# 1st off

**Interpretation: All debaters must have a wiki on the HSLD 2021 page.**

**Violation: They don’t – screenshots below:**

**Standards:**

**1] Safety – contact info’s the only way to check trigger warnings before the round for what debaters are comfortable reading, anything else creates a hostile environment – for example, checking about scenes of violence authors may mention. Safety is a voting issue – we can’t debate unless we feel safe to do so.**

**2] Disclosure – Contact info is necessary to contact the other debater before the round – that’s good – creates more nuanced argumentation since we have time to research and rigorously test arguments – even if disclosure is bad – we should have the opportunity to debate that in round.**

**Paradigms – Fairness – debate is a competitive activity that requires fairness for objective evaluation. Drop the debater to deter future abuse.**

# 2nd off

#### Interp: Debaters must disclose round reports on the 2021-2022 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 none, they didn’t even create a page

#### Standards:

#### 1] Level Playing Field – big schools can go around and collect flows but independents are left in the dark so round reports are key for them to prep- they give you an idea of overall what layers debaters like going for so you can best prepare your strategy against 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 args– helps compensate for kids who can't afford coaches to prep out affs.

#### 3] Pre-round prep – NC’s gives especially give an idea of what type of debater someone is – they could go for NC theory every round– otherwise I enter every round unknowing whereas you have an idea of what you want to go for from the start – key to good clash

#### Votes

#### Fairness is a voter cuz it skews the debate

#### [1] DTD on disclosure –

#### a) disclosure cannot be drop the argument because it would just drop you because you’re the norm

#### b) deterrence, also dropping them is key now because it’s the beginning of the season which is key to norms creation

#### [2] No RVI on disclosure –

#### a) prevents people from checking back for bad disclosure – means we never get better wikis because they’re afraid to lose off the RVI

#### b) they know that people will read disclosure on them so they prep a counterinterp just to win off the RVI – leads to infinitely abusive norms

#### [4] CI –

#### 1] reasonability is arbitrary – impossible to know what is reasonable until you establish a brightline

#### 2] bites judge intervention cuz they have to gut check what they think is good

#### 3] reasonability collapses cuz u use offense defense to evaluate offense under the BL

#### 4] norms – you can sidestep norms by selectively choosing a different brightline you meet every round.

# 3rd off

#### Thus, the prefer utilitarianism.

#### A] Aggregation – every policy benefits some and harms others, which also means side constraints freeze action.

#### B] No intent-foresight distinction – If we foresee a consequence, then it becomes part of our deliberation which makes it intrinsic to our action since we intend it to happen.

#### 2] No act-omission distinction –

#### A] Psychology – choosing to omit is an act itself – governments decide not to act which means being presented with the aff creates a choice between two actions, neither of which is an omission.

#### B] Actor specificity – governments are culpable for omissions cuz their purpose is to protect the constituency – otherwise they would have no obligation to make murder illegal. Only util can escape culpability in the instance of tradeoffs – i.e. it resolves the trolley problem cuz a deontological theory would hold you responsible for killing regardless. Actor spec o/w – different agents have different ethical standings that affect their obligations and considerations.

# 4th off

#### WTO TRIPS deepens the global north-south divide and causes biopiracy

Erin Kathleen **Bender 3**, J.D., University of Tulsa College of Law, Tulsa, Oklahoma, May 2004; B.A., summa cum laude, Letters, University of Oklahoma, Norman, Oklahoma, May 2000, “North and South: The WTO, Trips, and the Scourge of Biopiracy,” 9-1-2003,<https://digitalcommons.law.utulsa.edu/cgi/viewcontent.cgi?article=1201&context=tjcil>

