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### ADV – COVID

#### The time to expand vaccination on a global level is now---highly contagious mutations facilitate continued spread.

Kumar 7-12 Rajeesh Kumar, Rajeesh Kumar is Associate Fellow at Manohar Parrikar Institute for Defence Studies and Analyses, New Delhi., 7-12-2021, "WTO TRIPS Waiver and COVID-19 Vaccine Equity," Manohar Paprikar Institute for Defence Studies and Analyses, <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>, EH and brett

Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines.

Vaccine Inequity

According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11

Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021.

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

#### That renders current vaccines ineffective

Dransfield 21 Sarah Dransfield, 3-30-2021, “Two-thirds of epidemiologists warn mutations could render current COVID vaccines ineffective in a year or less”, https://www.oxfam.org/en/press-releases/two-thirds-epidemiologists-warn-mutations-could-render-current-covid-vaccines, accessed 7/23/2021 EH and brett

Epidemiologists from some of the world’s leading academic institutions delivered a stark warning today of the risk the world is taking by failing to ensure all countries have sufficient vaccines to protect people from COVID-19.

In a survey of 77 epidemiologists from 28 countries, carried out by The People’s Vaccine Alliance, two-thirds thought that we had a year or less before the virus mutates to the extent that the majority of first-generation vaccines are rendered ineffective and new or modified vaccines are required. Of those surveyed, almost a third gave a timeframe of nine months or less. Fewer than one in eight said they believed that mutations would never render the current vaccines ineffective.

The overwhelming majority - 88 per cent - said that persistent low vaccine coverage in many countries would make it more likely for vaccine resistant mutations to appear.

The People’s Vaccine Alliance, a coalition of over 50 organisations including African Alliance, Oxfam, Public Citizen and UNAIDS warned that at the current rate it was likely that only 10 per cent of people in the majority of poor countries will be vaccinated in the next year.

Nearly three-quarters of those surveyed - who included epidemiologists, virologists and infectious disease specialists from institutions including Johns Hopkins, Yale, Imperial College, London School of Hygiene and Tropical Medicine, Cambridge University, the University of Edinburgh and The University of Cape Town - said that open sharing of technology and intellectual property could increase global vaccine coverage. The People's Vaccine Alliance is calling for the lifting of pharmaceutical monopolies and the sharing of technology to urgently boost vaccine supply.

Devi Sridhar, Professor of Global Public Health at the University of Edinburgh, said: “The more the virus circulates, the more likely it is that mutations and variants will emerge, which could make our current vaccines ineffective. At the same time, poor countries are being left behind without vaccines and basic medical supplies like oxygen.

“As we've learned, viruses don't care about borders. We have to vaccinate as many people as possible, everywhere in the world, as quickly as possible. Why wait and watch instead of getting ahead of this?”

While he didn’t specify a timeframe, Gregg Gonsalves, Associate Professor of Epidemiology at Yale University, echoed the urgency to vaccinate globally. Gonsalves said: “With millions of people around the world infected with this virus, new mutations arise every day. Sometimes they find a niche that makes them more fit than their predecessors. These lucky variants could transmit more efficiently and potentially evade immune responses to previous strains. Unless we vaccinate the world, we leave the playing field open to more and more mutations, which could churn out variants that could evade our current vaccines and require booster shots to deal with them.

“We all have a self-interest in ensuring that everyone around the world, no matter where they live have access to COVID-19 vaccines. The virus doesn’t respect borders and new variants somewhere on the planet mean none of us are safe.”

#### Waiving IP protections is essential to expand manufacturing and global exports. A litany of countries possess capacity but lack know-how -- the plan is key.

Kumar 7-12 Rajeesh Kumar, Rajeesh Kumar is Associate Fellow at Manohar Parrikar Institute for Defence Studies and Analyses, New Delhi., 7-12-2021, "WTO TRIPS Waiver and COVID-19 Vaccine Equity," Manohar Paprikar Institute for Defence Studies and Analyses, <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>, brett

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

#### Boosting manufacturing capacity is critical to a timely response to COVID AND ensures preparedness for future pandemics.

