## **First off- DA**

#### **Covid-19 has supercharged innovation in the status quo**

**Ramalingam & Prabhu 20** [Ben Ramalingam- Overseas Development Institute, United Kingdom. Jaideep Prabhu University of Cambridge, United Kingdom. “Innovation, development and COVID-19: Challenges, opportunities and ways forward.” OECD. 1 December 2020. Link: <https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/>] JV

Coronavirus (COVID-19) innovation: what is happening? A global perspective At the same time as causing a huge impact on health and livelihoods around the world, COVID-19 has a created fertile breeding ground for novel solutions and approaches (OECD Observatory of Public Sector Innovation, n.d.[2]). The most comprehensive survey of global research and development (R&D) funding commitments for COVID-19, undertaken by the US-based Policy Cures programme, shows that investment in health-related innovation has been unprecedented (Policy Cures, 2020[3]). The scale of innovation resources mobilised globally is remarkable: USD 9 billion in seven months. By comparison, the total global funding disbursed for Ebola R&D between 2014 and 2018 was USD1.9 billion. The nature of the innovation processes that have been deployed is also notable. In the six months since the outbreak began, the US Food and Drug Administration (FDA) has approved almost 100 COVID-19 tests, in contrast to the three months the FDA took to approve the first Ebola test during the 2014 West Africa outbreak. The first COVID-19 vaccine entered into human trials within a record-breaking 69 days of identifying the causative agent of the outbreak[1](https://www.oecd.org/coronavirus/policy-responses/innovation-development-and-covid-19-challenges-opportunities-and-ways-forward-0c976158/#endnotea0z2) – a remarkable achievement, considering that it took 25 months for the first vaccine to reach the human trial stage during the previous global coronavirus outbreak (SARS in 2002–04).

#### **Medical innovation is crucial to prevent pandemics and mitigate economic harms during shut downs**

**Mulligan 21** [Casey B. Mulligan– American economist and author. He is a Professor in Economics at the University of Chicago. “Economic activity and the value of medical innovation during a pandemic” Cambridge University Press. 9 June 2021. Link: <https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/economic-activity-and-the-value-of-medical-innovation-during-a-pandemic/864F8042F794D4417E64C643999C9280>] JV

Medical innovation can reduce the duration and severity of pandemics. In doing so, innovation reduces the duration and severity of the direct health costs as well as the costs of economic shutdowns intended to mitigate the health costs. As long as it remains a major barrier to medical innovation, regulation will unnecessarily add to the economic and health costs of the current pandemic (Peltzman, 1973; Philipson & Sun, 2008). Innovation is not finished when scientists discover a new medicine, device, or technique and demonstrate its safety. Pandemic medicines and equipment need to be manufactured and distributed on a massive scale. Personnel need to be trained to administer new treatments. These processes can be slowed by regulatory barriers ranging from federal inspections of facilities manufacturing drugs and devices to state occupational licensure. Although not new, disease testing and contact tracing are essential techniques that are scalable in principle, but early in the pandemic were unavailable in the USA in more than small quantities. Regulatory barriers slow both the manufacturing of these devices and techniques as well as the development of more scalable methods for distributing them.

#### **The risks associated with creating new drugs means that patents are key to biopharmaceutical innovation**

**Cockburn & Long 15 [**Iain Cockburn, Richard C. Shipley Professor of Management. Genia Long, senior advisor and part of analysis group. “The importance of patents to innovation: updates cross-industry comparison with biopharmaceuticals.” Taylor & Francis online, Volume 25, Issue 7, 2015. Published online: 30 April 2015. Link: <https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762>] JV

