency for other countries will be to enhance their own border protections. But even in the absence of U.S. leadership, other countries are better served by increasing their international diplomacy and engagement, rather than buttressing their own defenses. **The coronavirus has exposed the preexisting conditions for major war. How countries respond will help determine whether or not the pandemic will hasten the drift toward more conflict**, or if that trend can be reversed.

## ADV – WTO Cred

#### Only a universal IP waiver can solve the WTO’s declining credibility – it’s bad, but it can get better.

Meyer 6/18

[https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/, The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn, David Meyer, 6/18/21] [SS]

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

#### Solves COVID.

Brant and Burns 7/29

[Trade restrictions are delaying the COVID response. The WTO must act, <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>, Jennifer Brant, Thaddeus Burns, 7/29/21] [SS]

Tariffs and export restrictions have delayed the distribution of vaccines, therapies and diagnostics needed to fight the pandemic. The World Trade Organization (WTO) needs to act on this when it meets in Geneva this November. WTO members should focus on eliminating tariffs across the value chain for COVID-related products. When World Trade Organization (WTO) members meet in Geneva in November, they must do more than agree a high-level trade and health declaration. They should take concrete action to eliminate the trade-distorting measures affecting global value chains for the vaccines, therapies, and diagnostics needed to fight the pandemic. Measures such as tariffs and export restrictions continue to create unnecessary costs in these value chains, undermining the COVID-19 response and setting back efforts to extend manufacturing capacity. Ministers should launch new talks to address these trade barriers. 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. Have you read? How can we fight fake COVID-19 vaccines? This new technology uses your smartphone to test for COVID-19 The COVID vaccine market is worth at least $150 billion. Can we stop it being flooded with fakes? 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. Trade policy action is needed to support this effort. The November Ministerial Conference will give WTO members an opportunity to accelerate the COVID response and improve future pandemic preparedness. Recent talks about a package of COVID-related trade measures is a welcome development. While discussions remain in the early stages, action in the areas of tariffs, export restrictions and regulatory coordination could help to remove impediments to the COVID response and future pandemic preparedness.

#### Solve Nuclear War

Hamann 9, Georgia. "Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System." Vand. J. Transnat'l L. 42 (2009): 993. (an associate in Lewis, Roca, Rothberger’s Litigation Practice Group, J.D. from Vanderbilt University Law School, May 2009)//Elmer