However, the United States and Europe have refused to entertain any suggested changes to the TRIPS Agreement. 332 The North is far too **invested in protecting corporate monopoly** interests to consider such changes at this point . 33 As noted above, drug companies largely have not followed the exceptions set forth in Article 27, paragraphs 2 and 3, which allow nations to suspend drug patents when necessary for the protection of human health and life.334 Where they have taken steps, the steps have been minimal, at best. Political pressure to follow all of the TRIPS Agreement, including those sections not as favorable to Northern corporations, would have to be applied. Otherwise, developed countries would be likely to **disregard farmers' rights** provisions, just as they have disregarded the drug patent exception. In short, if any such change is to be accomplished, it must begin with political pressure from the peoples of the U.S. and of the E.U. The people of the North must realize that change in the global system is necessary if we are to live in harmony. The North has long relied upon formal IP systems to promote technology and safeguard trade interests. 336 Patents, in particular, **have proven to be formidable weapons** in pursuing those interests. However, globalization has raised awareness of the near certainty that such systems currently serve to exploit the resources of countries in the South 7 Vandana Shiva expresses these concerns succinctly: Western IPR regimes have **emerged as major instruments of North-South inequality**. Not only do they block technology transfer but [they] also **facilitate piracy of** the **indigenous knowledge and biodiversity** of Third World countries. They could, if not revised and reviewed, make northern countries monopoly owners of knowledge including knowledge that has evolved cumulatively and collectively in indigenous cultures, selling it at high cost to already impoverished and indebted countries of the South, **pushing them further into poverty and debt**.338 As evidenced by Shiva's remarks, the critics of the effects of Northern IP systems take this threat to Southern countries quite seriously. They argue that while proponents of current trade and IP systems profess that their institutions shelter poor countries from unilateral actions by stronger nations, the systems in fact serve to stifle development in the South and ensure the **continued dominance of the North**Y. 3 9 These critics believe that imminent change must take place within the international community, or else **the "very existence of agrarian communities" will be in jeopardy**. 340 Because many Southern countries possess rich biological diversity, and because many rely heavily on agriculture as they struggle to gain a foothold in the growing global market, critics have paid special attention to patent systems and plant varieties protection as tools of Northern conquest.34 ' As the current system is so ingrained, and is so dominated by the U.S., it is largely up to the American people to call 342 for change. Abraham Lincoln, one of the greatest American Presidents, charged us "to do all which may achieve and cherish a just and lasting peace among ourselves and with all nations. In the recent past, the American people have often failed to consider the South when constructing the global scheme.344 After the events of September 11, 2001, many may be tempted to disregard the interests of the South altogether. However, Lincoln's charge holds even more meaning today.345 The United States is currently embroiled in a war with Iraq, and the unrest amongst other Middle Eastern countries is deafening. If the North is to live in peace with the South, everyone's interests must be taken into account. Just as Lincoln charged the U.S. to focus on forgiveness and to look beyond out borders after the Civil War, so must we look beyond our borders to the needs of developing countries as they struggle to find their place in this world that we have created.346

#### Biopiracy causes environmental disaster

James Ming **Chen 13**, Justin Smith Morrill Chair in Law, Michigan State University; Of Counsel, Technology Law Group of Washington, D.C. 5-15-13. “BIOPROSPECT THEORY,”<https://www.uakron.edu/dotAsset/989023a4-c9c1-49a6-854d-26ea7eb01cca.pdf>

