### Framework

#### I value morality. The standard is maximizing well being.

#### All moral obligations revolve around potential consequences of actions

Sam Harris (NYT Bestselling author, BA in phil from Stanford, PhD in neuroscience from UCLA). The Moral Landscape: How Science Can Determine Human Values. 5 October 2010. p3. <http://notabenoid.com/book/22437/73890?Orig_page=3>

Here is my (consequentialist) starting point **all questions of value** (right and wrong, good and evil, etc.) **depend upon the possibility of experiencing such value. Without potential consequences at the level of experience**—happiness, suffering, joy, despair, etc.—**all talk of value is empty.** Therefore, **to say that an act is morally necessary**, or evil, or blameless, **is to****make** (tacit) **claims about its consequences in the lives of conscious creatures** (whether actual or potential). I am unaware of any interesting exception to this rule.Needless to say, **[For example,] if one is worried about pleasing God or His angels, this assumes that such** invisible **entities are** conscious(in some sense) and **cognizant of human behavior** It also generally assumes **[and] that it is possible to suffer their wrath or enjoy their approval**, either in this world or the world to come. **Even within religion**, therefore, **consequences and conscious states remain the foundation of all values.**

#### Utilitarianism comes first –approaches can *only* be ethical when they consider externalities.

Chandler ‘14

(David Chandler is Professor of International Relations at the Department of Politics and International Relations, University of Westminster – “Beyond good and evil: Ethics in a world of complexity” – International Politics, Vol. 51, No. 4 (2014), pp.441-457 – #CutWithKirby - Available at: http://www.davidchandler.org/wp-content/uploads/2014/10/International-Politics-Evil-PUBLISHED-2.pdf)

Self-reflexive ethics redistribute responsibility and emphasize the indirect, unintended and relational networks of complex causation. Collective problems are reconceived ontologically: as constitutive of communities and of political purpose. This is why many radical and critical voices in the West are drawn to the problems of 'side effects', of 'second-order' consequences - of a lack of knowledge of the emergent causality at play in the complex interconnections of the global world. The more these interconnections are revealed, though the work of self-reflexivity and self-reflection, the more ethical authority can be regained by governments and other agents of governance. We learn and learn again that we are responsible for the world, not because of our conscious choices or because our actions lacked the right ethical intention, but because the world's complexity is beyond our capacity to know and understand in advance. The unknowability of the outcomes of our action does not remove our ethical responsibility for our actions, it, in fact, heightens our responsibility for these second-order consequences or side effects. In a complex and interconnected world, few events or problems evade appropriation within this framing, providing an opportunity for recasting responsibility in these ways. The new ethics of indirect responsibility for market consequences can be seen (observed) clearly in the idea of environmental taxation, both state-enforced through interventions in the market and as taken up by both firms and individuals. The idea that we should pay a carbon tax on air travel is a leading example of this, in terms of governmental intervention, passing the burden of such problems on to 'unethical' consumers who are not reflexive enough to consider the impact of package holidays on the environment. At a broader level, the personalized ethico-political understanding that individuals should be responsible for and measure their own 'carbon footprint' shifts the emphasis from an understanding of broader inter-relations between modernity, the market and the environment to a much narrower understanding of personal indirect responsibility, linking all aspects of everyday decision making to the problems of global warming (see, for example, Marres, 2012). The shared responsibility for the Breivik murders is not different -ontologically - from the societally shared responsibility for global warming or other problematic appearances in the world. Through our actions and inactions we collectively constitute the frameworks in which others act and make decisions -failing to raise our voice against 'borderline racism' or extremism in a bar makes us indirectly responsible for acts of racism or extremism in the same way that failing to save water or minimize air travel makes us indirectly responsible for the melting polar ice caps.

#### Reject the “one percent” doctrine – it’s incoherent and makes policymaking impossible. Anything could potentially cause extinction – default to high probability impacts.