Due to distinctive economic characteristics, patents and regulatory exclusivity have long been considered essential to prescription drug development. These characteristics include the costly, lengthy, and risky nature of innovative research and development (R&D) and the much lower investment required for generic drugs. Because of this disparity, without patent protection and regulatory exclusivity, particularly in the USA, innovators would be unlikely to make the substantial investments required to bring new drugs to market. Whereas drug development is global, patent law and regulation are country-specific. In the USA, regulatory exclusivity operates in parallel with patents, defining when generics or biosimilars may not submit abbreviated applications and/or enter the market. Generic imitation may require several million dollars, whereas the cost to bring a single FDA-approved drug to market (including the cost of failed attempts) has been estimated at $1.4 billion in out-of-pocket costs and $2.6 billion including the cost of capital [[1,2]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). New drug R&D requires more than a decade, including pre-clinical testing, clinical trials, and US regulatory approval [[1,2]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In comparison, clinical testing is not required for generics; manufacturers need only demonstrate bioequivalence to an already-approved drug. Risk is also high; the vast majority of candidates are eliminated, most before clinical testing. For those that begin clinical testing, the probability of proceeding to approval averages only 12% [[2,3]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Therefore, R&D must be funded by a few successful, on-market medicines [[4]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Generally, in the USA, once patent protection and any 180-day generic exclusivity end, multiple generics launch, and generic share increases rapidly. For all new molecular entities experiencing first generic entry in 2011–12, the average brand’s unit share of molecule sales declined to 16% 12 months after generic entry, versus 44% in 1999–00 [[5]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In 2013, generics represented 86% of all US prescriptions [[6]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In addition to distinctive R&D and market competition economic characteristics, biopharmaceuticals are also distinguished from other industries by a large gap between the statutory patent term (20 years from the effective patent filing date) and the effective patent term (years remaining at launch), even after any patent term restoration and additional regulatory exclusivity (e.g., for pediatric studies). The average time between brand launch and first generic sale for drugs experiencing initial generic entry in 2011–12 was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, and 12.9 years overall [[5]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In contrast, assuming < 3 years for the US Patent and Trademark Office to examine and approve a patent application (overall average of 29 months for FY2013), the remaining duration (assuming 20 years from the effective patent filing date) would be > 17 years in other industries [[7]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762).

#### **Pharma collapses without strong IP protections**

**Buckland 17** - Danny Buckland (award-winning journalist who writes about health, general features and news, shortlisted for the prestigious Mind Media Awards for his work covering mental health issues), April 26, 2017, “Patents are lifeblood of pharmas”, https://www.raconteur.net/legal/intellectual-property/patents-are-lifeblood-of-pharmas/ WJ

**Pharmaceutical companies are staffed by ranks of attorneys, and the intellectual property (IP) specialist is now a pivotal position in the research and development (R&D) cycle that keeps a company profitable** and new drugs flowing to patients.

**Tighter regulatory frameworks** and even tighter purse strings controlled by healthcare systems **are putting the squeeze on pharma returns and limiting R&D budgets**. Figures from analysts Deloitte in 2016 reported projected return on investment was at a six-year low while development costs had risen by almost a third.

The litany of market changes is vexing for the industry. **The generation of blockbuster drugs, with massive returns**, **has ended,** national healthcare budgets are receding, traditional management methods are being challenged and new players, such as electronics and software companies, are entering the arena.

“**For pharmaceutical companies, the patent system is its lifeblood and it simply wouldn’t survive without it**,” says Simon Wright, a patent attorney with J A Kemp and chairman of the Chartered Institute of Patent Attorneys’ life sciences committee. “**The cost of getting a product to market is high and there is a high failure rate**, so you are not going to get investment unless you can protect your product and innovation. **Quite frankly, it would all collapse without good IP**.”

#### **Pandemics are a non-linear, existential risk---encompasses AND outweighs other threats. Empirically proven by historic epidemics such as the Black Death and Spanish flu**

**Pamlin and Armstrong 15**, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, <https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf> //Re DE EK

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a **large region**; for instance **several continents**, or even **worldwide**. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the **greatest causes of mortality in history**. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a **power law with a small exponent**: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the **single largest pandemic**. **Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.**267 There are other grounds for suspecting that such a highimpact epidemic will have a ***greater probability*** *than* ***usually assumed****.* All the features of an extremely devastating disease **already exist in nature**: essentially **incurable** (Ebola268), nearly always **fatal** (rabies269), **extremely infectious** (common cold270), and **long incubation periods** (HIV271). If a pathogen were to emerge that somehow **combined these features** (and influenza has demonstrated **antigenic shift**, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that **modern transport** and **dense human population** allow infections to spread much more rapidly, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the **ripple effect** of the fatalities and the policy responses. These would include **political and agricultural disruption** as well as **economic dislocation** and damage to the world’s **trade network** (including the food trade). **Extinction risk** is only **possible** if the aftermath of the epidemic **fragments and diminishes human society** to the extent that recovery becomes impossible277 before humanity succumbs to **other risks** (such as **climate change** or **further pandemics**). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

## **Framing**

#### **Pleasure and pain are intrinsically valueable and disvalueable – everything else regresses. Evolutionary knowledge is reliable – broad consensus and robust neuroscience prove.**

**Blum et al. 18**

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**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10]. Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14]. Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals. Evolutionary theories of pleasure: The love connection BO:D Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it. It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring. Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding. There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health. Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage. Finding happiness is different between apes and humans As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure. Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even **produce the opposite** of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered. Desire and reward centers It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation. In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41]. Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42]. Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans. In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45]. Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations. Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50] In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders. In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS. Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