Conventional wisdom treats biodiversity and biotechnology as rivalrous values. The global south is home to most of earth’s vanishing species, while the global north holds the capital and technology needed to develop this natural wealth. The south argues that intellectual property laws enable pharmaceutical companies and seed breeders in the industrialized north to commit **biopiracy**.1 By contrast, the United States has characterized calls for profit-sharing as a threat to the global life sciences industry.2 Both sides magnify the dispute, on the apparent consensus that commercial exploitation of genetic resources holds the key to biodiversity conservation. Both sides of this debate misunderstand the relationship between biodiversity and biotechnology.3 Both sides have overstated the significance of bioprospecting. It is misleading to frame the issue as whether intellectual property in the abstract can coexist with the international legal framework for preserving biodiversity. As a matter of legal gymnastics, any lawyer can reconfigure intellectual property to embrace all of the intangible assets at stake, including raw genetic resources, advanced agricultural and pharmaceutical research, and ethnobiological knowledge. The real challenge lies in directing the law of biodiversity conservation and the law of intellectual property toward appropriate preservation and exploitation of the global biospheric commons.5 Commercial development aids biodiversity primarily by overcoming perverse economic incentives to consume scarce natural resources that may turn out to have greater global, long-term value. We contest these issues not because we are rational, but precisely because we are not. Indeed, legal approaches to biodiversity and biotechnology are so twisted that they represent an extreme application of prospect theory. Nearly half a century before Daniel Kahneman and Amos Tversky published Prospect Theory: An Analysis of Decision Under Risk, 6 the 1979 article that became the foundational work of behavioral economics and the principal basis for Kahneman’s 2002 Nobel Prize in Economics,7 the Supreme Court of the United States succinctly summarized a core tenet of prospect theory: “Threat of loss, not hope of gain, is the essence of economic coercion.”8 In plainer terms, “losing hurts worse than winning feels good.”9 Stated in formal terms, prospect theory posits that most individuals, as an expression of innate risk aversion, fear potential losses far more than they covet potential gains.10 The law of biodiversity and biotechnology appears to reverse this presumption. Although humans innately fear losses more than they value gains, worldwide policy appears to assign relatively little value to biodiversity as an invaluable, incommensurate, and indefinitely important component of global ecological health.11 Biodiversity loss is **staggering and undeniable**.12 Humans are responsible for the sixth great extinction spasm of the Phanerozoic Eon, a unit of geologic time spanning half a billion years.13 Cataclysmic loss of biological diversity is merely one of several ecological threats looming over Holocene humanity.14 In assembling this brief analysis, I hasten to add this observation: so far I have assigned no weight to global climate change, a threat that has raised the probability of human extinction to a non-negligible value. Risks as grandiose as these, sufficient in their magnitude to portend the end of civilization, possibly even the survival of humans as a species, support the most dismal of theorems in the dismal science of economics: “the catastrophe-insurance aspect of such a fat-tailed unlimited-exposure situation, which can never be fully learned away, can dominate the social-discounting aspect, the pure-risk aspect, and the consumptionsmoothing aspect.”15 In plainer language, the dismal theorem posits that “under limited conditions concerning the structure of uncertainty and societal preferences, the expected loss from certain risks such as climate change is infinite and that standard economic analysis cannot be applied.”16 By contrast, the global north and the global south alike have reached an **apparent consensus** that the primary object of the international debate over “biopiracy” is the **appropriate profit-sharing** protocol (including the possibility of no redistributive mechanism whatsoever) for gains from bioprospecting.17 Such gains, at best, are **highly speculative**.18 Even if profits from bioprospecting are ever realized, they will be extremely concentrated. No champion of redistributive justice on a global scale could defend a system of transferring northern wealth that would favor Brazil, Costa Rica, and Madagascar while neglecting Bolivia, Mali, and Afghanistan. There