### DA

#### 1] Aff solves the DA – it’s wraps:

#### A] The aff only occurs through limited IP waivers during public health emergencies which still allows for future innovations – innovations that occur during public health emergencies past the basic vaccine will have patent extensions which increases incentives during a time of high demand – that should be framed through specificity. They haven’t done the warranting for why innovation NEEDS to happen in the next year

#### B] It’s a question of access: we aren’t accessing our full innovation potential because smaller countries don’t have the resources to innovate. Allowing for patents incentivizes third-world innovations and improvements to vaccines.

#### C] Frame this through scale-up: even if innovation occurs access to innovation is limited because of lack of distribution – only the aff has a risk of distribution of innovation to solve pandemics.

#### 2] Evergreening DA: patents are being misused to extend monopolies with useless tweaks that shields producers from competition which prevents innovation and prevent competitors from innovating – 1AC Gurgula. No new 2n responses—allows for sandbagging and time crunches the 3 minute 2ar.

#### 3] 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.

#### No link.

Gupta and Ramachandran 9/24 [Ravi and Reshma; 9/24/21; Penn LDI and Yale School of Medcine; “A Covid-19 Vaccine IP Waiver Won’t Kill Pharma Innovation,” Bloomberg, <https://news.bloomberglaw.com/ip-law/a-covid-19-vaccine-ip-waiver-wont-kill-pharma-innovation>] Justin

A False Choice Between Access and IP Waivers and Innovation But the trade-off between ensuring global access to Covid-19 vaccines through IP waivers and innovation is a false choice for several reasons, especially amidst a devastating pandemic. First, in the case of Covid-19 vaccines, such monopoly rights are duplicative and unnecessary. Through Operation Warp Speed, the U.S. government underwrote Covid-19 vaccine development, spending an unprecedented $18 billion. This included advance purchasing agreements for the vaccines before they were shown to be effective, essentially eliminating companies’ risk of failure. Moreover, key technology that led to the currently available mRNA vaccines was developed by the U.S. government. For Moderna, continued development of booster vaccines has been in collaboration with and through the support of the National Institutes of Health. Second, companies have already profited handsomely from Covid-19 vaccines. Pfizer will earn $33 billion and Moderna $18 billion in sales in 2021 alone. Because this pandemic will likely not end anytime soon, companies will continue to make profits from Covid-19 vaccines, including from more expensive booster shots. The White House recently purchased an additional 200 million doses of the Pfizer/BioNTech vaccine at a higher price than last year, and prices were also set higher in recent EU orders. Such trends will likely continue. Third, manufacturers’ prioritization of higher-revenue markets in wealthier countries has meant that vaccines, particularly for infections with pandemic potential, have historically been neglected. An Ebola vaccine, for instance, languished since the early 2000s. Promising vaccine candidates for SARS-CoV-1, the coronavirus that led to the SARS outbreak in 2003, quickly lost funding once the outbreak ended. If this research had continued, we may have had earlier vaccine and treatment options for the related Covid-19. While long-term reform is needed to address this innovation void, democratizing Covid-19 vaccine manufacturing through an IP waiver would have minimal, if any, negative effect. Fourth, a Covid-19 IP waiver is unlikely to harm drug development for non-pandemic diseases. As currently constructed, the waiver is limited in time and scope to only Covid-19. But to the extent that an IP waiver would diminish Covid-19 vaccine profits, the non-partisan Congressional Budget Office recently found that limiting pharmaceutical profits would lead to a relatively small reduction in new drug launches. Moreover, these few drugs may not reflect truly transformative innovation that meets the needs of our patients to begin with. Companies frequently invest in new drugs that treat diseases with existing treatments (“me-too” drugs) and focus more on stock buybacks than on research and development. There is thus little reason to believe that reducing further profit margins from Covid-19 vaccines through an IP waiver would harm innovation for non-pandemic diseases. Fifth, Covid-19 has quickly validated novel vaccine platforms, particularly mRNA, which holds the tantalizing potential of treating other serious infections and cancers. This ability to repurpose largely publicly funded vaccine platforms for other diseases means that companies will continue to benefit beyond the current pandemic. Concerns that an IP waiver could affect future uses of mRNA are tempered by the reality that ownership rights such as patents will still exist. Unquestionably, the remarkable organizational capacity of pharmaceutical companies helped bring Covid-19 vaccines to fruition and they have been rewarded. But enacting an IP waiver to allow additional manufacturers to overcome the ongoing supply shortfall is essential in curbing the threat of new variants, ending this pandemic, and saving millions of lives around the world. There are admittedly real challenges even after an IP waiver, but these are addressable difficulties and many manufacturers stand ready to collaborate. Continued, long-term inequity that further fuels what is now a preventable disease ought to be an unacceptable outcome to this plague. During the UN General Assembly, our world leaders would do well to fight for equitable vaccine access to end this pandemic and to stand on the side of people over profits.