Meskill 9 — (David Meskill, professor at Colorado School of Mines and PhD from Harvard, “The "One Percent Doctrine" and Environmental Faith,” 12-9-2009, http://davidmeskill.blogspot.com/2009/12/one-percent-doctrine-and-environmental.html)

Tom Friedman's piece today in the Times on the environment (http://www.nytimes.com/2009/12/09/opinion/09friedman.html?\_r=1) is one of the flimsiest pieces by a major columnist that I can remember ever reading. He applies Cheney's "one percent doctrine" (which is similar to the environmentalists' "precautionary principle") to the risk of environmental Armageddon. But this doctrine is both intellectually incoherent and practically irrelevant. It is intellectually incoherent because it cannot be applied consistently in a world with many potential disaster scenarios. In addition to the global-warming risk, there's also the asteroid-hitting-the-earth risk, the terrorists-with-nuclear-weapons risk (Cheney's original scenario), the super-duper-pandemic risk, etc. Since each of these risks, on the "one percent doctrine," would deserve all of our attention, we cannot address all of them simultaneously. That is, even within the one-percent mentality, we'd have to begin prioritizing, making choices and trade-offs. But why then should we only make these trade-offs between responses to disaster scenarios? Why not also choose between them and other, much more cotidien [quotidian], things we value? Why treat the unlikely but cataclysmic event as somehow fundamentally different, something that cannot be integrated into all the other calculations we make?∂ And in fact, this is how we behave all the time. We get into our cars in order to buy a cup of coffee, even though there's some chance we will be killed on the way to the coffee shop. We are constantly risking death, if slightly, in order to pursue the things we value. Any creature that adopted the "precautionary principle" would sit at home - no, not even there, since there is some chance the building might collapse. That creature would neither be able to act, nor not act, since it would nowhere discover perfect safety.∂ Friedman's approach reminds me somehow of Pascal's wager - quasi-religious faith masquerading as rational deliberation (as Hans Albert has pointed out, Pascal's wager itself doesn't add up: there may be a God, in fact, but it may turn out that He dislikes, and even damns, people who believe in him because they've calculated it's in their best interest to do so). As my friend James points out, it's striking how descriptions of the environmental risk always describe the situation as if it were five to midnight. It must be near midnight, since otherwise there would be no need to act. But it can never be five \*past\* midnight, since then acting would be pointless and we might as well party like it was 2099. Many religious movements - for example the early Jesus movement - have exhibited precisely this combination of traits: the looming apocalypse, with the time (just barely) to take action.

### Contention 1: Access to Medicine

#### **Status quo pandemic management is plagued with inequality.**

Jenni Fink, 7-30-2021, "WHO warns world "blind to understanding" COVID spread, hurting ability to end pandemic," Newsweek, https://www.newsweek.com/who-warns-world-blind-understanding-covid-spread-hurting-ability-end-pandemic-1614722