Voluntary compliance with WTO rules and procedures is of the utmost importance to the international trading system.100 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO as a cohesive force and arbiter of disputes that likely will become more frequent and injurious.101 The work of the WTO cannot be overstated in a nuclear-armed world, as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance.102 Demagogues in the Unites States may decry the rise of China as a geopolitical threat,103 and extremists in Russia may play dangerous games of brinksmanship with other great powers, but trade keeps politicians’ fingers off “the button.”104 The WTO offers an astounding rate of compliance for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO.105 In order to promote voluntary compliance, the WTO must maintain a high level of credibility.106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions.107 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization’s credibility.108 [Footnote 106 begins here] 106. See Rufus Yerxa, supra note 100, at 4 (“The WTO System works only to the extent Members want it to work, and only if they decide that compliance is in their overall economic interest. It therefore rests on the credibility of the rules, and also on the credibility of the dispute settlement decisions.”); see also DEBRA P. STEGER, PEACE THROUGH TRADE: BUILDING THE WTO 290–91 (2004) (linking issues of the WTO’s “external legitimacy” to the effectiveness of the institutional decision). 107. The goal of the WTO is to prevent unilateral decisions as to the justifiability of trade retaliation, a goal which can only be upheld by global adherence to the WTO and condemnation of unilateral retaliation outside it. See Gabrielle Marceau, Consultations and the Panel Process in the WTO, in KEY ISSUES IN WTO DISPUTE SETTLEMENT: THE FIRST TEN YEARS, supra note 17, at 29, 30–31; see also Marcelo de Paiva Abreu, Trade in Manufactures: The Outcome of the Uruguay Round and Developing Country Interests, in THE URUGUAY ROUND AND THE DEVELOPING COUNTRIES, supra note 12, at 59, 69 (discussing the importance of “the WTO’s capacity to create a level playing field among contracting parties of different sizes and heterogeneous bargaining power”). [Footnote 107 ends here] Credibility is lost where a supranational organization appears irredeemably partisan or where nations lack a sense of obligation to give effect to the organization’s judgments.109 GATT, the precursor to the WTO, could not approach the level of effectiveness of the WTO due to the system’s close ties to the interests of the developed nations.110 Developing nations saw no advantage associated with participation in GATT.111 Thus, a secondary organizational goal of the WTO was to create a system to accurately reflect the changing nature of economic development.112 To some extent, developed economies may feel a sense of responsibility to help developing and less-developed nations who desire material prosperity;113 however, WTO compliance and participation need not rest on humanitarian considerations alone— the rise of previously imperiled economies such as India demonstrates the continual flux of the global economy and the correlating incentives.114 Although developed nations frequently feel a sense of responsibility to nations whose people live in poverty, developed nations also recognize the advantages of incorporating developing economies into the global trade system and encouraging peaceful trade within and among such economies.115 [Footnote 115 begins here] 115. Ruggiero, supra note 101, at 17 (noting that, absent inclusion in the trading system, rising nations such as India and China will develop preferential trading agreements along potentially questionable lines). [Footnote 115 ends here] Accordingly, the interests of developing nations have garnered a considerable amount of attention within the organization116 and the critical literature surrounding the undertakings of the WTO.117 The participation of developing nations has increased, but not sufficiently.118 The global trading system (both the WTO as an institution and the countries with an economic stake in a smoothly-functioning global economy) must work to encourage these nations to utilize the availability of WTO proceedings as a means of resolving economic disputes.119 The decision in Antigua-Gambling has an impact analogous to a marketing campaign—promoting incentives for developing countries to join the WTO.120 If Antigua can successfully challenge the U.S. refusal to comply with WTO arbitration,121 and if there are mechanisms in place to enable Antigua to effect meaningful change in U.S. economic,122 then the WTO truly is a forum where each member nation can expect a fair remedy.

#### Nuclear war is existential – climate, mass starvation, Ice Age, and meltdowns

Starr 14 [Steven, Senior Scientist for Physicians for Social Responsibility (www.psr.org) and Director of the Clinical Laboratory Science Program at the University of Missouri. Starr has published in the Bulletin of the Atomic Scientists and the Strategic Arms Reduction (STAR) website of the Moscow Institute of Physics and Technology, June 5, “The Lethality of Nuclear Weapons: Nuclear War has No Winner,” http://www.globalresearch.ca/the-lethality-of-nuclear-weapons-nuclear-war-has-no-winner/5385611]