### FW

#### Ethics must begin a priori:

#### [A] Naturalistic fallacy – experience only tells us what is since we can only perceive what is, not what ought to be. But it’s impossible to derive an ought from descriptive premises, so there needs to be additional a priori premises to make a moral theory.

#### [B] Constitutive Authority – practical reason is the only unescapable authority because to ask for why we should be reasoners concedes its authority since it uses reason – anything else is nonbinding and arbitrary.

#### [C] Action theory – only evaluating action through reason solves since reason is key to evaluate intent, otherwise we could infinitely divide actions. For example: If I was brewing tea, I could break up that one big action into multiple small actions. Only our intention, to brew tea unifies these actions if we were never able to unify action, we could never classify certain actions as moral or immoral since those actions would be infinitely divisible.

#### That justifies universality –a priori principles like reason apply to everyone since they are independent of human experience and – any non-universalizable norm justifies someone’s ability to impede on your ends i.e. if I want to eat ice cream, I must recognize that others may affect my pursuit of that end.

#### Thus, the standard is consistency with the categorical imperative. Prefer:

#### [1] Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify a standard without first willing that we can pursue ends free from others.

#### [2] Consequences fail: a] Yes act/omission distinction – there are infinite events occurring over which you have no control, so you can never be moral b] Every action has infinite stemming consequences so we can’t predict. c] Induction is circular because it assumes nature will hold uniform d] aggregation impossible – impossible to measure pain and pleasure e] Every action is infinitely divisible, only intents unify

#### [3] Only universalizable reason can effectively explain the perspectives of agents – that’s the best method for combatting oppression.

Farr 02 Arnold Farr (prof of phil @ UKentucky, focusing on German idealism, philosophy of race, postmodernism, psychoanalysis, and liberation philosophy). “Can a Philosophy of Race Afford to Abandon the Kantian Categorical Imperative?” JOURNAL of SOCIAL PHILOSOPHY, Vol. 33 No. 1, Spring 2002, 17–32.

