# Grapevine Prelim

### 1AC – Adv – Pandemics

#### Only the plan can solve covid access – inequalities heighten the risk of mutations and uneven development – neg objections miss the boat.

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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

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

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.

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.

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.

India’s Role in Ensuring Vaccine Equity India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver. India’s Vaccine Maitri initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.29 The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries’ regulatory bodies approve the vaccine. If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed. Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country’s generic medicine industry and boost India’s economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines’ production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics. Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's Vaccine Maitri initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region. In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

#### Studies show that vaccine distribution solve COVID. Reject any ev that don’t assume vaccine nationalism.

* Compares two models of HARs and LARs
* Allows for mutation simulations

**Princeton University 8/17** Princeton University. "Vaccine stockpiling by nations could lead to increase in COVID-19 cases, novel variant emergence, study finds." ScienceDaily. ScienceDaily, 17 August 2021. <www.sciencedaily.com/releases/2021/08/210817152552.htm>. //Nato

The allocation of COVID-19 vaccine between countries has thus far tended toward vaccine nationalism, wherein countries stockpile vaccines to prioritize access for their citizenry over equitable vaccine sharing. The extent of vaccine nationalism, however, may strongly impact global trajectories of COVID-19 case numbers and increase the potential emergence of novel variants, according to a Princeton University and McGill University study published Aug. 17 in the journal Science. "Certain countries such as Peru and South Africa that have had severe COVID-19 outbreaks have received few vaccines, while many doses have gone to countries experiencing comparatively milder pandemic impacts, either in terms of mortality or economic dislocation," said co-first author Caroline Wagner, an assistant professor of bioengineering at McGill University who previously served as a postdoctoral research associate in Princeton's High Meadows Environmental Institute (HMEI). "As expected, we have seen large decreases in case numbers in many regions with high vaccine access, yet infections are resurging in areas with low availability," said co-first author Chadi Saad-Roy, a Princeton graduate student in ecology and evolutionary biology and the Lewis-Sigler Institute for Integrative Genomics. "Our goal was to explore the effects of different vaccine-sharing schemes on the global persistence of COVID-19 infections -- as well as the possibility for the evolution of novel variants -- using mathematical models," Saad-Roy said. The researchers projected forward the incidence of COVID-19 cases under a range of vaccine dosing regimes, vaccination rates, and assumptions related to immune responses. They did so in two model regions: One with high access to vaccines -- a high-access region (HAR) -- and a low-access region (LAR). The models also allowed for the regions to be coupled either through case importation, or the evolution of a novel variant in one of the regions. "In this way, we could assess the dependence of our epidemiological projections on different immunological parameters, regional characteristics such as population size and local transmission rate, and our assumptions related to vaccine allocation," Wagner said. Overall, the study found that increased vaccine-sharing resulted in reduced case numbers in LARs. "Because it appears that vaccines are highly effective at reducing the clinical severity of infections, the public health implications of these reductions are very significant," said co-author Michael Mina, an assistant professor at the Harvard T. H. Chan School of Public Health. Senior author C. Jessica E. Metcalf, a Princeton associate professor of ecology and evolutionary biology and public affairs and associated faculty in HMEI, added: "High case numbers in unvaccinated populations will likely be associated with higher numbers of hospitalizations and larger clinical burdens compared to highly vaccinated populations." The authors also drew on a framework developed in their prior work to begin trying to quantify the potential for viral evolution under different vaccine sharing schemes. In their model, repeat infections in individuals with partial immunity -- either from an earlier infection or a vaccine -- may result in the evolution of novel variants. "Overall, the models predict that sustained elevated case numbers in LARs with limited vaccine availability will result in a high potential for viral evolution," said senior author Bryan Grenfell, Princeton's Kathryn Briger and Sarah Fenton Professor of Ecology and Evolutionary Biology and Public Affairs and an associated faculty member in HMEI. "As with our earlier work, the current study strongly underlines how important rapid, equitable global vaccine distribution is," Grenfell said. "In a plausible scenario where secondary infections in individuals who have previously been infected strongly contribute to viral evolution, unequal vaccine allocation appears particularly problematic." As the pandemic progresses, viral evolution may play an increasingly large role in sustaining transmission, said senior author Simon Levin, Princeton's James S. McDonnell Distinguished University Professor in Ecology and Evolutionary Biology and an associated faculty member in HMEI. "In particular, antigenically novel variants have the potential to threaten immunization efforts globally through several mechanisms," he said," including higher transmissibility, reduced vaccine efficacy, or immune escape." Saad-Roy added: "In this way, global vaccine coverage will reduce the clinical burden from novel variants, while also decreasing the likelihood that these variants emerge." There are additional considerations for vaccine equity beyond epidemiological and evolutionary ones, said co-author Ezekiel Emanuel, the Diane v.S. Levy and Robert M. Levy University Professor and co-director of the Healthcare Transformation Institute at the University of Pennsylvania. "Ethics also argues against countries stockpiling vaccines or allocating doses for boosters," Emanuel said. "This study strongly supports that ethical position showing that stockpiling will undermine global health."

#### Yes scale-up for covid.

Erfani et al 21 [Parsa; Lawrence Gostin; Vanessa Kerry; Parsa Erfani is a Fogarty Global Health Scholar at Harvard Medical School and the University of Global Health Equity. Lawrence Gostin is a professor at Georgetown University Law Center, director of the school’s O’Neill Institute for National and Global Health Law, and director of the World Health Organization Center on National and Global Health Law. Vanessa Kerry is a critical care physician at Massachusetts General Hospital, director of the Program for Global Public Policy at Harvard Medical School, and CEO of Seed Global Health, a nonprofit that trains health workers in countries with critical shortages; “Beyond a symbolic gesture: What’s needed to turn the IP waiver into Covid-19 vaccines,” STAT; 5/19/21; <https://www.statnews.com/2021/05/19/beyond-a-symbolic-gesture-whats-needed-to-turn-the-ip-waiver-into-covid-19-vaccines/>] Justin

Currently many idle suppliers can’t begin vaccine production until they upgrade and repurpose existing manufacturing capacity for new technology. Opponents often argue that this step is the true barrier to rapid scale-up. One high-profile detractor, BIO President and CEO Michelle McMurry-Heath, argues that “handing [needy countries] the blueprint to construct a kitchen that — in optimal conditions — can take a year to build will not help us stop the emergence of dangerous new Covid variants.”

This argument ignores two core truths: In many cases, manufacturing capacity needs only repurposing which can take mere months. And Covid-19, at the current global response and vaccination rates, will be a threat for years.

Both truths suggest that we pass the blueprint and build the kitchen.

Facilitating structures to transfer technology and capacity are already in place. The WHO launched the mRNA technology transfer hub model last month to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up vaccine manufacturing capacity. Scores of manufacturers in these countries have already expressed interest. This initiative, however, requires recipient manufacturers to acquire the IP necessary for mRNA technologies— which is currently missing.

#### Independently strategic patenting harms innovation incentives during pandemics – encourages reproduction of generics and decrease breakthroughs.

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As the COVID-19 pandemic is sweeping through the world, thousands of people urgently need access to affordable medicines. Based on past experience of treatments for other life-threatening diseases, there is a fear that access to any vaccines and treatment that may be developed in the future will be affected by patents, leading to unaffordably high prices. However, the problem of high drug prices is not new. It had been inflating healthcare budgets and posing a serious risk to the affordability and accessibility of medicines for society well before the pandemic.Footnote3 This problem is further exacerbated by the fact that, despite the alleged surge in investments into pharmaceutical R&D, current statistics indicate that the number of new breakthrough medicines is decreasing.Footnote4 On the other hand, the number of drugs that contain modifications of existing medicines is growing, demonstrating that pharmaceutical companies have been increasingly focusing their research on incremental drug development, rather than on breakthrough innovation.Footnote5 Various reasons for high drug prices and the growing focus on incremental innovation are put forward by pharmaceutical companies, including the complexity of drug discovery and development, as well as the expensive and lengthy regulatory procedures involved.Footnote6 While these reasons play an important role in this regard, some practices by pharmaceutical companies substantially contribute to this problem.Footnote7 In particular, pharmaceutical companies have been increasingly engaging in strategic patenting to delay or even block generic competition.Footnote8 These practices attracted the attention of the European Commission, which discussed them more than a decade ago in its 2009 Pharmaceutical Sector Inquiry Report.Footnote9 The Commission identified a series of patent strategies which it described as aiming “to extend the breadth and duration of [originators’] patent protection”Footnote10 and “to delay or block the market entry of generic medicine”.Footnote11 Such findings have fuelled debates as to whether these strategies may be deemed unlawful and violate EU competition rules, while also being justifiable business practices under patent law. Until today, no agreement has been reached either on the legality of these practices, or on an efficient legal tool to assess them. As a result, despite there being solid evidence that such strategies may block generic competition, allowing originators to maintain artificially high drug prices and preventing patients from accessing cheaper generics, they remain outside the ambit of the Commission’s activities. Instead, the Commission has been focusing on more straightforward patent-related practices, such as reverse payment agreements.