#### **Thus, the standard is maximizing expected well-being or act hedonistic util. Prefer additionally –**

#### **1] Outweighs – A] Predictability – most authors assume util when discussing the cost/benefit tradeoffs of voting B] topic ed – other frameworks don’t engage with key questions of implemented policy impacts – that’s key, b/c we only have 2 months for this topic. C] TJFs first because they assume the framework being good for debate**

#### **2] Death is bad and outweighs – a) agents can’t act if they fear for their bodily security which constrains every ethical theory, b) it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life**

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

## 

## **On Case:**

#### **Capitalism is key to growth – and also reductions in poverty.**

**Skarbek, 10** – Research Fellow at the Independent Institute, founding Director of the Institute's Center on Entrepreneurial Innovation (COEI) and the COEI Government Cost Calculator, and Lecturer in the Department of Political Economy at King's College in London, England. She received her Ph.D. in economics from George Mason University, and she has been Assistant Professor of Economics at San Jose State University and an F.A. Hayek Scholar, and she is the recipient of the Don Lavoie Memorial Award.

Emily C. Skarbek, “Capitalism and Economic Growth,” Independent Institute. April 15, 2010. <https://www.independent.org/issues/article.asp?id=2769>

When the current administration talks of entrepreneurship, they speak of politically favored businesses and privileged recipients of the taxpayers’ dollars. To be clear, that is not entrepreneurship. It has become conventional to say that those who openly embrace capitalism, free markets and free trade are dogmatic, **ideologues, idealistic, or market fundamentalists**. And if you look to the media and our leaders, you get the impression that being in favor of free markets is **somehow an unreasonable position.**

Unless one is **ashamed of unprecedented increases in income**, rising life expectancy, greater education, and more political freedom, **there is no reason to be a fair-weather fan of capitalism**. Sprawling free markets in countries that became more capitalist over the last 25 years have meant many more people enjoy improvements in well being and opportunities to advance human capabilities.

There is no evidence that countries that **eschewed freer markets** and **embraced substantially greater state control** performed better on any of these major indicators. On the contrary, those countries that adopt increased taxation, increased regulation, fiscal mismanagement and enormous public debt have **performed demonstrably worse.**

From a global perspective, **we have witnessed remarkable progress** of mankind through the increased acceptance of free market policies in both rich and poor countries. Before the industrial revolution, **80% of the world’s population** lived in abject poverty. By 1980, that number has fallen to 34.8% and by 2000, less than 20% of the population lives on less than $1 a day. In five years, **the number is expected to fall to 10% if free trade is allowed to flourish.**

In just the past 25 years increased private ownership, increased free trade, and lower taxes all came at the hands of politicians like Deng Xiaoping in China, Margaret Thatcher in England, and Ronald Reagan in United States. In the years following the adoption of these policies by these global leaders, per capita income nearly doubled from 1980 to 2005; Tariffs fell and trade increased; Schooling and life expectancy grew rapidly, while infant mortality and poverty fell just as fast.

In the average country that became more capitalist over the last 25 years, the average citizen gained a 43% increase in income, nearly half a decade in life expectancy, and a 2-year increase in the average years of schooling. In my lifetime alone, freer markets have improved the lives of billions of people from all walks of life.

When we look back at our own history, the tremendous economic growth that Americans experienced from the time of the original Tea Party up to 1914 was the result of economic freedom from government regulation, open boarders for free immigration, and very few trade restrictions on the global flow of goods, services, and capital. Anyone could get on a boat, land on Ellis Island and become an immigrant and this benefited both domestic Americans and the immigrant alike. Business and labor were free to be entrepreneurial—and entrepreneurship created wealth. But we don’t want wealth for wealth’s sake. Wealth allows for the improvement of the human condition.

For example, in 1905, our average life expectancy in the U.S. was 47. Today it is 78. A hundred years ago only 14% of homes had a bathtub; 8% had a phone; 95% of all births took place at home; most women washed their hair once a month; and the average worker made about $300 per year.

As recent as 1984, it took the average American wage earner 456 hours of labor to earn enough to purchase a cellphone. Today, it takes the average American 4 hours. A computer has fallen from costing 435 hours of labor to less than 20. None of this accounts for the tremendous improvements in technological capacity. There are several reasons that the costs of goods have dropped so drastically, but perhaps the biggest is increased international trade.

Simply put, **the free market means the poor are less poor**. Globalization extends and deepens a capitalist system that has for generations been lifting American living standards—for **high-income** households, of course, **but for low-income ones as well**. When the world embraces free market reforms, the world economy expanded greatly, the quality of life improves sharply for billions of people, and **dire poverty was substantially scaled back**. This is not a coincidence.