simply is **no defensible basis** for treating ethnobiological knowledge as the foundation of a globally coherent approach to economic development. Yet the global community continues to spend its extremely small and fragile storehouse of political capital on this contentious corner of international environmental law.19 Global economic diplomacy should be made of saner stuff. The fact that it is not invites us to treat the entire charade as a distinct branch of behavioral law and economics: bioprospect theory. Upon closer examination, prospect theory and related branches of behavioral economics do supply a powerful explanation for international economic law’s systematic failure to reach the optimal solutions for biodiversity conservation. Prospect theory arises from three basic features of human beings’ core cognitive system:20 1. All decisionmaking takes place relative to a neutral reference point, or “adaptation level.” Outcomes exceeding this reference point are gains. Outcomes below the reference point are losses. 2. Loss aversion means that losses, when directly weighted or compared against gains, loom larger. 3. Diminishing sensitivity applies to upward and downward perceptions and to evaluation of changes of wealth. In concert, these three principles — neutral reference point, loss aversion, diminishing sensitivity — can be illustrated through a graph showing an asymmetrical sigmoid curve whose inflection point occurs at the neutral adaptation level, whose steeper slope below the adaptation level demonstrates loss aversion, and whose declining rate of change in both directions reflects diminishing sensitivity to gains and losses:21 19. See Chen, supra note 5, at 506. 20. See KAHNEMAN, supra note 10, at 282. 21. Id. at 282-83. One readily implemented way of parametrically modeling prospect theory with closed-form expressions and elementary functions is the cumulative distribution function of the log-logistic 2014] BIOPROSPECT THEORY 23 “If prospect theory had a flag, this image would be drawn on it.”22 The asymmetrical utility curve that emerges from prospect theory’s reevaluation of conventional accounts of expected economic utility leads to some apparent contradictions.23 In mixed gambles, for instance, where a decisionmaker may realize either a gain or a loss, loss aversion leads to extreme, even costly risk aversion. This is the primary conclusion of prospect theory, the one most readily summarized by the slogan, “losing hurts worse than winning feels good.”24 But prospect theory predicts affirmatively risk-seeking behavior in other circumstances. When a decisionmaker is confronted with nothing but “bad choices” — specifically, those “where a sure loss is compared to a larger loss that is merely probable” — diminishing sensitivity to losses will generate a greater willingness to absorb risk.25 Prospect theory therefore rests on two principal insights. First, humans “attach values to gains and losses rather than to wealth.”26 Second, humans making decisions assign “weights . . . to outcomes [that] are different from 22. KAHNEMAN, supra note 10, at 282. Graph reproduced from Basic Concepts: Prospect Theory, THE DICKINSON COLLEGE WIKI, http://wiki.dickinson.edu/index.php/Basic\_Concepts#Prospect\_Theory (last modified May 3, 2007). 23. See KAHNEMAN, supra note 10, at 285. 24. GRIZZARD, supra note 9; accord GARAGIOLA, supra note 9. 25. KAHNEMAN, supra note 10, at 285. 26. Id. at 316-17. 24 AKRON INTELLECTUAL PROPERTY JOURNAL [7:19 probabilities.”27 The combination of these two heuristics generates “a distinctive pattern of preferences” that Kahneman and Tversky have called the “fourfold pattern”:28 The four-fold pattern Gains Losses High probability (certainty effect) E.g., a 95% chance to win $10,000 leads to . . . Risk aversion (annuities and sinecures) E.g., a 95% chance to lose $10,000 leads to . . . Risk seeking (rogue trading and other reckless gambles) Low probability (possibility effect) E.g., a 5% chance to win $10,000 leads to . . . Risk seeking (lotteries) E.g., a 5% chance to lose $10,000 leads to . . . Risk aversion (insurance) Let us examine more closely each of the four vanes in prospect theory’s pinwheel of fortune. Three of these four behavioral possibilities have long been understood; prospect theory merely provided the means by which to describe them formally.29 The cell at top left describes how risk aversion leads people to lock in a sure gain below the expected value of a gamble. Annuities work on this principle, as do employment guarantees in unionized trades or on tenure-protected university faculties. The cell at lower right describes insurance: individuals will pay much more than the expected value of a loss to insure themselves against the disturbing prospect of a catastrophic loss.30 On the flip side of that transaction, insurance companies can pool risks assigned to them by risk-averse policyholders and profit from the spread between expected losses and premium payments. These risk-averse decisions reflect the core instinct of prospect theory. But there is also a risk-seeking side to this account of human behavior. Lotteries routinely exploit the possibility effect. When the potential payout is enormous, ticket buyers become indifferent to their miniscule chances of winning. This is the behavioral pattern reflected by the lower left cell. It is 27. Id. at 317. 