This article argues that strategic patenting by pharmaceutical companies requires a long-overdue intervention by competition authorities. It aims to attract their attention to the harmful effects of strategic patenting. Specifically, it will contest the argument traditionally put forward by originator pharmaceutical companies that the intervention of competition law into patenting practices will reduce their incentives to innovate. The paper will argue to the contrary that, along with a more immediate negative effect in the form of high drug prices that is widely explored in the literature,Footnote12 strategic patenting also affects dynamic competition by stifling innovation. Importantly, it will be explained that the assessment of the effect of this practice should focus not only on innovation by originators, but should also take a wider market perspective by assessing its effect on follow-on innovation by generic companies. The latter argument is often overlooked. The paper will outline the current approach to strategic patenting that considers this practice lawful, and will provide arguments for the intervention of competition law. This, in turn, will open the possibility for competition authorities to investigate this practice in order to prevent its harmful effect on innovation and consumer welfare. Moreover, while patent law may provide certain mechanisms to deal with strategic patenting, such as raising the bar for patentability of pharmaceutical follow-on inventions,Footnote13 these tools may not be effective in all cases. Therefore, as will be explained further, competition law may be a more suitable tool to address the negative effects of strategic patenting.Footnote14

The article will be organised as follows. It will first discuss the complex structure of the pharmaceutical industry, focusing on its key players for the purpose of this article: originators and generic companies. It will further explore patenting practices employed by pharmaceutical companies and will define the notion of strategic patenting. The article will then argue that the latter strategy is against the rationale of patent and competition laws, as it stifles competition by impairing incentives to innovate of both originators and generic companies. Finally, it will discuss the current approach to strategic patenting that considers this practice lawful, and will argue that it should be subject to scrutiny under the rules of competition law, to address its negative effects.

Pharmaceutical Innovation and Generic Competition in the Pharmaceutical Industry

The pharmaceutical industry is unique in its complexity. It is characterised by heavy state regulation and, sometimes, by the competing interests of the pharmaceutical business and society. It also involves multiple actors, including originators,Footnote15 marketing authorisation bodies, generic companies,Footnote16 doctors, pharmacies and patients. Each of them plays their part in the lengthy and complicated process of transforming a chemical compound into an effective and affordable medicine, which is then prescribed, dispensed and consumed. In these complex relationships, the two key players have crucial roles. On the one hand, originators play an important role in developing new and improved medicines for the benefit of society. On the other hand, generic companies benefit society by supplying cheaper equivalents of the originators’ medicines, which leads to the reduction of drug prices and facilitates access to affordable medicines. When the interests of these two players are kept in balance, benefits are maximised for society, which receives innovative and improved medicines, as well as timely access to generic drugs. However, if the balance swings towards one of the players, then society loses out, as there will be insufficient access to either innovative or affordable medicines. Therefore, both pharmaceutical innovation and generic competition must be duly incentivised and protected.

Moreover, these two elements of the pharmaceutical industry are constantly interacting and have a profound impact on each other. In particular, pharmaceutical innovation is the backbone of the pharmaceutical industry, in which originators play an important role. The process of drug development is long and complicated, requires significant investments, and bears considerable commercial risks.Footnote17 It is also highly regulated, including, among other things, the requirement for originators to obtain a special authorisation from a designated state authority to market a drug. Such marketing authorisations are granted to the originators only if they can prove that the drug is safe and effective, which typically requires lengthy and expensive clinical trials.Footnote18

In order to protect these significant efforts and investments, pharmaceutical companies rely heavily on the exclusivity granted by intellectual property rights, and in particular, patents.Footnote19 Patents provide a 20-year monopoly right, during which a pharmaceutical company enjoys market exclusivity and can charge a monopoly price for its products. Originators argue that strong patent protection is essential in order to recoup investments, as well as to incentivise them to engage in further innovation.Footnote20 Once such patent protection expires, however, other companies may develop generics of a branded drug, and start competing with the originator for the market. This is called generic competition. Generic drugs are bioequivalent versions of a branded drug that has lost its patent protection.Footnote21 It is estimated that the generic entry typically leads to, on average, an 80 per cent market share loss and a 20–30 per cent reduction of a drug price, with further price decreases with each additional generic entrant, leading, in some instances, to a fall in price of up to 90 per cent.Footnote22 A representative example of the effect of generic competition on the originators’ drug prices is the significant decrease in price and dramatic loss of profits by Eli Lilly. The expiration of a patent protecting its blockbusterFootnote23 antidepressant Prozac in 2001 resulted in a loss of almost 70 per cent of its market and $2.4 billion in annual U.S. sales.Footnote24 This effect of generic competition is beneficial for society, as it reduces the financial pressure on healthcare budgets and increases the accessibility of drugs.

Patenting Practices by Pharmaceutical Companies

As was mentioned above, generic competition is prevented during the life of a patent protecting an active compound of a drug (a so-called “basic” or “primary” patent).Footnote25 Such a basic patent covers an active ingredient itself and, therefore, provides the strongest protection for the product. Therefore, generic competition normally starts only after the basic patent expires, or if a generic company succeeds in invalidating it. While in the past pharmaceutical companies mainly protected their products with a single patent covering an active compound,Footnote26 they now increasingly seek additional patent protection on various aspects of a drugFootnote27 in order to protect their market position.Footnote28 Such additional patents are often called secondary patents.Footnote29 A pharmaceutical company may want to obtain secondary patents, which protect such aspects of a drug as, for example, its process of manufacture, formulation and/or specific form, etc. Therefore, even after the basic patent protecting an active compound expires, a drug may still be protected by other secondary patents. This may result in the extension of the scope and length of the protection of a product, especially if secondary patents have a later expiration date than a basic patent.Footnote30 This, in particular, may occur if, for example, the process of producing an active compound disclosed in the basic patent is sufficient only for reproducing this compound in a laboratory, but it is unsuitable for producing it on a large commercial scale.Footnote31 If the originator was able to secure a secondary patent that protects such a large scale manufacturing process, it would prevent generics from using this process for producing their generic versions of a drug; otherwise they would risk infringing this secondary patent.Footnote32 However, a unique feature of pharmaceuticals is that an active ingredient can be manufactured using different methods and processes, can exist in different forms or can be used in different formulations. Therefore, when a basic patent on an active ingredient expires, other companies can develop alternative methods of production, forms or formulations of this active compound and start competing with the originator company.Footnote33 While such patenting strategies by originators are lawful in principle, some of them may be problematic. In particular, in anticipation of the loss of patent protection, originators may engage in strategic patenting which artificially prevents generic competition and results in an extension of their market monopoly.Footnote34

Defining Strategic Patenting

In its Sector Inquiry Report, the European Commission explained that the drug development process consists of three main stages: (i) the R&D stage, which ends with the launch of a drug on the market; (ii) the period between the launch and the patent expiry; and (iii) the period after the patent expiration, when generics can enter the market.Footnote35 During the second stage, i.e. after the launch of a drug, originators seek to maximise their income from the product in order to recoup their R&D investments and earn profits before the commencement of generic competition.Footnote36 It is also during this stage that pharmaceutical companies seek to prolong their market exclusivity.

