#### 1AC – Framing

#### 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] Empirical uncertainty – evil demon could deceive us, dreaming, simulation, and inability to know others’ experience make empiricism an unreliable basis for universal ethics. Outweighs since it would be escapable since people could say they don’t experience the same.

#### [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

#### [D] 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.

#### Next, the relevant feature of reason is universality – 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 and demand the value of my end be recognized by others which also means universalizability acts as a side constraint on all other frameworks. It’s impossible to will a violation of freedom since deciding to do would will incompatible ends since it logically entails willing a violation of your own freedom.

#### [E] Darkness Paradox – big bang proves our theory true – independent of material conditions there was some existence which necessitates objective truth absent material reality.

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

#### [A] Practical identities – we find our lives worth living under practical identities such as student but that presupposes agency.

**Korsgaard 92** CHRISTINE M. Korsgaard 92 [I am a Professor of Philosophy at Harvard University, where I have taught since 1991. From July 1996 through June 2002, I was Chair of the Department of Philosophy. (The current chair is Sean Kelly.) From 2004-2012, I was Director of Graduate Studies in Philosophy. (The current DGS is Mark Richard.) Before coming here, I held positions at Yale, the University of California at Santa Barbara, and the University of Chicago, as well as visiting positions at Berkeley and UCLA. I served as President of the Eastern Division of the American Philosophical Association in 2008-2009, and held a Mellon Distinguished Achievement Award from 2006-2009. I work on moral philosophy and its history, practical reason, the nature of agency, personal identity, normativity, and the ethical relations between human beings and the other animals], “The Sources of Normativity”, THE TANNER LECTURES ON HUMAN VALUES Delivered at Clare Hall, Cambridge University 16-17 Nov 1992, BE

The Solution: Those who think that the human mind is internally luminous and transparent to itself think that the term “self-consciousness” is appropriate because what we get in human consciousness is a direct encounter with the self. Those who think that the human mind has a reflective structure use the term too, but for a different reason. The reflective structure of the mind is a source of “self-consciousness” because it forces us to have a conception of ourselves. As Kant argues, this is a fact about what it is like to be reflectively conscious and it does not prove the existence of a metaphysical self. From a third person point of view, outside of the deliberative standpoint, it may look as if what happens when someone makes a choice is that the strongest of his conflicting desires wins. But that isn’t the way it is for you when you deliberate. When you deliberate, it is as if there were something over and above all of your desires, something that is you, and that chooses which desire to act on. This means that the principle or law by which you determine your actions is one that you regard as being expressive of yourself. To identify with such a principle or law is to be, in St. Paul’s famous phrase, a law to yourself.6 An agent might think of herself as a Citizen in the Kingdom of Ends. Or she might think of herself as a member of a family or an ethnic group or a nation. She might think of herself as the steward of her own interests, and then she will be an egoist. Or she might think of herself as the slave of her passions, and then she will be a wanton. And how she thinks of herself will determine whether it is the law of the Kingdom of Ends, or the law of some smaller group, or the law of the egoist, or the law of the wanton that is the law that she is to herself. The conception of one’s identity in question here is not a theoretical one, a view about what as a matter of inescapable scientific fact you are. It is better understood as a description under which you value yourself, a description under which you find your life to be worth living and your actions to be worth undertaking. So I will call this a conception of your practical identity. Practical identity is a complex matter and for the average person there will be a jumble of such conceptions. You are a human being, a woman or a man, an adherent of a certain religion, a member of an ethnic group, someone’s friend, and so on. And all of these identities give rise to reasons and obligations. Your reasons express your identity, your nature; your obligations spring from what that identity forbids.

#### That hijacks roles of the ballots since the judge is one such practical identity, and other frameworks since implies first valuing ourselves to value other normative judgements

#### [B] Ethical frameworks must be theoretically legitimate. All frameworks are functionally topicality interpretations of the word ought so they must be theoretically justified: prefer on resource disparities—a focus on evidence and statistics privileges debaters with the most preround prep which excludes lone-wolfs who lack huge evidence files. A debate under my framework can easily be won without any prep since only analytical arguments are required. That controls the internal link to other voters because a pre-req to debating is access to the activity.