Nuclear war has no winner. Beginning in 2006, several of the world’s leading climatologists (at Rutgers, UCLA, John Hopkins University, and the University of Colorado-Boulder) published a series of studies that evaluated the long-term environmental consequences of a nuclear war, including baseline scenarios fought with merely 1% of the explosive power in the US and/or Russian launch-ready nuclear arsenals. They concluded that the consequences of even a “small” nuclear war would include catastrophic disruptions of global climate[i] and massive destruction of Earth’s protective ozone layer[ii]. These and more recent studies predict that global agriculture would be so negatively affected by such a war, a global famine would result, which would cause up to 2 billion people to starve to death. [iii] These peer-reviewed studies – which were analyzed by the best scientists in the world and found to be without error – also predict that a war fought with less than half of US or Russian strategic nuclear weapons would destroy the human race.[iv] In other words, a US-Russian nuclear war would create such extreme long-term damage to the global environment that it would leave the Earth uninhabitable for humans and most animal forms of life. A recent article in the Bulletin of the Atomic Scientists, “Self-assured destruction: The climate impacts of nuclear war”,[v] begins by stating: “A nuclear war between Russia and the United States, even after the arsenal reductions planned under New START, could produce a nuclear winter. Hence, an attack by either side could be suicidal, resulting in self-assured destruction.” In 2009, I wrote an article[vi] for the International Commission on Nuclear Non-proliferation and Disarmament that summarizes the findings of these studies. It explains that nuclear firestorms would produce millions of tons of smoke, which would rise above cloud level and form a global stratospheric smoke layer that would rapidly encircle the Earth. The smoke layer would remain for at least a decade, and it would act to destroy the protective ozone layer (vastly increasing the UV-B reaching Earth[vii]) as well as block warming sunlight, thus creating Ice Age weather conditions that would last 10 years or longer. Following a US-Russian nuclear war, temperatures in the central US and Eurasia would fall below freezing every day for one to three years; the intense cold would completely eliminate growing seasons for a decade or longer. No crops could be grown, leading to a famine that would kill most humans and large animal populations. Electromagnetic pulse from high-altitude nuclear detonations would destroy the integrated circuits in all modern electronic devices[viii], including those in commercial nuclear power plants. Every nuclear reactor would almost instantly meltdown; every nuclear spent fuel pool (which contain many times more radioactivity than found in the reactors) would boil-off, releasing vast amounts of long-lived radioactivity. The fallout would make most of the US and Europe uninhabitable. Of course, the survivors of the nuclear war would be starving to death anyway. Once nuclear weapons were introduced into a US-Russian conflict, there would be little chance that a nuclear holocaust could be avoided. Theories of “limited nuclear war” and “nuclear de-escalation” are unrealistic.[ix] In 2002 the Bush administration modified US strategic doctrine from a retaliatory role to permit preemptive nuclear attack; in 2010, the Obama administration made only incremental and miniscule changes to this doctrine, leaving it essentially unchanged. Furthermore, Counterforce doctrine – used by both the US and Russian military – emphasizes the need for preemptive strikes once nuclear war begins. Both sides would be under immense pressure to launch a preemptive nuclear first-strike once military hostilities had commenced, especially if nuclear weapons had already been used on the battlefield. Both the US and Russia each have 400 to 500 launch-ready ballistic missiles armed with a total of at least 1800 strategic nuclear warheads,[xi] which can be launched with only a few minutes warning.[xii] Both the US and Russian Presidents are accompanied 24/7 by military officers carrying a “nuclear briefcase”, which allows them to transmit the permission order to launch in a matter of seconds.

## 1AC – Plan - Short

#### Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for COVID-19 medicines.

#### Enforcement through limited IP waivers solve – patent term extensions are normal means and solves innovation and scale-up.

Young and Potts-Szeliga 21 [Roberta; Counsel in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Los Angeles; Jamaica Potts-Szeliga; Partner in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Washington, DC. She also provides advice on FDA regulatory issues and is part of the firm’s Health Care, Life Sciences, and Pharmaceuticals team; “A Third Option: Limited IP Waiver Could Solve Our Pandemic Vaccine Problems,” IP Watch Dog; 7/21/21; <https://www.ipwatchdog.com/2021/07/21/third-option-limited-ip-waiver-solve-pandemic-vaccine-problems/id=135732/>] Justin

Limited Waiver Approach

This article suggests a third option, between voluntary vaccine donation and the full IP waiver proposal, that may offer a way forward. The third proposed solution is incentivized limited IP waivers that could encourage (or require) private companies to engage in licensing agreements with nations to share some, but not all, of the knowledge and designs covering the COVID-19 vaccines to the developing world. The limited IP waivers could cover the minimum necessary portions of the technology to produce basic COVID-19 vaccines. The waivers could be limited in time to the duration of the pandemic, or another term agreed to by the WTO. The term could also be defined as ending when widespread vaccination and immunity goals are achieved. The incentive for pharmaceutical companies to support such limited IP waivers could be provided in the form of patent term extensions for the technology covered by the limited IP waivers.

Extensions of patent term are already known and widely used. In the U.S., patent term adjustments are automatically added on to the patent lifespan to account for any delays by the USPTO in the patent prosecution process. In some cases, these mechanisms may extend the patent term for years. Patent term extensions also are available for regulatory delays (35 U.S.C. § 156). In particular, patents covering, inter alia, drug products approved by the United States Food & Drug Administration may be eligible for up to five years of additional patent term to give back time required to complete the regulatory review process. Both patent term adjustments and patent term extensions arise from activities beyond the control of the pharmaceutical companies. A pandemic patent term extension fashioned after such known extensions could be made used to compensate for the current pressing global health needs.

This third proposal may be achievable at the WTO. Hurdles remain and it could be months or years before the WTO reaches an agreement on any waiver of IP protections, and years before countries build factories, gather materials, and gain the expertise to produce the vaccines. A steep hurdle is that mRNA is a new technology, with no machines or experts for hire. Nonetheless, the third solution offers hope to find a middle ground that may begin to be implemented before the end of the current pandemic and be in place for the future.

