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### A2 Innovation DA

#### Medical innovation in crisis now – rarely do new drugs improve health outcomes due to new patents being only marginally better then older drug

Naci et al. 15 [Huseyin Naci, assistant professor of health policy at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science , Alexander W Carter policy fellow, at the Institute of Global Health Innovation, Imperial College London, Elias Mossialos, professor of health policy, , at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science, 10-23-2015, “Why the drug development pipeline is not delivering better medicines,” BMJ, https://sci-hub.se/https://www.bmj.com/content/351/bmj.h5542.full]/Kankee

Many in the pharmaceutical sector suggest that the industry is in crisis. Industry analysts fret that financial rewards are no longer sufficient for companies to maintain the investment needed to develop clinically useful drugs.1 Despite these concerns, regulators in the US and Europe granted marketing authorisations to a record number of new medicines in 2014. However, the majority of new medicines offer few clinical advantages over existing alternatives. We discuss how both government and drug company practices contribute to the ongoing innovation deficit in the sector. Paucity of clinically superior medicines Patients and clinicians commonly understand innovation to mean a medicine that has transformed management and treatment,2 either by providing treatments for conditions with no current (satisfactory) remedies or by offering meaningful improvement over existing options. In recent years, however, industry analysts have adopted other definitions to measure innovation (box 1).3 Currently, the most common approach to measure innovation is to count the number of new drug approvals.3 The number of drug approvals has increased over the past five decades, culminating in 41 approvals in the US and 40 in Europe in 2014 alone; this compares with a 50 year average of 20 approvals a year.4 5 Large numbers of new drugs have been taken as a proxy for the innovative capacity of the industry. Unfortunately, rather than new breakthroughs, most of the new drugs are relatively minor modifications of existing treatments.6 Studies evaluating the clinical importance of new drugs over the past decades consistently report a negative trend.7-11 Regardless of differences in analytical approach and time period, all characterise only a minority of new drugs as clinically superior to existing alternatives.3 Luijn found that 10% of 122 new medicines on the European market between 1999 and 2005 were superior to drugs already on offer.12 Among drugs reviewed by German authorities between 2012 and 2013, about 20% were concluded to offer some benefit over existing alternatives and none was deemed to offer major benefit.13 Between 1990 and 2003, only 6% of 1147 drugs approved in Canada provided a substantial improvement over existing drug products,14 and Canadian authorities considered 10% of new drugs approved between 2004 and 2009 as highly innovative.15 Despite the paucity of clinically superior drugs, the pharmaceutical market grew by a factor of 2.5 in real terms between 1990 and 2010 (fig 1⇓). Much of the increased expenditure on drugs was the result of increasing industry investment in “me-too” medicinesrather than clinically superior medications.14 Drug companies have remained profitable over this period while the proportion of health spending on drugs has increased and drugs have become less affordable.16 17 Over the past 30 years, firms lost their number one position in the Fortune 500 ranking of US companies only in 2003, coming third behind oil and financial companies. In 2012, the top five pharmaceutical companies included in the Fortune 500 earned over $50bn (£30bn; €40bn) in net profits.

#### Turn - Repatenting old drugs wards off competition through endless monopolies and deterring generic entry to the market – both harm innovation

Gurgula 20 [Olga Gurgula, lecturer of intellectual property law at Brunel University London, 10-28-2020, "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?," IIC - International Review of Intellectual Property and Competition Law, https://link.springer.com/article/10.1007/s40319-020-00985-0]/Kankee

Strategic Patenting Impairs Originators’ Incentives to Innovate While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish. Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84 the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share. In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85 Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92 Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93 A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly. Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns. Strategic Patenting Impairs Follow-on Innovation of Generic Companies Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators: The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97 Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100 As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns. Strategic Patenting is Considered Lawful Under the Current Approach

#### Incremental changes increase average patent expiration dates, delaying generics and competition for decades

Nawrat 19 [Allie Nawrat, journalist with a BS in history and politics from the University of York, 11-12-2019, "From evergreening to thicketing: exploring the manipulation of pharma patents," Pharmaceutical Technology, https://www.pharmaceutical-technology.com/features/pharma-patents-manpulation/]/Kankee

The Initiative for Medicines, Access & Knowledge (I-MAK) argued in a 2018 report titled Overpatented, Overpriced that the current system is out of balance as “drugmakers have transformed the patent system in to a defensive business strategy to avoid competition in order to earn outsized profits on medicines for many years beyond what was intended.” University of California (UC) Hastings Center for Innovation director and distinguished professor of law Robin Feldman adds: “Patents are supposed to last for a limited period of time. After that, competitors should enter to drive prices down, but that’s not what is happening. Rather, drug companies pile new protections on to their drugs to extend the protection cliff.” The two most common practices employed by the industry to artificially extend protection, are ‘evergreening’ and ‘thicketing’, as Feldman describes them in a 2018 Journal of Law and the Biosciences research paper titled May Your Drug Price Be Evergreen. They involve making small changes to branded drugs – such as through modes of administration, new dosages and, as Scrip noted, even simply the colour of the drug itself – which sometimes do not confer more therapeutic benefit to the patients. Feldschreiber acknowledges “there are instances where it is very questionable as to whether slight changes to molecules do actually have an effect on safety and efficacy” and “there is something wrong with that”. It can also encompass protecting certain steps in the production and manufacturing process and recycling drugs for other similar indications. Some companies have also sought to find more creative loopholes in the law to extend their monopoly over a drug. For example, to fight legal challenges to its patents, Allergan transferred all patents for its eye drug Restasis to the St Regis Mohawk Tribe in September 2017, because the Native American tribe holds sovereign immunity against intellectual property lawsuits. The deal was subsequently defeated in the US courts, with the Supreme Court rejecting Allergan’s petition to appeal the case in April this year, but it’s a powerful example of the creative lengths some firms will go to extend patent protection. Scale of pharma patent manipulation Feldman’s research, which looked at all drugs on the market between 2005 and 2015 and every instance where a company added a new patent or exclusivity, concluded “stifling competition is not limited to a few pharma bad apples. Rather, it is a common and pervasive problem endemic to the pharmaceutical industry.” She found that 78% of drugs associated with new patents are not new drugs, but existing ones, and almost 40% of all drugs on the market had additional market barriers through further exclusivities. Although this manipulation trend exists across the industry, Feldman’s research found that manipulative extension practices were particularly pronounced among blockbuster drugs. More than 70% of the 100 best-selling drugs between 2005 and 2015 had their protection extended at least once, with almost 50% receiving more than one exclusivity extension. I-MAK’s 2018 report identified a similar trend among the 12 best selling drugs in the US in 2017; it found that the drugs have an average of 38 years of exclusivity – almost double the 20 year original patent protection – and an average of 125 patent applications. AbbVie and Humira: an example of bad behaviour One of the worst offenders according to I-MAK is AbbVie’s anti-inflammatory blockbuster Humira. Both Feldman and Dutfield picked out Humira as a particularly bad example of patent manipulation According to I-MAK’s 2018 report, AbbVie has filed 247 patent applications for the drug in the US with the aim of extending its exclusivity for 39 years – 137 patents have been awarded to date. This is in addition to 76 patent applications in the European Union and 63 in Japan. Humira is currently the world’s best-selling drug and the second best-selling drug of all time – it has generated around $100bn in sales for AbbVie since it was launched in 2002 and it is responsible for two-thirds of AbbVie’s total revenue. I-MAK concludes that “AbbVie’s pricing practices are protected by an aggressive evergreening patent strategy to extend the life cycle of Humira in order to deliberately delay competition.” These profits are also connected to other practices by AbbVie that have led to the price of the drug increasing 18% every year between 2012 and 2016; however, I-MAK concludes these are not consistent with rises in the price of manufacture or inflation. “Patents, like all good things, must come to an end” Although she acknowledges that drug development is expensive and patents are “important for creating the possibility of reward for that investment”, Feldman argues that these manipulations mean “the cycle of innovation, reward, then competition is being distorted into a system of innovation, reward, and then more rewards”. She calls for a focus on incentivising companies to focus on drug development through a “one-and-done approach, in which each drug invention receives one—and only one—period of exclusivity” as “patents, like all good things, must come to an end”, and not be allowed to be extended seemingly indefinitely. Dutfield suggests an alternative approach to incentivising drug R&D. “At the United Nations, there are proposals that the costs of research and development should not be recouped through high [drug] prices, but by other funding mechanisms in proportion either to the R&D costs, or to the global positive health impacts of the medicines in question,” he explains. While there are concerns about where exactly these ‘other funding mechanisms’ would come from, this approach could help to resolve an unbalanced patent system and ensure proper rewards for genuine innovation in disease areas or drug types where there is less potential profits, such as antibiotics and vaccines against healthcare crises primarily affecting developing countries.

