## 1AC

Give 30 speaks- they are arbitrary and don’t reflect true skill

### Shell

Graphical user interface, text, application, email

Description automatically generated

#### Interp: Debaters must disclose round reports on the 2020-21 NDCA LD wiki for every round they have debated this season. Round reports disclose which positions (AC, NC, K, T, Theory, etc.) were read/gone for in every speech.

#### Violation: screenshot in the doc – they have not for r1

#### Standards:

#### 1] Level Playing Field – big schools can go around and scout and collect flows but independents are left in the dark so round reports are key to prep- they give you an idea of overall what layers debaters like going for so you can best prepare your strategy when you hit them. Accessibility first and independent voter – it’s an impact multiplier

#### 2] Strategy Education – round reports help novices understand the context in which positions are read by good debaters and help with brainstorming potential 1NCs vs affs – helps compensate for kids who can’t afford coaches to prep out affs.

#### Education is a voter- why schools fund debate and the terminal impact

#### Drop the debater – a] deter future abuse and b] set better norms for debate c] indicts the debater

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices c] you can’t win for having good disclosure practices

### 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] 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

#### 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] Every action has infinite stemming consequences, because every consequence can cause another consequence so we can’t predict or calculate. [B] Induction is circular because it relies on the assumption that nature will hold uniform and we could only reach that conclusion through inductive reasoning based on observation of past events. [C] Aggregation fails – suffering is not additive can’t compare between one migraine and 10 head aches

### Advocacy

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

#### Enforcement is to eliminate all IPR for medicines

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This contribution explicitly supports and is supplemental to the R&D Agreement contribution submitted by MSF, KEI, and others that focuses on rationalizing and strengthening incentives, and legal frameworks for R&D, that promote innovation and access to health technologies. However, this contribution focuses primarily on access and calls for the dismantling of global, regional, bilateral, and national IP regimes that negatively impact the global community’s access needs. It focuses on patents, the most obvious and important source of exclusivity for right holders, but also on data and regulatory market exclusivities and linkages, trade secret law, and trademark and copyright protections, which are increasingly embedded in operating systems of diagnostics and other health technologies. At present, the vast majority of countries are members of the World Trade Organization. As members, they are subject to the minimum standards of IP protections set forth in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Although there are transition periods that still apply to least developed country members, most WTO members are now subject to the whole panoply of IPRs and IP enforcement mechanisms set forth in TRIPS. As such, for IP barriers to be dismantled on health technologies, it will be necessary to amend or otherwise supersede TRIPS’s application to those technologies. The proposed non-application of TRIPS to medical technologies could be accomplished as follows: Article 6bis: Exhaustion and Non-Application to Medical Technologies 1. For the purposes of dispute settlement under this Agreement, subject to the provisions in Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights. 2. Nothing in this Agreement shall apply to medical technologies as defined. Definition of medical technologies: pharmaceutical and biologic products, vaccines, diagnostics, and related health technologies. Article 7bis Right to health and other objectives The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to the fulfillment of the human right to health, and to a balance of rights and obligations. Members shall not implement the Agreement in a manner that weakens the promotion or protection of the right to health and of access to health technologies. Article 13 bis Exemptions, limitations and exceptions Members shall confine limitations and exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the interests of the right holder. This section shall not apply to copyrights, trademarks and related rights embedded in health technologies, including the systems of internet or other transmission of health-related information from a health technology elsewhere. Article 27(1) bis Subject to the provisions of paragraph 2, 3, 6, and 7, patents shall be available, whether for products or processes, in all fields of technology, except health technologies, provided that they are new, involve an inventive step and are industrially applicable. Article 27(4) bis Members shall exclude health technologies. Article 39.3bis 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use. In addition, Members shall need not protect such data against disclosure, except where such disclosure is necessary to protect the public in the public interest, or unless steps are taken to ensure that the data are protected from unfair commercial use. In addition to amending the TRIPS Agreement, it will be necessary to formally amend multiple regional and bilateral trade and economic partnership agreements and investment treaties/provisions. Many regional and bilateral trade agreements contain IPR provisions similar to those in the TRIPS Agreement and/or provisions that are TRIPS-plus. These agreements are binding on parties, so to achieve the desired IPR reform, such agreements need to be amended to remove IPR protections on health technologies. There are far too many such agreements to list or discuss, but reform must be undertaken. Similarly, it will be necessary to reform the WIPO Patent Cooperation Treaty to exempt health technologies from patent filings and to do the same with respect to the Harare Protocol (relating to the African Regional Intellectual Property Organization), the Bangui Agreement (relating to the African Intellectual Property Organization), the Eurasian Patent Convention (affecting the Eurasian Patent Organization), and any other relevant regional patent processing entities. Addressing agreements on IPRs is not enough unless investment agreements are also amended to remove investor protections on health technologies. Just as there was a carve-out for Tobacco in the recently negotiated Trans-Pacific Partnership Agreement (however imperfect), there could be a new and stronger carve out for health technologies. At present, more and more investment agreements directly cover IPRs and give foreign investor rights to bring private investor-state-dispute-settlement (ISDS) claims directly to private arbiters. These new IPR enforcement rights are particularly dangerous as they give right holders powers to directly challenge government IP policy and decisions that adversely impact their expectation of unbridled profits, as is currently claimed in the US$500 million Eli Lilly v. Canada ISDS case. To complete the reform process, it will be necessary to revise IP laws at the national level to incorporate the health technology exclusion. This will be an enormous undertaking technically and politically, even more so where IP is constitutionally protected. Even in these circumstances, if the interests of inventors and creators are adequately protected under a new R&D incentive system, then constitutional requirements may well be satisfied. Similarly, protecting the interests of creators and sometimes inventors under international human rights regimes does not require resort to IPRs. The economic and attributional interests of inventors and creators can be met through other means.