#### [C] 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.

**Consequences fail: [A] They only judge actions after they occur, which fails action guidance [B] Every action has infinite stemming consequences, because every consequence can cause another consequence. Probability doesn’t solve because 1) Probability is improvable, as it relies on inductive knowledge, but induction from past events can’t lead to deduction of future events and 2) Probability assumes causation, we can’t assume every act was actually the cause of tangible outcomes [C] Every action is infinitely divisible, only intents unify action because we intend the end point of an action – but consequences cannot determine what step of action is moral or not. [D] If you’re held responsible for things other than an intention ethics aren’t binding because there are infinite events occurring over which you have no control, so you can never be moral as you are permitting just action. [E] There’s no objective arbiter to evaluate consequences [F] You can’t aggregate consequences, happiness and sadness are immutable – ten headaches don’t make a migraine**

### Advocacy

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

### Offense

#### [1] Intellectual property protection violates the formula of autonomy – multiple warrants.

**Hale 18** Zachary A., 4-4-2018, "Patently Unfair: The Tensions Between Human Rights and Intellectual Property Protection," Arkansas Journal of Social Change and Public Service, <https://ualr.edu/socialchange/2018/04/04/patently-unfair/> JG

Before entering discussion of more recent institutional developments, it is germane to the object of this paper to examine the role of intellectual property in the United Nations preceding the incorporation of the WIPO. As noted above, intellectual property rights were included in the UDHR. Article 27 of the UDHR states that: 1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. 2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[17] This should not be interpreted as a consensus amongst the international community on how intellectual property should be regulated, or even on how to define the “moral and material” interests that deserved protection. As with many aspects of the UDHR, the inclusion of intellectual property was highly contested.[18] While a large number of states disagreed with Article 27, they were overpowered by states convinced of the material value of intellectual property protection. As Paul Torremans notes: [T]he initial strong criticism that [intellectual property] was not properly speaking a Human Right or that it already attracted sufficient protection under the regime of protection afforded to property rights in general was eventually defeated by a coalition of those who primarily voted in favour because they felt that the moral rights deserved and needed protection and met the Human Rights standard and those who felt the ongoing internationalization of copyright needed a boost and that this could be a tool in this respect.[19] This shift from discussion of intellectual property as a matter of trade law to discussion of intellectual property as a matter of human rights was furthered by the inclusion of intellectual property rights in Article 15 of the ICESCR, which took force in January of 1976. Article 15 states: 1. The States Parties to the present Covenant recognize the right of everyone: (a) To take part in cultural life; (b) To enjoy the benefits of scientific progress and its applications; (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture. 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity. 4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.[20] The sub-clauses of 15.1 are essentially a reiteration of Article 27, but the mention of “development and diffusion” in 15.2 and “co-operation in the scientific and cultural fields” in 15.4 represent a radical shift in intellectual property interpretation. The conception of innovation in terms of market value and incentive systems was being challenged by ideas about human development, as is reflected in the suggestion that “the full realization” of the human rights aspect of intellectual property requires “the diffusion of science and culture,” a suggestion that was not present in the UDHR.[21] The Patents Cooperation Treaty (PCT),[22] arguably the most important development in international intellectual property law between the ICESCR (1976) and the TRIPs (1995), serves as an example of the continued dominance of traditional intellectual property notions, even within the diverse arena of the United Nations. The PCT came into effect under the authority of the United Nations in 1978, four years after the incorporation of the WIPO. This treaty, certainly the most consequential undertaking of the international intellectual property community since the 19th century, was engineered by a group of neoliberal economists led by Edward Brenner (US Commissioner of Patents) and Arpad Bogsch (Deputy Director of BIRPI and first Director General of WIPO) in response to the concerns of multinational corporations about international patent applicability.[23] The PCT set out to ensure that corporations with patents enjoyed equal protection in every country. This meant that a large pharmaceutical company could prosecute pharmaceutical actors around the world for using patented formulas as a starting point for generic drugs development. This protection provides a particular advantage to companies that already hold a large number of patents, as they can use patent-extending strategies to maintain a monopoly over formulas and technologies beyond the standard twenty-year limit.[24] Thus, twelve years after United Nations member states affirmed the value of diffusing scientific and cultural knowledge in the ICESCR, the WIPO became responsible for overseeing the regulation of such knowledge through the PCT. This protection, which largely favors companies with pre-existing patents,[25] set the tone for the most controversial institutionalization of intellectual property thus far, the TRIPs.[26] The TRIPs, established in the 1994 Uruguay Round of the General Agreements on Tariffs and Trade, was the first attempt to put forth comprehensive protection for intellectual property through the World Trade Organization (WTO).[27] This agreement represented a monumental change in the field of international intellectual property law, pushing the protection of intellectual property into the center of international trade law.[28] It forced a minimum standard of copyright and patent protection on all 162 WTO members, severely hindering the distribution and development of agricultural and pharmaceutical innovations.[29] Though there have been subsequent agreements aimed at increasing access to “essential drugs,”[30] the TRIPs and its restrictive prescriptions continue to dominate the institutional framework of international intellectual property.[31] III. Conflict Between Intellectual Property Protection and Human Rights 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] States shouldn’t be forced to submit to a legal framework outside of their own anarchic conditions – that’s a violation of their own choice which is a contradiction in will.