In recent years, pharmaceutical companies have been increasingly relying on the strategic use of the patent system to combat the pressure of generic competition. Such practices are often called “life cycle management” by originators and proponents of the practice. For example, as Burdon and Sloper explained, “[a] key element of any life cycle management strategy … is to extend patent protection beyond the basic patent term for as long as possible, by filing secondary patents which are effective to keep generics off the market”.Footnote37 However, critics have characterised the practice as “evergreening”,Footnote38 as it essentially evergreens the patent protection and the exclusivity of a product.Footnote39 For instance, Bansal et al. explain that evergreening “refers to different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly, particularly over highly lucrative ‘blockbuster’ drugs, by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the ‘parent’ patent”.Footnote40

During its investigation into the pharmaceutical industry, the European Commission found that the number of patents granted and pending applications significantly increases with the value of a drug, i.e. “blockbuster medicines can even be protected by up to nearly 100 INNFootnote41-specific EPO patented bundles and applications …, which in one particular case led to 1,300 patents and applications across all the EU Member States”.Footnote42 The Commission also found that the ratio of primary to secondary patents is 1:7, where the latter “mostly concern formulations, processes and non-formulation products…, such as salts, polymorphic forms, particles, solvates and hydrates”.Footnote43 As a result, the Commission concluded that the practice of “maximising patent coverage in such a way is the creation of a web of patents”, which affects the generics’ ability to “develop a generic version of the medicine in form of a salt, crystalline or amorphous form”, because it “would inevitably infringe a patent (for example, a patent for the relevant salt, crystalline or amorphous form of the medicine)”.Footnote44 Each of such patents would typically have a later expiration date, which effectively extends a period of market exclusivity beyond the expiration of a basic patent.Footnote45 In addition, most of these patents that protect such follow-on modifications are so-called “sleeping” patents, i.e. patents which a company has no intention of commercialising.Footnote46 Moreover, such modifications may provide little or no therapeutic benefits to the patient compared to the original drug.Footnote47 Nevertheless, such patents allow originators to secure the most efficient, broadest and longest possible protection for their successful products.Footnote48

The denser the web of secondary patents, the more difficult it is for generics to develop their generic equivalents, even if they know that only a few patents of a large portfolio would, in fact, be valid and infringed by their products.Footnote49 Despite such knowledge, it is impossible to be certain before introducing a generic whether this will be the case and, thus, whether the generic company will be subject to injunctions preventing the sale of their generic products.Footnote50 Such practice, therefore, provides an appreciable competitive advantage for originators by creating a significant legal and commercial uncertainty for generics in relation to the possibility of their market entry.Footnote51

This paper argues that such a strategic use of the patent system by pharmaceutical companies is against the shared goal of patent and competition laws of facilitating innovation for the benefit of society. As will be explained further, in addition to a more immediate negative effect in the form of high drug prices, strategic patenting may also impair innovation by reducing originators’ incentives to innovate, and affecting generics’ ability to develop alternative generic products. Strategic patenting, therefore, may enable originators to avoid competitive pressures by preventing generic competition without a need to engage in genuine innovation.

Strategic Patenting Contradicts the Rationale of the Patent System and Competition Law

In the competitive markets, the success of a company is based on its business performance.Footnote52 In order to compete on performance by “offering better quality and a wider choice of new and improved goods and services”Footnote53 firms must innovate. Realising the importance of protecting innovation, which is considered to be the main driver of economic growth,Footnote54 states have put in place various mechanisms to ensure a suitable environment for its advancement. These include granting the property rights to the results of innovation in the form of patents, as well as implementing competition law rules to stimulate dynamic competition.Footnote55

Specifically, one of the main justifications for the patent system is the encouragement of innovationFootnote56 that serves as an engine for economic growth and development.Footnote57 The patent system pursues this aim by offering the patent owners a period of exclusive rights as a reward for their innovative efforts and an incentive to engage in further innovation.Footnote58 Therefore, intellectual property rules, and patents in particular, are seen as an essential element of undistorted competition on the internal market.Footnote59 These exclusive rights are considered to be a necessary incentive to invest in R&D and innovation, particularly in such sectors as pharmaceuticals, where the R&D costs are high, but the costs of copying the R&D results are marginal.Footnote60 At the same time, the “innovation theory”, embodied in the EU competition law rules and policy, is designed to stimulate innovation by fostering competition on the markets.Footnote61 The competition law rules keep markets innovative by maintaining effective competition through preventing the foreclosure of markets and maintaining access to them.Footnote62 The rationale is that firms react to pressures of competition by continuously seeking to innovate.Footnote63 Therefore, patent and competition laws complement each other, as on the one hand, existing competition creates pressures on firms, forcing them to innovate, the so-called “stick”, while on the other hand, patent law provides a “carrot” in the form of the exclusive right, thus inducing innovators to innovate.Footnote64 These two bodies of laws are seen as “complementary efforts to promote an efficient marketplace and long-run, dynamic competition through innovation”.Footnote65 As the European Commission noted “both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof”.Footnote66 These two bodies of laws, therefore, have the same fundamental goal of enhancing innovation for the benefit of consumer welfare.

Importantly, patent and competition laws are designed to stimulate not only innovation of “pioneer” innovators, but they are also aimed at facilitating follow-on innovation.Footnote67 Patent law contains provisions that require inventors to disclose information about their inventions, as well as providing exceptions such as experimental use and compulsory licensing, which allow third parties to access the inventions still under patent protection.Footnote68 Therefore, along with pioneer innovators, the rationale of incentives to innovate in patent law also applies to follow-on innovators, balancing the interests of these two types of inventors.Footnote69 Similarly, competition law aims at stimulating all types of innovation, including follow-on innovation.

On the other hand, EU competition law proscribes practices that reduce incentives to innovate both for “pioneer” and follow-on innovators. This is enshrined in Art. 102(b) TFEU, which prohibits abuses that consist of, inter alia, limiting technological development. For example, in AstraZeneca the General Court considered that the company’s practice of misusing the patent system had the potential of reducing its incentives to innovate and was anticompetitive.Footnote70 In MagillFootnote71 and Microsoft,Footnote72 the courts found that the IP rights owners abused their dominant positions by blocking innovation of their potential competitors. More recently, several decisions by the European Commission also emphasised the importance of protecting innovation. In January 2018, the Commission fined QualcommFootnote73 €997 million for abusing its market dominance in LTEFootnote74 baseband chipsets.Footnote75 The Commission considered that the exclusivity payments that Qualcomm paid to Apple denied rivals the possibility to compete on the merits, and deprived European consumers of genuine choice and innovation.Footnote76 Furthermore, in July 2018, the Commission found in Google Android that Google abused its dominant position, and fined the company €4.34 billion for anticompetitive restrictions it had imposed on mobile device manufacturers and network operators to strengthen its dominant position in general internet search.Footnote77 The Commission considered that Google’s restrictive practices denied other companies the chance to compete on the merits and innovate.Footnote78 Finally, in 2017 the Commission issued its decision, in which it took the view that Amazon abused its dominant positions on the markets for the retail distribution of e-books by inserting the so-called “parity clauses” in the agreements with its e-book suppliers.Footnote79 It concluded that these clauses had the potential of reducing the incentives to innovate both by e-book suppliers and retailers.Footnote80

These decisions demonstrate that the European Commission recognises the fundamental importance of protecting innovation. They confirm that strategies that are capable of stifling innovation and reducing the incentives to innovate may constitute an abuse of dominance under Art. 102 TFEU. It is argued in this article that, along with the practices condemned by the Commission in the decisions discussed above, strategic patenting can also harm innovation by impairing incentives to innovate of both originators and generic companies, and therefore should raise competition law concerns.

Strategic Patenting Impairs Originators’ Incentives to Innovate

While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish.

Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84

the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share.

In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85

Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92

Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93

A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly.

Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns.

Strategic Patenting Impairs Follow-on Innovation of Generic Companies

Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators:

The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97

Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100

As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns.

#### Corona escalates security threats that cause extinction – cooperation thesis is wrong.

Recna 21 [Research Center for Nuclear Weapon Abolition; Nagasaki, Japan; “Pandemic Futures and Nuclear Weapon Risks: The Nagasaki 75th Anniversary pandemic-nuclear nexus scenarios final report,” Journal for Peace and Nuclear Disarmament; 5/28/21; <https://www.tandfonline.com/doi/full/10.1080/25751654.2021.1890867>] Justin

The Challenge: Multiple Existential Threats

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

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

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

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

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

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

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

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

#### Even if COVID doesn’t cause extinction – the aff sets precedent to solve for future pandemics which unchecked solves extinction.