### Offense

#### 1] The categorical imperative rejects the idea of intellectual property as it suppresses freedom by preventing others from innovating and suppressing speech in the name of a copyright.

Pievatolo 10 Pievatolo, Maria. “Freedom, Ownership and Copyright: Why Does Kant Reject the Concept of Intellectual Property?” *Freedom, Ownership and Copyright: Why Does Kant Reject the Concept of Intellectual Property?*, 7 Feb. 2010, bfp.sp.unipi.it/chiara/lm/kantpisa1.html. SJEP

In the Metaphysics of Morals, Kant seems to take for granted that the objects of real rights are only corporeal entities or res corporales: «Sache ist ein Ding, was keiner Zurechnung fähig ist. Ein jedes Object der freien Willkür, welches selbst der Freiheit ermangelt, heiß daher Sache (res corporalis)». [32](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2478823) Theoretically, however, such a negative definition could have been appropriate to incorporeal things as well. According to Kant, the rightful possession of a thing should be distinguished from its sensible possession. Something external would be rightfully mine «only if I may assume that i could be wronged by another's use of a thing even though I am not in possession of it» (AA.06 [245:13-16](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/245.html)). The rightful possession is an intelligible, not sensible, relation. I can claim that my bicycle is mine only if I am entitled to require that nobody takes it even when I leave it alone in the backyard. Kant's theory of property is very different from Fichte's principle of property as explained in his 1793 essay, according to which we are the rightful owners of a thing, the appropriation of which by another is physically impossible. For this reason, according to Fichte, the originality of the exposition entitles an author to claim a rightful property on his work. Is it really so obvious that originality implies property? Property is a comfortable social convention that allows us to avoid to quarrel all the time over the use of material objects. It is so comfortable just because it is physically possible to appropriate things; we do not need to invoke property when something cannot be separated from someone. I say both that my fingerprints or my writing style are "mine" and that my bicycle is "mine". But these two "mine" have a different meaning: the former is the "mine" of attribution; the latter is the "mine" of property. The former can be used to identify someone, and conveys the historical circumstance that something is related exclusively to someone; the latter points only to an accidental relation with an external thing, if we consider it from a physical point of view. It is possible to lie on a historical circumstance, by plagiarizing a text, i.e. by attributing it to a person who did not wrote it. However, properly speaking, no one can "steal" the historical connection between "my" writing style and me: the convention of property is useless, in this case. Besides, if Fichte's principle were the only justification of property right, it would undermine the very concept of it: as it is physically possible to "attribute" my bicycle to another, when I leave it alone in the backyard, everyone would be entitled to take it for himself. As Kant would have said, a legal property right cannot be founded on sensible situations, but only on intelligible relations. Although he defines things as res corporales, Kant determines the rightful possession of a thing as a possession without detentio, by ignoring all its sensible facets. Such a possession - a possession of a thing without holding it - is exerted on an object that is "merely distinct from me", regardless of its position in space and time. Space and time, indeed, are sensible determinations and should be left out of consideration. According to the postulate of practical reason with regard to rights, property is justified by a permissive law of reason: [33](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533469) if a rightful possession were not possible, every object would be a res nullius and nobody would be entitled to use it. Kant implicitly denies that a res nullius can be used by everyone