A lack of testing for COVID-19 in parts of the world is preventing countries from having a clear picture of how the virus is spreading and therefore hurting the world's chances at fighting the virus and ending the pandemic, according to the World Health Organization. Health inequities throughout the world have plagued the global response to COVID-19 from the outset and WHO has pushed higher income countries to help lower income countries in the interest of ending the pandemic. Along with restricted access to vaccines, lower income countries have struggled to have sufficient testing, meaning the virus is likely going undetected in certain areas, further enabling its ability to spread. Low testing rates is "leaving the world blind to understanding where the disease is and how it's changing," Dr. Tedros Adhanom Ghebreyesus, director general of the WHO said on Friday during a press briefing. Without improving global testing rates, Ghebreyesus said the world can't "fight the disease" or mitigate the risk it poses to people around the globe. who blind covid spread cases On Friday, the World Health Organization warned the world is "blind" to how COVID-19 is spreading because of a lack of testing in certain places. WHO Director-General Tedros Adhanom Ghebreyesus attends a daily press briefing on the new coronavirus dubbed COVID-19, at the WHO headquaters on March 2, 2020, in Geneva. FABRICE COFFRINI//AFP/GETTY IMAGES NEWSWEEK NEWSLETTER SIGN-UP > One of Ghebreyesus' biggest frustrations with the pandemic response is the failure to evenly distribute the vaccine around the world. In some countries, like the United States and other higher-income nations, significant portions of the population have been vaccinated. While those large vaccinated populations help reduce the spread of the virus in some areas, other countries, especially those in Africa, haven't been able to vaccinate even 10 percent of their population. This puts the entire world at risk because when the virus is able to spread throughout communities it has the ability to mutate, thereby increasing the possibility that a mutation could evade the vaccines. It's a scenario public health officials have been warning about for months and Ghebreyesus said on Friday that "hard won gains are in jeopardy" or have already been lost because the virus has been able to spread. Nearly 30 countries have high or rising oxygen needs and the shortage of life-saving oxygen could lead to increased deaths. More than 196 million cases of COVID-19 have been reported around the world, according to a Johns Hopkins University tracker, and more than 4.2 million people have died. Ghebreyesus suspected the number of cases would top 200 million within the next two weeks and warned that health systems in many countries are being overwhelmed. Preventing hospitals from exceeding capacity was a massive concern when the pandemic first broke out and a year later, parts of the U.S. are having their health systems strained as the more transmissible Delta variant spreads. On Thursday, Arkansas Governor Asa Hutchinson declared a public health emergency that allows the state to bring in health care workers from outside Arkansas and makes it easier for retired health care workers and medical students to become licensed. The goal is to help alleviate stress on health care systems and Hutchinson said they've had people waiting in ambulances because there wasn't an open spot in a hospital. That strain will only become more exacerbated if a mutation occurs that evades the vaccine, as inoculations have proven effective at helping to keep people out of the hospital. Ghebreyesus warned that more variants will emerge if global access to vaccines and testing doesn't improve. "The pandemic will end when the world chooses to end it. It is in our hands. We have all the tools we need. We can prevent this disease. We can test for it and we can treat it," Ghebreyesus said.

#### Historical data proves our thesis– up to 80% of all new patents are not new drugs but old ones.

**Feldman 2** Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—**drug companies are focusing their time and effort extending the patent life of old products.** **This**, of course, **is not the innovation one would hope for**. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, **78% of the drugs associated with new patents** in the FDA’s records **were not new drugs** coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost **40% of all drugs** available on the market **created additional market barriers by having patents or exclusivities added** to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### IP protections are vital to resolve vaccine deficiencies. History disproves all pro patent arguments

Kumar, PhD, 7-12-21

(Rajeesh, Associate Fellow Manohar Parrikar Institute for Defence Studies and Analysis, https://www.idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721)

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).1 The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines. Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.2 It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal. On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.3 At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.4 The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.5 At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad. TRIPS and its Exceptions TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).6 In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).7 Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.8 Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver. The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.9 In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033. COVID-19 and TRIPS Waiver Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines. Vaccine Inequity According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11 Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021. Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14 This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution. TRIPS: Barrier to Equitable Health Care Access The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16 Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19 A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21 Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding. Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines. Source: Katharina Buchholz, “COVID-19 Vaccines Lift Pharma Company Profits”, Statista, 17 May 2021. One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally. India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing. Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

### Contention 2: Drug Prices

#### Intellectual property protections keep drug prices high.

Amin 18 Tahir Amin 6-27-2018 "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system" [High drug prices caused by US patent system, not 'foreign freeloaders' (cnbc.com)](https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html) <https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html> (co-founder of nonprofit I-MAK.org)//Elmer

