**1AC Evergreening**

**Plan**

#### Plan – The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

#### The Plan solves Evergreening.

Feldman 3 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

### Evergreening Advantage

#### Extensive IP restrictions encourage the production of trivial patents that stifle R&D by creating legal minefields.

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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. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, **the U.S.** patent **system** at present **is out of balance.** Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: **the number of patents** granted annually **has skyrocketed** roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as **patent trolls**: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, **a law** that is **supposed to encourage innovation has turned into a legal minefield** for many would-be innovators. In the pharmaceutical industry, firms have abused the law by **piling up patents for** trivial, therapeutically **irrelevant “innovations” that allow them to extend** their **monopolies and** keep raising **prices** long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror is the largest medical threat—it outweighs natural pandemics

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Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a **mistake** to underestimate the **threats from natural pathogens**. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology **to cause harm on a staggering scale**, by either cruelty or carelessness. Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts. The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with **no attention to** maintaining or improving **traits that enhance fitness in other environments**. If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of **a**n especially persistent **horde of 5-year-olds**, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time. By contrast, modern **biologists are gaining the ability to see the whole field**, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens **poses serious concerns**. It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist. It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about **23 are known or suspected to have** maintained **biological weapons** programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ **vulnerability to biological threats**, has done little to mitigate this danger. **Accidental releases pose** an **additional** source of **anthropogenic biorisk.** Thanks to the U.S. government’s monitoring program, we know that **dozens of agents** and toxins with the potential to pose a severe threat to public health and agriculture **are** reported **accidentally lost or released** from U.S. labs **every year**. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength. Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing. Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.

#### Bioterrorism leads to extinction – modern technologies can be used to isolate deadly pathogens and target vast populations.

Kellman ‘08 (Barry, Professor of Law, Director, International Weapons Control Center, International Human Rights Law Institute @ DePaul U., Futurist, May 2008, “Bioviolence: A Growing Threat,” http://www.britannica.com/bps/additionalcontent/18/31535413/Bioviolence-A-Growing-Threat)

According to the National Academies of Science, "The threat spectrum is broad and evolving – in some ways predictably, in other ways unexpectedly. In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics." For as far into the future as we can possibly see, every passing day it be- comes slightly easier to commit a vio lent catastrophe than it was the day before. Indeed, the rapid pace of advancing science helps explain why policies to prevent such a catastrophe are so complicated. Bioviolence Jihad? Some experts argue that terrorists and fanatics are not interested in bio- violence and that the danger might therefore be overblown. Since there have been no catastrophic bioviolence attacks, these experts argue, terrorists lack the intention to make bioweapons. Hopefully, they are correct. But an enormous amount of evidence suggests they are wrong**. From the dawn of biology's ability to isolate pathogens, people have pursued hostile applications** of biological agents. It is perilous to ignore this extensive history by presuming that today's villains are not fervent about weaponizing disease. Not a single state admits to having a bioweapons program, but U.S. intelligence officials assert that as many as **10 states** might have active programs, including North Korea, Iran, and Syria. Moreover, many **terrorist organizations have expressed interest** in acquiring biological weapons. Whatever weight the taboo against inflicting disease might have for nation-states, it is obviously irrelevant to terrorists, criminals, and lunatics. Deterrence by threat of retaliation is essentially meaningless for groups with suicidal inclinations who are likely to intermingle with innocent civilians. Al-Qaeda and affiliated Islamic fundamentalist organizations have abling them to spread in regions where there is no natural immunity. The **polio** virus **has been synthesized from scratch**; its creators called it an "animate chemical." Soon, it may be resynthesized into a form that is contagious even **among vaccinated populations**. Recreation of long-eradicated livestock diseases could **ravage herds** severely lacking in genetic diversity, **damage food supplies, and cause devastating economic losses**. Perhaps the greatest biothreat is the manipulation of the flu and other highly contagious viruses, such as Ebola. Today, scientists can change parts of a virus's genetic material so that it can perform specific functions. The genomic sequence of the Spanish flu virus that killed upwards of 40 million people nearly a century ago has been widely published; **any** savvy **scientist could reconstruct it**. The avian flu is even more lethal, albeit not readily contagious via casual aerosol delivery. A malevolent bio- scientist might augment its contagiousness. The Ebola virus might be manipulated so that it kills more slowly, allowing it to be spread farther before its debilitating effects al- together consume its carrier. A bit further off is genetic manipulation of the measles virus--one of the great killers in human history--rendering useless the immunizations that most of us receive in early childhood. Soon, laboratory resynthesis of smallpox may be possible. Advanced drug delivery systems can be used to **disseminate lethal agents to broad populations**. Bio- regulators--small organic compounds that modify body systems-- could enhance targeted delivery technologies. Some experts are concerned that new weapons could be aimed at the immune, neurological, and neuroendocrine systems. Nanotechnology that lends itself to mechanisms for advanced disease detection and drug delivery--such as gold nanotubes that can administer drugs directly into a tumor--could also de- liver weaponized agents deep into the body, substantially raising the weapon's effectiveness. Altogether, techniques that were on the frontiers of science only a dec- ade or two ago are rapidly mutating A looming danger confronts the world--the threat of bioviolence. It is a danger that will only grow in the future, yet we are increasingly failing to confront it. With every passing day, committing a biocatastrophe becomes a bit easier, and this condition will perpetuate for as long as science progresses. Biological warfare is as old as conflict, of course, but in terms of the objectives of traditional warfare-- gaining territory or resources, compelling the surrender of an opposing army--biological weapons weren't very effective. If the objective is to inflict mass death and panic on a mixed population, however, emerg- ing bioweapons offer remarkable potential. We would be irresponsible to presume that radical jihadists like al- Qaeda have ignored said potential.