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling. The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals. The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually. Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recently estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction. The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.z Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon. Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced. The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

### 1AC – Plan

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

#### Enforcement through eliminating product patents solve- empirically proven through India to lower prices, create generics, and foster innovation

He 2019 He, Juan (Graduate Student Graduate School at Shenzhen Tsinghua University) . "Indian Patent Law and Its Impact on the Pharmaceutical Industry: What Can China Learn from India?." Innovation, Economic Development, and Intellectual Property in India and China. Springer, Singapore, 2019. 251-269./SJKS

The *Report on the Revision of the Patent Law* submitted by the Patent Law Amendment Commission in 1959,[34](https://link.springer.com/chapter/10.1007/978-981-13-8102-7_11#Fn34) which was led by Shri Justice N. Rajagopala Ayyangar, pointed out that at that time foreigners held 80% to 90% of India’s patents, of which 90% of the patented products were not manufactured in the Indian territory. Foreign companies could block the production of their patented drugs in India, causing the stagnation of the Indian domestic pharmaceutical industry. Thus, the Commission believed that the patent system had been used by multinational corporations to monopolize the market, especially in the food, pharmaceutical, and chemical industries. Market monopolies also led to high product prices. Therefore, the Commission recommended that only methods or processes in the abovementioned fields be patentable, as opposed to the Indian Patents and Designs Act of 1911, which granted patent to both product and process inventions in the pharmaceutical sector. This suggestion was adopted by the Patents Act of 1970, which has laid the foundation for the boom in India’s generic drug industry. According to the Patents Act of 1970, no patent shall be granted in respect of claims for substances intended for use or capable of being used as medicine or drug or relating to substances prepared or produced by chemical processes. The reason that the Patents Act of 1970 only grants method patents in the fields of pharmaceuticals and chemicals is because product patents have an inhibitory effect on other related research, as they can prevent others from obtaining the same products through different methods. Once product patents are granted to drugs, patentees can control the production of patented drugs and thereby unreasonably raise the prices of essential medicines.[35](https://link.springer.com/chapter/10.1007/978-981-13-8102-7_11#Fn35) Thus, the rejection of the drug product patents guaranteed that India’s generic companies could produce drugs with the same or similar composition through reverse engineering and avoid being accused of infringement. India denied product patents in the pharmaceutical sector until the expiration of the transition period of the TRIPS Agreement on January 1, 2005. The rejection of product patents in the pharmaceutical sector for more than 30 years has created an opportunity for the development of the generic drug industry in India. After comparing drug prices among India, the United Kingdom, Malaysia, and Nigeria, before and after the Indian Patents Act of 1970, R.B. Saxena, consultant at the Indian Council for Research on International Economic Relations, found[36](https://link.springer.com/chapter/10.1007/978-981-13-8102-7_11#Fn36) that the prices of pharmaceutical products in India were highest before the enactment of the Patents Act of 1970 and that in 1987 the prices in India for commonly used drugs, such as analgin tablets, doxycycline capsules, diazepam tablets, and metronidazole tablets, were low compared to those of other countries. The research also found that some of the important new drugs could be introduced into India with a time lag ranging between only 4 and 6 years. Thus, Saxena pointed out that the changes relating to process patenting incorporated in the Indian Patents Act of 1970 had benefited Indian consumers in terms of prices paid for drugs and medicines and, meanwhile, it also became possible to produce many new pharmaceutical products in India much faster than what could have been otherwise.

#### The plan is critical to boosting WTO legitimacy.

Navnit 21 [Brajendra; Ambassador and Permanent Representative of India to WTO; “Science has delivered, will the WTO deliver?” Helsinki Times; 1/18/21; <https://www.helsinkitimes.fi/columns/columns/viewpoint/18561-science-has-delivered-will-the-wto-deliver.html>] Justin

TRIPS waiver proposal from India, South Africa and other members

A proposal by India, South Africa and eight other countries calls on the World Trade Organisation (WTO) to exempt member countries from enforcing some patents, and other Intellectual Property (IP) rights under the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPS, for a limited period of time.

It is to ensure that IPRs do not restrict the rapid scaling- up of manufacturing of COVID-19 vaccines and treatments. While a few members have raised concerns about the proposal, a large proportion of the WTO membership supports the proposal. It has also received the backing of various international organizations, multilateral agencies and global civil society.

Unprecedented times call for unorthodox measures. We saw this in the efficacy of strict lockdowns for a limited period, as a policy intervention, in curtailing the spread of the pandemic.International Monetary Fund (IMF) in its October 2020 edition of World Economic Outlook states “…However, the risk of worse growth outcomes than projected remains sizable. If the virus resurges, progress on treatments and vaccines is slower than anticipated, or countries’ access to them remains unequal, economic activity could be lower than expected, with renewed social distancing and tighter lockdowns”. The situation appears to be grimmer than predicted, we have already lost 7% of economic output from the baseline scenario projected in 2019. It translates to a loss of more than USD 6 trillion of global GDP. Even a 1% improvement in global GDP from the baseline scenario will add more than USD 800 billion in global output, offsetting the loss certainly of a much lower order to a sector of economy on account of the Waiver.

"While making the vaccines available was a test of science, making them accessible and affordable is going to be a test of humanity"

Merely a signal to ensure timely and affordable access to vaccines and treatments will work as a big confidence booster for demand revival in the economy. With the emergence of successful vaccines, there appears to be some hope on the horizon. But how will these be made accessible and affordable to global population? The fundamental question is whether there will be enough of Covid-19 vaccines to go around. As things stand, even the most optimistic scenarios today cannot assure access to Covid-19 vaccines and therapeutics for the majority of the population, in rich as well as poor countries, by the end of 2021. All the members of the WTO have agreed on one account that there is an urgent need to scale-up the manufacturing capacity for vaccines and therapeutics to meet the massive global needs. The TRIPS Waiver Proposal seeks to fulfil this need by ensuring that IP barriers do not come in the way of such scaling up of manufacturing capacity.

Why existing flexibilities under the TRIPS Agreement are not enough

The existing flexibilities under the TRIPS Agreement are not adequate as these were not designed keeping pandemics in mind. Compulsory licenses are issued on a country by country, case by case and product by product basis, where every jurisdiction with an IP regime would have to issue separate compulsory licenses, practically making collaboration among countries extremely onerous. While we encourage the use of TRIPS flexibilities, the same are time-consuming and cumbersome to implement. Hence, only their use cannot ensure the timely access of affordable vaccines and treatments. Similarly, we have not seen a very encouraging progress on WHO’s Covid19-Technology Access Pool or the C-TAP initiative, which encourages voluntary contribution of IP, technology and data to support the global sharing and scale-up of the manufacturing of COVID- 19 medical products. Voluntary Licenses, even where they exist, are shrouded in secrecy. Their terms and conditions are not transparent. Their scope is limited to specific amounts or for a limited subset of countries, thereby encouraging nationalism rather than true international collaboration.

Why is there a need to go beyond existing global cooperation initiatives?

Global cooperation initiatives such as the COVAX Mechanism and the ACT-Accelerator are inadequate to meet the massive global needs of 7.8 billion people. The ACT-A initiative aims to procure 2 billion doses of vaccines by the end of next year and distribute them fairly around the world. With a two-dose regime, however, this will only cover 1 billion people. That means that even if ACT-A is fully financed and successful, which is not the case presently, there would not be enough vaccines for the majority of the global population.

Past experience

During the initial few months of the current pandemic, we have seen that shelves were emptied by those who had access to masks, PPEs, sanitizers, gloves and other essential Covid-19 items even without their immediate need. The same should not happen to vaccines. Eventually, the world was able to ramp up manufacturing of Covid-19 essentials as there were no IP barriers hindering that. At present, we need the same pooling of IP rights and know-how for scaling up the manufacturing of vaccines and treatments, which unfortunately has not been forthcoming, necessitating the need for the Waiver.

It is the pandemic – an extraordinary, once in a lifetime event – that has mobilized the collaboration of multiple stakeholders. It is knowledge and skills held by scientists, researchers, public health experts and universities that have enabled the cross-country collaborations and enormous public funding that has facilitated the development of vaccines in record time – and not alone IP!

Way forward

The TRIPS waiver proposal is a targeted and proportionate response to the exceptional public health emergency that the world faces today. Such a Waiver is well-within the provisions of Article IX of the Marrakesh Agreement which established the WTO. It can help in ensuring that human lives are not lost for want of a timely and affordable access to vaccines. The adoption of the Waiver will also re-establish WTO’s credibility and show that multilateral trading system continues to be relevant and can deliver in times of a crisis. Now is the time for WTO members to act and adopt the Waiver to save lives and help in getting the economy back on the revival path quickly.

While making the vaccines available was a test of science, making them accessible and affordable is going to be a test of humanity. History should remember us for the “AAA rating” i.e. for Availability, Accessibility and Affordability of Covid19 vaccines and treatments and not for a single “A rating” for Availability only. Our future generations deserve nothing less.