**'Evergreening'** Instead of going to new medicines, the study finds that 74 percent of new patents during the decade went to drugs that already existed. It found that 80 percent of the nearly 100 best-selling drugs extended their exclusivity protections at least once, and 50 percent extended their patents more than once—with the effect of **prolonging** the **time before generics** could reach the market **as drug prices continued to rise**. The strategy is called “evergreening”: drug makers add on new patents to prolong a drug’s exclusivity, even when the additions aren’t fundamentally new, non-obvious, and useful as the law requires. One of the most expensive cancer drugs on the market, **Revlimid**®, is a case in point: **priced at** over $**125,000** per year of treatment, Celgene has sought **105 patents** on Revlimid®, many of which have been granted, extending its monopoly until the end of 2036. That gives the Revlimid® patent portfolio a lifespan of 40 years, which is being used to block or deter generic competitors from entering the market. But a recent I-MAK analysis finds that several of Celgene’s patents are mere add-ons—not fundamentally new to deserve a patent. And because of the thicket of patents around Revlimid®, **payers** are **projected to spend $45 billion** **in excess costs** on that drug alone as compared to what they could be paying if generic competitors were to enter when the first patent expires in 2019. Meanwhile, Celgene is also among the pharmaceuticals that have been recently scolded by the FDA for refusing to share samples with generic makers so they can test their own products against the brands in order to attain FDA approval. **In the absence of** genuine **competition** in the U.S. prescription drug market, **monopolies are yielding reckless pricing schemes and prohibitively expensive drugs** for Americans (and people around the world) who need them. In 2015, for example, U.S. Senators Wyden and Grassley found after an 18-month bipartisan investigation that the notorious $84,000 price tag for the hepatitis C drug made by Gilead was based on “a pricing and marketing strategy designed to maximize revenue with little concern for access or affordability.” Gilead’s subsequent hepatitis C drug Harvoni® was introduced to the market at a still higher cost of $94,500. Who benefits when drugs are priced so high? Not the 85 percent of Americans with hepatitis C who are still not able to afford treatment.

#### High Drug Prices forces patients to go underground for drugs.

Bryant 11 Clifton Bryant 2011 “The Routledge Handbook of Deviant Behaviour” (former professor of sociology at VA Tech)//Elmer

Now, the field of medicine is able to achieve seemingly miraculous results, through organ transplantation, reviving patients who have been "clinically" dead, and curing supposedly "incurable diseases." Medical miracles are not cheap, however, and the costs of medical care and drugs have risen (and continue to rise) at a near-astronomical rate. Consequently, neither private medical insurance plans nor Medicare will now cover certain procedures, treatments, and medicines. In the future, with continuing reform of the US healthcare system, even fewer procedures, treatments, and medications might will be covered. Certainly, some medical treatment will be "rationed," and particular categories of people (such as the elderly) may be systematically denied the coverage they need. As a result of all this, medical- and health-related crime and deviance will inevitably rise. Medical insurance, Medicare, and Medicaid fraud, which is already prevalent today, will increase exponentially. Smugglers will "bootleg" ever more pharmaceuticals into the US, and a large, thriving, nationwide black market will develop for those who cannot afford to buy uncovered medications. More medicines and diagnostic equipment will be stolen, and back- street medical procedures using such stolen equipment may well be offered for cash with no questions asked. Armed robberies of valuable pharmaceuticals from drug stores and super- markets will increase, too. Bribery to obtain insurance-uncovered or rationed medical care (or, indeed, any kind of medical care where demand exceeds supply) will likely mushroom. This is actually common in some countries around the world. Counterfeiting expensive pharmaceuticals will be prevalent, and medical frauds of all kinds will be very widespread. Many of these frauds will be directed at the elderly population as it continues to increase in size. The elderly will be particularly vulnerable because they are most likely to be denied coverage for certain medical procedures or treatments. For instance, private health insurance and Medicare will both refuse to cover a woman in her mid-80s for potentially life-saving heart-bypass surgery. As a result, she will be a prime candidate for victimization by medical fraud that offers her affordable, but bogus, treatment. There is already a thriving international black market in human organs (Schepper-Hughes 2009). Kidneys are obtained from poor individuals in impoverished countries for relatively modest sums of money. This cash allows the donors to purchase luxuries, such as a small automobile, educate their children, or simply sustain their families for a few months. The organs are sometimes transferred quickly to a hospital in the donor's own country for transplant surgery. But on other occasions they are transported to the US or another Western country. In the US, obtaining an organ for transplantation in this fashion is illegal. Nevertheless, the practice will undoubtedly increase greatly in the future. Where medical care and medicines become exorbitantly expensive, cheaper ways to obtain them, even when these are illicit, will be sought. Where there are shortages of medical care or medicines, perhaps because of rationing, other means of obtaining them, even if deviant, will surely be employed. As the cost and the difficulty of obtaining medical care and medicines increase, the implications for increased crime and deviance become almost limitless.