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### Plan

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

### Framing

#### The standard is maximizing expected wellbeing

#### [1] Death is bad under my framework because it destroys the subject and prevents any possibility of wellbeing – that’s the version of maximizing wellbeing I defend

#### [2] Pleasure and pain are intrinsically valuable – they’re the starting point for moral reasoning

Blum et al. 18 Kenneth Blum, 1Department of Psychiatry, Boonshoft School of Medicine, Dayton VA Medical Center, Wright State University, Dayton, OH, USA 2Department of Psychiatry, McKnight Brain Institute, University of Florida College of Medicine, Gainesville, FL, USA 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA 5Department of Precision Medicine, Geneus Health LLC, San Antonio, TX, USA 6Department of Addiction Research & Therapy, Nupathways Inc., Innsbrook, MO, USA 7Department of Clinical Neurology, Path Foundation, New York, NY, USA 8Division of Neuroscience-Based Addiction Therapy, The Shores Treatment & Recovery Center, Port Saint Lucie, FL, USA 9Institute of Psychology, Eötvös Loránd University, Budapest, Hungary 10Division of Addiction Research, Dominion Diagnostics, LLC. North Kingston, RI, USA 11Victory Nutrition International, Lederach, PA., USA 12National Human Genome Center at Howard University, Washington, DC., USA, Marjorie Gondré-Lewis, 12National Human Genome Center at Howard University, Washington, DC., USA 13Departments of Anatomy and Psychiatry, Howard University College of Medicine, Washington, DC US, Bruce Steinberg, 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA, Igor Elman, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, David Baron, 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA, Edward J Modestino, 14Department of Psychology, Curry College, Milton, MA, USA, Rajendra D Badgaiyan, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, Mark S Gold 16Department of Psychiatry, Washington University, St. Louis, MO, USA, “Our evolved unique pleasure circuit makes humans different from apes: Reconsideration of data derived from animal studies”, U.S. Department of Veterans Affairs, 28 February 2018, accessed: 19 August 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6446569/> //nmhs PM

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.

#### [3] Current debate renders real violence invisible – it distances us from actual harm by focusing on ridiculous extinction scenarios.

Reid-Brinkley: Reid-Brinkley, Dr. Shanara. [Ph.D., Assistant Professor and Co-Director of Forensics at California State University, Fullerton] “The Harsh Realities of ‘Acting Black’: How African-American Policy Debaters Negotiate Representation Through Racial Performance and Style.” University of Georgia, Spring 2008. CV/CH

Genre Violation Four: Policymaker as Impersonal and the Rhetoric of Personal Experience. Debate is a competitive game. 112 It requires that its participants take on the positions of state actors (at least when they are affirming the resolution). Debate resolutions normally call for federal action in some area of domestic or foreign policy. Affirmative teams must support the resolution, while the negative negates it. The debate then becomes a “laboratory” within which debaters may test policies. 113 Argumentation scholar Gordon Mitchell notes that “Although they may research and track public argument as it unfolds outside the confines of the laboratory for research purposes, in this approach students witness argumentation beyond the walls of the academy as spectators, with little or no apparent recourse to directly participate or alter the course of events.” 114 Although debaters spend a great deal of time discussing and researching government action and articulating arguments relevant to such action, what happens in debate rounds has limited or no real impact on contemporary governmental policy making. And participation does not result in the majority of the debate community engaging in activism around the issues they research. Mitchell observes that the stance of the policymaker in debate comes with a “sense of detachment associated with the spectator posture.” 115 In other words, its participants are able to engage in debates where they are able to distance themselves from the events that are the subjects of debates. Debaters can throw around terms like torture, terrorism, genocide and nuclear war without blinking. Debate simulations can only serve to distance the debaters from real world participation in the political contexts they debate about. As William Shanahan remarks: …the topic established a relationship through interpellation that inhered irrespective of what the particular political affinities of the debaters were. The relationship was both political and ethical, and needed to be debated as such. When we blithely call for United States Federal Government policymaking, we are not immune to the colonialist legacy that establishes our place on this continent. We cannot wish away the horrific atrocities perpetrated everyday in our name simply by refusing to acknowledge these implications” (emphasis in original). 116 The “objective” stance of the policymaker is an impersonal or imperialist persona. The policymaker relies upon “acceptable” forms of evidence, engaging in logical discussion, producing rational thoughts. As Shanahan, and the Louisville debaters’ note, such a stance is integrally linked to the normative, historical and contemporary practices of power that produce and maintain varying networks of oppression. In other words, the discursive practices of policyoriented debate are developed within, through and from systems of power and privilege. Thus, these practices are critically implicated in the maintenance of hegemony. So, rather than seeing themselves as government or state actors, Jones and Green choose to perform themselves in debate, violating the more “objective” stance of the “policymaker” and require their opponents to do the same.

#### [4] Probability First

Rescher: Rescher, Prof. of Philosophy, 83 Nicholas Rescher, University of Pittsburgh Professor of Philosophy, “Risk: A Philosophical Introduction to the Theory of Risk Evaluation and Management” 1983

A probability is a number between zero and one. Now numbers between zero and one can get to be very small indeed: As N gets bigger, 1/N will grow very, very small. What, then, is one to do about extremely small probabilities in the rational management of risks? On this issue there is a systemic disagreement between probabilists working in mathematics or natural science and decision theorists who work on issues relating to human affairs. The former take the line that small numbers are small numbers and must be taken into account as such. The latter tend to take the view that small probabilities represent extremely remote prospects and can be written off. (De minimis non curat lex, as the old precept has it: there is no need to bother with trifles.) When something is about as probable as it is that a thousand fair dice when tossed a thousand times will all come up sixes, then, so it is held, we can pretty well forget about it as worthy of concern. The "worst possible case fixation" is one of the most damaging modes of unrealism in deliberations about risk in real-life situations. Preoccupation about what might happen "if worst comes to worst" is counterproductive whenever we proceed without recognizing that, often as not, these worst possible outcomes are wildly improbable (and sometimes do not deserve to be viewed as real possibilities at all).

### Advantage

#### Without reducing vaccine Intellectual property protections, millions in developing countries will die from the current “vaccine apartheid” due to medical monopolies and a lack of access

Lennard 21 [Natasha Lennard, educator of Critical Journalism at the New School for Social Research and Contributing Writer for the Intercept, 6-11-2021, "The G7 Upheld Vaccine Apartheid. Officials From the “Global South” Are Pushing Back.," Intercept, <https://theintercept.com/2021/06/17/vaccine-g7-covid-internationalism-summit/>]/Kankee