28. Id. 29. See id. at 317-18. 30. See, e.g., Jim Chen, Modern Disaster Theory: Evaluating Disaster Law as a Portfolio of Legal Rules, 25 EMORY INT’L L. REV. 1121 (2011); Jim Chen, Postmodern Disaster Theory (Mich. State Univ. Coll. of Law Legal Studies Research Paper Series, Paper No. 11-17, 2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2141591. 2014] BIOPROSPECT THEORY 25 sufficiently powerful that banks and credit unions have resorted to depositor lotteries to induce lower- to middle-income customers to open and fund savings accounts.31 What Kahneman and Tversky found most surprising was the fourth possibility, the one described in the risk-seeking cell at upper right. When humans face the high probability of severe losses, they engage in affirmatively riskier behavior. Prospect theory identifies two reasons for this sudden shift in strategy.32 First, diminishing sensitivity means that humans react very adversely to a sure loss: “the reaction to a loss of $900 is more than 90% as intense as the reaction to a loss of $1,000.”33 Second and perhaps even more significant, humans assign a much lower decision weight to an extreme loss than its rationally expected value as calculated by the laws of probability. The certainty effect, coupled with diminishing sensitivity, enhances the aversiveness of a sure loss and reduces the aversiveness of the gamble. This is the ugly corner of human decisionmaking where otherwise responsible parties find themselves tempted to take risks that can “turn[] manageable failures into disasters.”34 “Rogue traders” who have amassed appalling losses let it all ride on a single act of reckless arbitrage. That gamble may destroy a systemically important financial institution.35 “Because defeat is so difficult to accept,” chief executive officers and field marshals suffer from a comparable inability to cut their losses and salvage what is left of their companies and armies.36 Bioprospect theory helps explain why international economic and environmental law reaches such perverse outcomes in its approach to biodiversity conservation and **bioprospecting**. Biodiversity policy is perverse because it disobeys the standard risk-averse pattern of human conduct and follows instead the contrary axis of risk-seeking behavior. The fate of the biosphere presents either (1) a low probability of immense gain (through bioprospecting) **or** (2) a **high probability of immense loss** (through global climate change). The lottery effect readily explains the overvaluing of commercial bioprospecting. Pharmaceutical companies and protesters accusing them of biopiracy have this much in common: both sides are **bedazzled — irrationally** — by the possibility that some **lucrative cure for cancer may lurk in a Brazilian rain forest**.37 The looming **loss of global biological diversity**, on a **geologically significant scale**, poses an even **more disturbing prospect**. The magnitude of ecological losses is increasing at an alarming rate, even more so once we move past the relatively narrow frame of biodiversity and contemplate the possibility of complete disruption of global climatic systems. As the costs and the likely futility of mitigating action increase,38 humans find their own heuristics shoving their collective decisionmaking processes further onto the frontier of desperation where risk-averse acts such as insurance lose their appeal and yield ground to active risk-seeking. System 1 — the rapid, automatic decisionmaking system that has propelled humanity from Pleistocene competitiveness to Holocene dominance39 — may be **pushing Homo sapiens sapiens to the edge of extinction by its own talented hand.** The global **collapse of biodiversity** is the ultimate ecosystem service provided by indicator species: “never send to know for whom the bell tolls; it tolls for thee.”40 Bioprospect theory provides the blueprint by which humanity might **eschew** the **remote prospect of wealth**, if only momentarily, and focus on how it might **better manage** anthropogenic **ecological disasters** before they become full-blown, irreversible cataclysms of global proportions.