#### Counterfeit drugs kill millions.

Greenberger 20 Phyllis E. Greenberger 12-3-2020 "Counterfeit Medicines Kill People" <https://www.healthywomen.org/health-care-policy/counterfeit-medicines-kill-people/who-suffers-because-of-counterfeit-drugs> (HealthWomen’s Senior Vice President of Science & Health Policy)//Elmer

**Over 1 million people die each year from fake drugs**. COVID-19 Have you ever had a hard time getting a prescription filled? Or maybe you've had to wrestle with your insurance provider to get them to pay for a medication vital for your health? Worse, maybe you're one of the 27.5 million uninsured Americans who find it difficult to get health care, let alone obtain the prescription drugs you may need. If you've had any of these experiences, then perhaps you've turned to the internet to buy medications that would require a prescription. While legal online pharmacies do exist, many online pharmacies are fraudulent, selling counterfeit medications, and millions of people have fallen victim to these scammers. Make no mistake: **Counterfeit medicine is not real**. The **active ingredients** that help you stay healthy may be **missing** **or diluted** to levels that are no longer potent. This **can be dangerous and even life-threatening**, as people rely on their medications to keep them well, and sometimes even alive. Many counterfeit medicines aren't even drugs at all, but rather **snake oil cures that make people sick** — they may even **contain** **dangerous ingredients such as heavy metals, highway paint or even rat poison.** The World Health Organization (WHO) estimates that over 1 million people die each year from these substandard drugs. It's estimated that more than 10% of all pharmaceuticals in the global supply chain are counterfeit in normal times, and during COVID-19, the increased use of telehealth and the appearance of fraudulent doctors has led to a surge in drug fraud. In October of this year, Peter Pitts, president of the Center for Medicine in the Public Interest, a nonpartisan research organization, said pharmaceutical fakery was a "spreading cancer." Counterfeiting is a major problem that requires the federal government to step up to slow — and eventually prevent — its spread. It's also vital that consumers know exactly what's at stake when taking these fake drugs. Who suffers because of counterfeit drugs? Expensive prescription medications and generic drugs in nearly every therapeutic class may be counterfeited. Out of $4.3 billion worth of counterfeit medications seized between 2014 and 2016, 35% were marked as antibiotics. Some of the other most common culprits in counterfeit medicine are used to "treat" HIV/AIDS, erectile dysfunction and weight loss. No matter what condition or disease the counterfeit medication is intending to treat, the outcome can be disastrous. **Counterfeit medications exacerbate other existing health crises**. The United States, for example, is in the midst of an opioid epidemic that is killing 130 people per day. As of 2018, counterfeit drugs containing illegally imported fentanyl (a powerful opioid) had contributed to this tragedy by causing deaths in 26 states. The U.S. Department of Justice found that, in at least one case, these counterfeit drugs had been sold through a fraudulent online pharmacy.