IF THE GROUP of Seven summit in the United Kingdom last week made anything clear, it is that those powers cannot be trusted to end the urgent crises facing life on Earth — for humans and nonhumans alike. When it comes to the Covid-19 pandemic, the G7 nation-states reaffirmed their commitment to global vaccine apartheid through neoliberal governance, only slightly obscured under a guise of charitable offerings. The concessions are insufficient at best. Amnesty International condemned the G7’s pledge to provide 1 billion doses to middle- and low-income countries as a “drop in the ocean.” G7 leaders failed to agree to waive vaccine intellectual property rules and commit to knowledge and technology sharing. Under the current medicine monopoly regime, it is projected to take until 2078 for the world’s poorest countries to vaccinate their populations. G7 countries are expected to vaccinate their populations by January 2022. Later this week, government ministers from many of the countries that will suffer most — and have already suffered — from this abhorrent vaccine inequality are convening online alongside scientists and global health advocates to forge a different path out of the pandemic. The summit, hosted by Progressive International, recognizes vaccine internationalism as the necessary order of the day. Politicians from states including Cuba, Venezuela, Vietnam, Kenya, Kerala — which is in India — and Argentina will attend, alongside Western parliamentarian progressive allies like the U.K.’s Jeremy Corbyn and Greece’s Yanis Varoufakis. The question is whether a solidarity-based bloc can be established with sufficient power and cooperation to undo vaccine apartheid. The stakes could not be higher. Covid-19 is all but assured to shift from a pandemic into an endemic disease, with the victims of historic and ongoing colonialism left to die by the millions. “We do not have a system that protects against unequal access,” Varsha Gandikota-Nellutla, an India-based coordinator with Progressive International, told me by email. She pointed to the disparities between the European Union and countries in Africa. “Consider this: the EU has already made a deal with BioNTech/Pfizer for 1.8 billion booster shots even as the entire continent of Africa has vaccinated less than 2 percent of its population with the first and second doses.” Gandikota-Nellutla noted that at current rates, it will take nearly six decades for the world to be vaccinated — a statistic echoed by the People’s Vaccine Alliance, a coalition of organizations including Amnesty International, Health Justice Initiative, Oxfam, Stop AIDS Campaign, and UNAIDS. She said, “We’re witnessing the ills of nationalism, imperialism, and racial capitalism all play out in the most grotesque of ways in the vaccine race.” WE KNOW WHAT vaccine nationalism looks like: Powerful countries, aided by World Trade Organization regulations, make deals with leviathan pharmaceutical companies to buy up and hoard vaccines. Poorer countries are forced into positions of dependence on insufficient charity; Big Pharma gets bigger. Meanwhile, intellectual property fetishist Bill Gates asserts, despite evidence from international scientists to the contrary, that poorer nations are per se incapable of developing, regulating, and distributing vaccines safely and efficiently. A system of health care scarcity is developed by design, with results no less than genocidal. The basic means of surviving a pandemic are held as a political cudgel by the richest countries over the poorest. At present, for example, Venezuela has been shut out of receiving any of the half a billion Pfizer vaccine doses President Joe Biden pledged to donate to COVAX, short for COVID-19 Vaccines Global Access, the initiative purportedly committed to equitable international vaccine distribution. Despite Biden stating that vaccine donations “don’t include pressure for favors or potential concessions,” Venezuela has been shut out of COVAX access due to ongoing, brutal U.S. sanctions against the country. “No country has the right to obstruct the access to health of any other,” Venezuelan Foreign Minister Jorge Arreaza, who will be attending the Summit for Vaccine Internationalism, said in a statement. “Obstructing a people’s access to vaccines during the pandemic is a crime against humanity and the free peoples of the world must unite and design mechanisms to avoid this medical apartheid, where a few have access to vaccines and others are excluded.” ANY SORT OF robust vaccine internationalism — in which collective potentials for vaccine production and distribution are truly unlocked — has so far been off the table. Yet we have seen a number of recent examples of production and sharing outside the top-down control of powers like the U.S. and the EU. At the end of May, Mexico received its first batches of locally produced AstraZeneca vaccines and sent half the consignment to its production partner, Argentina. Alongside establishing a stronger political bloc to put pressure on Western nation-states and the WTO, the upcoming summit could see agreements made for future vaccine production and sharing partnerships, which eschew precarious dependence on the world’s richest countries. “This is not going to be another talking shop,” David Adler, general coordinator for Progressive International, tweeted, referring to the summit. “These governments are really coming together to build something new — a system based on South-South cooperation, a serious plan to end the pandemic where the G7 refused to find one.” As Gandikota-Nellutla told me, inspiration for the “New International Health Order” that the summit aims to create can be found in the New International Economic Order first proposed in the 1970s. The plan, introduced by a number of poorer nations to challenge the post-war economic colonialism of the West, was adopted by the United Nations in 1974. As with vaccine internationalism, the idea of the New International Economic Order was to foster greater cooperation between heavily exploited countries, while ensuring states’ sovereignty over their resources, and a dramatic overhaul of the rules and procedures of unequal international trade, particularly as related to commodities. Nearly half a century later, and aside from a few concessions, the plan has never been even close to fully realized; U.S. hegemony and the neoliberal order of corporate globalization and extractivism won the day. The prospect of a New International Health Order may seem equally beyond reach, yet the extraordinary circumstances of this pandemic have, in a number of ways, created openings for previously foreclosed political economic shifts. In the U.S. alone, although too short-lived and too temporary, pandemic exigencies led to eviction moratoria and fair unemployment benefits. The government leaders and advocates meeting to build vaccine internationalism are all too aware of the urgency of the project. “Our very survival is at stake,” Gandikota-Nellutla told me. “Not only are we set on resolving vaccine access in our countries in the present pandemic, but strengthening the foundations of a world order that will not allow such injustices to ever occur again.”

#### The intellectual property protection regime is at the heart of medicine disparities which cyclically kill millions – ending them is key to solve

Vanni 21 – Dr. Amaka Vanni is Lecturer in Law at the University of Leeds. ("On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism," 3-23-2021, <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>) julian

Intellectual property rights (IPRs) are time-limited legal rights granted to inventors and creators. IPRs include copyrights, trademarks, patents, trade secrets, and geographical indications, while protected subject-matters include, but are not limited to, brands, inventions, designs, and biological materials. Importantly, IPRs overlap as a product may be covered by a series of rights. For example, a pharmaceutical medicine, defined by Britannica as a ‘substance used in the diagnosis, treatment, or prevention of disease’, is protected by patents, trademarks, and trade secrets. Patents are the most common form of IPR used for the protection of innovation in pharmaceuticals. Patents grant inventors limited market exclusivity for their inventions, and, in exchange, the inventor must disclose sufficient information such that competitors will be able to step into the market. This disclosure allows a competitor to make preparation to enter the market at the end of the monopoly period. Due to this legally-mandated exclusivity, patent owners – usually multinational corporations – have the right to prevent others from making, using, or selling a patented invention. The TRIPS Agreement, concluded as part of the Uruguay Round of multilateral trade negotiation and in force since 1995, provides a minimum of 20 years patent protection. The belief is that the duration allows corporations to recoup the expenses of developing, testing and upscaling an innovative pharmaceutical product.

From the onset, the TRIPS IP regime created imbalance between innovation, market monopoly, and medicines access, because it failed to take into consideration the health burden, development needs and local conditions of the various countries that make up the WTO. This has led to several issues. First, the market monopoly of IP rights, which allows the corporation to set the market for drugs, has created a privileged societal class with access to lifesaving medication distinguishing them from those excluded from access to available medications. This phenomenon is vividly illustrated in the HIV/AIDS crisis of the 1990s and early 2000s. While HIV/AIDS patients in developed countries were able to afford antiretroviral (ARVs) treatments, which had been developed, approved and patented as early as 1987, many patients in Africa and other parts of the developing world could not afford the approximately USD 12,000 per annum treatment at that time. By 2001, approximately 2.4 million people in the region had died of AIDS. The South African government intervened to reduce the cost of ARVs by amending its domestic patent laws to allow the authorization of parallel imports of patented pharmaceuticals and to encourage the use of generic drugs, but it was sued by the US industry group Pharmaceutical Research and Manufacturers of America (PhRMA). Though the lawsuit was eventually dropped, it highlights the measures pharmaceutical corporations, backed by some national governments, are willing to take to protect their profits at the cost of human lives. Significantly, we see how law (or the threat of legal action) is used not only to protect and expand the profitability of a certain kind of property but, as Anjali Vats and Deidré Keller have taught us, also reveals IP law’s racial investments in whiteness and its continuing implications for racial (in)equality, particularly in the way it informs systems of ownership, circulation, and distribution of knowledge. Similarly, Natsu Saito takes up the analysis of IP, race and capitalism by theorizing some of the ways in which ‘value’ in IP law concentrated in the hands of large corporations is calculated in terms of its profitability rather than what it contributes to the well-being of society. However, the proverbial chickens have come home to roost as even rich countries are beginning to feel the bite of the dysfunctional IP system.

The issue of excessive pricing for medicines is a growing problem in developed countries as well and has now become the single biggest category of healthcare spending in these states, particularly the US. An empirical report by I-MAK reveals how excessive pharmaceutical patenting is extending monopolies and driving up drug prices. The report, for example, notes that over half of the top twelve drugs in the US have more than 100 attempted patents per drug. Specifically, the report revealed that Humira® by AbbVie (used in the treatment of Crohn’s disease and the US’s highest grossing drug) has been issued 130 patents. The drug costs USD 44,000 annually and generated more than USD 19.2 billion for the company in 2019 alone. The Report also notes that the first patent filed for Herceptin® – used in the treatment for certain breast and stomach cancers – was in 1985 but currently has pending patent applications that could extend its market monopoly for 48 more years. Meanwhile, Celgene has over 105 patents for its oral cancer drug Revlimid® (used in the treatment of multiple myeloma) extending its monopoly until the end of 2036 – a patent lifespan of 40 years. In addition to excessive patenting and pricing, we have also come to understand the power of data in this context.

Second, regulatory agencies worldwide require drugs to undergo safety and efficacy testing to ensure they are harmless before approval. These tests, known as clinical trials, involve human subjects and are costly because they can run up to three separate phases. The data collected during these clinical trials are the proprietary materials of the company conducting the tests. Because it is expensive and time-consuming, generic drug companies usually rely on the safety and efficacy data of brand name companies to seek regulatory approval as long as they can prove their generic version is chemically and biologically equivalent to the original. Relying on the test data of brand name companies reduces the production cost for generic medicines and allows for quicker market entry. However, recent years have seen a promotion of time-limited, legally mandated protection against the non-proprietary use of such data by generic companies. This is known as data exclusivity. Put differently, data exclusivity is a period when a generic company cannot use the clinical trial data of an innovator pharmaceutical company to receive regulatory approval for a generic medicine. In so doing, data exclusivity provides a layer of protection in addition to patent protection to further delay market entry of generic medicines.