**Continued biodiversity loss will cause extinction**

Carrington 10/29 [(Damian, the Guardian's Environment editor)

"Humanity has wiped out 60% of a animal populations since 1970, report finds," The Guardian, 10/29/18] Humanity has wiped out 60% of mammals, birds, fish and reptiles since 1970, leading the world’s foremost experts to warn that the annihilation of wildlife is now an emergency that threatens civilisation.The new estimate of the massacre of wildlife is made in a major report produced by WWF and involving 59 scientists from across the globe. It finds that the vast and growing consumption of food and resources by the global population is destroying the web of life, billions of years in the making, upon which human society ultimately depends for clean air, water and everything else.“We are sleepwalking towards the edge of a cliff” said Mike Barrett, executive director of science and conservation at WWF. “If there was a 60% decline in the human population, that would be equivalent to emptying North America, South America, Africa, Europe, China and Oceania. That is the scale of what we have done.”“This is far more than just being about losing the wonders of nature, desperately sad though that is,” he said. “This is actually now jeopardising the future of people. Nature is not a ‘nice to have’ – it is our life-support system.”“We are rapidly running out of time,” said Prof Johan Rockström, a global sustainability expert at the Potsdam Institute for Climate Impact Research in Germany. “Only by addressing both ecosystems and climate do we stand a chance of safeguarding a stable planet for humanity’s future on Earth.”Many scientists believe the world has begun a sixth mass extinction, the first to be caused by a species – Homo sapiens. Other recent analyses have revealed that humankind has destroyed 83% of all mammals and half of plants since the dawn of civilisation and that, even if the destruction were to end now, it would take 5-7 million years for the natural world to recover.The Living Planet Index, produced for WWF by the Zoological Society of London, uses data on 16,704 populations of mammals, birds, fish, reptiles and amphibians, representing more than 4,000 species, to track the decline of wildlife. Between 1970 and 2014, the latest data available, populations fell by an average of 60%. Four years ago, the decline was 52%. The “shocking truth”, said Barrett, is that the wildlife crash is continuing unabated.Wildlife and the ecosystems are vital to human life, said Prof Bob Watson, one of the world’s most eminent environmental scientists and currently chair of an intergovernmental panel on biodiversity that said in March that the destruction of nature is as dangerous as climate change.“Nature contributes to human wellbeing culturally and spiritually, as well as through the critical production of food, clean water, and energy, and through regulating the Earth’s climate, pollution, pollination and floods,” he said. “The Living Planet report clearly demonstrates that human activities are destroying nature at an unacceptable rate, threatening the wellbeing of current and future generations.”The biggest cause of wildlife losses is the destruction of natural habitats, much of it to create farmland. Three-quarters of all land on Earth is now significantly affected by human activities. Killing for food is the next biggest cause – 300 mammal species are being eaten into extinction – while the oceans are massively overfished, with more than half now being industrially fished.Chemical pollution is also significant: half the world’s killer whale populations are now doomed to die from PCB contamination. Global trade introduces invasive species and disease, with amphibians decimated by a fungal disease thought to be spread by the pet trade.The worst affected region is South and Central America, which has seen an 89% drop in vertebrate populations, largely driven by the felling of vast areas of wildlife-rich forest. In the tropical savannah called cerrado, an area the size of Greater London is cleared every two months, said Barrett.“It is a classic example of where the disappearance is the result of our own consumption, because the deforestation is being driven by ever expanding agriculture producing soy, which is being exported to countries including the UK to feed pigs and chickens,” he said. The UK itself has lost much of its wildlife, ranking 189th for biodiversity loss out of 218 nations in 2016.The habitats suffering the greatest damage are rivers and lakes, where wildlife populations have fallen 83%, due to the enormous thirst of agriculture and the large number of dams. “Again there is this direct link between the food system and the depletion of wildlife,” said Barrett. Eating less meat is an essential part of reversing losses, he said.The Living Planet Index has been criticised as being too broad a measure of wildlife losses and smoothing over crucial details. But all indicators, from extinction rates to intactness of ecosystems, show colossal losses. “They all tell you the same story,” said Barrett.Conservation efforts can work, with tiger numbers having risen 20% in India in six years as habitat is protected. Giant pandas in China and otters in the UK have also been doing well.But Marco Lambertini, director general of WWF International, said the fundamental issue was consumption: “We can no longer ignore the impact of current unsustainable production models and wasteful lifestyles.”The world’s nations are working towards a crunch meeting of the UN’s Convention on Biological Diversity in 2020, when new commitments for the protection of nature will be made. “We need a new global deal for nature and people and we have this narrow window of less than two years to get it,” said Barrett. “This really is the last chance. We have to get it right this time.”Tanya Steele, chief executive at WWF, said: “We are the first generation to know we are destroying our planet and the last one that can do anything about it

#### AND, bioprospecting causes global war over Antarctica

Doaa **Abdel-Motaal 17**, Doaa Abdel-Motaal was Deputy Chief of Staff of the World Trade Organization (WTO) in Switzerland, and advisor to the head of the organization on environmental issues and climate change. She was also Chief of Staff of the United Nations for International Fund for Agricultural Development (IFAD) in Italy. 2-21-2017, "Averting the Battle for Antarctica," Yale Journal, http://yalejournal.org/article\_post/averting-the-battle-for-antarctica/