**One** of the most popular **criticism**s **of Kant’s moral philosophy is that it is too formalistic.**13 That is, the universal nature of the categorical imperative leaves it devoid of content. Such a principle is useless since moral decisions are made by concrete individuals in a concrete, historical, and social situation. This type of criticism lies behind Lewis Gordon’s rejection of any attempt to ground an antiracist position on Kantian principles. The rejection of universal principles for the sake of emphasizing the historical embeddedness of the human agent is widespread in recent philosophy and social theory. I will argue here on Kantian grounds that **although a distinction between the universal and the concrete is** a **valid** distinction, **the unity of the two is required for** an understanding of human **agency.** The attack on Kantian formalism began with Hegel’s criticism of the Kantian philosophy.14 The list of contemporary theorists who follow Hegel’s line of criticism is far too long to deal with in the scope of this paper. Although these theorists may approach the problem of Kantian formalism from a variety of angles, the spirit of their criticism is basically the same: The universality of the categorical imperative is an abstraction from one’s empirical conditions. **Kant is** often **accused of making the moral agent an abstract, empty**, noumenal **subject. Nothing could be further from the truth. The Kantian subject is** an embodied, empirical, concrete subject. However, this concrete subject has a dual nature. Kant claims in the Critique of Pure Reason as well as in the Grounding that human beings have an intelligible and empirical character.15 It is impossible to understand and do justice to Kant’s moral theory without taking seriously the relation between these two characters. The very concept of morality is impossible without the tension between the two. By “empirical character” Kant simply means that we have a sensual nature. We are physical creatures with physical drives or desires. **The** very **fact that I cannot simply satisfy my desires without considering the rightness** or wrongness **of my actions suggests that my empirical character must be held in check** by something, or else I behave like a Freudian id. My empiri- cal character must be held in check **by my intelligible character**, which is the legislative activity of practical reason. It is through our intelligible character that **we formulate principles that keep our** empirical **impulses in check.** The categorical imperative is the supreme principle of morality that is constructed by the moral agent in his/her moment of self-transcendence. What I have called self-transcendence may be best explained in the following passage by Onora O’Neill: In restricting our maxims to those that meet the test of the categorical imperative we refuse to base our lives on maxims that necessarily make our own case an exception. The reason why a universilizability criterion is morally signiﬁcant is that it makes our own case no special exception (G, IV, 404). In accepting the Categorical Imperative we accept the moral reality of other selves, and hence the possibility (not, note, the reality) of a moral community. **The Formula of Universal Law enjoins no more than that we act only on maxims that are open to others also.**16 O’Neill’s description of the universalizability criterion includes the notion of self-transcendence that I am working to explicate here to the extent that like self-transcendence, universalizable moral principles require that the individ- ual think beyond his or her own particular desires. The individual is not allowed to exclude others **as** rational **moral agents** who have the right to act as he acts in a given situation. For example, if I decide to use another person merely as a means for my own end I must recognize the other person’s right to do the same to me. I cannot consistently will that I use another as a means only and will that I not be used in the same manner by another. **Hence,** the **universalizability** criterion **is a principle of consistency and** a principle of **inclusion.** That is, in choosing my maxims **I** attempt to **include the perspective of other moral agents.**

#### [4] Neg must not contest both the aff framework and offense – to clarify you can not read an alternative framework and contest the 1ac fw offense. A) Strat skew – forces the 1ar to cover multiple layers while the 2nr can just collapse to one layer to win – supercharged by the fact that the 1ar is 4 min long and the long 2nr will always dust the short 1ar B) Depth of education - u go deeper on one layer of the debate either framework or the offense instead of spreading thin on both. depth outweighs cuz ud rather read 100 pages from one book than one page from 100 books

#### No RVI on 1ac theory that has a pre-emptive violation--they would have 7 minutes to answer a minute-long shell and the debate would end right there--the entire 1ac cant be the shell because then they could just choose not to violate it

#### 1AC Theory is DTD—its key to making sure they’re held accountable since they chose to violate it

#### Competing interps on 1AC Theory- 7 minutes is more than enough time to robustly justify their counter interp and reasonability is arbitrary

#### Fairness outweighs: 1] testing – if we can’t answer their arguments we don’t know if they’re right 2] minority debaters will just quit if the activity is unfair which supercharges abuse

### Advocacy

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

### Offense

#### [1] IPP unjustifiably restricts agents from setting and pursuing ends in healthcare because patents prevent people from taking part in scientific advancements in medicine – that violates freedom in multiple ways

**Hale 18** (Zachary Hale, 4-4-2018, accessed on 8-22-2021, The Arkansas Journal of Social Change and Public Service, "Patently Unfair: The Tensions Between Human Rights and Intellectual Property Protection - The Arkansas Journal of Social Change and Public Service", <https://ualr.edu/socialchange/2018/04/04/patently-unfair/>) BHHS AK

Although the right to the protection of “moral and material interests resulting from any scientific, literary, or artistic production,”[32] is a human right as defined in the UDHR and the ICESCR, the current system of intellectual property protection conflicts with and even violates rights that are considered to be fundamental to human life. Although intellectual property instruments are certainly used to violate essential civil and political freedoms like the freedom of expression, and economic and social freedoms like the freedom to share in the scientific advancements of society, the most blatant violations of human rights caused by intellectual property protection occur in the fields of nutrition, healthcare, and culture.[33] Of these essential entitlements, the rights to food and health are made even more significant by their relationship to the most fundamental of all human rights: the right to life.