The patent term extension could be provided for countries with patent offices and could be adapted based on laws and conditions in each country. Pandemic-related patent term extensions could be given for a period of time that the compulsory license is in force. With current pandemic projections of six months to two years for sufficient distribution, providing a patent term extension is reasonable and in line with the time period of many patent term extensions. Given that most pharmaceutical patents are prosecuted in multiple countries, this provides an incentive to participate in a limited waiver program.

Let’s Not Repeat Past Mistakes

It’s been a century since the last pandemic devastated the globe and the only certainty is that this will not be the last pandemic. Solutions created today lay a foundation for mitigation of the next pandemic. It’s been said that those who refuse to learn from history are doomed to repeat it, a thought too painful to contemplate with a pandemic. The industrial nations of the world have technology that others are literally dying to obtain—a high price to pay. Incentivized limited IP waivers may offer a compromise to bridge the gap between maintaining IP rights (and thus relying on charity alone) and arbitrary compulsory licensing that could deter the technological investment to create life-saving solutions in the future.

#### Promotes distribution – plan enables global affordable access.

Chen 4 [Joe Chen (Associate at Fox Rothschild LLP, JD from Seton Hall School of Law, Ph.D in biology from Indiana University Bloomington). “Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic”. Law School Student Scholarship @ Seton Hall University. 6/22/21. Accessed 8/2/21. https://scholarship.shu.edu/student\_scholarship/1197/ //found duongie, cut Xu]

4.7. Participating in medicine patent pool and Open COVID Pledge The patent pooling mechanism can be an effective tool to spur drug discovery and development for control and treatment of the COVID-19 pandemic. It acts as an intermediary or a clearinghouse to pool inbound licenses on a broad array of medical IPRs and research data from IPRs owners across the globe.114 The pooled licenses can be sublicensed on a royalty-free basis or on equitable terms to qualified developers or manufacturers. 115 Through the patent pooling mechanism, various IPRs owned by different owners are combined, which serves as a one-stop shop for all parties.116 Hence, transaction costs and risks will be substantially reduced. In addition, the patent pooling mechanism will facilitate the access to research data and collaborative innovation of relevant health technologies, thus accelerating response to the COVID-19 pandemic. The pooling mechanism can potentially increase equitable and affordable access to health technologies in these desperate times. Recently, a proposal for a global intellectual property pooling mechanism was proposed by Costa Rica, which received prompt support from the WHO.117; 118 One of the important advantages of patent pooling is that it negotiates licenses from a public health perspective. 119 In addition, the licenses under the patent pooling mechanism are transparent and predictable. All agreements are made available to the public on the organization’s website. This is an improvement over voluntary licenses, the terms of which are generally kept secret. As the COVID-19 pandemic continues to negatively impact the world, a number of initiatives, such as “Open COVID Pledge,” have been launched to address the challenges associated with the sharing of IP and knowledge in the fight against the COVID-19 pandemic.120 The Open COVID Pledge was developed by a group of scientists, lawyers, and entrepreneurs to encourage businesses and research facilities to make their intellectual property available for use in the fight against COVID-19.121 The Open COVID Pledge is aimed to encourage sharing of IP and technologies to combat and end the pandemic without the need for timely and costly licenses or royalty agreements.122 The main concern for patent pooling and the Open COVID Pledge is the degree of participation by IPRs owners. IPRs owners devote a substantial sum of capital to develop their IP, with the expectation of recouping their investments through IPRs. Thus, it remains unclear how IPRs owners balance data sharing and open access to technologies against financial stability and potential legal issues that may arise from participating in patent pooling or the Open COVID Pledge due to IPRs owners’ legal obligations to their sponsors and other IP stakeholders. 4.8. Invoking Article 73 security exceptions of the TRIPS Agreement To facilitate production and distribution of medical products to combat the COVID-19 pandemic, governments across the globe are taking steps to bypass or override patents and other IPRs. The recent paper by Abbott et al. explores the possibility to invoke Article 73 (“Security Exceptions”) of the TRIPS Agreement as the legal basis to override IPRs by classifying the COVID-19 as an “emergency in international relations.” 123 Abbott et al. concluded that the COVID-19 pandemic can be considered an emergency in international relations under Article 73(b)(iii), which permits governments to take necessary measures to protect essential security interests.124 In supporting invocation of Article 73 security expectations, it is first determined the COVID-19 constitutes an emergency in international relations. Article 73 provides “Nothing in this [TRIPS] Agreement shall be construed … to prevent a member from taking any action which it considers necessary for the protection of its essential security interests … taken in time of war or other emergency in international relations ….” 125 One of the major issues in combating and ending the pandemic involves allocating medical products such as vaccines, medicines, personal protection equipment (PPE) among nations as COVID-19 is transmitted across national borders and affects people in many geographic regions. Under the present pandemic, the needs of LMICs for medical devices and medicines will not be met in a timely way. Thus, the allocation of scarce resources can be an issue of “international relations,” and a viable mechanism should be established to ensure equitable and affordable access to these resources.126 In addition to the allocation issue of scarce resources, other pandemic-related issues can lead to an emergency in international relations, including a significant slowdown of international trade and a deeply contracted economy.127 Abbott et al. concluded that overriding IPRs is among the actions considered necessary “for the protection of its essential security interests” under Article 73(b).128 Use of Article 73 by a WTO member to override IPRs or market exclusivity interests in medical devices or medicines will allow its domestic manufacturers or importers to use protected technologies of foreign IPR owners that are critical for fighting the COVID-19 pandemic. Such use of Article 73 to override IPRs is reasonably and directly related to addressing the national security interest.129 However, as with many other policy measures, overriding IPRs may face challenges based on national laws. Article 73 only addresses the challenges from another member in the WTO but not potential domestic law problems.130