It is a well-established fact that when people are free to buy from, sell to, and invest with one another as they choose, they can achieve far more than when governments attempt to control economic decisions. Widening the circle of people with whom we transact—including across political borders—brings benefits to consumers in the form of lower prices, greater variety, and better quality, and it allows companies to reap the benefits of innovation, specialization, and economies of scale that larger markets bring. **Free markets are essential to prosperity**, and expanding free markets as much as possible enhances that prosperity.

Voluntary economic exchange is inherently fair and does not justify government intervention. When two free people come together on terms they have agreed upon to exchange peacefully, both benefit. Government intervention in voluntary economic exchange on behalf of some citizens at the expense of others is inherently unfair. One person is coerced in order to privilege another. It really is that simple.

When goods, services, labor and capital flow freely across U.S. borders, Americans can take full advantage of the opportunities of the international marketplace. They can buy the best or least expensive goods and services the world has to offer; they can sell to the most promising markets; they can choose among the best investment opportunities; and they can tap into the worldwide pool of capital. Study after study has shown that countries that are **more open to the global economy grow faster** and achieve higher incomes than those that are relatively closed. This is capitalism.

**Growth is not guaranteed**. It seems obvious that the central challenges facing America have to do with the with predatory regulatory and tax policies conducted by governments domestic and abroad. From an economic perspective, then, the case for unilateral trade liberalization—that is reducing our own trade barriers and subsidies without preconditions or reciprocal commitments from other countries—is the best policy to promote peace and prosperity globally.

Politically, however, the concentrated and organized beneficiaries of protectionism are powerful relative to the much larger, disorganized, beneficiaries of free trade. Politicians tend to be most responsive to the loudest interest groups and are therefore inclined to view free trade unfavorably. But we as Americans must be clear—**capitalism is not evil**. **It has done more good for more people than any acts of state, any stimulus spending**, any health program or welfare initiative. Americans can no longer afford to fear freedom.

Finally, acknowledging the relationship between free markets and economic prosperity does not make someone “dogmatic”. It is unreasonable to continue to ignore these facts. Capitalism’s superiority for economic growth and development deserves the unqualified support of everyone who believe that **wealth is better than poverty**, **life is better than death**, and **liberty is better than oppression.**

#### **The issue is supply, not patents---tons of barriers that the plan cannot overcome.**

Alex **Tabarrok 21**. Alex Tabarrok is Bartley J. Madden Chair in Economics at the Mercatus Center and a professor of economics at George Mason University. “Patents are Not the Problem!” Marginal Revolution, May 6, 2021, <https://marginalrevolution.com/marginalrevolution/2021/05/ip-is-not-the-constraint.html>, RJP, **DebateDrills**.

**Patents are not the problem.** All of the vaccine manufacturers are trying to increase supply as quickly as possible. Billions of doses are being produced–more than ever before in the history of the world. **Licenses are widely available**. AstraZeneca have licensed their vaccine for production with [manufactures around the world](https://www.astrazeneca.com/what-science-can-do/topics/technologies/pushing-boundaries-to-deliver-covid-19-vaccine-accross-the-globe.html), including in India, Brazil, Mexico, Argentina, China and South Africa. J&J’s vaccine has been licensed for production by multiple firms in the United States as well as with firms in Spain, South Africa and France. Sputnik has been licensed for production by firms in India, China, South Korea, Brazil and pending EMA approval with firms in Germany and France. Sinopharm has been licensed in the UAE, Egypt and Bangladesh. Novavax has licensed its vaccine for production in South Korea, India, and Japan and it is desperate to find other licensees but technology transfer isn’t easy and there are[limited supplies of raw materials](https://endpts.com/as-fears-mount-over-jj-and-astrazeneca-novavax-enters-a-shaky-spotlight/):

Virtually overnight, [Novavax] set up a network of outside manufacturers more ambitious than one outside executive said he’s ever seen, but they struggled at times to **transfer their technology** there amid pandemic travel restrictions. They were kicked out of one factory by the same government that’s bankrolled their effort. Competing with larger competitors, they’ve found themselves short on raw materials as diverse as Chilean tree bark and bioreactor bags. They signed a deal with India’s Serum Institute to produce many of their COVAX doses but now face the realistic chance that even when Serum gets to full capacity — and they are behind — India’s government, dealing with the world’s worst active outbreak, won’t let the shots leave the country.