#### [3] People can invent things at the same time – under IP one person is blocked from their invention which is a violation of their ability to pursue civil rights like expression, and to share in scientific advancements.

#### [4] Patents attempt to assert ownership over nature and impede individuals’ abilities to pursue their own ends.

Long 95 [(Roderick T., professor of philosophy at Auburn University, editor of the Journal of Ayn Rand Studies, director and president of the Molinari Institute and a Senior Fellow at the Center for a Stateless Society) “The Libertarian Case Against Intellectual Property Rights,” Free Nation Foundation, 1995] JL recut Lex VM

The moral case against patents is even clearer. A patent is, in effect, a claim of ownership over a law of nature. What if Newton had claimed to own calculus, or the law of gravity? Would we have to pay a fee to his estate every time we used one of the principles he discovered?

Defenders of patents claim that patent laws protect ownership only of inventions, not of discoveries. (Likewise, defenders of copyright claim that copyright laws protect only *implementations* of ideas, not the ideas themselves.) But this distinction is an artificial one. Laws of nature come in varying degrees of generality and specificity; if it is a law of nature that copper conducts electricity, it is no less a law of nature that this much copper, arranged in this configuration, with these other materials arranged so, makes a workable battery. And so on.

Suppose you are trapped at the bottom of a ravine. Sabre-tooth tigers are approaching hungrily. Your only hope is to quickly construct a levitation device I've recently invented. You know how it works, because you attended a public lecture I gave on the topic. And it's easy to construct, quite rapidly, out of materials you see lying around in the ravine.

But there's a problem. I've patented my levitation device. I own it — not just the individual model I built, but the universal. Thus, you can't construct your means of escape without using my property. And I, mean old skinflint that I am, refuse to give my permission. And so the tigers dine well.

This highlights the moral problem with the notion of intellectual property. By claiming a patent on my levitation device, I'm saying that you are not permitted to use your own knowledge to further your ends. By what right?

Another problem with patents is that, when it comes to laws of nature, even fairly specific ones, the odds are quite good that two people, working independently but drawing on the same background of research, may come up with the same invention (discovery) independently. Yet patent law will arbitrarily grant exclusive rights to the inventor who reaches the patent office first; the second inventor, despite having developed the idea on his own, will be forbidden to market his invention.