Data exclusivity periods vary depending on the jurisdiction. For example, it is twelve years in US and ten years in the EU. While the TRIPS Agreement does not create property rights over registration data, the US and the EU have continued to champion and export data exclusivity through free trade agreements, particularly for biologics. For example, the US Affordable Health Care for America Act in 2009 extended a 12-year exclusivity period for biologics. This US interpretation for registration data was also included in the United States-Mexico-Canada Agreement (USMCA), which sought a 10-year data exclusivity for new biologics. However, after intense negotiations, the data exclusivity protection was reduced to 5 years for new pharmaceuticals. In this instance, we see a crystallising of Euro-American ideas of property and a willingness to promote those property interests through the law, both domestic and international. In fact, certain scholars assert that this pursuit of higher TRIPS standards is driven, in part, by the US desire to achieve levels of protection it anticipated from the TRIPS Agreement but failed to secure. Given the influence of the industry and its representative group, PhRMA, in seeking stronger protection on a global scale, it is not surprising that the US’s post-TRIPS policies continue to rachet up standards in ways that undermine access to affordable medicines, and perpetuate social hierarchy and subordination.

Third, patent practices in recent decades have seen pharmaceutical companies engaging in trivial and cosmetic tweaking of a drug whilst still reaping the benefit of 20 years of patent protection. This tweaking sometimes involves making minor changes to patented drugs, such as changes in mode of administration, new dosages, extended release, or change in color of the drug. These changes normally do not offer any significant therapeutic advantage even though pharmaceutical companies argue they provide improved health outcomes to patients. These additional patents on small changes to existing drugs, known as evergreening or patent thickets, block the early entry of competitive, generic medicines that drive medicine prices down. For example, while not mandated by TRIPS, many US led TRIPS-plus free trade agreements have expanded the scope for evergreening. These include the US-Jordan FTA (2000), US-Australia FTA (2004) as well as the US-Korea FTA (2007), which allow for the patenting of new forms, uses, or methods of using existing products.

The cancer drug Gleevec®, owned by Novartis, is another example of how pharmaceutical companies often secure patents on new, more convenient versions with marginal therapeutic benefit to patients whilst blocking the entry of generic medicines. In 2013, Novartis’ patent application for Gleevec®– the β crystalline form of the salt imatinib mesylate – was rejected by the Indian Supreme Court because it lacked novelty. However, the company has secured patents for this product in other jurisdictions such as the US and has maintained a high price of Gleevec there. But in India the price of Gleevec® was reduced from approximately USD 2,200 to USD 88 for one month’s treatment in the generic drugs market as a result of the 2013 Indian Supreme Court judgement. Novartis is not the only culprit. The depression drug Effexor® by Pfizer was granted an evergreen patent when the company introduced an extended-release version, Efexor-XR®, even though there was no additional benefit to patients. Eventually, the patent was declared invalid, but by then it had already cost an estimated USD 209 million to Australian taxpayers and kept generic competition off the market for two and a half years. In another instance, Pfizer went on to secure an additional patent for the Pristiq®, which contained identical chemical compound as Efexor-XR®,and again with no added therapeutic benefit.

These evergreening practices, of course, have material effects. Apart from delaying the entry of generic versions, they give brand-name pharmaceutical companies free reign in the market, which allows them to set the market price. Recent years have seen monopoly prices rise exorbitantly causing significant financial strain to patients, domestic healthcare services and even insurance companies in developed countries. A notorious example is Martin Shkreli, who in 2015 bought the rights to an anti-malarial drug, then raised the price by 5,000 per cent from a cost of USD 13.50 to USD 750. Similarly, a white paper by I-MAK shows how excessive patenting and related strategies are driving families to overspend on lifesaving medicines. Celgene, the makers of Revlimid® raised the price of the drug by more than 50 per cent since 2012 to over USD 125,000 per year of treatment. Using the example of Solvadi® by Gilead, which costs USD 84,000 per treatment, Feldman notes the drug would cost the US Department of Defense more than USD 12 billion to treat all hepatitis-infected patients in US Veterans Affairs. But the US is not alone. In Europe, expensive drugs have prompted a growing backlash against pharmaceutical corporations. Reacting to these price hikes, Dutch pharmacies are bypassing these exorbitant prices by preparing medicines in-house for individual patients. The broken IP system ranging from an extraordinarily low standard for granting patents to permissions of patent thickets around a single molecule has not only severely distorted the system of innovation, but they have also skewed access to life-saving drugs. As a result, prices for new and existing medicines are constantly rising, making essential medicines inaccessible for millions of people around the world.

### Solvency

#### [1] The plan reverse casually ensures the reduction of vaccine imperialism.

Vanni 21 – Dr. Amaka Vanni is Lecturer in Law at the University of Leeds. ("On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism," 3-23-2021, <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>) julian

This brings us to the present and how this dysfunction continues to be normalised in the current pandemic. Moderna, for example, has filed over 100 patents for the mRNA technology used in its vaccine, despite receiving funds from the US government with its IP partly owned by the US National Institutes of Health. Pfizer/BioNTech have also filed multiple patents on not only their COVID-19 vaccine product, but also on the manufacturing process, method of use and related technologies even though BioNtech was given $450 million by the German government to speed up vaccine work and expand production capacity in Germany. It has become increasingly plain that IP makes private rights out of public funds while benefitting particular corporate interests. In fact, reports show the US government under Operation Warp Speed led by the US Department of Health also funded other vaccines developed in 2020 by several pharmaceutical corporations including Johnson and Johnson, Regeneron, Novavax, Sanofi and GlaxoSmithKline, AstraZeneca, and others. In spite of this boost from public funds, and with many governments wholly taking on the risks for potential vaccine side effects, drug manufacturers fully own the patents and related IP rights and so can decide how and where the vaccines get manufactured and how much they cost. As a result, taxpayers are paying twice for the same shot: first for its development, then again for the finished product. Meanwhile, a New York Times report has revealed that in some of the agreements between pharmaceutical companies and states, governments are prohibited from donating or reselling doses. This prohibition helps explain the price disparity in vaccine purchases among countries where poor countries are paying more. For example, Uganda is paying USD 8.50 per dose of the AstraZeneca vaccine while the EU is paying only USD 3.50 per dose. By prioritizing monopoly rights of a few western corporations, IP dysfunction not only continues to reproduce old inequities and inequality in health access, but helps frame our understanding about the creation and management of knowledge. And perhaps we begin to see the refusal of drug makers to share knowledge needed to boost global vaccine supply for what it truly is: an extension in capitalist bifurcation of who is imagined as a legitimate intellectual property owner and who is envisioned as a threat to the (intellectual) propertied order.

Despite calls to make COVID-19 vaccines and related technologies a global public good, western pharmaceutical companies have declined to loosen or temporarily suspend IP protections and transfer technology to generic manufacturers. Such transfer would enable the scale-up of production and supply of lifesaving COVID-19 medical tools across the world. Furthermore, these countries are also blocking the TRIPS waiver proposal put forward by South Africa and India at the WTO despite being supported by 57 mostly developing countries. The waiver proposal seeks to temporarily postpone certain provisions of the TRIPS Agreement for treating, containing and preventing the coronavirus, but only until widespread vaccination and immunity are achieved. This means that countries will not be required to provide any form of IP protection on all COVID-19 related therapeutics, diagnostics and other technologies for the duration of the pandemic. It is important to reiterate the waiver proposal is time-limited and is different from TRIPS flexibilities, which are safeguards within the Agreement to mitigate the negative impact of patents such as high price of patented medicines. These safeguards include compulsory licenses and parallel importation. However, because of the onerous process of initiating these flexibilities as well as the threat of possible trade penalties by the US through the United States Trade Representative (USTR) “Special 301” Report targeting countries even in the absence of illegality, many developing countries are reluctant to invoke TRIPS flexibilities for public health purposes. For example, in the past, countries such as Colombia, India, Thailand and recently Malaysia have all featured in the Special 301 Report for using compulsory licenses to increase access to cancer medications. It is these challenges that the TRIPS waiver seeks to alleviate and, if approved, would also provide countries the space, without fear of retaliation from developed countries, to collaborate with competent developers in the R&D, manufacturing, scaling-up, and supply of COVID-19 tools. However, because this waiver is being opposed by a group of developed countries, we are grappling with the problem of artificially-created vaccine scarcity. The effect of this scarcity will further prolong and deepen the financial impact of this pandemic currently estimated to cost USD 9.2 trillion, half of which will be borne by advanced economies. Thus, in opposing the TRIPS waiver with the hopes of reaping huge financial rewards, developed countries are worsening pandemic woes in the long term.