Jecker & Atuire 21, Dr Nancy S Jecker, Department of Bioethics & Humanities, University of Washington School of Medicine. Department of Philosophy, University of Johannesburg, Auckland Park, Gauteng, South Africa. Caesar A Atuire, Department of Philosophy and Classics, University of Ghana, Accra, Accra, Ghana. All Souls College, University of Oxford, Oxford, Oxfordshire, UK. Journal of Medical Ethics 2021;47:595-598. “What’s yours is ours: waiving intellectual property protections for COVID-19 vaccines.” <https://jme.bmj.com/content/47/9/595> brett

Since consequentialist justifications treat the value of IP as purely instrumental, they are also vulnerable to counterarguments showing that a sought-after goal is not the sole or most important end. During the COVID-19 pandemic, we submit that the vaccinating the world is an overriding goal. With existing IP protections intact, the world has fallen well short of this goal. Current forecasts show that at the current pace, there will not be enough vaccines to cover the world’s population until 2023 or 2024.15 IP protections further frustrate the goal of universal access to vaccines by limiting who can manufacturer them. The WHO reports that 80% of global sales for COVID-19 vaccines come from five large multinational corporations.16 Increasing the number of manufacturers globally would not only increase supply, but reduce prices, making vaccines more affordable to LMICs. It would stabilise supply, minimising disruptions of the kind that occurred when India halted vaccine exports amidst a surge of COVID-19 cases.

It might be objected that waiving IP protections will not increase supply, because it takes years to establish manufacturing capacity. However, since the pandemic began, we have learnt it takes less time. Repurposing facilities and vetting them for safety and quality can often happen in 6 or 7 months, about half the time previously thought.17 Since COVID-19 will not be the last pandemic humanity faces, expanding manufacturing capacity is also necessary preparation for future pandemics. Nkengasong, Director of the African Centres for Disease Control and Prevention, put the point bluntly, ‘Can a continent of 1.2 billion people—projected to be 2.4 billion in 30 years, where one in four people in the world will be African—continue to import 99% of its vaccine?’18

#### COVID escalates every hotspot---extinction.

RECNA et al. 21, Research Center for Nuclear Weapons Abolition, Nagasaki University (RECNA), Asia Pacific Leadership Network (APLN), and the Nautilus Institute. Journal for Peace and Nuclear Disarmament Volume 4, 2021. “Pandemic Futures and Nuclear Weapon Risks: The Nagasaki 75th Anniversary pandemic-nuclear nexus scenarios final report” <https://www.tandfonline.com/doi/full/10.1080/25751654.2021.1890867> brett

The relationship between pandemics and war is as long as human history. Past pandemics have set the scene for wars by weakening societies, undermining resilience, and exacerbating civil and inter-state conflict. Other disease outbreaks have erupted during wars, in part due to the appalling public health and battlefield conditions resulting from war, in turn sowing the seeds for new conflicts. In the post-Cold War era, pandemics have spread with unprecedented speed due to increased mobility created by globalization, especially between urbanized areas. Although there are positive signs that scientific advances and rapid innovation can help us manage pandemics, it is likely that deadly infectious viruses will be a challenge for years to come.

The COVID-19 is the most demonic pandemic threat in modern history. It has erupted at a juncture of other existential global threats, most importantly, accelerating climate change and resurgent nuclear threat-making. The most important issue, therefore, is how the coronavirus (and future pandemics) will increase or decrease the risks associated with these twin threats, climate change effects, and the next use of nuclear weapons in war.5

Today, the nine nuclear weapons arsenals not only can annihilate hundreds of cities, but also cause nuclear winter and mass starvation of a billion or more people, if not the entire human species. Concurrently, climate change is enveloping the planet with more frequent and intense storms, accelerating sea level rise, and advancing rapid ecological change, expressed in unprecedented forest fires across the world. Already stretched to a breaking point in many countries, the current pandemic may overcome resilience to the point of near or actual collapse of social, economic, and political order.

In this extraordinary moment, it is timely to reflect on the existence and possible uses of weapons of mass destruction under pandemic conditions – most importantly, nuclear weapons, but also chemical and biological weapons. Moments of extreme crisis and vulnerability can prompt aggressive and counterintuitive actions that in turn may destabilize already precariously balanced threat systems, underpinned by conventional and nuclear weapons, as well as the threat of weaponized chemical and biological technologies. Consequently, the risk of the use of weapons of mass destruction (WMD), especially nuclear weapons, increases at such times, possibly sharply.

The COVID-19 pandemic is clearly driving massive, rapid, and unpredictable changes that will redefine every aspect of the human condition, including WMD – just as the world wars of the first half of the 20th century led to a revolution in international affairs and entirely new ways of organizing societies, economies, and international relations, in part based on nuclear weapons and their threatened use. In a world reshaped by pandemics, nuclear weapons – as well as correlated non-nuclear WMD, nuclear alliances, “deterrence” doctrines, operational and declaratory policies, nuclear extended deterrence, organizational practices, and the existential risks posed by retaining these capabilities – are all up for redefinition.