### 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.

#### 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.

#### 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."

#### 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.

#### Nuclear detonations cause nuclear winter and extinction, and the rainout effect is wrong – self-lofting means soot goes above the clouds

Starr 15 Steven Starr, 10-14-2015, "Nuclear War, Nuclear Winter, and Human Extinction," Federation Of American Scientists, [Steven Starr is the director of the University of Missouri’s Clinical Laboratory Science Program, as well as a senior scientist at the Physicians for Social Responsibility. He has been published in the Bulletin of the Atomic Scientists and the Strategic Arms Reduction (STAR) website of the Moscow Institute of Physics and Technology.], https://fas.org/pir-pubs/nuclear-war-nuclear-winter-and-human-extinction/, SJBE

While it is impossible to precisely predict all the human impacts that would result from a nuclear winter, it is relatively simple to predict those which would be most profound. That is, a nuclear winter would cause most humans and large animals to die from nuclear famine in a mass extinction event similar to the one that wiped out the dinosaurs. Following the detonation (in conflict) of US and/or Russian launch-ready strategic nuclear weapons, nuclear firestorms would burn simultaneously over a total land surface area of many thousands or tens of thousands of square miles. These mass fires, many of which would rage over large cities and industrial areas, would release many tens of millions of tons of black carbon soot and smoke (up to [180 million tons](http://climate.envsci.rutgers.edu/pdf/ToonRobockTurcoPhysicsToday.pdf), according to peer-reviewed studies), which would rise rapidly above cloud level and into the stratosphere. [For an explanation of the calculation of smoke emissions, see [Atmospheric effects & societal consequences of regional scale nuclear conflicts](http://climate.envsci.rutgers.edu/pdf/acp-7-1973-2007.pdf).] The scientists who completed the most recent peer-reviewed studies on nuclear winter discovered that the sunlight would heat the smoke, producing a self-lofting effect that would not only aid the rise of the smoke into the stratosphere (above cloud level, where it could not be rained out), but act to keep the smoke in the stratosphere for 10 years or more. The longevity of the smoke layer would act to greatly increase the severity of its effects upon the biosphere. Once in the stratosphere, the smoke (predicted to be produced by a range of strategic nuclear wars) would rapidly engulf the Earth and form a [dense stratospheric smoke layer](http://www.nucleardarkness.org/warconsequences/hundredfiftytonessmoke/). The smoke from a war fought with strategic nuclear weapons would quickly prevent up to 70% of sunlight from reaching the surface of the Northern Hemisphere and 35% of sunlight from reaching the surface of the Southern Hemisphere. Such an enormous loss of warming sunlight would produce Ice Age weather conditions on Earth in a matter of weeks. For a period of 1-3 years following the war, temperatures would fall below freezing every day in the central agricultural zones of North America and Eurasia. [For an explanation of nuclear winter, see [Nuclear winter revisited with a modern climate model and current nuclear arsenals: Still catastrophic consequences](http://climate.envsci.rutgers.edu/pdf/RobockNW2006JD008235.pdf).] Nuclear winter would cause average global surface temperatures to become colder than they were at the height of the last Ice Age. Such extreme cold would eliminate growing seasons for many years, probably for a decade or longer. Can you imagine a winter that lasts for ten years? The results of such a scenario are obvious. Temperatures would be much too cold to grow food, and they would remain this way long enough to cause most humans and animals to starve to death. Global nuclear famine would ensue in a setting in which the infrastructure of the combatant nations has been totally destroyed, resulting in massive amounts of chemical and radioactive toxins being released into the biosphere. We don’t need a sophisticated study to tell us that no food and Ice Age temperatures for a decade would kill most people and animals on the planet. Would the few remaining survivors be able to survive in a radioactive, toxic environment? It is, of course, debatable whether or not nuclear winter could cause human extinction. There is essentially no way to truly “know” without fighting a strategic nuclear war. Yet while it is crucial that we all understand the mortal peril that we face, it is not necessary to engage in an unwinnable academic debate as to whether any humans will survive.