#### WTO cred solves wars that go nuclear.

Hamann 09 [Georgia; 2009; J.D. Candidate, Vanderbilt University Law School; “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System,” VANDERBILT JOURNAL OF TRANSNATIONAL LAW, http://www.jogoremoto.pt/docs/extra/duqJ53.pdf] Justin

Both Antigua and the U.S. claimed the resolution of the arbitration as a victory.99 In reality, the decision reached a midpoint between the respective countries’ positions, establishing a victory for the evolution of the international trading system itself. Voluntary compliance with WTO rules and procedures is of the utmost importance to the international trading system.100 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO as a cohesive force and arbiter of disputes that likely will become more frequent and injurious.101 The work of the WTO cannot be overstated in a nuclear-armed world, as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance.102 Demagogues in the Unites States may decry the rise of China as a geopolitical threat,103 and extremists in Russia may play dangerous games of brinksmanship with other great powers, but trade keeps politicians’ fingers off “the button.”104 The WTO offers an astounding rate of compliance for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO.105 In order to promote voluntary compliance, the WTO must maintain a high level of credibility.106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions.107 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization’s credibility.108

### 1AC – Framing

#### The standard is maximizing life and biological death outweighs— A] agents can’t act if they fear for their bodily security. B] It’s is a prerequisite to any alternative advocacy.

#### Prefer additionally

#### 1] Actor spec – governments must use util because they don’t have intentions and are constantly dealing with tradeoffs—takes out calc indicts since they are empirical denied.

#### 2] Extinction Outweighs

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

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

#### 3] Physicalism is true and leads to util – ignore non-material circumstances.

Papineau 9 Papineau, David, "Naturalism", The Stanford Encyclopedia of Philosophy (Spring 2009 Edition), Edward N. Zalta (ed.), URL = <http://plato.stanford.edu/archives/spr2009/entries/naturalism/>.