#### [2] IPP is inconsistent with free market principles

**Kinsella 11** (Stephan Kinsella, 5-25-2011, accessed on 8-23-2021, Foundation for Economic Education, "How Intellectual Property Hampers the Free Market | N. Stephan Kinsella", <https://fee.org/articles/how-intellectual-property-hampers-the-free-market/>) BHHS AK

But are they? There are good reasons to think that IP is not actually property—that it is actually antithetical to a private-property, free-market order. By intellectual property, I mean primarily patent and copyright. It’s important to understand the origins of these concepts. As law professor Eric E. Johnson notes, “The monopolies now understood as copyrights and patents were originally created by royal decree, bestowed as a form of favoritism and control. As the power of the monarchy dwindled, these chartered monopolies were reformed, and essentially by default, they wound up in the hands of authors and inventors.” Patents were exclusive monopolies to sell various goods and services for a limited time. The word patent, historian Patricia Seed explains, comes from the Latin patente, signifying open letters. Patents were “open letters” granted by the monarch authorizing someone to do something—to be, say, the only person to sell a certain good in a certain area, to homestead land in the New World on behalf of the crown, and so on. It’s interesting that many defenders of IP—such as patent lawyers and even some libertarians—get indignant if you call patents or copyright a monopoly. “It’s not a monopoly; it’s a property right,” they say. “If it’s a monopoly then your use of your car is a monopoly.” But patents are State grants of monopoly privilege. One of the first patent statutes was England’s Statute of Monopolies of 1624, a good example of truth in labeling. Granting patents was a way for the State to raise money without having to impose a tax. Dispensing them also helped secure the loyalty of favorites. The patentee in return received protection from competition. This was great for the State and the patentee but not for competition or the consumer. In today’s system we’ve democratized and institutionalized intellectual property. Now anyone can apply. You don’t have to go to the king or be his buddy. You can just go to the patent office. But the same thing happens. Some companies apply for patents just to keep the wolves at bay. After all, if you don’t have patents someone might sue you or reinvent and patent the same ideas you are using. If you have a patent arsenal, others are afraid to sue you. So companies spend millions of dollars to obtain patents for defensive purposes. Large companies rattle their sabers or sue each other, then make a deal, say, to cross-license their patents to each other. That’s fine for them because they have protection from each other’s competition. But what does it do to smaller companies? They don’t have big patent arsenals or a credible countersuit threat. So patents amount to a barrier to entry, the modern version of mercantilist protectionism. What about copyright? The roots literally lie in censorship. It was easy for State and church to control thought by controlling the scribes, but then the printing press came along, and the authorities worried that they couldn’t control official thought as easily. So Queen Mary created the Stationer’s Company in 1557, with the exclusive franchise over book publishing, to control the press and what information the people could access. When the charter of the Stationer’s Company expired, the publishers lobbied for an extension, but in the Statute of Anne (1710) Parliament gave copyright to authors instead. Authors liked this because it freed their works from State control. Nowadays they use copyright much as the State originally did: to censor and ban books. (More below.) IP, American Style The American system of IP began with the U.S. Constitution. Article 1, Section 8, Clause 8 authorizes (but doesn’t require) Congress “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Despite modern IP proponents’ claims to the contrary, the American founders did not view intellectual property as a natural right but only as a policy tool to encourage innovation. Yet they were nervous about monopoly privilege, which is why patents and copyrights were authorized only for a limited time. Even John Locke, whose thought influenced the Founding Fathers, did not view copyright and patent as natural rights. Nor did he maintain that property homesteading applied to ideas. It applied only to scarce physical resources. Granted, some state constitutions had little versions of copyright before the American Constitution. (See Tom W. Bell, Intellectual Privilege: Copyright, Common Law, and the Common Good, part 1, chapter 3, section B.1.) On occasion, the language of natural rights was used to defend it, but this was just cover for the monopolies they granted to special interests. Natural rights do not expire after 15 years. Natural rights are not extended to Americans only. Natural rights wouldn’t exclude many types of innovation and intellectual creativity and cover only a few arbitrary types. And what is the result of this system? In the case of patents we have a modern statute administered by a huge federal bureaucracy that grants monopolies on the production and trade of various things, which means holders may ask the federal courts to order the use of force to stop competitors. But the competitors have not done anything that justifies force. They merely have used information to guide their actions with respect to their own property. Is that compatible with private property and the free market?