[**Plastic bags are a bigger bottleneck than patents**](https://www.news18.com/news/opinion/single-use-plastic-bioreactor-bags-to-filters-why-india-needs-them-from-us-for-covid-vaccines-3681092.html)**.** The US embargo on vaccine supplies to India was precisely that the Biden administration used the DPA to prioritize things like bioreactor bags and filters to US suppliers and that meant that India’s Serum Institute was having trouble getting its production lines ready for Novavax. CureVac, [another potential mRNA vaccine](https://www.reuters.com/business/healthcare-pharmaceuticals/curevac-says-mass-vaccine-rollout-thrown-into-doubt-by-us-restrictions-2021-05-04/), is also finding it difficult to find supplies due to US restrictions (which means supplies are short everywhere). As [Derek Lowe said](https://blogs.sciencemag.org/pipeline/archives/2021/04/22/a-look-at-novavax):

Abolishing patents will not provide more shaker bags or more Chilean tree bark, nor provide more of the key filtration materials needed for production. These processes have a *lot* of **potential choke points** and rate-limiting steps in them, and there is no wand that will wave that complexity away.

Technology transfer has been difficult for AstraZeneca–which is one reason they have had production difficulties–and their vaccine uses relatively well understood technology. The mRNA technology is new and has never before been used to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Moderna or Pfizer would be happy to license since they are producing in their own factories 24 hours a day, seven days a week (monopolies restrict supply, remember?). Why do you think China hasn’t [yet produced](https://www.scmp.com/news/china/politics/article/3128998/revolutionary-mrna-vaccines-made-chinese-firms-will-be-ready) an mRNA vaccine? Hint: **it isn’t fear about violating IP**. Moreover, even Moderna and Pfizer don’t yet fully understand their production technology, they are learning by doing every single day. Moderna has said that they won’t enforce their patents during the pandemic but no one has stepped up to produce because no one else can.

The US trade representative’s announcement is virtue signaling to the anti-market left and will do little to nothing to increase supply.

### **Access/Supply**

#### **There is a fundamental issue in the drug practices and markets in poor countries – patented drugs are not the problem**

**Silverman et al 19**[Rachel Silverman is a policy fellow at the Center for Global Development, where she leads policy-oriented research on global health financing and incentive structures. Janeen Madan Keller is a senior policy analyst and assistant director of global health at the Center for Global Development. Amanda Glassman is executive vice president and senior fellow at the Center for Global Development and also serves as chief executive officer of CGD Europe. Kalipso Chalkidou is the Director of Global Health Policy and a Senior Fellow at the Center for Global Development, Center for Global Development, “New Study Finds Some Poor Countries Paying 20 to 30 Times More for Basic Medicines Than Others”, June 17. 2019, <https://www.cgdev.org/article/new-study-finds-some-poor-countries-paying-20-30-times-more-basic-medicines-others>] DD MN

WASHINGTON – **Basic,** **everyday drugs can cost up to 20 to 30 times more in some poor countries** than others, **according to a new study released today by the Center for Global Development. The study examined billions of dollars of health spending on common, life-saving medicines in developing countries, mostly in Africa and Asia.** To date, it is one of the largest-ever studies on global health procurement.

“Developing countries are often paying far more for everyday drugs than they should be. Why do some poor countries pay 20 to 30 times as much as others for common medicines to relieve pain or treat hypertension? In large part, **because of flawed drug buying practices and broken generic medicines markets**,” said Amanda Glassman, one of the authors of the study and the executive vice president at the Center for Global Development.

“A robust market for generic drugs is a core part of an affordable health system. But in way too many countries, generic drug markets are broken and patients are paying the price,” said Kalipso Chalkidou, the director of global health policy at the Center for Global Development and an author of the study. “You need enough competition to keep prices low and quality assurance that consumers trust, or essential medicines are going to be much more expensive than they should be.”

The study had three main findings:

**In developing countries, prices for basic generic medicines can** vary widely and **far exceed wealthy-country prices**. Some purchasers in low- and middle-income countries pay as much as 20 to 30 times more for basic generic medicines like omeprazole, used to treat heartburn, or acetaminophen (also known as paracetamol), a common pain reliever.

**Low- and middle-income countries purchase more expensive branded generic drugs rather than unbranded quality-assured generics**. In the US, most drugs are either on-patent medicines or unbranded generics, but in many developing countries more expensive brand-name generics are widely used, because people are concerned about unsafe or counterfeit drugs. **In the poorest countries, unbranded generics are only 5 percent of the pharma**ceutical **market** by volume—**in comparison to the US where unbranded** quality-assured **generics are 85 percent of the market** by volume.

**There is little competition in the supply of** essential medicines in low- and middle-income countries. The largest seller of products like contraceptives, cancer medicines, and antiparasitics can account for upwards of 85 percent of all sales in some countries.

“We’re talking about access to **common medications for pain or high blood pressure, not the latest cutting-edge cancer drugs**,” Glassman said.

“It’s not as exciting to talk about procurement as new health technologies or biotech breakthroughs,” she continued. “But drug purchasing is incredibly important, and if it’s done badly you end up with the poorest countries in the world paying some of the highest drug prices.”