#### Increases vaccine innovation.

Chen 2 [Joe Chen (Associate at Fox Rothschild LLP, JD from Seton Hall School of Law, Ph.D in biology from Indiana University Bloomington). “Balancing Intellectual Property Rights and Public Health to Cope with the COVID-19 Pandemic”. Law School Student Scholarship @ Seton Hall University. 6/22/21. Accessed 8/2/21. https://scholarship.shu.edu/student\_scholarship/1197/ //found duongie, cut Xu]

4.1. Restricting patent evergreening by applying stricter patentability criteria Patent evergreening is a patenting strategy pharmaceutical companies often employ to seek new monopolies or prolong market exclusivity. It is in the public interest of all nations to refrain from allowing “patent evergreening” through secondary patents derived from a parent patent by applying stricter patentability criteria. While excluding entire fields of technology (e.g., medicines, food) is no longer permitted under the TRIPS Agreement, countries can set more stringent patenting standards to meet the domestic needs of public health and economy. This will help to limit granting secondary and new use patents—a practice that often leads to patent evergreening. Under the present IP systems, whether to grant or refuse a secondary patent is judged based on its merits. It is important to determine if the secondary patent is separately patent-eligible. The mere fact that an innovation is incremental is not a ground for refusing a secondary patent claim. In fact, most innovation is incremental by nature. Some health policy-makers argue that therapeutic efficacy should be included as an additional criterion to restrict evergreening and that secondary patents should be granted only if the embodied incremental innovation provides sufficient therapeutic benefits.64 Although the therapeutic value of a product is not a patentability criterion in most jurisdictions, superior therapeutic advantages over the prior art may be considered when evaluating nonobviousness (or inventive step) of the product. 65 In limiting patent evergreening, some countries have revised their legislation to adopt narrower patentability criteria. Section 3(d) of India’s Patents Act 1970 and Section 26.2 of the Philippines’ Intellectual Property Code are two examples of a narrow definition of patentability criteria.66 Other countries apply different approaches. For example, many patent offices, such as Argentina, Brazil, China, Germany, the UK, the US, and EPO patent offices, have established examination guidelines for pharmaceutical inventions.67 The examination guidelines for patent examiners adopted by Argentina are along similar lines as Section 3(d) of India’s Patents Act 1970.68 Thus, the goal of limiting patent evergreening can be achieved at both legislative and administrative levels. 4.2. Restricting patenting of repurposed or combination drugs Second medical use patents are permitted for repurposed medicines and combination therapies in some jurisdictions, including the US. The patentability of medical indications is relevant to our fight against the COVID-19 pandemic considering many of the ongoing clinical trials are based on either repurposing or combining known drugs. Drug repurposing (also known as drug repositioning or therapeutic switching) is re-tasking an approved drug for the treatment of a different disease or medical condition than its original purpose of development. 69 Drug repurposing has been pursued to develop safe and effective COVID-19 treatments.70; 71 Several existing antiviral medications, previously developed for treating severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), HIV/AIDS, and malaria, have been investigated as potential COVID‑19 treatments, some of which are currently being tested in clinical trials.72; 73; 74 For example, the world’s largest COVID-19 clinical trial was launched by the United Kingdom (UK) to test repurposed drugs.75 In particular, drugs included in the trial protocol are all existing medicines repurposed for COVID-19, such as AbbVie’s Kaletra (lopinavir/ritonavir), commonly used to treat HIV infection; dexamethasone, an anti-inflammatory steroid; hydroxychloroquine, an antimalarial drug; and the antibiotic azithromycin.76 Currently, there are eleven registered COVID-19 clinical trials for remdesivir alone. Remdesivir is an antiviral drug, which was originally developed by Gilead Sciences to treat Hepatitis C and was then tested against Ebola virus disease and Marburg virus disease, but was ineffective for all of these viral infections.77; 78; 79 It is thought that remdesivir may be beneficial for treating patients with COVID-19, and the FDA recently granted emergency use of remdesivir during the pandemic.80 In January 2020, the Wuhan Institute of Virology applied for a patent covering the use of remdesivir as a treatment for COVID-19. However, such a move to claim patent rights over unproven use of the treatment, made in the midst of a rapidly worsening public health crisis, was heavily criticized.81 The need for claiming such patent rights was also questioned, since the national law implementing the TRIPS Agreement explicitly permits compulsory licensing. Given the fact that the candidate therapeutics of many (if not most) of the ongoing clinical trials are repurposed drugs, this paper calls on all countries to refrain from granting COVID-19- related second medical use patents based on repurposed medicines and combination therapies.