### Contention 3: Innovtion

#### The current pharmaceutical industry is hindering innovation.

Mazzucato 18 [Mariana Mazzucato, 10-17-2018, "Opinion," Washington Post, https://www.washingtonpost.com/news/theworldpost/wp/2018/10/17/pharmaceutical/]/ISEE

The global pharmaceutical industry is no longer innovating. Research shows that 78 percent of patents approved by the U.S. Food and Drug Administration correspond to medications already on the market, while those disease areas not considered growth markets are ignored. From 2000 to 2011, only 4 percent of newly-approved products globally were designed to treat neglected diseases that affect lower- and middle-income countries. Part of the problem is how pharmaceuticals use the patent system. Instead of creating new drugs, they extend existing patents beyond the initial 20-year protection set by the United States and use gimmicks, such as overly-wide patents, to block knowledge creation and issue patents for what is essentially the same drug. Losec, for example, which is produced by AstraZeneca to treat heartburn and ulcers, was later tweaked and placed under a new name. This enabled the company to issue a new patent for the barely modified medication, effectively extending the company’s monopoly on this type of drug well beyond the period granted by the original patent. What’s more, while taxpayers are largely footing the bill for drug research, pharmaceuticals are reaping all the gains. Sofosbuvir, which treats hepatitis C, emerged from over 10 years of U.S. taxpayer-funded research — through the Department of Veterans Affairs and the National Institutes of Health. But when the private biotech company Gilead Sciences later acquired the drug, it priced a 12-week course of pills at $84,000 in the U.S. market. By the end of 2017, Sofosbuvir had generated over $50 billion in sales. Sofosbuvir is not an exception. The U.S. taxpayer has funded research for every single one of the 210 new drugs that the FDA approved between 2010-16. Yet the companies that have access to this research are increasingly viewing pharmaceuticals in the same way that banks view their financial product — opportunities for short-term returns. Large pharma companies spend more on share buybacks to boost share prices (and stock options — the main way that executives get paid) than on research and development. Pfizer, for example, spent $139 billion on share buybacks and dividends in the past decade — and just $82 billion on research and development in the same period. (The chief executive’s pay was also a reported $27.9 million in 2017.)

#### While patents first-glance may seem like a good idea, the problem is that many corporations use them to get rid of rivals, functionally monopolizing the market. As a result, medical innovation has slowed down tremendously.

**Gubby 19** [Hellen Gubby, professor at the Rotterdam School of Management at Amarus University with a PhD in law, 9-6-2019, "Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective," Wiley Online Library, https://onlinelibrary.wiley.com/doi/10.1111/1758-5899.12730]/Kankee