In the middle of the nineteenth century the conservation of kinetic plus potential energy came to be accepted as a basic principle of physics (Elkana 1974). In itself this does not rule out distinct mental or vital forces, for there is no reason why such forces should not be ‘conservative’, operating in such a way as to compensate losses of kinetic energy by gains in potential energy and vice versa. (The term ‘nervous energy’ is a relic of the widespread late nineteenth-century assumption that mental processes store up a species of potential energy that is then released in action.) However, the **conservation of energy** does **imply**  that any such special forces must be governed by strict **deterministic laws:** if mental or vital forces arose spontaneously, then there would be nothing to **ensure** that they never led to energy increases. During the course of the twentieth century received scientific opinion became even more restrictive about possible causes of physical effects, and came to reject sui generis mental or vital causes, even of a law-governed and predictable kind. Detailed physiological research, especially into nerve cells, gave no indication of any physical effects that cannot be explained in terms of basic physical forces **that** also **occur outside** living bodies. By the middle of the twentieth century, belief in sui generis mental or vital forces had become a minority view. **This led to** the widespread acceptance of the doctrine now known as the‘causal closure’or the ‘causal completeness’ of the physical realm, according to which **all** physical **effects** **can be accounted for by** basicphysical causes (where ‘physical’ can be understood as referring to some list of fundamental forces) non-physical causes of physical effects. As a result, the default philosophical view was a non-naturalist interactive pluralism which recognized a wide range of such non-physical influences, including spontaneous mental influences (or ‘determinations of the soul’ as they would then have been called). The nineteenth-century discovery of the conservation of energy continued to allow that sui generis non-physical forces can interact with the physical world, but required that they be governed by strict force laws. This gave rise to an initial wave of naturalist doctrines around the beginning of the twentieth century. Sui generis mental forces were still widely accepted, but an extensive philosophical debate about the significance of the conservation of energy led to a widespread recognition that any such mental forces would need to be law-governed and thus amenable to scientific investigation along with more familiar physical forces.[5] By the middle of the twentieth century, the acceptance of the casual closure of the physical realm led to even stronger naturalist views. The causal closure thesis implies that any **mental** and biological causes **must** themselves **be physical**ly constituted**, if they are to produce** physical **effects.** It thus gives rise to a particularly strong form ofontological naturalism, namely the physicalist doctrine that any state that has physical effects must itself be physical. From the 1950s onwards, philosophers began to formulate arguments for ontological physicalism. Some of these arguments appealed explicitly to the causal closure of the physical realm (Feigl 1958, Oppenheim and Putnam 1958). In other cases, the reliance on causal closure lay below the surface. However, it is not hard to see that even in these latter cases the causal closure thesis played a crucial role. Thus, for example, consider J.J.C. Smart's (1958) thought that we should identify mental states with brain states, for otherwise those mental states would be "nomological danglers" which play no role in the explanation of behaviour. Or take David Lewis's (1966) and David Armstrong's (1968) argument that, since mental states are picked out by their causal roles, and since we know that physical states play these roles, mental states must be identical with those physical states. Again, consider Donald Davidson's (1970) argument that, since the only laws governing behaviour are those connecting behaviour with physical antecedents, mental events can only be causes of behaviour if they are identical with those physical antecedents. At first sight, it may not be obvious that these arguments require the causal closure thesis. But a moment's thought will show that none of these arguments would remain cogent if the closure thesis were not true, and that some physical effects (the movement of matter in arms, perhaps, or the firings of the motor neurones which instigate those movements) were not determined by prior physical causes at all, but by sui generis mental causes. Sometimes it is suggested that the indeterminism of modern quantum mechanics creates room for sui generis non-physical causes to influence the physical world. However, even if quantum mechanics implies that some physical effects are themselves undetermined, it provides no reason to doubt a quantum version of the causal closure thesis, to the effect that the chances of those effects are fully fixed by prior physical circumstances. And this alone is enough to rule out sui generis non-physical causes. For such sui generis causes, if they are to be genuinely efficiacious, must presumably make an independent difference to the chances of physical effects, and this in itself would be inconsistent with the quantum causal closure claim that such chances are already fixed by prior physical circumstances. Once more, it seems that anything that makes a difference to the physical realm must itself be physical. Even if it is agreed that anything with physical effects must in some sense be physical, there is plenty of room to debate exactly what ontologically naturalist doctrines follow. The causal closure thesis says that (the chance of) every physical effect is fixed by a fully physical prior history. So, to avoid an unacceptable proliferation of causes, any prima facie non-physical cause of a physical effect will need to be included in that physical history. But what exactly does this require? The contemporary literature offers a wide range of answers to this question. In part the issue hinges on the ontological status of causes. Some philosophers think of causes as particular events, considered in abstraction from any properties they may possess (Davidson 1980). Given this view of causation, a mental or other apparently non-physical cause will be the same as some physical cause as long as it is constituted by the same particular (or ‘token’) event. For example, a given feeling and a given brain event will count as the same cause as long as they are constituted by the same token event. However, it is widely agreed that this kind of ‘token identity’ on its own fails to ensure that prima facie non-physical causes can make any real difference to physical effects. To see why, note that token identity is a very weak doctrine: it does not imply any relationship at all between the properties involved in the physical and non-physical cause; it is enough that the same particular entity should possess both these properties. Compare the way in which an apple's shape and colour are both possessed by the same particular thing, namely that apple. It seems wrong to conclude on this account that the apple's colour causes what its shape causes. Similarly, it seems unwarranted to conclude that someone's feelings cause what that person's neuronal discharges cause, simply on the grounds that these are both aspects of the same particular event. This could be true, and yet the mental property of the event could be entirely irrelevant to any subsequent physical effects. Token identity on its own thus seems to leave it open that the mental and other prima facie non-physical properties are ‘epiphenomenal’, exerting no real influence on effects that are already fixed by physical processes (Honderich 1982, Yalowitz 2006 Section 6, Robb and Heil 2005 Section 5). These considerations argue that causation depends on properties as well as particulars. There are various accounts of causation that respect this requirement, the differences between which do not matter for present purposes. The important point is that, if mental and other prima facie non-physical causes are to be equated with physical causes, [any] non-physical properties must somehow be constituted by physical properties. If your anger is to cause what your brain state causes, the property of being angry cannot be ontologically independent of the relevant brain properties. So much is agreed by nearly all contemporary naturalists. At this point, however, consensus ends. One school holds that epiphenomenalism can only be avoided by type-identity, the strict identity of the relevant prima facie non-physical properties with physical properties. On the other side stand ‘non-reductive’ physicalists, who hold that the causal efficacy of non-physical properties will be respected as long as they are ‘realized by’ physical properties, even if they are not reductively identified with them. Type-identity is the most obvious way to ensure that non-physical and physical causes coincide: if exactly the same particulars and properties comprise a non-physical and a physical cause, the two causes will certainly themselves be fully identical. Still, type-identity is a very strong doctrine. Type identity about thoughts, for example, would imply that the property of thinking about the square root of two is identical with some physical property. And this seems highly implausible. Even if all human beings with this thought must be distinguished by some common physical property of their brains—which itself seems highly unlikely—there remains the argument that other life-forms, or intelligent androids, will also be able to think about the square root of two, even though their brains may share no significant physical properties with ours (cf. Bickle 2006). This ‘variable realization’ argument has led many philosophers to seek an alternative way of reconciling the efficacy of non-physical causes with the causal closure thesis, one which does not require the strict identity of non-physical and physical properties. The general idea of this ‘non-reductive physicalism’ is to allow that a given non-physical property can be ‘realized’ by different physical properties in different cases. There are various ways of filling out this idea. A common feature is the requirement that non-physical properties should metaphysically supervene on physical properties, in the sense that any two beings who share all physical properties will necessarily share the same non-physical properties, even though the physical properties which so realize the non-physical ones can be different in different beings. This arguably ensures that nothing more is required for any specific instantiation of a non-physical property than its physical realization—even God could not have created your brain states without thereby creating your feelings—yet avoids any reductive identification of non-physical properties with physical ones. (This is a rough sketch of the supervenience formulation of physicalism. For more see Stoljar 2001 Sections 2 and 3.) Some philosophers object that non-reductive physicalism does not in fact satisfy the original motivation for physicalism, since it fails to reconcile the efficacy of non-physical causes with the causal closure thesis (Kim 1993. Robb and Heil 2005 Section 6). According to non-reductive physicalism, prima facie non-physical properties are not type-identical with any strictly physical properties, even though they supervene on them. However, if causes are in some way property-involving, this then seems to imply that any prima facie non-physical cause will be distinct from any physical cause. Opponents of non-reductive physicalism object that this gives us an unacceptable proliferation of causes for the physical effects of non-physical causes—both the physical cause implied by the causal closure thesis and the distinct non-physical cause. In response, advocates of non-reductive physicalism respond that there is nothing wrong with such an apparent duplication of causes if it is also specified that the latter metaphysically supervene on the former. The issue here hinges on the acceptability of different kinds of overdetermination (Bennett 2003). All can agree that it would be absurd if the physical effects of non-physical causes always had two completely independent causes. This much was assumed by the original causal argument for physicalism, which reasoned that no sui generis non-physical state of affairs can cause some effect that already has a full physical cause. However, even if ‘strong overdetermination’ by two ontologically independent causes is so ruled out, this does not necessarily preclude ‘weak overdetermination’ by both a physical cause and a metaphysically supervenient non-physical cause. Advocates of non-reductive physicalism argue that this kind of overdetermination is benign, on the grounds that the two causes are not ontologically distinct—the non-physical cause isn't genuinely additional to the physical cause (nothing more is needed for your feelings than your brain states). There is room to query whether non-reductive physicalism amounts to a substantial form of naturalism. After all, the requirement that some category of properties metaphysically supervenes on physical properties is not a strong one. A very wide range of properties would seem intuitively to satisfy this requirement, including moral and aesthetic properties, along with any mental, biological, and social properties. (Can two physically identical things be different with respect to wickedness or beauty?) Supervenience on the physical realm is thus a far weaker requirement than that some property should enter into natural laws, say, or be analysable by the methods of the natural sciences. Indeed some philosophers are explicitly anti-naturalist about categories that they allow to supervene on the physical—we need only think of G.E. Moore on moral properties, or Donald Davidson and his followers on mental properties (Moore 1903, Davidson 1980). In response, those of naturalist sympathies are likely to point out that any viable response to the argument from causal closure will require more than metaphysical supervenience alone (Horgan 1993, Wilson 1999). Supervenience is at least necessary, if non-reductive physicalists are to avoid the absurdity of strong overdetermination. But something more than mere supervenience is arguably needed if non-reductive physicalists are to make good their claim that non-physical states cause the physical effects that their realizers cause. Metaphysical supervenience alone does not ensure this. (Suppose ricketiness, in a car, is defined as the property of having some loose part. Then ricketiness will supervene on physical properties. In a given car, it may be realized by a disconnected wire between ignition and starter motor.This disconnected wire will cause this car not to start. But it doesn't follow that this car's then not starting will be caused by its property of ricketiness. Most rickety cars start perfectly well.) So it looks as if the causal closure argument requires not only that non-physical properties metaphysically supervene on physical properties, but that they be natural in some stronger sense, so as to qualify as causes of those properties' effects. It is a much-discussed issue how this demand can be satisfied. Some philosophers seek to meet it by offering a further account of the nature of the relevant non-physical properties, for example, that they are second-order role properties whose presence is constituted by some first-order property with a specified causal role (Levin 2004). Others suggest that the crucial feature is how these properties feature in certain laws (Fodor 1974) or alternatively the degree of their explanatory relevance to physical effects (Yablo 1992). And reductive physicalists will insist that the demand can only be met by type-identifying prima-facie non-physical properties with physical properties after all.[6] There is no agreed view on the requirements for prima facie non-physical properties to have physical effects. This difficult issue hinges, inter alia, on the nature of the causal relation itself, and it would take us too far afield to pursue it further here. For the purpose of this entry, we need only note that the causal closure argument seems to require that properties with physical effects must be ‘natural’ in some sense that is stronger than metaphysical supervenience on physical properties. Beyond that, we can leave it open exactly what this extra strength requires. Some philosophers hold that mental states escape the causal argument, on the grounds that mental states cause actions rather than any physical effects. Actions are not part of the subject matter of the physical sciences, and so a fortiori not the kinds of effects guaranteed to have physical causes by any casual closure thesis. So there is no reason, according to this line of thought, to suppose that the status of mental states as causes of actions is threatened by physics, nor therefore any reason to think that mental states must in some sense be realized by physical states (Hornsby 1997, Sturgeon 1998). The obvious problem with this line of argument is that actions aren't the only effects of mental states. On occasion mental states also cause unequivocally physical effects. Fast Eddie Felsen's desire to move a pool ball in a certain direction will characteristically have just that effect. And now the causal closure argument bites once more. The snooker ball's motion has a purely physical cause, by the causal closure thesis. This will pre-empt Fast Eddie's desire as a cause of that motion, unless that desire is in some sense physically realized (Balog 1999, Witmer 2000). Other philosophers have a different reason for saying that mental states, or more particularly conscious mental states, don't have physical effects. They think that there are strong independent arguments to show that conscious states can't possibly supervene metaphysically on physical states. Putting this together with the closure claim that physical effects always have physical causes, and abjuring the idea that the physical effects of conscious causes are strongly overdetermined by both a physical cause and an ontologically independent conscious cause, they conclude that conscious states must be ‘epiphenomenal’, lacking any power to causally influence the physical realm (Jackson 1981; 1985. See also Chalmers 1995).[7] The rejection of physicalism about conscious properties certainly has the backing of intuition. (Don't zombies—beings who are physically exactly like humans but have no conscious life—seem intuitively possible?) However, whether this intuition can be parlayed into a sound argument is a highly controversial issue, and one that lies beyond the scope of this entry. A majority of contemporary philosophers probably hold that physicalism can resist these arguments. But a significant minority take the other side.[8] If the majority are right, and physicalism about conscious states is not ruled out by independent arguments, then physicalism seems clearly preferable to epiphenomenalism. In itself, epiphenomenalism is not an attractive position. It requires us to suppose that conscious states, even though they are caused by processes in the physical world, have no effects on that world. This is a very odd kind of causal structure. Nature displays no other examples of such one-way causal intercourse between realms. By contrast, a physicalist **naturalism** about conscious states will **integrate the mental** realm **with** the causal unfolding of the spatiotemporalworld in an entirely familiar way. Given this, general principles of theory choice would seem to argue strongly for physicalism over epiphenomenalism.[9] If we focus on this last point, we may start wondering why the causal closure thesis is so important. If general principles of theory choice can justify physicalism, why bring in all the complications associated with causal closure? The answer is that causal closure is needed to rule out interactionist dualism. General principles of theory choice may dismiss epiphenomenalism in favour of physicalism, but they do not similarly discredit interactionist dualism. As the brief historical sketch earlier will have made clear, interactionist dualism offers a perfectly straightforward theoretical option requiring no commitment to any bizarre causal structures. Certainly the historical norm has been to regard it as the default account of the causal role of the mental realm.[10] Given this, arguments from theoretical simplicity cut no ice against interactionist dualism. Rather, the case against interactionist dualism hinges crucially on the empirical thesis that all physical effects already have physical causes. It is specifically this claim that makes it difficult to see how dualist states can make a causal difference to the physical world. It is sometimes suggested that physicalism about the mind can be vindicated by an ‘inference to the best explanation’. The thought here is that there are many well-established synchronic correlations between mental states and brain states, and that physicalism is a ‘better explanation’ of these correlations than epiphenomenalism (Hill 1991, Hill and McLaughlin 1999). From the perspective outlined here, this starts the argument in the middle rather than the beginning, by simply assuming the relevant mind-brain correlations. This assumption of pervasive synchronic mind-brain correlations is only plausible if interactionist dualism has already been ruled out. After all, if we believed interactionist dualism, then we wouldn't think dualist mental states needed any help from synchronic neural correlates to produce physical effects. And it is implausible to suppose that we have direct empirical evidence, prior to the rejection of interactive dualism, for pervasive mind-brain correlations, given the paucity of any explicit examples of well-established neural correlates for specific mental states. Rather our rationale for believing in such correlations must be that the causal closure of the physical realm eliminates interactive dualism, whence we infer that mental states can only systematically precede physical effects if they are correlated with the physical causes of those effects. G.E. Moore's famous ‘open question’ argument is designed to show that moral facts cannot possibly be identical to natural facts. Suppose the natural properties of some situation are completely specified. It will always remain an open question, argued Moore, whether that situation is morally good or bad. (Moore 1903.) Moore took this argument to show that moral facts comprise a distinct species of non-natural fact. However, any such non-naturalist view of morality faces immediate difficulties, deriving ultimately from the kind of causal closure thesis discussed above. If all physical effects are due to a limited range of natural causes, and if moral facts lie outside this range, then it follow that moral facts can never make any difference to what happens in the physical world (Harman, 1986). At first sight this may seem tolerable (perhaps moral facts indeed don't have any physical effects). But it has very awkward epistemological consequences. For beings like us, knowledge of the spatiotemporal world is mediated by physical processes involving our sense organs and cognitive systems. **If moral facts cannot influence the physical world,** then it is hard to see how we **can have** any **knowledge of them.**