#### Certainty of the plan spills over

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Technology pooling Guzman acknowledged that a waiver was “not a silver bullet” but said he supported it because it “opened the possibility for legal certainty using the current multilateral trading system.” “This certainty is likely to increase public and private investment in low and middle income countries and therefore manufacturing capacity to produce covid vaccines without the threat of being sued or prosecuted,” he said. “It [also] signals that the US government is serious about moving beyond the status quo to increase access to covid vaccines, and it offers the world the possibility to learn about using measures that were previously seen as radical or unthinkable and even re-examine IP rights in the context of health emergencies.”

## Framework

#### Pleasure and pain are intrinsic value and disvalue – everything else regresses – robust neuroscience proves

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**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10].

Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14].

Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals.

Evolutionary theories of pleasure: The love connection BO:D

Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it.

It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring.

Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding.

There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health.

Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage.

Finding happiness is different between apes and humans

As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure.

Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even produce **the opposite** of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered.

Desire and reward centers

It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation.

In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41].

Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42].

Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans.

In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45].

Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations.

Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50]

In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders.

In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS.

Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

#### **Thus, the standard is maximizing expected well being**

Prefer additionally:

#### **1]outweighs on actor specificity since governments make policies as a whole that benefit and help some people and side constraints freeze action – actor spec outweighs and turns since it’s better than no action, states don’t have wills and intentions since they are not indivuals actors, different agents have different obligations**

#### **2] no act omission distinction -- governments control everything that happens in the public sphere since they yes/no bills – act omission distinction would make the yemen war moral**

#### **3] extinction first**

Pummer 15 [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### 4] use epistemic modesty – multiply probability of the fwk times the magnitude of the impacts A) clash – encourages both substantive and phil debates so that we talk about all the offense B) leads to the net most morality and proves that only beating fwk is not enough to win the debate

#### 5] Nothing in the aff triggers presumption and permissibility but they affirm: A) we presume statements true before false– if I say my name is Saranya Singh then you believe me B) To negate means to deny the truth and if they neg hasn’t proved the aff wrong then they lose C) All truth statements depend on other statements so if we presume everything false then we can’t prove anything true D) we’d need to justify everything including breathing E) if anything is permissible then so is the aff because there’s no reason not to do it

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