#### **Reduced manufacturers result in the lack of supply of drugs in developing countries**

**Hirschler 16**[Reuters pharma correspondent in London, Reuters, “Drug shortages prompt question: are some medicines too cheap?”, March 31, 2016, <https://www.reuters.com/article/us-health-medicine-shortages-insight/drug-shortages-prompt-question-are-some-medicines-too-cheap-idUSKCN0WY3NT>] DD MN

**Drug shortages are due to** a variety of factors from **manufacturing, quality and raw material problems to unexpected spikes in demand**, but such upsets are aggravated **when there are few suppliers.**

“It can be really problematic,” said Aubrey.

The **rise in shortages has gone hand in hand with** a wave of consolidation among the **companies making generic drugs** - which range from global pharmaceutical giants to smaller firms in countries such as India - **reducing** the number of **manufacturers making individual product lines.**

Downward pressure on generic drug prices is good news for healthcare systems in the short term, but it may fuel disruption if a supplier hits production problems. While the lack of a patent means other suppliers could also make the same drug, they would still need regulatory approval and that can take years.

**The result**, according to experts, **is a worryingly fragile supply chain, particularly for injectable medicines such as chemotherapy treatments and certain antibiotics.**

**Benzathine penicillin, for example, a vital drug for preventing transmission of syphilis from mother to child, has been in short supply for years because of manufacturing problems, inconsistent demand and a relatively low price.**

“Medicines can be too cheap,” said Hans Hogerzeil, professor of global health at Groningen University in the Netherlands and a former director for essential medicines at the WHO. “For a viable market model you need at least three and preferably five different manufacturers.”

The idea of minimum prices for certain essential medicines contrasts sharply to traditional pricing debates about how to reduce the sky-high cost of new patented drugs for diseases such as cancer and hepatitis C.

Drug shortages will be discussed as a specific topic for the first time at this year’s WHO World Health Assembly in May, and U.S. and European regulators told Reuters more needed to be done to address the problem.

**Shortages in the United States hit a peak in 2011 due to manufacturing outages, yet the American Society of Health-System Pharmacists still lists 155 products as being in short supply.**

**The European Association of Hospital Pharmacists says more than four out of five of its members face regular shortages, while doctors in Canada have been grappling this year with tight supply of a widely-used epilepsy drug.**

#### **Waiving IP kills incentive for vaccines for future pandemics – exacerbates impacts**

**Iancu, April** 13, 2021, "No evidence that patents slow vaccine access," STAT, <https://www.statnews.com/2021/04/13/no-evidence-patents-slow-vaccine-access/> // DD AP

All governments now share the goal of quick and worldwide vaccination. To reach this goal, many are latching onto the idea of [suspending intellectual property rights](https://www.statnews.com/pharmalot/2021/03/29/coronavirus-covid19-vaccine-jnj-patents-opioids/) for Covid-19 vaccines and medicines, including [more than 400](https://www.politico.com/news/2021/03/21/coronavirus-vaccine-wto-477272) health, labor, religious, and other groups. Late last year, the governments of India and South Africa [petitioned the World Trade Organization](https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm) to waive patent protections for Covid-19 therapies. To take effect, that proposal would have to be approved by member countries and, so far, the United States, the United Kingdom, the European Union, Japan, and others have withheld their approval. But international organizations, like [Doctors Without Borders](https://www.msf.org/msf-urges-wealthy-countries-not-block-covid-19-patent-waiver), as well as a number of [U.S. lawmakers](https://www.commondreams.org/news/2021/03/11/we-need-peoples-vaccine-not-profit-vaccine-sanders-urges-biden-support-push-suspend), support the call to strip away patent rights for Covid-19 vaccines and therapies**. President Biden is**[**reportedly weighing**](https://www.cnbc.com/2021/03/26/covid-vaccine-updates-white-house-mulls-lifting-intellectual-property-shield.html)**whether to back the waiver. Proponents of the idea say it would boost vaccine supply and access. The problem is, there is no evidence for this claim.** In fact, the push by [India](https://www.reuters.com/article/health-coronavirus-india-vaccine/not-without-india-worlds-pharmacy-gears-up-for-vaccine-race-idUSKBN28K10E) and [South Africa](https://theconversation.com/vaccine-production-in-south-africa-how-an-industry-in-its-infancy-can-be-developed-153204) appears to be disingenuous, aimed not at curbing the pandemic but at allowing domestic companies to make money off of others’ intellectual property. **Gutting patent rights** is a dangerous prospect. Drug invention **is highly risky**: [Fewer than 12%](https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html) of new molecular entities that make it to the clinical trial stage get to the marketplace. The endeavor depends on [$100 billion](https://www.researchamerica.org/sites/default/files/Publications/InvestmentReport2019_Fnl.pdf) in annual private-sector investment, on top of billions in taxpayer money. Kill the patents taken out on these advances **and** you **kill the incentive to invest. That** would **mean even worse trouble when the next pandemic comes around, in five, 10, or 20 years. So before governments take the risk of waiving patents, they should evaluate whether intellectual property rights are really standing in the way of vaccine manufacturing and distribution.** **The issues about making more vaccines and distributing them to every country are far more complex than those proposing to waive intellectual property rights on these vaccines would have us believe.** **Manufacturing and distributing these vaccines is extremely complicated, posing issues well beyond patents.** Almost every factory on the planet that can make these vaccines is already doing so. One of the biggest, the Serum Institute in India, has contracts with AstraZeneca and others to make millions of doses. Under deals like these, manufacturing plants in India will produce [3 .6 billion doses](https://timesofindia.indiatimes.com/india/at-3-6-billion-india-pegged-to-produce-most-covid-19-vaccine-doses-after-us-in-2021/articleshow/80254075.cms) of vaccine this year, second only to the United States.