#### 4] Util is key to debates about IP.

Kar 19 [Mohit; Writer at the Original Position; “Utilitarianism in the Context of Intellectual Property,” The Original Position; 9/18/19; <https://originalpositionnluj.wordpress.com/2019/09/18/utilitarianism-in-the-context-of-intellectual-property/>] Justin

Jeremy Bentham is known as the founder of modern utilitarianism. He believed in production of the greatest possible quantity of happiness, on the part of those whose interest is in view. With regards to intellectual property, he had opined that inventors and authors should be given absolute privilege over their work, which would ensure they get remunerated duly for their work, thus leading to further creative actions being taken by them. In this article, the author will make an analysis of the utilitarian theory as proposed by Jeremy Bentham and its interplay with Intellectual Property.

According to utilitarians, the main purpose of property rights is the maximization of common well-being.[i] According to Jeremy Bentham, the common well-being here mentioned is the good for the greatest number of people in a population. He defined the principle of utility as carrying an object of production of maximum happiness in a given time in a particular society.[ii]

The wealth of a society consists of the cumulative wealth of each of its individual members. The most effective way to increase individual wealth is to leave the management of wealth to the individual himself, since – between the individual and the government – it is the individual who can best manage his own wealth. The society gains benefits because the increase in individual wealth is also the increase of collective wealth. Sharing this wealth is managed by the government, through taxes. Bentham argued that the value of outcome of a society is positive if the total quantity of pleasure gained by each individual under its influence is greater than the total quantity of pain.[iii] Thus, Bentham put stress on the happiness and wealth of individuals in a society.

Jeremy Bentham’s utilitarianism advocates the maximization of common well-being and the proper use of resources available. To show us a practical point of view, he criticized the kind of trade strategies where a country prevents the purchase of cheaper products from another country only to protect its market. In his opinion, to pay more for a product that can be manufactured elsewhere with the same quality standards only to favor the national industry is a waste of resources.[iv] Bentham believed that trade barriers to foreign imports cannot increase trade and commerce in a particular country.[v] He termed it as a necessary evil which would give rise to monopolies and lower the quality of production.[vi]

Transposing this theory to intellectual property rights, for the maximization of common welfare to be made, the legislators should strike a balance between, the monopoly of rights to stimulate creation and giving access to the population to inventions. Bentham defended the idea of ​​a limited period of protection for patents and he believed in the absolute privilege of the inventor, so that the latter can recover the amounts invested during the inventive process, while being paid for his creative activity.[vii] The right must also help the inventor since without any laws to protect him; any third party could copy his invention and thus enjoy his work without any compensation being granted. The logic to defend the monopoly stems from the fact that, without the latter, the inventor would not be encouraged to put his product or invention on the market. In this case, it would be the society that would have lost wealth which could have been added to the common well-being. In the name of enriching common well-being, Bentham stresses the importance of patents in a society and even argues that their concession should be a free service offered to inventors.[viii]

The contemporary version of this theory has been presented to us by William Landes and Richard Posner in two separate works, one on copyright and the other on trademark law.[ix] Economic analysis of intellectual property rights presented by these two authors demonstrates that the protection of intellectual property may be too expensive for society and it limits the use of products. If we extrapolate a little, this contemporary utilitarian vision can assert that the products by intellectuals should be easily copied since the copies of a product do not prevent the use of the same product by several people.

William Landes and Richard Posner consider the creative process as divided into two parts.[x] If we use a book as an example, its production is split between the part comprising author’s time and effort plus publishing costs, and the second part includes publication and distribution costs of the book. Generally, it is the first of these two elements that demands the most investment. The second will be more or less expensive, depending on the quantity of copies that will be produced. When the work is complete, its reproduction does not require any investment at the creative level. Hence, they stated that striking a correct balance between access and incentives is one of the central problems of copyright law.[xi] In this way, as already mentioned, the lack of remuneration of creators for the exploitation of their works may have as a consequence the diminution of the cultural wealth of a society, given that the creators will not have the desire to continue to create unless paid. It is important to note that the lack of protection conferred by copyright would not change this problem. In a society where copyright protection does not exist, a book could be easily copied without the act of copying being considered an offense. When the contemporary utilitarian vision is applied, it indicates that the benefits that they bring to a society are: It makes it easier for consumers to choose the product which has the qualities corresponding most to its needs. Since consumers already know the brand, they should not search among a whole range of products available on the market; It encourages producers to maintain good quality of their products, because consumers associate the product quality with the brand attached to it; It improves the language. Landes and Posner believe that the brands create new words that end up being incorporated in the lexicon of the language.[xii]

Suppose the utilitarian theory – that of Bentham, or Posner’ and Landes’ – would be applied to intellectual property as it stands today: the benefits that would be brought to society by this analysis would be the incentive for creativity, the optimization of production and the disappearance or diminution of similar inventions made by different individuals.

Among these three advantages, we can consider the incentive to creation as the most important. In this case, the monopoly guaranteed by intellectual property stimulates creation in a society and, especially with regard to patents; inventions will bring more happiness and pleasure to society in general. This justifying argument is in harmony with Bentham’s utilitarianism. The problem here is that no one really knows what kind of invention would bring more or less happiness or pleasure to the society. Moreover, the term “monopoly concession” for patents, trademarks and copyright is not based on any empirical or objective study and is rather random.

Optimization of production sees ownership monopolies intellectual property as a “service” to society since data from sale indicates the products for which the company has the most need. This approach could even justify increasing the period of protection of intellectual property products. The logic here is that the decrease in the protection period or even the removal of the protection would deprive the producers of information that enables them to optimize their production. Thereby, the withdrawal or diminution of protection could even be considered harmful to society. However, if we do not impose limitations to this theory, the result could be a disparity of investments in intellectual property over investments in other areas, such as education and health, as well as in general research activities.

CONCLUSION

Utilitarianism, as it stands today, is intimately linked to the information obtained from the use of intellectual property monopolies. The goal is to avoid duplication of production. The problem in this case is that in a society which values ​​and encourages the production of new patents and new technologies, the plethora of patents complicates the process. This finding is based on the fact that new inventions normally rely on existing patents and the production of a new patented product will require a large number of licenses before it can begin. As Richard Posner said in his blog: ‘Patents are a source of great social costs, and only occasionally of commensurate benefits. Most firms do not actually want patents; for those firms, the costs involved in obtaining licenses from patentees are not offset by the prospect of obtaining license fees on their own patents.’