Another kind of scarcity caused by vaccine nationalism has also reduced equitable access. Vaccine nationalism is a phenomenon where rich countries buy up global supply of vaccines through advance purchase agreements (APA) with pharmaceutical companies for their own populations at the expense of other countries. But perhaps it is time to reorient our sight and call the ongoing practices of buying up global supply of vaccine what it truly is – vaccine imperialism. If we take seriously the argument put forward by Antony Anghie on the colonial origins of international law, particularly how these origins create a set of structures that continually repeat themselves at various stages, we will begin to see COVID-19 vaccine accumulation not only as political, but also as imperial continuities manifesting in the present. Take, for instance, the report released by the Duke Global Health Innovation Center that shows that high-income countries have already purchased nearly 3.8 billion COVID-19 vaccine doses. Specifically, the United States has secured 400 million doses of the Pfizer-BioNTech and Moderna vaccines, and has APAs for more than 1 billion doses from four other companies yet to secure US regulatory approval. The European Union has similarly negotiated nearly 2.3 billion doses under contract and is negotiating for about 300 million more. With these purchases, these countries will be able to vaccinate their populations twice over, while many developing states, especially in Africa, are left behind. In hoarding vaccines whilst protecting the IP interests of their pharmaceutical multinational corporations, the afterlife of imperialism is playing out in this pandemic.

Moreover, these bilateral deals are hampering initiatives such as the COVID-19 Vaccine Global Access Facility (COVAX) – a pooled procurement mechanism for COVID-19 vaccine – aimed at equitable and science-led global vaccine distribution. By engaging in bilateral deals, wealthy countries impede the possibility of effective mass-inoculation campaigns. While the usefulness of the COVAX initiative cannot be denied, it is not enough. It will cover only the most vulnerable 20 per cent of a country’s population, it is severely underfunded and there are lingering questions regarding the contractual obligations of pharmaceutical companies involved in the initiative. For instance, it is not clear whether the COVAX contract includes IP-related clauses such as sharing of technological know-how. Still, even with all its faults, without a global ramping-up of production, distribution and vaccination campaigns via COVAX, the world will not be able to combat the COVID-19 pandemic and its growing variants. Health inequity and inequalities in vaccine access are not unfortunate outcomes of the global IP regime; they are part of its central architecture. The system is functioning exactly as it is set up to do.

#### [2] Killing IPP is more effective for mass production and collaboration

Correa 21 [Carlos M. Correa, Director of the Center for Interdisciplinary Studies on Industrial Property and Economics and of the Post-graduate Course on Intellectual Property at the Law Faculty of International Centre for Trade and Sustainable Development, "04-2021, “Expanding the production of COVID-19 vaccines to reach developing countries Lift the barriers to fight the pandemic in the Global South,” South Center, https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf]/Kankee

On the first argument, it is worth noting how intellectual property, particularly patents, relates to the production and commercialization of COVID-19 vaccines. A study by the World Intellectual Property Organization (WIPO) found - already in 2012 – 11,800 patent families for different components of vaccines to prevent some infectious diseases.13 113 patent families relating to the mRNA technology used by several COVID-19 vaccines producers were identified in 2020; many of these patents have been applied for through the Patent Cooperation Treaty with numerous States included, which means that these will enter to national phase processing in many developing countries.14 Moderna, Inc., the producer of one mRNA based vaccine for COVID-19, is reported to hold “over 270 issued or allowed U.S. and foreign patents protecting mRNAbased technology, with over 600 worldwide pending patent applications. The company has identified at least seven granted U.S. patents that it alleges protect its COVID-19 mRNA-1273 vaccine”. 15 Although Moderna has pledged not to enforce its patents “while the pandemic continues”, it is unclear when it will consider that the pandemic is over.16 The company has been involved in litigation over three patents held by Arbutus Biopharma.17 Pfizer and its partner BioNTech have been sued by Allele Biotechnology and Pharmaceuticals, Inc. over the alleged infringement of a patent on a monomeric fluorescent protein used in assays of their COVID-19 vaccine.18 The US National Institute of Health has obtained a patent over a stabilized coronavirus spike protein that may impact the production and sale of at least 5 COVID-19 vaccines, including Moderna’s mRNA vaccine.19 The US patent office also granted a researcher at Tel Aviv University a patent for technology that could accelerate the development of a vaccine for COVID-19. 20 The second argument - the possible use of compulsory licenses, one of the important TRIPS flexibilities - ignores that issuing compulsory licenses takes time particularly if a previous negotiation with the patent holder is needed under the applicable law. In addition, it is often difficult to identify all the patents or other intellectual property rights covering a product or process, and patent applications are not published for 18 months after their filing. The waiver proposal provides a more functional and appropriate approach than individual and uncoordinated actions based on individual compulsory licenses. A waiver would allow “uninterrupted collaboration in the development and scale-up of production and supply of health products and technologies and collectively addresses the global challenge facing all countries”.21 In effect, compulsory licenses can only be granted case-by-case and productby-product and the manufacture of a vaccine encompasses a large number of components. Importantly, a compulsory license applies only to already granted patents and not to pending applications and, unless article 31bis of the TRIPS Agreement (as incorporated in 2017) is applied with its cumbersome requirements,22 a compulsory license can only be issued to predominantly supply the domestic market. 23 Further, in some jurisdictions the decision to grant a compulsory license may be appealed and its implementation suspended until a final decision is made. Finally, given the territorial character of patents, there would be a need to sim- ultaneously obtain compulsory licenses in several jurisdictions in order to put in place an efficient supply chain. The third argument - negative impact on innovation - is particularly weak in the context of the COVID-19 emergency as there is no market failure that inhibits return from innovation, the basic economic justification for the grant of intellectual property rights. The demand is huge - as the vaccines need to reach at least all the world adult population - and governments as well as COVAX are competing against each other to secure the supply of vaccines. In addition, the Western companies now supplying vaccines have received massive subsidies from governments. Thus, Moderna received nearly 1 US$ billion of taxpayers’ money to develop and produce the COVID-19 vaccine,24 Pfizer/BioNTech received US$ 445 million from the German government.25 Overall, the COVID-19 producers may have received around £6.5bn from governments while not-for-profit organizations have provided nearly £1.5bn.26 Public financing also reduced the risk of failure, as exemplified by the failed Merck/IAVI vaccine backed by the US Biomedical Advanced Research and Development Authority (BARDA).27 The fourth argument alludes to the need to obtain know-how, data, etc. to initiate the production of vaccines. This is correct, but access to these inputs may be impeded or limited rather than facilitated by the enforcement of intellectual property rights. In addition, there are many manufacturers in developed and developing countries28 that may produce COVID-19 vaccines, in some cases by repurposing plants used for the production of other biologicals. Access to know-how and data would allow them to move fast, but acquiring the needed skills would not be otherwise impossible if scientific and industrial support is available for the different phases of manufacturing (active ingredient, formulation, fill and finish). Much is needed to be done to achieve a stage in which vaccines and other products to face a pandemic are truly treated as global public goods. This will require a reform of the current research and development (R&D) model essentially based now on the appropriation through intellectual property rights of the outcomes of innovation. From a long-term perspective, such a paradigmatic change will also ask for a reinterpretation or revision of the TRIPS Agreement in order to allow, for instance, for a broader exception to patent rights for the export of pharmaceutical products.

#### [3] Many firms globally have the capability to make millions of extra vaccines

Lerner and Fang 21 [Sharon Lerner, Investigative Reporter at The Intercept covering health, science, and the environment, Lee Fang, contributing writer at The Nation with a BA in government and politics from the University of Maryland, 04-29-2021, https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/?utm\_campaign=theintercept&utm\_medium=social&utm\_source=twitter]/Kankee