at the same time. His tacit assumption suggests that the objects of property, besides being distinct from the subjects, are excludable and rivalrous as well, just like the res corporales. Kant asserts that something external is mine if I would be wronged by being disturbed in my use of it even though I am not in possession of it (AA.6, [249:5-7](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/249.html)). If property is a merely intelligible relation with an object that is simply distinct from the subject, we have no reason to deny that such an object might be immaterial as well, just like the objects of intellectual property. Why, then, does Kant refrain from using the very concept of it? According to him, a speech is an action of a person: it belongs to the realm of personal rights. A person who is speaking to the people is engaging a relationship with them; if someone else engages such a relationship in his name, he needs his authorization. The reprinter, as it were, does not play with property: he is only an agent without authority. Speeches, by Kant, cannot be separated from persons: he has seen the unholy promised land of intellectual property without entering it. According to Kant, before the acquired rights, everyone has a moral capacity for putting others under obligation that he calls innate right or internal meum vel tuum (AA.06, [237:24-25](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/237.html)). The innate right is only one: freedom as independence from being constrained by another's choice, insofar it can coexist with the freedom of every other in accordance with a universal law. Freedom belongs to every human being by virtue of his humanity: in other words, it has to be assumed before every civil constitution, because it is the very possibility condition of law. Freedom implies innate equality, «that is, independence from being bound by others to more than one can in turn bind them; hence a human being's quality of being his own master (sui iuris), as well as being a human being beyond reproach (iusti) since before he performs any act affecting rights he has done no wrong to anyone, and finally his being authorized to do to others anything that does not in itself diminish what is theirs, so long as they do not want to accept it - such things as merely communicating his thoughts to them.» (AA.06, [237-238](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/237.html)) [34](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533617) In spite of his intellectual theory of property, [35](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533628) Kant does not enter in the realm of intellectual property for a strong systematic reason. Liberty of speech is an important part of the innate right of freedom. It cannot be suppressed without suppressing freedom itself. If the ius reale were applied to speeches, a basic element of freedom would be reduced to an alienable thing, making it easy to mix copyright protection and censorship. [36](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533656) Property rights are based on the assumption that its objects are excludable and rivalrous and need to be appropriated by someone to be used. We cannot, however, deal with speeches as they were excludable and rivalrous things that need to be appropriated to be of some use, because excluding people from speeches would be like excluding them from freedom. Therefore, Kant binds speeches to the persons and their actions, and limits the scope of copyright to publishing, or, better, to the publishing of the age of print: the Nachdruck is unjust only when someone reproduces a text without the author's permission and distributes its copies to the public. If someone copies a book for his personal use, or lets others do it, or translates and elaborates a text, there is no copyright violation, just because it is not involved any intrinsic property right, but only the exercise of the innate right of freedom. The boundary of Kant's copyright is the public use of reason, as a key element of a basic right that should be recognized to everyone. Kant does not stick to the Roman Law tradition because of conservatism, but because of Enlightenment.