#### Outweighs –

#### A] Most articles about IP are written through util – means other frameworks can never engage with core questions of the lit and decks predictability – equal topic lit means fair ground.

#### B] TJFs first – substance begs the question of a framework being good for debate – fairness is a gateway issue to deciding the winner and education is the reason schools fund debate.

### 1AC – Method

#### 1] Fiat is good. A] Sustains the concept of agency through influencing others, B] Motivates action which creates change, and C] Generates literature that we can discuss the harms about.

Shove and Walker 07 [Elizabeth Shove, prof of Sociology at Lancaster, and Gordon Walker, prof of Geography at Lancaster. 2007. “CAUTION! Transitions ahead: politics, practice, and sustainable transition management.”] //Nato

For academic readers, our commentary argues for loosening the intellectual grip of ‘innovation studies’, for backing off from the nested, hierarchical multi-level model as the only model in town, and for exploring other social scientific, but also systemic theories of change. The more we think about the politics and practicalities of reflexive transition management, the more complex the process appears: for a policy audience, our words of caution could be read as an invitation to abandon the whole endeavour. If agency, predictability and legitimacy are as limited as we’ve suggested, this might be the only sensible conclusion. However, we are with Rip (2006) in recognizing the value, productivity and everyday necessity of an ‘illusion of agency’, and of the working expectation that a difference can be made even in the face of so much evidence to the contrary. The outcomes of actions are unknowable, the system unsteerable and the effects of deliberate intervention inherently unpredictable and, ironically, it is this that sustains concepts of agency and management. As Rip argues ‘illusions are productive because they motivate action and repair work, and thus something (whatever) is achieved’ (Rip 2006: 94). Situated inside the systems they seek to influence, governance actors – and actors of other kinds as well - are part of the dynamics of change: even if they cannot steer from the outside they are necessary to processes within. This is, of course, also true of academic life. Here we are, busy critiquing and analysing transition management in the expectation that somebody somewhere is listening and maybe even taking notice. If we removed that illusion would we bother writing anything at all? Maybe we need such fictions to keep us going, and maybe – fiction or no - somewhere along the line something really does happen, but not in ways that we can anticipate or know.

#### **2] The ROTB is to determine whether the impacts of the Aff policy are good a] Fairness – opposing frameworks moot the 1AC – there are infinite parts they could problematize which forces a 1ar restart b] Clash – Our scholarship is tied to the consequences of the plan – their model lets them get through the 2NR without addressing the aff skewing our time.** c] Saying the state ought not commit acts of violence doesn’t presuppose the state being good d] Role playing is key to better tackle problems of oppression and create tangible solutions.

Nixon 2KMakani Themba-Nixon, Executive Director of The Praxis Project. “Changing the Rules: What Public Policy Means for Organizing.” Colorlines 3.2, 2000. Organic Intellectual

Getting It in Writing Much of the work of framing what we stand for takes place in the shaping of demands. By getting into the policy arena in a proactive manner, we can take our demands to the next level. Our demands can become law, with real consequences if the agreement is broken. After all the organizing, press work, and effort, a group should leave a decision maker with more than a handshake and his or her word. Of course, this work requires a certain amount of interaction with "the suits," as well as struggles with the bureaucracy, the technical language, and the all-too-common resistance by decision makers. Still, if it's worth demanding, it's worth having in writing-whether as law, regulation, or internal policy. From ballot initiatives on rent control to laws requiring worker protections, organizers are leveraging their power into written policies that are making a real difference in their communities. Of course, policy work is just one tool in our organizing arsenal, but it is a tool we simply can't afford to ignore. Making policy work an integral part of organizing will require a certain amount of retrofitting. We will need to develop the capacity to translate our information, data, stories that are designed to affect the public conversation [and]. Perhaps most important, we will need to move beyond fighting problems and on to framing solutions that bring us closer to our vision of how things should be. And then we must be committed to making it so.

### 1AC – Pre Empt – Innovation DA

#### 1] Non-unique – innovation stalling because of failing clinical trials, drug prices, econ.

Langley 4/21 [(Kare, reporter for The Wall Street Journal in New York, where she primarily covers the U.S. stock market), “Biotech Stocks Fall Out of Favor After Disappointing Trial Results, Big Rally “, WSJ, 4/21/2021, https://www.wsj.com/amp/articles/biotech-stocks-fall-out-of-favor-after-disappointing-trial-results-big-rally-11619016330] TDI // Re-Cut Justin

Shares of Sarepta Therapeutics Inc., Amicus Therapeutics Inc. and Frequency Therapeutics Inc. are among the recent losers for biotech investors, having lost more than half their value so far this year. “It’s felt like a kitchen sink in terms of the number of factors weighing on biotech sentiment in the near term,” said Andy Acker, who manages the Janus Henderson Global Life Sciences Fund. Among those are disappointing clinical trials, concern about the possibility of renewed focus on drug prices in Washington and the recent rotation into economically sensitive stocks. Biotech shares enjoyed a powerful rally last year. The Nasdaq biotech gauge soared 26% in 2020 on excitement about the potential for Covid-19 treatments and vaccines as well as a broader rally in shares of companies that can perform when the economy is struggling. The S&P 500, meanwhile, gained 16% last year, and the Nasdaq Composite surged 44%. Rapid gains or losses in share prices following clinical-trial results or regulatory decisions are a feature of biotech investing, but a smattering of negative news has damped enthusiasm in recent months. Shares of Sarepta Therapeutics plunged 51% on Jan. 8 after mixed results from a study of a drug targeting a form of muscular dystrophy. The shares are now down 58% for the year. Amicus Therapeutics shares dropped 33% on Feb. 12 after trial results for its treatment of a rare disorder called Pompe disease disappointed investors. And shares of Frequency Therapeutics plunged 78% on March 23 after the company found its lead drug aimed at treating sensorineural hearing loss didn’t lead to any hearing benefit when given in a four-dose schedule. Those stocks are down 57% and 72%, respectively, this year. Also weighing on sentiment: The Federal Trade Commission has indicated it is preparing to take a harder line on drug-company mergers, which are a source of potential value for investors in small biotech shops. The commission in March said it would reconsider its approach to scrutinizing deals that could harm competition. “Biotech can be driven by mergers,’ said Jeremie Capron, director of research at ROBO Global, a research and investment-advisory firm. “A change at the FTC, it reduces the probability of a favorable outcome in terms of an acquisition.” Analysts will also be keeping an eye on any efforts in Washington to reduce drug prices. Some investors are betting against companies in the industry. Biotech stocks accounted for five of the 10 most-shorted stocks on U.S. exchanges at the end of March, according to S&P Global Market Intelligence. Short interest in Esperion Therapeutics Inc.stood at 34% of shares outstanding as of March 31, followed by Clovis Oncology Inc. at 31% and Inovio Pharmaceuticals Inc. at 26%, an S&P analysis showed. As Covid-19 vaccines reach more people and the economy picks up, investors have favored shares of banks, energy producers and other companies that tend to do well in a strong economy. They have been less interested in stocks that hold out the prospect of innovation-driven growth in fields like technology and biotech. Expectations of a strong recovery have also been seen in the bond market, where falling prices lifted the yield on the benchmark 10-year U.S. Treasury note to 1.566% on Wednesday from 0.913% at the end of last year. As yields climb, borrowing costs for businesses also rise. That often lands hard on biotech companies, where hefty bills for research and development can arrive long before revenue.

#### 2] No link: strong innovation incentives.

So 20 [Anthony; Professor of the practice in International Health and the founding director of the Innovation+Design Enabling Access (IDEA) Initiative; “WTO TRIPS Waiver for COVID-19 Vaccines,” John Hopkins; 5/10/21; <https://www.jhsph.edu/covid-19/articles/wto-trips-waiver-for-covid-19-vaccines.html>] Justin

Another question raised by opponents of the waiver is: Have companies been able to make a strong return on their investment? The answer appears to be yes. In a market almost entirely created by public sector purchase of vaccines for a pandemic, Pfizer brought in $3.5 billion in COVID-19 vaccine revenues in the first quarter of this year, with estimated profit margins in the high 20% range, by far its greatest revenue generator. Pfizer’s partner, BioNTech, received upfront public financing, both from the German government and the European Investment Bank, while Pfizer itself has secured 6 billion dollars thus far from the U.S. government in guaranteed purchases of its COVID-19 vaccine. So even if the TRIPS waiver were to enable other vaccine producers to meet the huge unmet demand, it is hard to argue that the public sector has not already provided multibillion-dollar incentives to bring forward needed innovation.