As the economy has largely shifted from industrial manufacturing to high-tech, life science and information processing industries, intellectual property has become more and more important. **Corporations have become increasingly aware** **of the potential of the patent**, **not just as a shield to protect against imitation, but as a strategic tool to block competition** **and dominate markets**. Patents have come to have a broader strategic function in which **innovation may only play a small part**. Although many patents do not produce any income: ‘In terms of strategy, though, the patent can be much more valuable’ (Macdonald, 2004, p. 143). Patent strategy is directly related to the business context. The Carnegie Mellon Survey of the US manufacturing sector in 1994 revealed that **firms often used patents as strategic tools, rather than** as simply **a means of protecting an invention from wrongful imitation** (Cohen et al., 2000). In their examination of motives to patent, Blind et al. (2009) recognised that, although protection from imitation was still the most important factor, ‘the importance of the strategic motives to patent are confirmed’ (Blind et al., 2006, p. 671). Patent strategies **The decision to patent has become** in part uncoupled from the original core purpose of the patent: **to protect an invention from unfair imitation by other market participants**. **Larger firms, with the capital assets to pay for the cost of patenting, use their patent portfolios strategically**. **Patents have become** useful as **bargaining chips; they provide leverage**. **Large patent portfolios are a means to get access to important co-operations or cross-licensing arrangements** (Blind et al., 2009, p. 431). Yet while building **the portfolio** requires enormous legal costs, it **contributes little to research incentives**. Furthermore, **these** **portfolios** can be used not just to oblige competitors to take licences, but also the terms of these licences can **restrict competitors to certain areas of technology** (Barton, 2000). **Larger firms** **can** afford to play the ‘wrap around’ strategy. Instead of **apply**ing **for** a single patent to cover an invention, other **patents** are filed **around the main patent**. **These** **related** **patents lock down the discrete features of an invention**. **The tactic hinders entry to the market**. **Competitors will be put to time, effort and cost to fight their way through all the relevant patents covering the technology**. Furthermore, **the chance** that **the competitor's invention may infringe one of the many claims in one of the many patents is high**. Not only can **damages be awarded for infringement, but also an injunction**. **Injunctions prevent the party accused of infringement from producing any products that require the use of the tech**nology **covered by the infringed patent and all infringing products are removed from the market.** Patents may be used simply to block competitors. **Using a patent as a blocking strategy is common practice** (Neuhäusler, 2012). **Defensive blocking is used to protect a firm's own freedom to operate**: **it does not want to be shut out by the patents of its rivals**. An offensive blocking strategy is where **patents are filed to cover products or processes that the firm does not intend to practice itself, but which could be viable alternatives to competitors**. **By patenting all conceivable alternatives, research by competitors that might threaten their own technological lead can be thwarted**. As in general **a patentee is under no obligation to license out its technology to another, the strategy can deter market entry or new product launch.** This offensive blocking of competitors by means of **patents**, ‘is clearly a case of the patent system being used for purposes other than for which it was originally intended’ (Blind, 2009, p. 436). However, both defensive and offensive **blocking** should be a policy concern, as they **can reduce economic** **efficiency**. **Defensive patenting increases cost to firms without necessarily producing any benefit and offensive patenting can reduce technological progress and increase consumer costs by reducing competition** (Thumm, 2004, p. 533). Using data from a large-scale survey of patent applications, Torrisi discovered that **a substantial share of patents remained unused and a substantial number of patent applications were filed to block other patents**. There were institutional differences; there were more unused patents in Japan and the EU than in the USA. Although cautious to make generalisations about unused patents, as some unused patents are there to ensure freedom to operate or simply because of management inefficiency, Torrisi et al. did conclude that: ‘[**o**]**ur results highlight that there might be substantial benefits that patent owners draw from being able to keep patent rights unused**. These would have to be balanced against possible harm imposed on other economic agents’ (Torrisi et al., 2016; , p. 1384). These strategies show a disconnect with the original purpose of the patent system. Patent strategies impact on innovation, and this in turn impacts on society. Concern was already expressed quite forcibly some years ago by Turner: Surely when the framers of the [US] Constitution empowered Congress to grant monopolies to ‘promote the progress of science and the useful arts’, they did not envision the beneficiaries of this grant would use it to bury new technologies to protect market share or capital investments. (Turner, 1998, p.209) Administrative failures Patent offices have been struggling to cope with the increasing number of patent applications: in 2017, more than 3 million patent applications were filed worldwide (WIPO, 2018). This influx has resulted in substantial application backlogs, with an increasingly long time between the patent filing and the patent grant: five years is not unusual. Complaints of poor quality control have been made concerning the US Patent and Trademark Office as well as the European Patent Office (Abbott, 2004; Mabey, 2010). The WIPO recognised a consistent upward trend in patent filings is putting patent offices under enormous pressure (WIPO, 2017, p. 13). Why are these administrative failings dangerous from a societal perspective? **Patents** **grant a monopoly that can impact innovative processes for 20 years or more**. **Patents have been granted that should not have been granted**. **When an overly broad patent is granted, this can block further innovation by others**. **Broad patents may mean** that **access to vital research is not available because** the **results** of that research **are covered by patent claims**. In particular, **broad** basic **patents on fundamental research** **can block and deter follow-on** **research**. **The incentive to innovate is reduced** (Barton, 2000; Henry and Stiglitz, 2010).1 Back in 1966, the societal implication of overly broad grants was expressed clearly by the US Supreme Court when it rejected a broad claim covering a group of chemicals: ‘**Such a patent may confer power to block off whole areas of scientific development** without compensating benefits to the public.’2

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

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