A pandemic has potential to destabilize a nuclear-prone conflict by incapacitating the supreme nuclear commander or commanders who have to issue nuclear strike orders, creating uncertainty as to who is in charge, how to handle nuclear mistakes (such as errors, accidents, technological failures, and entanglement with conventional operations gone awry), and opening a brief opportunity for a first strike at a time when the COVID-infected state may not be able to retaliate efficiently – or at all – due to leadership confusion. In some nuclear-laden conflicts, a state might use a pandemic as a cover for political or military provocations in the belief that the adversary is distracted and partly disabled by the pandemic, increasing the risk of war in a nuclear-prone conflict. At the same time, a pandemic may lead nuclear armed states to increase the isolation and sanctions against a nuclear adversary, making it even harder to stop the spread of the disease, in turn creating a pandemic reservoir and transmission risk back to the nuclear armed state or its allies.

In principle, the common threat of the pandemic might induce nuclear-armed states to reduce the tension in a nuclear-prone conflict and thereby the risk of nuclear war. It may cause nuclear adversaries or their umbrella states to seek to resolve conflicts in a cooperative and collaborative manner by creating habits of communication, engagement, and mutual learning that come into play in the nuclear-military sphere. For example, militaries may cooperate to control pandemic transmission, including by working together against criminal-terrorist non-state actors that are trafficking people or by joining forces to ensure that a new pathogen is not developed as a bioweapon.

To date, however, the COVID-19 pandemic has increased the isolation of some nuclear-armed states and provided a textbook case of the failure of states to cooperate to overcome the pandemic. Borders have slammed shut, trade shut down, and budgets blown out, creating enormous pressure to focus on immediate domestic priorities. Foreign policies have become markedly more nationalistic. Dependence on nuclear weapons may increase as states seek to buttress a global re-spatialization6 of all dimensions of human interaction at all levels to manage pandemics. The effect of nuclear threats on leaders may make it less likely – or even impossible – to achieve the kind of concert at a global level needed to respond to and administer an effective vaccine, making it harder and even impossible to revert to pre-pandemic international relations. The result is that some states may proliferate their own nuclear weapons, further reinforcing the spiral of conflicts contained by nuclear threat, with cascading effects on the risk of nuclear war.

### ADV – Legitimacy

#### The WTO is on the brink -- the TRIPS waiver is the critical factor determining the survival of multilateral trade AND creates momentum for structural reforms

Meyer 6-18 David Meyer, 6-18-2021, "The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn – Fortune," Fortune, https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/amp/, EH and brett

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.

#### HIV/AIDS prove legitimacy damage from patent controversy---every bit of delay saps credibility---now is key

Bacchus 20 James Bacchus [member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland. ], 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines accessed 7/20/2021 EH

Balancing IP Rights and Access to Medicines Not New to WTOThis waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itselfwere all damaged byanextended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.

#### Perception alone solves, regardless of success, issuing the waiver is a sign of goodwill that shores up legitimacy

Winslett 5-27, Gary Winslett is an associate fellow for finance and trade at the R Street Institute. He is also an assistant professor of political science at Middlebury College. May 27, 2021. National Interest, “The Political Significance of the TRIPS Waiver” <https://nationalinterest.org/feature/political-significance-trips-waiver-186246> brett

Fourth, the U.S. government supporting a limited TRIPS waiver is a massive step toward rebuilding the perceived legitimacy of the WTO. The perception that the WTO was slowing the global response to the coronavirus, however oversimplified and unfair, would have been a potentially devastating blow to an institution that has already been under attack. A TRIPS waiver buys considerable goodwill from developing countries. It also buys goodwill from Democrats. That could help the whole party take a more trade-friendly stance on everything from an Environmental Goods Agreement to an e-commerce trade deal, to say nothing of the broader benefit of convincing Democrats to like trade even more than they already do—79 percent of Democrats view trade as more of an opportunity than a threat versus only 44 percent of Republicans who say the same.

#### Restoring credibility de-escalates every conflict.

GEORGIA L. Hamann 9, associate in Lewis, Roca, Rothberger’s Litigation Practice Group, J.D. from Vanderbilt University Law School. May 2009, “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System”, <http://www.vanderbilt.edu/jotl/manage/wp-content/uploads/hamann-cr_final_final.pdf> brett

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

\*\*\*start footnote 6\*\*\*

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).

\*\*\*end footnote 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.

\*\*\*Start footnote 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").

\*\*\*end footnote 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

### Solvency

#### Plan: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines related to the prevention, containment, and treatment of COVID-19.

#### Enforcement is done through waiving TRIPS protections and modifying relevant domestic law to ensure patent protections are reduced---spec is delineated in the card.