**Waiving patent and intellectual property protections is not a panacea for global vaccine distribution**

**Bolle and Obstfield, 21** (Monica de Bolle (PIIE) and Maurice Obstfeld (PIIE), Maurice Obstfeld has been nonresident senior fellow at the Peterson Institute for International Economics since February 2019. He is the Class of 1958 Professor of Economics and former chair of the department of economics (1998–2001) at the University of California, Berkeley, where he has taught since 1991. He previously taught at Harvard University (1989–90), the University of Pennsylvania (1986–89), and Columbia University (1979–86).In addition to his academic positions, Obstfeld served at the International Monetary Fund (IMF) as economic counsellor and director of the research department5-12-2021, PIIE, "Waiving patent and intellectual property protections is not a panacea for global vaccine distribution", https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not)//AK

The Biden administration's decision in early May 2021 to support temporary waivers of intellectual property rights (IPRs) on COVID-19 vaccines produced by the world's largest pharmaceutical companies is a welcome step intended to help countries with low access to vaccines. Unfortunately, however, the waivers by themselves will do little to aid global vaccination in the near term. In fact, these actions could be counterproductive if governments become complacent and fail to finance and organize vaccine supply chains worldwide, without which vaccines will not get to those who need them. As the pandemic has exploded in India and fears for Africa have intensified, the pressure on the United States, the European Union, and other advanced vaccine-producing countries to relax IP protections in World Trade Organization (WTO) agreements has intensified. Policymakers have also increasingly understood that no one is safe from COVID-19 until everyone is safe. Led by **India and South Africa**, the developing world **ha[ve]** **been arguing** on moral and practical grounds **that IP waivers are essential to accelerating vaccine distribution** and containing the pandemic worldwide. Absent widespread vaccination in less prosperous countries, experts say, all countries, even those with high vaccination rates, would remain vulnerable. **But IP waivers** alone **will not necessarily accomplish that goal**. Among the obstacles to getting wide distribution of vaccines are bureaucratic hurdles within the WTO, the difficulty for many poor countries of producing vaccines even if they have the legal right to do so, and the fact that **vaccine production depends on global supply chains** **that cannot quickly be mobilized to deliver shots to low- and middle-income countries**. Navigating the procedural obstacles to get WTO agreement on a streamlined mechanism for suspending IP protections is not as easy as it would seem. It is already possible to waive protections in the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). But the WTO's track record suggests that roadblocks may lie ahead in expanding the scope of its waiver procedure. Since August 2003, the WTO has explicitly allowed emergency departures from the TRIPS agreement, enabling countries with manufacturing capacity to suspend IP protections to produce life-saving drugs and vaccines, not just for domestic use but also for export to countries that lack manufacturing capacity of their own. However, the process of negotiating the August 2003 decision—which created a temporary procedure for export waivers—took 14 months, and it was not until January 2017 that two-thirds of WTO members had ratified it as a formal amendment to the TRIPS agreement. Because of this painful negotiation process, the bureaucratic procedures for exercising IP flexibility are so cumbersome that there are very few instances of its use. The best known (though not very successful) example occurred with Canadian exports of an AIDS treatment to Rwanda in 2007. Complicating matters further has been the opposition of some major countries to revisiting the issue, as well as the likely need for WTO members to revise their domestic legal frameworks to accommodate patent waivers. These factors make it clear that renewed negotiations within the WTO are unlikely to yield results with the speed that the current health emergency demands or result in a meaningfully better framework. Recognizing the likely difficulty of negotiations, WTO Director-General Ngozi Okonjo-Iweala has suggested a December 3, 2021 deadline for completion—but like past initial deadlines in this space, this one could well prove overoptimistic. The second, and arguably more intractable, challenge is technical: **Even if they overcome IP obstacles** and get permission to produce vaccines**, less prosperous countries lack the know-how, facilities, and trained personnel to produce them**. Despite the abysmal decades-long record of vaccine distribution in those countries, existing **TRIPS flexibilities have done nothing to improve the situation**. A smoother IP waiver process might help, but only as a component of a broader effort. True, patent protection is the main obstacle to creation of generic small-molecule drugs, which chemists can synthesize. But other major obstacles exist for