Bill Gates, the billionaire philanthropist whose foundations help manage the United States and Europe’s primary Covid-19 outreach efforts to the developing world, known as Covax, was even more blunt. “It’s not like there’s some idle vaccine factory, with regulatory approval, that makes magically safe vaccines,” Gates said last weekend by way of explaining to Sky News why he thought the recipe for making coronavirus vaccine should not be shared. Except it is exactly like that. Factory owners around the globe, from Bangladesh to Canada, have said they stand ready to retrofit facilities and move forward with vaccine production if given the chance. “We have this production capacity and it’s not being used,” said John Fulton, a spokesperson for Biolyse Pharma, a company based in St. Catharines, Ontario, that produces injectable cancer treatments. Fulton noted that Biolyse has spent years buying equipment to produce biologics and is uniquely prepared to start getting ready to produce vaccines. The company, which Fulton said is best suited for replicating the Johnson & Johnson vaccine, could produce as many as 20 million vaccines per year, he estimated. Abdul Muktadir, chair and managing director of Incepta, a pharmaceutical firm based in Dhaka, Bangladesh, has told reporters that his firm has the capacity to fill vials for 600 million to 800 million doses of vaccine per year. He has reportedly reached out to Moderna, Johnson & Johnson, and Novavax. “Now is the time to use every single opportunity in every single corner of the world,” Muktadir told the Washington Post. “These companies should make deals with as many countries as possible.” Other firms in South Korea and Pakistan have also reportedly expressed an interest in producing vaccines or vaccine components. So far, much of the pressure to share technology has centered on messenger RNA vaccines, such as those made by Pfizer-BioNTech and Moderna, which are approved in the U.S. and highly effective against Covid-19. The mRNA model also offers the advantage of having a production process that’s simpler than that of some other vaccines and may be quickly adapted to respond to emerging variants of the virus. But the companies that have pioneered the mRNA vaccines have yet to offer to share their knowledge and expertise. Earlier this month, the World Health Organization established the mRNA technology transfer hub, through which manufacturers of medical products and owners of patented vaccine technology have been invited to provide know-how, process training, and intellectual property rights so that low- and middle-income countries can produce their own vaccines. On Tuesday, Martin Friede, coordinator of the WHO’s Initiative for Vaccine Research, said that the hub had already received some 50 expressions of interest from companies, including some that have patents on components or processes involved in vaccine manufacturing. But Moderna; BioNTech, the German company that has developed an mRNA vaccine in partnership with Pfizer; and CureVac, another German company that has developed an mRNA vaccine with a longer shelf life, have yet to respond to the call, according to Friede. Friede emphasized that a lack of know-how, as opposed to patent protections, are the major barrier to expanding production. Others agree sharing know-how is key — and getting cooperation from the companies that created the mRNA vaccines is necessary before deciding to retrofit or build facilities to make them. “It’s useless to focus on that if BioNTech and Pfizer and Moderna are not going to surrender the information on how to do it,” Edward Hammond, an independent consultant who works on vaccine manufacturing, said in a recent online roundtable about vaccine production capacity. “If it is the case that we don’t have an open and cooperative and productive technology transfer environment, then the capacity situation looks a little bit different because you’re going to be relying on a different set of technologies.” Scaling up supply to meet the global need will also require overcoming shortages of various components, including the tiny fat droplets that enable the mRNA in the vaccine to enter cells, which may also slow the the process of upscaling production. Gates suggested that it could be unsafe to share the critical information that allows vaccines to be more widely produced: “There’s only so many vaccine factories in the world, and people are very serious about the safety of vaccines. And so moving something that had never been done — moving a vaccine, say, from a [Johnson & Johnson] factory into a factory in India — it’s novel — it’s only because of our grants and expertise that that can happen at all.” The delay in getting vaccines to low- and middle-income countries, he added, was shorter than expected. “Typically in global health, it takes a decade between when a vaccine comes into the rich world and when it gets to the poor countries.” Yet, in the past few months, the danger of not transferring the knowledge more quickly has become painfully clear, with deaths climbing in India, Brazil, and other parts of the world that have been unable to procure adequate supplies of vaccines while richer countries stockpile them. The inequality is only increasing. The state of Florida, which has a population of 21.5 million, has now received some 20 million vaccine doses — more than Covax has delivered to all of Africa, which is home to 1.2 billion people. Worldwide, Covax, which is now supplying vaccines to over 100 economies, has only delivered 49 million doses so far, less than have been distributed in California and Illinois. Meanwhile, wealthy countries are already in the process of purchasing booster shots. Canada just made a deal with Pfizer to get 35 million doses of boosters by next year, which means they will arrive before most people around the world receive their first shot.

#### [4] The plan also solves long term medicine disparities in general

Parthasarathy 20 – Shobita Parthasarathy is Professor of Public Policy and Director of the Science, Technology, and Public Policy Program at University of Michigan. (“Innovation Policy, Structural Inequality, and COVID-19,” 2020, pg. 105-107) julian

The private sector then capitalizes on the results of this scientific curiosity to develop socially beneficial technologies, which are made available in the marketplace. Key to this is the modern patent system: the government incentivizes inventors by providing them with patent rights, to commercialize and profit from their new technologies exclusively and for a limited period of time (Parthasarathy 2017). The US Congress reinforced the links among government funding, university science, and the marketplace with the 1980 Bayh-Dole Act, which allowed universities to retain the rights to patents on inventions created through government-funded research (Popp Berman 2012). The more inventions were patented and made available to the private sector, the logic went, the more technology would be available to the public. Today, increasingly cash-strapped universities encourage their researchers to patent inventions, and license these patents to private companies who will develop and commercialize them (Kleinman 2003). As a result, there has been a sharp rise in US patents granted, and high-tech industries have blossomed. And countries across the world have adopted these innovation policies, seeking to replicate the US approach (Siepmann 2004).

But the COVID-19 crisis has shown us that these innovation policies do not serve citizens equally, in at least three ways:

(1) Minimal Funding for Health Disparities Research. The US approach to research funding has left us unprepared for and unable to manage the disproportionate health impacts of the virus among people of color, especially Black communities. The NIH, the world’s largest public funder of biomedical research, devotes little money to this subject. One analysis found that it spends 500 times more on genetics research as on structural racism and its impacts on health (Krieger 2005). This is not surprising in a system where scientists drive funding priorities, and where investigators from historically disadvantaged minority groups struggle to receive funding. The needs and concerns of disadvantaged minorities may seem less important or urgent to most scientists (Shavers et al. 2005). But this scarcity has left us without the evidence to understand why communities of color are disproportionately suffering and dying from COVID-19, or what steps to take to address this imbalance.

2) Uncoordinated Research and Development Creates Uneven Access to Diagnostic Testing. Absent the “rigid controls” that Bush dismissed, the US innovation system is highly decentralized and market-driven. So, diagnostic testing for SARS-CoV-2 (the virus that causes COVID-19) has been essentially impossible to coordinate. Traditionally, the Centers for Disease Control and Prevention and public laboratories funded by state and local governments lead infectious disease surveillance, but they have limited capacity (Crawford et al. 2010). The COVID-19 pandemic created demand that far outstripped what these laboratories could provide, but there was no systematic way to expand capacity. A variety of laboratories, including at universities, stepped up, but it remains difficult to connect supply and demand (Maxmen 2020). Different electronic records platforms cannot communicate. Some hospitals have exclusive partnerships with big commercial laboratories. And, even as testing has become more available, white and higher income communities gain access more easily (McMinn et al. 2020).

By contrast, South Korea has been widely praised for its SAR-CoV-2 testing strategy (Thompson 2020). Three weeks after the Chinese government shared the virus’s genome sequence on January 12, the South Korean government approved multiple diagnostic tests developed by its biotechnology sector (The Government of the Republic of Korea 2020). The country’s National Health Insurance Corporation purchased and distributed them. Ultimately, testing was plentiful and widespread, and the government implemented a companion contact-tracing program that minimized the number of COVID-19 cases and deaths.

Certainly, South Korea has learned from its experiences with previous coronaviruses, and benefits from a nationally coordinated healthcare system. But the rapid and straightforward development and distribution of diagnostic testing is also the result of a different approach to innovation policy than what the United States has taken up. Since the 1960s, South Korea’s government has played a major role in shaping research and development including in the industrial sector, by building capacity and setting priorities (Yim and Kim 2005). Government and industry have close professional ties and a sense of shared goals. In the years before COVID-19, for example, the South Korean government funded multiple companies developing viral diagnostic testing (The Government of the Republic of Korea 2020). With these relationships, technologies, and coordination with the healthcare system established, the government was able to immediately ask the private sector to develop SARS-CoV-2 tests. Three of the first five companies to receive emergency regulatory approval had received government funding for their diagnostics research. This proactive capacity building ensured that there was no need to ration testing, and therefore no inequality in access.

#### [5] Developing countries have the tech and know-how– that speeds up vaccine production

Kavanagh and Sunder 21 [Matthew Kavanagh, director of the Global Health Policy & Politics Initiative at Georgetown University’s O’Neill Institute for National and Global Health Law and assistant professor of international health, and Madhavi Sunder, associate dean for International and Graduate Programs and law professor at Georgetown University Law Center, 03-10-2021, "Opinion: Poor countries may not be vaccinated until 2024. Here’s how to prevent that.," Washington Post, https://www.washingtonpost.com/opinions/2021/03/10/dont-let-intellectual-property-rights-get-way-global-vaccination/]/Kankee

Two decades ago, in the midst of the AIDS crisis, the WTO’s Doha Declaration affirmed intellectual property rules “should not prevent members from taking measures to protect public health.” But the clarification of the right of nations to issue compulsory licenses and make generic medicines came too late: More than 5 million people in low- and middle-income countries died from AIDS waiting for the WTO to clarify its rules. Now we are in the middle of another global health emergency. Two-thirds of WTO members back waiving patent rules during the pandemic, but the United States and others argue that patents are critical for innovation and are not slowing the global supply of vaccines. Neither is true. First, patents played little, if any, role in stimulating the “warp speed” development of covid-19 vaccines. The Moderna vaccine was almost entirely funded by the U.S. government, with an additional $1 million donated by Dolly Parton. It is inappropriate for a private company to monopolize technology funded by taxpayers. Moderna itself recognizes this, having previously announced that it will not seek to enforce its vaccine patents.