Jones et al. 21, Mike Jones, J.D., cum laude, Brooklyn Law School, 2014. Sean McConnell, University of Pittsburgh School of Law, J.D., 2002. Lauren Giambalvo, University of Georgia School of Law, J.D., magna cum laude, Order of the Coif, 2019; Georgia Law Review. Emily Harmon, Villanova University Charles Widger School of Law, J.D., 2020. Ipwatchdog, August 9, 2021. “What is a ‘Patent Waiver’ Anyway? Zooming Out on the TRIPS COVID IP Waiver Debate” <https://www.ipwatchdog.com/2021/08/09/patent-waiver-anyway-zooming-trips-covid-ipwaiver-debate/id=136381/> brett

Scientists, engineers, and everyday people have developed solutions for testing, preventing, and treating the COVID-19 disease. Ordinarily, we wouldn’t think twice about granting patents on these inventions. But, today, when COVID-19 is spreading all over the world and killing millions of people, some world leaders are questioning whether we should be granting the exclusionary rights of patent protection on inventions that help respond to the pandemic. Included in that group is the Biden-Harris Administration, which, in May, announced their support of an “IP waiver” on COVID 19 vaccines.

Patent Waiver

The “patent waiver” is a proposal to waive certain provisions of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement for three years. The TRIPS Agreement requires certain member countries (“Members”), including the United States, to have certain minimum intellectual property protections. While this proposal is often referred to as a “patent waiver,” the proposal would also waive sections associated with copyright, industrial designs, and undisclosed information.

The proposal seeks to waive Part II, Section 5 Patents of the TRIPS Agreement and the associated enforcement sections only with respect to “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19” for a period of three years. Article 27 of Section 5 requires that certain Members issue patents to inventions that “are new, involve an inventive step and are capable of industrial application.” However, Members have the option to refuse to grant patents to certain categories of inventions, including, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” Article 28 explains that an owner of a patent can prevent others from “making, using, offering for sale, selling, or importing” (“infringing”) the patented inventions. Finally, Part III of the TRIPS Agreement explains the potential consequences of infringing a patent. Among other things, the infringer can be liable for money damages and the judicial authority of the Member may order injunctions.

Therefore, as the TRIPS Agreement currently stands, each Member must have patent laws that give patents to inventions that meet certain requirements, and each must provide avenues for patent holders to enforce its patent rights. As applied to the current situation, Members are required to grant patents to qualifying inventions related to “the prevention, containment and treatment of COVID-19” (with exceptions for pharmaceuticals if the Member does not allow pharmaceutical patents). Infringers could be liable for money damages and the judicial authority of the Member may order injunctions.

If provisions in Part II, Section 5 and the associated enforcement sections are waived, Members would no longer be required to issue patents or provide avenues for patent holders to enforce patent rights. The proposal does not, however, require Members to waive their own domestic patent rights. In other words, the proposal to waive certain provisions of the TRIPS Agreement, the “patent waiver,”

does not directly waive any patent protections. Rather, the patent waiver grants to Members permission to waive their own domestic patent protections.

Patent laws are geographically limited; they only protect an invention in the country that issued the patent. For example, one cannot make, use, offer to sell, sell, or import an invention protected only by a U.S. patent in the U.S; however, one may do those things in another country where corresponding patent protection does not exist. Therefore, in order to waive patent protections worldwide, each Member subject the TRIPS Agreement’s requirement to have certain minimum intellectual property protection would have to waive its own domestic patent protections.

The United States patent laws are codified in Title 35 to the U.S. Code. It provides that inventors may obtain patents for their new and useful inventions and infringers are liable for making, using, offering to sell, selling, or importing into the U.S. patented inventions without the patent holders consent. Because the power to enact patent laws lies with Congress, Congress would likely have to waive these laws. If Congress chooses not to waive the U.S.’s patent laws, patent holders will continue to be able to enforce their U.S. patent rights in the U.S.

### Framing

#### The standard is maximizing expected well-being, or hedonistic act utilitarianism.

#### 1] Neuroscience- pleasure and pain *are* intrinsic value and disvalue – everything else regresses.

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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 bettear 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.

#### 2] Actor spec—governments must use util because they don’t have intentions and are constantly dealing with tradeoffs—outweighs since different agents have different obligations—takes out calc indicts since they are empirically denied.

#### 3] Impact calc -- Extinction is categorically prior:

#### A] Magnitude -- trillions of future lives are lost that are just as valuable as current ones – anything else says some lives are worth less than others which is a slippery slope to genocide.

#### B] Reversibility -- extinction forecloses future improvement;