vaccines, which are biologics. For the latter category of drugs, an identical product requires an identical production technology, with most steps categorized as hard-to-replicate trade secrets rather than patentable innovations. Thus, **Moderna announced in October 2020 that it would not enforce its COVID-19-related patents during the pandemic**. **But** this step, however laudable, is of limited immediate help to would-be producers of a "generic" version of the Moderna vaccine. Without precisely replicating all steps of Moderna's production process, including the many quality controls, **a generic version would have untested immunogenicity** (the ability to induce the body to generate an immune response) and thus would require extensive clinical trials before release. **Production glitches**—**such as those** that afflicted the Janssen/Johnson & Johnson vaccine in the United States—**could prompt widespread vaccine skepticism, damaging pandemic control efforts**. The replication hurdle is especially high for the new and more sophisticated messenger ribonucleic acid (mRNA) vaccines, which have proven most effective against SARS-CoV-2 (the virus that causes COVID-19) and which are likely to provide the most adaptable platforms for the vaccines of the future. The genetic vaccines produced by Pfizer-BioNTech and Moderna require considerable technical knowledge and sophisticated techniques to generate a version of the viral spike protein that elicits a strong immune response.1 Therefore, from a biological standpoint, patent and IP waivers alone cannot resolve the existing lack of capacity in most countries to produce genetic vaccines at scale locally. A final challenge is that vaccine supply chains are intricate and global in scope. **Different stages of vaccine manufacturing are spread across different parts of the globe**, with various countries supplying key inputs and equipment. Patent and **IP waivers cannot resolve export restrictions** that these countries may decide to impose—and in fact have imposed—throughout the pandemic. Nor can poor countries with production waivers easily integrate into global supply chains. At the moment, **current production capacity and quality standards continue to constrain global supply.** A streamlined mechanism for IP waivers can be useful, but the back and forth of waiver negotiations within the WTO will prove counterproductive if it distracts from necessary immediate and longer-term measures to contain the pandemic and prepare for future threats. In the short run, global vaccine production by existing producers should be ramped up with more global sharing, and at subsidized prices for poor countries. All countries can start by renouncing export restrictions that threaten global supply chains. Rich countries must also step up to provide financial support for vaccine purchases and immunization programs and also to directly share vaccine doses that are now in oversupply. Political leaders in the rich countries should explain to their citizens that aiding poor countries is in their own interest. That is because the pandemic is producing potentially more transmissible and deadlier variants that will inevitably spread worldwide. Over the long run, the global community needs to build a cooperative infrastructure to address the likelihood of the current pandemic lasting a long time, while preparing for future pandemics that could arrive with increasing frequency. In February 2021, the Group of Seven nations proposed a global health treaty that would help create a framework for more effective and coordinated pandemic response. Systematic worldwide genomic surveillance of current and potential pathogens is one aspect of such a treaty that would be imperative in order to inform public health policymakers and guide rapid vaccine development. Another useful step could be a vaccine investment and trade agreement, as suggested by Thomas J. Bollyky and Chad P. Bown, which would enable countries to coordinate vaccine development, supply chains, and production to eliminate beggar-thy-neighbor policies and speed vaccine development and deployment worldwide. The public-private partnerships underlying such an agreement might incorporate reform of the TRIPS patent and IP flexibilities acceptable to all parties. Unfortunately, finance ministers and central bank governors did little more than rehearse broad principles at their April 2021 Group of Twenty (G20) meeting, even as the COVID-19 outlook has deteriorated in India and elsewhere. Italy will host the next important international public health meeting on May 21, 2021 at a Global Health Summit in Rome. Participants may consider proposals by the High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, which the G20 established in January 2021 and which Dr. Okonjo-Iweala co-chairs. International engagement over patents and other IP protections will be immensely more beneficial as a component of much broader commitments to speed vaccine deployment in the near term and build a robust cooperative framework for ongoing pandemic response. By the time of their October leaders' meeting, G20 countries should be well along in implementing an ambitious global public health framework rather than squabbling over the narrower issue of IP protections.