#### 2] Property rights can’t be universalizable when they forgo the opportunity for an individual to access their own freedom. Medical patents restrict an individual to pursue freedom from death by foreclosing treatment.

Merges 11 Merges, Robert P. *Justifying Intellectual Property*. Harvard University Press, 2011. SJEP

Under Kant’s Universal Principle of Right (UPR), “laws secure our right to external freedom of choice to the extent that this freedom is compatible with everyone else’s freedom of choice under a universal law.”8 As I ex- plained in Chapter 3, Kant’s theory of property rights expresses a special instance of this general principle: property is widely available, yet denied when individual appropriation interferes with the freedom of others. Kant says that although the need for robust property drives the formation of civil society, property rights are nonetheless subject to this “universalizing” principle. Under the operation of the UPR, property rights are constrained: they must not be so broad that they interfere with the freedom of fellow citizens. In a Kantian state, individual property is both necessary—to pro- mote autonomy and self-development; see Chapter 3—and necessarily re- stricted under the UPR.9 Death is the ultimate restraint on autonomy; there is no more “self” to guide after a person dies. So when a claim to property by person A leads to the death of [a]person B, Kant’s Universal Principle would seem to rebut that claim. As with other issues, however, Kant’s views in this regard are not so simple. In particular, he expressed complex views on the legal defense of “necessity,” which bears a close resemblance to the property-limiting prin- ciple I am attributing to him here.10 Kant says, in effect, that in at least one important example of necessity—where A kills B, or at least puts B in im- mediate grave danger, to save A’s own life—one who commits a necessary act is *culpable* but not *punishable.*11 As with so much in the Kantian canon, there is a great deal of debate over just what Kant was trying to say about necessity. One view—at least as plausible as most others, and more plausible than some—holds that Kant thought of necessity as something like an excuse or defense: a wrong act is not made right by necessity, but it is insulated from formal legal liability.12 This view, well described by among others the Kant scholar Arthur Ripstein, depends on the distinction between formal, positive law (“external,” in Kant’s terminology; see Chap- ter 3) and “internal” morality. Property for Kant is an absolute right, and taking it without permission is always objectively wrong. But at the same time, some takings are not punishable by the state because they fall outside the proper bounds of legitimate lawmaking. Because Kant did not explicitly discuss the necessity defense as it per- tains to property rights, any application of his thinking to the case of phar- maceutical patents can only be speculation. Even so, there is one point to make. As I explained in some detail in Chapter 3, there is generally a high degree of symmetry between Kant’s thinking on law and his theory of property. The UPR is a good example; as I explained in Chapter 3, the idea that property can extend only up to the point that it interferes with the freedom of others is simply one specific application of the general Kantian take on law and freedom. Thus, the analysis of the pharmaceutical patents problem would turn on the issue of property’s effect on the freedom of those suffering from treatable diseases. To put it simply, it is difficult to be sure of the exact conclusion Kant would reach with regard to the issue, but I am sure that the analysis would turn on the freedom-restricting qualities of pharmaceutical patents. It is hard to know the right answer, but not hard to pose the right question: should property extend so far as to cut off or restrain the freedom of those who might be treated? In my view, the freedom of disease sufferers is so constrained that the property rights in pharmaceutical patents must give way. As I said, this is not the only plausible reading of Kant’s Universal Principle with respect to the problem at hand. But I think it is the best reading, and it is certainly the best I can do, given Kant’s text and the problem of pharmaceutical patents as I understand it.

#### 3] Property rights minimize the opportunity of innovation which limits individual freedom through creating monopolies. They also limit the use of tangible objects such as medicines for good purposes.