Various forms of economic activities are gaining ground in Antarctica. Take tourism, for example, which has undergone exponential growth in recent years and is barely regulated by the Antarctic Treaty. In 2013–2014, nearly twenty-eight thousand tourists made landings on the continent, 30 percent of whom were American, 13 percent Australian, and 11 percent Chinese. This represents a doubling since 2000.[xxxii] Or take **bioprospecting** – the exploitation of Antarctica’s **living biological resources**. The discovery and commercialization of **new products** based on Antarctica’s biological riches is starting to **flourish**, similarly under limited treaty regulation.[xxxiii] Fishing activity continues to expand around the continent. In fact, the term ‘illegal, underreported, and unregulated’ fishing was first coined in the Antarctic to describe the plight of the Southern Ocean.[xxxiv] The world was quick to declare CCAMLR a success when, at the end of October 2016, after five years of negotiations, twenty-four countries and the European Union unanimously agreed to create the world’s biggest marine protected area (MPA) in Antarctica’s Ross Sea. But the famed MPA was carved around fishing interests.[xxxv] Iselin Bank, which is the Ross Sea’s main fishing ground for the lucrative Antarctic toothfish, and which is considered the most important ecological hotspot for seabirds and other wildlife, is not protected in the new reserve. Furthermore, about half of the sanctuary was already protected under other CCAMLR rules, with the MPA in that portion simply capturing the status quo. Clearly the MPA is better than nothing, but the widespread claim that it has succeeded in protecting Antarctica’s waters, is grossly exaggerated. In fact, it is not only the Southern Ocean that is suffering from poor environmental governance but Antarctica as a whole. On a continent with no indigenous habitants, where we are told there is no major commercial activity, and where mining is banned it is highly surprising that parties to the Antarctic Treaty would have only designated 1.5 percent of the continent’s ice-free territory as a protected area.[xxxvi] This statistic alone makes Antarctica the world’s least environmentally protected continent. In neighboring Australia, for example, 18 percent of the country has been declared a protected area. If the race for Antarctica continues to accelerate amid such limited governance, its fragile environment will be in serious peril. Triggers for a Bigger Battle So, will there be a bigger battle for Antarctica? The continent’s warming climate is likely to make its resources **more accessible** and its landmass potentially habitable. On March 24, 2015, a temperature of positive 17.5 degrees Celsius was recorded at Esperanza weather station on the northern tip of the Antarctic Peninsula, setting a record for the highest temperature ever recorded on the continent.[xxxvii] Antarctica’s climate experts cannot ascertain whether these changes are due to increased greenhouse gas concentrations since weather stations were only established on the continent in the 1950s. What is clear, however, is that the Antarctic Peninsula in particular is warming. As Antarctica warms and starts to become more habitable, many other parts of the globe will become increasingly uninhabitable. This could increase the **pressure** to develop and exploit the seventh continent. In addition, technological progress is steadily increasing our **ability** to **access** and inhabit Antarctica. In November 2015, the Australian Antarctic Division and Royal Australian Air Force flew a C-17A Globemaster to Antarctica.[xxxviii] The aircraft covered 3,450 kilometers in just over five hours carrying 12,340 kilograms of cargo and equipment, making it the largest aircraft to have reached the Wilkins Aerodrome on the western side of the continent. Opened in 2009, Belgium’s Princess Elizabeth Station, which represents state-of-the-art architecture in Antarctica, has successfully harnessed the power of wind and sun to achieve near-full energy autonomy.[xxxix] Similarly, some research stations in Antarctica are now growing their own food.[xl] **Clearly** the race for Antarctica is **about to intensify** and the world **must prepare itself**. It could be triggered by the rise of even bigger human settlements or the extraction of minerals before or after 2048. If such a conflict occurs, it will be one of the **most complex** and **truly international contests** for habitable space and mineral resources of **modern times.** It will be a battle in which an **entire continent will be up for grabs** and which will take place against the complex history of the ATS and the unresolved “Question of Antarctica.” Peace in Antarctica is **fragile at best**.