The United States also argues the waiver is unnecessary because countries such as India can already begin producing covid-19 vaccines for their own populations,, and export them to developing countries under existing WTO rules. But the current machinery is cumbersome; implementation may take years. The waiver, however, would allow generic drug companies to begin making and distributing the vaccines as soon as possible. Finally, the United States and other opponents argue that even if generic drug companies get the patents, there is nobody who can make them. They suggest technology using mRNA underlying some of the new vaccines is so complicated that even respected generic drug companies cannot make the vaccines. This leads us to the next necessary step: tech transfer. If patent rights are waived, companies around the world, such as Biovac in South Africa or Cipla in India, could rapidly retool their manufacturing capacity to make these vaccines, with experts at the ready to help. But they also need the recipe. While a patent is supposed to explain how to make a product, many of today’s pharmaceutical patent filers intentionally obscure this information. Therefore, the companies making these vaccines should share exactly how they make them. Sharing technology with low- and middle-income countries is standard practice for many medicines. Gilead Sciences shared technology to help manufacturers based in Egypt, India and Pakistan to make and sell remdesivir as a covid-19 treatment last year; a company co-owned by Pfizer has done the same for HIV drugs. Vaccines are harder to engineer than AIDS drugs, so sharing tech is essential. Having funded key vaccine development, the U.S. government has the leverage to push companies to open up their vaccines to the world. The World Health Organization has already said it will help with expertise, and companies such as Moderna, Pfizer and Johnson & Johnson could receive royalties on the sales. But what they must not do is block producers in Africa, Asia and Latin America from making lifesaving vaccines and exporting them to their neighbors. We cannot afford to repeat the mistakes of the past. Just as the AIDS crisis in Africa necessitated the Doha Declaration, the covid-19 pandemic necessitates both a temporary intellectual property waiver from the WTO and a bold effort to share know-how — not in 2024, but now. Indeed, the covid-19 era should change the way we think about patents and public health. Intellectual property rights are not ends in themselves; they are tools to promote human flourishing.

#### [6] Government money for Covid vaccines means companies still innovate

Lindsey 21 [Brink Lindsey, vice president for research at the Cato Institute, 6-3-2021, "Why intellectual property and pandemics don’t mix," Brookings, https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/]/Kankee

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 noting 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.

#### [7] Vaccine charity can’t stop the pandemic

Omar 21 [Suhail Omar, campaign lead at People's Vaccine Kenya based in Nairobi, 07-30-2021, “COVAX isn't Africa's silver bullet,” IPS, https://www.ips-journal.eu/topics/democracy-and-society/vaccine-colonialism-5336/]/Kankee

At the onset of the Covid-19 pandemic, politicians across the world spoke about solidarity and called the virus the great equaliser. Now, with a solution in sight to end the pandemic – the vaccine – seems to remain a mere slogan. That’s because the Covid-19 Vaccine Global Access Facility (COVAX) – often praised as the light at the end of the tunnel – has turned out to be a nightmare for the developing world. A brainchild of the Vaccine Alliance Gavi, the World Health Organisation (WHO) and Coalition for Epidemic Preparedness Innovations (CEPI), COVAX is a global initiative aimed at creating global equitable access to the COVID-19 vaccine. Sadly, COVAX is not living up to its promise. The facility’s opaque nature of secret agreements with vaccine manufacturers ruled out transparency and reduced public trust. It also ignored growing concerns for accountability, as it remained unclear who COVAX – as an unelected body – reports to and who holds it accountable. COVAX has acknowledged issues with severe underfunding and vaccine hoarding hampering the implementation of its goals. The facility has so far shipped over 138 million vaccines to 136 participating countries. This includes high income countries like Canada that are underway to vaccinate their entire populations, while Africa is struggling to vaccinate priority groups – including healthcare workers. Of the over 3.79 billion vaccines administered worldwide, COVAX is only responsible for about 3.8 per cent of total inoculations. The rich outbidding the poor From the start, COVAX’s intended rollout was divided into two groups: high income countries (HIC) self-sponsoring the vaccines and lower income countries (LIC) having their vaccines financed through aid. However, COVAX’s strategy ultimately led to the entrenchment of inequal global vaccine access. Apart of the COVAX supply infrastructure, HICs had already entered into numerous bilateral agreements with individual vaccine manufacturers, giving them a head-start in vaccine procurement. African governments, on the other hand, knew that they did not have enough bargaining power in the race for vaccines. COVAX gave us the assurance that we would be provided for. But its ambition to be an equal treatment and access pool was slowly fading as a key director of the facility broke its doctrine for global equal treatment. The CEO of Gavi shared a statement about the possibility of choice for self-financing countries. Through the Optional Purchase Agreement, participants could choose to pick their vaccine of choice subject to supply availability. Furthermore, the trade-off based on preference for HIC participants would not jeopardise their ability to receive their full share of vaccines. Therefore, depending on efficacy levels, self-financing countries could access vaccines based on preference, leaving LIC with no choice but to take what is left over. To further ensure safety nets for HICs. COVAX increased the access ceiling for self-financing countries. This meant that HICs could access more vaccines than they had initially agreed with the facility. While low-income countries were only allowed to receive vaccines that amounted to inoculating 20 per cent of their populations, self-sponsoring countries had an increased access ceiling of up to 50 per cent of their total populations. Vaccine apartheid As of July 2021 COVAX is still facing major procurement and supply issues, especially since India’s ‘vaccine factory of the world’ fell short due to export controls amidst its fatal third wave. The Serum Institute of India had been the ‘lifeline’ of the COVAX facility. Visibly, rich nations have abandoned the very countries they claimed they stood in solidarity with. While in reality, some of the vaccines – such as Oxford’s AstraZeneca – were tried and tested in countries like Kenya, the fully vaccinated population there remains at 1.2 per cent. COVAX’s continued paternalism and colonial mindset is an ever-present reminder that ‘aid is dead’. Amidst vaccine nationalism by rich countries and what the People’s Vaccine Alliance – a global coalition of organisations and activists demanding the realisation of a free and accessible Covid-19 vaccine – have called ‘vaccine apartheid’, the Global North still holds countries labelled as ‘third world’ at the mercy of donations and occasional performances of white saviourism, all the while ignoring the root causes. There must be an access for all According to COVAX, the major obstacle for global vaccine access in Africa are supply constraints. But this is not the case. ‘Manufactured’ barriers, such as the denial to waive patent rights on vaccines, are intentionally prolonging the pandemic. Africa’s AIDS epidemic taught us that charity is not a public health plan. The refusal to back the waiver on Trade-Related Aspects of Intellectual property (TRIPS) – supported by the World Health Organization – is plain insistence on colonial gatekeeping of Big Pharma’s supply chains and profits. Arguably, the TRIPS waiver could’ve been cheaper and less risky compared to the architecture of the COVAX facility, allowing African states to control their own destinies in vaccinating their populations. As of July 2021, African countries such as Kenya have set up budgetary allocations for the vaccine roll-out. However, they can’t access vaccines as rich countries purchased them all and are still hoarding them in large quantities, waiting to send them out – close to expiry – to ‘third world’ countries. Using aid as a boost to a state’s public image obscures the fact that there is no feasible way to deliver and inoculate the intended populations any time soon. Instead, it just allows Western countries to absolve blame and deflect the shortcomings on the African countries. At the same time, other Global South countries like Cuba lead by example, with its recently developed ‘Abdala’ vaccine. The country is working on making its vaccine technologies more accessible to other states. It is no secret ‘there are companies in the Global South that are able to produce vaccines, but no one is giving them a chance,’ says global health consultant Mohga Kamal Yanni. With COVAX’s failures now visible, African states must insist on their right to manufacture and possibly develop – not just ‘fill and finish’ – vaccines. This also calls for radical policy change that combats the barriers of critical sharing of medical technologies at the global level. Moreover, African states must actively work on realising the ratification of the Abuja declaration, a pledge made by African Union countries in 2001 to spend ‘at least 15% of [the] annual budget to improve the health sector’. Only by ensuring the allocation of more funding can the already weakened health infrastructures on the continent be strengthened to respond to future pandemics.