Cernea and Uszkai 12 Cernea, Mihail-Valentin, and Radu Uszkai. *The Clash between Global Justice and Pharmaceutical Patents: A Critical Analysis*. 2012, the-clash-between-global-justice-and-drug-patents-a-critical-analysis.pdf. SJEP

To make this point clearer, we regard property as an ethical institution which emerged in the context of reiterated conflict between agents for tangible goods. A useful analogy would be, for example, the particular way in which David Hume discusses the emergence of justice in the context of scarcity in which agents pursue their own interests4 . As a result, the purpose of property rights would be that of avoiding or minimizing the possibility of conflict and that of increasing the costs of free-riding or trespassing. Let’s take the following example which will illustrate better our point. Assume that X is a philosophy student and has a copy of Immanuel Kant’s Groundwork of the Metaphysics of Morals. Y is a college of him but he does not have the book. They both have to write an essay on Kant’s categorical imperative. Because Y does not have the book, let’s assume that he decides, whether by the use of coercion or fraud to take his book. As a result, the theft leaves X without his property because tangible goods are rivalrous in consumption. Both student can’t, at the same time but in a different place read about Kant’s categorical imperative from the same copy. Now a different example: suppose X invents a new way of harvesting corn and Y harvests his corn accordingly. This situation is quite different in comparison to the case we presented earlier, because Y does not leaves X without either his new harvesting mechanisms which he created but neither without the idea behind the mechanism. It would be hard to say that Y stole something from X because the consumption of intangible goods such as ideas does not have the same rivalrous property as a copy of a book written by Kant. Actually, the existence of the patent system fosters the scarcity of ideas. In this context patents represent unjustified state-granted monopolies. Moreover, intellectual property rights have another profound immoral consequence: it limits the use of tangible objects which we acquired fully in line with market rules.

#### 4] 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.

### UV

#### [1] Presumption and permissibility affirm –

#### [a] Statements are true before false since if I told you my name, you’d believe me.

#### [b] Epistemics – we wouldn’t be able to start a strand of reasoning since we’d have to question that reason.

#### [c] Otherwise we’d have to have a proactive justification to do things like drink water.

#### [d] If anything is permissible, then definitionally so is the aff since there is nothing that prevents us from doing it.

#### 2] 1AR theory is legit otherwise the neg can be infinitely abusive and there would be no way to check back against that.

#### Comes first because it indicts the neg’s positions and skews my time allocation on other flows like T.

#### Competing interps – rzn is artbitrary and invites judge intervention and race to the top

#### 1AR theory is drop the debater – a 4 minute 1AR doesn’t have time to win both theory and substance – you must be punished.

#### No RVI on 1AR theory-It would be impossible to check back against neg abuse because the 2NR could just spend 6 minutes railing on the theory debate and the aff couldn’t win

**Answering the paradigm issues solves all combo-shell offense- abuse is about implementation not me reading them**

**First, what the neg reads doesn’t prove the resolution false, but challenges an assumption of it. Secondly, statements which make assumptions like the resolution should be read as a tacit conditional which is an if p then q statement. Thirdly, for all conditionals, if the antecedent is false, then the conditional as a whole is true**

### Adv

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

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According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

TRIPS: Barrier to Equitable Health Care Access

The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16

Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19

A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21

The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding.

Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines.

One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer.

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

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

#### Yes scale-up for covid.

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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.

#### 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.

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

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

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

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

Pharmaceutical Innovation and Generic Competition in the Pharmaceutical Industry

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

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

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

Patenting Practices by Pharmaceutical Companies

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

Defining Strategic Patenting

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

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

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

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

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

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

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

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

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

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

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

Strategic Patenting Impairs Originators’ Incentives to Innovate

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

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

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

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

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

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

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

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

Strategic Patenting Impairs Follow-on Innovation of Generic Companies

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

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

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

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