#### That affirms: Free market economies are the only ones that allow people to be free to pursue their own interests.

**Richman 12** [Sheldon Richman, 8-5-2012, "The Free Market Doesn't Need Government Regulation," Reason, <https://reason.com/2012/08/05/the-free-market-doesnt-need-government-r/>] // SJ AME

What regulates the conduct of these people? Market forces. (I keep specifying "in a freed market" because in a state-regulated economy, competitive market forces are diminished or suppressed.) Economically speaking, people cannot do whatever they want—and get away with it—in a freed market because other people are free to counteract them and it's in their interest to do so. That's part of what we mean by market forces. Just because the government doesn't stop a seller from charging $100 for an apple doesn't mean he or she can get that amount. Market forces regulate the seller as strictly as any bureaucrat could—even more so, because a bureaucrat can be bribed. Whom would you have to bribe to win an exemption from the law of supply and demand? (Well, you might bribe enough legislators to obtain protection from competition, but that would constitute an abrogation of the market.) It is no matter of indifference whether state operatives or market forces do the regulating. Bureaucrats, who necessarily have limited knowledge and perverse incentives, regulate by threat of physical force. In contrast, market forces operate peacefully through millions of cooperating participants, each with intimate knowledge of her own personal circumstances and looking out for her own well-being. Bureaucratic regulation is likely to be irrelevant or (more likely) inimical to what people in the market care about. Not so regulation by market forces.

### Underview

#### [1] Permissibility and Presumption: a] Statements are true before false since if I told you my name, you’d believe me. b] If anything is permissible, then so is the aff since there is nothing prohibiting us.

**[2] Aff gets 1AR theory – its dtd, ci, and the highest layer of the round – otherwise the neg can be infinitely abusive and there’s no way to check against this. The 1ars too short to rectify abuse and adequately cover substance**

#### **[3]** Check all neg interps and K/DA links in CX or drop them – avoids infinite regress due to links and interps

#### [4] The neg can only gain offense from one unconditional route to the ballot- Forces the neg to engage in the AC rather than just uplayering

#### [5] Theory or K indicts on spikes is drop the arg – my theory paradigms are simply presented models for debate

#### [6] If I win one layer vote aff- The NC has the ability to uplayer for 7 minutes and moot 6 minutes of case

#### [7] Negative arguments presuppose the aff being true since they begin with a descriptive premise about the affirmative such as the aff does x, and then justify why x is bad. However, if the aff does not have truth value, that entails the descriptive premise would also not have truth value, which is contradictory.

### Advantage

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

Kumar 21 [Rajeesh; Associate Fellow at the Institute, currently working on a project titled “Emerging Powers and the Future of Global Governance: India and International Institutions.” He has PhD in International Organization from Jawaharlal Nehru University, New Delhi. Prior to joining MP-IDSA in 2016, he taught at JamiaMilliaIslamia, New Delhi (2010-11& 2015-16) and University of Calicut, Kerala (2007-08). His areas of research interest are International Organizations, India and Multilateralism, Global Governance, and International Humanitarian Law. He is the co-editor of two books;Eurozone Crisis and the Future of Europe: Political Economy of Further Integration and Governance (London: Palgrave Macmillan, 2014); and Islam, Islamist Movements and Democracy in the Middle East: Challenges, Opportunities and Responses (Delhi: Global Vision Publishing, 2013); “WTO TRIPS Waiver and COVID-19 Vaccine Equity,” IDSA Issue Briefs; <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>] Justin

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.

#### 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.

Gurgula 20 [Olga; Lecturer in Intellectual Property Law at Brunel Law School, Brunel University London. She is also a Visiting Fellow at the Oxford Martin Programme on Affordable Medicines, University of Oxford; “Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?” Springer Link; 10/28/20; <https://link.springer.com/article/10.1007/s40319-020-00985-0#Sec4>] Justin

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.