# 5th off

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

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

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

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

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

TRIPS: Barrier to Equitable Health Care Access

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

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

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

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

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

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

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

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

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

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

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

#### Yes scale-up for covid.

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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.

#### 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.

#### Future diseases are coming- the aff sets a precedent for medicine sharing that is key to solve.

Brink Lindsey, June 3, 2021, Brookings, “Why intellectual property and pandemics don’t mix”, [https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/] mc

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference. Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. THE NATURE OF THE PATENT BARGAIN When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs.

**Future pandemics will cause extinction – it only takes one ‘super-spreader’.**

**Bar-Yam 16** Yaneer Bar-Yam 7-3-2016 “Transition to extinction: Pandemics in a connected world” <http://necsi.edu/research/social/pandemics/transition> (Professor and President, New England Complex System Institute; PhD in Physics, MIT)//Elmer

Watch as one of the more aggressive—brighter red — strains rapidly expands. After a time it goes extinct leaving a black region. Why does it go extinct? The answer is that it spreads so rapidly that it kills the hosts around it. Without new hosts to infect it then dies out itself. That the rapidly spreading pathogens die out has important implications for evolutionary research which we have talked about elsewhere [1–7]. In the research I want to discuss here, what we were interested in is the effect of adding long range transportation [8]. This includes natural means of dispersal as well as **unintentional dispersal by humans**, like adding airplane routes, which is being done by real world airlines (Figure 2). When we introduce long range transportation into the model, the success of more aggressive strains changes. They can use the **long range transportation** to find new hosts and **escape local extinction**. Figure 3 shows that the more transportation routes introduced into the model, the **more higher aggressive pathogens are able to survive and spread**. As we add more long range transportation, there is a critical point at which pathogens become so aggressive that **the entire host population dies**. The pathogens die at the same time, but that is not exactly a consolation to the hosts. We call this the phase transition to **extinction** (Figure 4). With increasing levels of global transportation, **human civilization** may be approaching **such a critical threshold**. In the paper we wrote in 2006 about the dangers of global transportation for pathogen evolution and pandemics [8], we mentioned the risk from Ebola. Ebola is a horrendous disease that was present only in isolated villages in Africa. It was far away from the rest of the world only because of that isolation. Since Africa was developing, it was only a matter of time before it reached population centers and airports. While the model is about evolution, it is really about which pathogens will be found in a system that is highly connected, and Ebola can spread in a highly connected world. The traditional approach to public health uses historical evidence analyzed statistically to assess the potential impacts of a disease. As a result, many were surprised by the spread of Ebola through West Africa in 2014. As the connectivity of the world increases, past experience is not a good guide to future events. A key point about the phase transition to extinction is its **suddenness**. Even a system that seems stable, **can be destabilized** by a few more long-range connections, and connectivity is continuing to increase. So how close are we to the tipping point? We don’t know but it would be good to find out before it happens. While Ebola ravaged three countries in West Africa, it only resulted in a handful of cases outside that region. One possible reason is that many of the airlines that fly to west Africa stopped or reduced flights during the epidemic [9]. In the absence of a clear connection, public health authorities who downplayed the dangers of the epidemic spreading to the West might seem to be vindicated. As with the choice of airlines to stop flying to west Africa, our analysis didn’t take into consideration how people respond to epidemics. It does tell us what the outcome will be unless we respond fast enough and well enough to stop the spread of future diseases, which may not be the same as the ones we saw in the past. As the world becomes more connected, the dangers increase. Are people in western countries safe because of higher quality health systems? Countries like the U.S. have highly skewed networks of social interactions with some very highly connected individuals that can be **“superspreaders.”** The chances of such an individual becoming infected may be low but events like a mass outbreak pose a much **greater risk** if they do happen. If a sick food service worker in an airport infects 100 passengers, or a contagion event happens in mass transportation, **an outbreak could very well prove unstoppable**.