# **Biopiracy Advantage**

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

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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

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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.

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

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### 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.

#### Framing

#### The standard is maximizing expected wellbeing

#### 1] Only pleasure and pain are intrinsically valuable – all other frameworks collapse.

Moen 16

[Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281]

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

#### 2] Actor specificity: A] Governments must aggregate since every policy benefits some and harms others, which also means side constraints freeze action. B] States lack wills or intentions since policies are collective actions. Actor-specificity comes first since different agents have different ethical standings. Takes out util calc indicts since they’re empirically denied and link turns them because the alt would be *no* action.

#### 3] Util is a lexical pre-requisite to any other framework – Threats to bodily security and life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis that inhibit the ideal moral conditions which other theories presuppose – so, util comes first and my offense outweighs theirs under their own framework.

#### 4] Weighability – only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first. Intuitions outweigh—they’re the foundational basis for any argument and theories that contradict our intuitions are most likely false even if we can’t deduce why.

### Theory

#### Theory:

#### [1] Aff gets 1AR theory because otherwise the neg can engage in infinite abuse, making debate impossible.

#### [2] DTD – the 1AR is too short for theory and substance so ballot implications are key to check abuse.

#### [3] No RVIs – they can dump 6 minutes of answers to a short argument and make the 2AR impossible.

#### [4] Competing interps – 1AR interps aren’t bidirectional and the neg should have to defend their norm since they have more time.

#### [5] Aff theory highest layer of the round – they get thirteen minutes on theory vs our seven minutes – they’ll say we can read 1AC theory but we can’t preempt every possible abuse story.

#### [6] No new 2NR theory or paradigm issues – makes the aff always lose since there’s no way to cover everything in the 2AR, and paradigm issues can be contested in the 1NC.

#### [7] Aff fairness comes prior to NC arguments cuz its key to compensate structural skew

Shah 19 [Sachin Shah, 2019, "A Statistical Analysis of Side-Bias on the 2019 January-February Lincoln-Douglas Debate Topic," NSD Update, http://nsdupdate.com/2019/a-statistical-analysis-of-side-bias-on-the-2019-january-february-lincoln-douglas-debate-topic/] AG accessed 6-22-2019

As a final note, it is also interesting to look at the trend over multiple topics. In the rounds from 93 TOC bid distributing tournaments (2017 – 2019 YTD), the negative won 52.99% of ballots (p-value < 0.0001) and 54.63% of upset rounds (p-value < 0.0001). This suggests the bias might be structural, and not topic specific, as this data spans six different topics.

### Permissibility and Presumption

#### Permissibility and presumption affirm:

#### [1] If not, we’d have to have a proactive justification to do things like drinking water.

#### [2] Linguistics

University of Missouri no date University of Missouri, "Ethical Theory," no date, University of Missouri School of Medicine, accessed 6 September 2021, <https://medicine.missouri.edu/centers-institutes-labs/health-ethics/faq/theory> ~ST~

Expanding the category of “morally right” to include three different subcategories better captures the distinctions we want:

1. morally wrong
2. morally right
   1. morally neutral
   2. morally obligatory
   3. morally supererogatory

#### [3] Logically safer since it’s better to be supererogatory than to fail to meet an obligation.

#### [4] If I told you my name was Adrian, you’d believe me until it was proven otherwise.

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

#### [6] Time skew – the neg gets 7 minutes to respond to the AC and 6 minutes to respond to the 1AR, outweighs because it controls access to the ballot.

#### [7] Reciprocity – aff proving obligation means it’s reciprocal for the neg to prove negative obligation.

#### [8] Affirming is harder, they know the AC, but we don’t know the NC. If the round ends up equal, I overcame a disadvantage and debated better, which means you affirm.