#### [8] Gifting exacerbates global dependency dynamics and neocolonialism

Harman et al. 21 [Sophie Harman, Professor of International Politics at the University of London, Parsa Erfani, Fogarty Global Health Fellow at the University of Global Health Equity and a medical student at Harvard Medical School, Tinashe Goronga, medical doctor and co-founder of the Centre for Health Equity Zimbabwe and a National Specialist at the United Nations Development Programme Inclusive Governance Initiative, Jason Hickel, Leverhulme Early Career Fellow at the Department of Anthropology, Michelle Morse, Instructor in Medicine and Department of Global Health and Social Medicine Affiliate, Harvard Medical School, a Hospitalist at Brigham and Women's Hospital, and founding director of EqualHealth, Eugene T. Richardson, Assistant Professor of Global Health and Social Medicine, Harvard Medical School Assistant Professor of Medicine, Brigham and Women's Hospital, 07-29-2021, “Global vaccine equity demands reparative justice — not charity,” London School of Economics, https://blogs.lse.ac.uk/covid19/2021/07/29/global-vaccine-equity-demands-reparative-justice-not-charity/]/Kankee

Three limited ‘solutions’ to vaccine inequity There are currently three approaches to reduce inequity in COVID-19 vaccine distribution: bilateral charity, multilateral charity and temporary waivers or suspensions of IP. The first is the most straightforward. States that stockpile COVID-19 vaccines have committed to sharing their leftovers with low-income and middle-income countries. Norway was one of the first nations to accede to donating doses to poorer countries in parallel with its vaccine programme. This is the weakest form of equity as it is unclear if this will be done for free, at a lower cost, tied to diplomacy or conditionality, or crucially, when these vaccines will be made available, where they will go, or how many will be delivered. The bilateral charity approach has little to do with equity and more to do with geopolitics, wealth and aid dependency. The second is multilateral charity, best exemplified by COVAX. In 2020, COVAX emerged as an international collaboration by the World Health Organisation (WHO), United Nations Children’s Fund, Gavi and the Coalition for Epidemic Preparedness Innovations to ensure equitable global access to COVID-19 vaccines. Rich countries can access doses for 10%–50% of their populations, depending on how much they have paid in, and poor countries can access doses for 20% through the scheme. It is the 20% for poor countries that has come to be COVAX’s unique selling point: here is a mechanism that ensures every country in the world can get the vaccine regardless of ability to pay. This is the first time such an initiative has been trialled. The shortcomings of COVAX are numerous. If vaccines are delivered as planned, COVAX may reach 27% of the population in lower-income countries by the end of 2021—a depressing goal compared with the estimated 70% coverage needed for herd immunity and the open vaccine access currently granted to Americans. Furthermore, COVAX is still significantly underfunded and there are concerns regarding supply chains. While capital and resource transfer from wealthy countries to poorer ones is surely needed in the current pandemic response, any system that solely relies on aid will ultimately fail to achieve equity. In the setting of vaccine scarcity, in which suppliers are unable to deliver doses as scheduled and countries are banning exports to keep vaccines at home, there is a risk that COVAX aid-recipient states will fall further down the priority list, awaiting the leftover vaccines from the rich country stockpiles. What may be most pernicious about the COVAX scheme, however, is that rich countries and their pharmaceutical companies have repeatedly used it as a shield to deflect demands for IP waivers. This is an enduring problem with aid: it papers over and distracts our attention away from the underlying structural violence. And in so doing, it maintains and perpetuates inequalities. Over 50 years ago, Kwame Nkrumah observed how aid is a ‘revolving credit’ which returns to countries of the global North in the form of increased profits. To the extent that COVAX is being leveraged to protect corporate patents and profits, Nkrumah’s words continue to be germane. The third approach is focused on pooling, temporary waivers, or suspension of IP. In May 2020, the WHO created the COVID-19 Technology Access Pool for companies to share IP and transfer technologies in a coordinated manner. But to date, not a single company has utilised the transfer process—likely because such forms of global IP sharing would quell profits, even if royalties are included. Pharmaceutical companies and universities prefer one-off transfer deals because it enables them to set their own terms with non-disclosure agreements. Given that they are accountable to shareholders and boards—not patients—financial incentives will drive transfer decisions, not public health demand. Following the blockages at the WHO around IP, attention shifted towards the World Trade Organisation (WTO). In October 2020, India and South Africa proposed a temporary waiver of IP rights to COVID-19 technologies for the duration of the pandemic, so that all manufacturers with sufficient capacity and shared know-how could start production. Although backed by over 100 countries within the WTO and a global campaign for the ‘People’s Vaccine,’ the proposal has been repeatedly blocked at every committee meeting since then by select wealthy countries with large pharmaceutical industries, including the UK, Japan and EU states. Those who oppose the IP waiver argue that it will not do anything to solve the problem: even if you were to liberate the recipe for the vaccines, low-income and middle-income countries do not have the capacity to produce it. But this argument is specious. For one, several middle-income countries—including India, Brazil, Senegal and South Africa—do have the ability to ramp up production by repurposing existing manufacturing capacity. In addition, an IP waiver can and should be supplemented with technology transfers, logistical support and financial investment to facilitate this repurposing process. And the most important point is that such a waiver could drastically reduce costs across the board, making vaccine imports more affordable for poor countries. Opponents of the waiver also claim that IP-related obstacles can be addressed through existing arrangements for ‘compulsory licensing’ under the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). But the past evidence suggests that this process is slow, cumbersome and subject to various shaming practices by the international community. Some point instead to the possibility of voluntary licensing. But voluntary licenses are often executed secretly and are limited to companies or governments that can afford them. The University of Pennsylvania, which owns IP rights relating to the mRNA vaccines, is helping Chulalongkorn University in Bangkok develop a vaccine production facility. This partnership was possible because Thailand—unlike other middle-income countries—was able to put up the money. Poorer countries are left out. Sharing of IP and technology transfers can and will accelerate global vaccine production. The question is on whose terms. Organisations such as the WHO and African Union are currently mobilising support and resources to accelerate production in low-income and middle-income countries. But these efforts will be to waste unless IP for COVID-19 technologies is shared broadly and quickly. Vaccine coloniality Donor-based approaches to vaccine equity are grounded in old, even colonial ideas of aid and dependency, which have failed to serve the health needs of the Majority World or deliver on health equity. This failed model has not promoted health equity in the past and is clearly inadequate in the present, on account of dependency on donor whims (the bilateral ‘leftovers’ approach), persistent funding gaps and shortfalls (COVAX), and time-consuming diplomacy and filibustering over what is or is it not within current trade rules (WTO). Vaccine apartheid is only one symptom of broader global health inequalities that have their roots in colonialism Once again in the political economy of global health, the charitable model of COVAX becomes the smokescreen for inequitable systems. When states are asked about their stockpiling, they point to COVAX. When pharmaceutical companies are asked about IP, they point to COVAX or their low-cost commitment. The focus on a donor-based model of aid in achieving vaccine equity has distracted leaders from the ideologies, economic systems and trade regulations that leave access to medicine to the forces of the marketplace rather than global health priorities. Achieving global vaccine justice requires a rapid shift in trade regulations and contract transparency that streamlines IP sharing and technology transfers. The resultant collaborations across economies will not only accelerate vaccine production but will also increase competition and push vaccine prices down. Finally, old models of vaccine equity have not kept pace with changes in discourse and thinking around global health governance, equity and justice. 2021 is not the early 2000s, where new public–private partnerships or funding models were de rigueur. Donor countries are increasingly wary of aid dependency as they pay the cost of continuing high profile health programmes with diminishing strategic returns. Aid-recipient countries are similarly exasperated by funding gaps that lead to delays and materiel shortfalls, the NGO-industrial complex and attendant consultants that rationalise them, and fundamentally, by the notion that their populations only seem to matter when another state can capitalise on them. Conclusion Vaccine apartheid is only one symptom of broader global health inequalities that have their roots in colonialism and persist today because of neocolonial forms of power. As Grosfoguel writes, ‘The heterogeneous and multiple global structures put in place over a period of 450 years did not evaporate with the juridical–political decolonisation of the periphery over the past 50 years. We continue to live under the same ‘colonial power matrix.’ With juridical–political decolonisation we moved from a period of ‘global colonialism’ to the current period of ‘global coloniality.’ Vaccine justice starts with moving beyond aid models of vaccine donation, in which poorer countries are gifted vaccine leftovers. It demands rapidly achieving global consensus for the IP waiver, democratising vaccine IP and know-how and supporting low-income and middle-income countries to build manufacturing capacity for this pandemic and the next. These steps can mark the start of a reparative justice movement in global health that demands we confront and overturn colonial legacies that continue to devastate the health of low- and middle-income countries. A commitment to funding vaccine justice in the face of the COVID-19 pandemic can be a first step in this direction.