# R6 NC

## 1

#### CP text: States should add more stringent requirements for filing patents for medicines.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

## 2

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The aff crushes innovation in the pharma sector---incentivizes them to focus on non-important issues.

Glassman 21 [Amanda; 5/6/21; Executive vice president and a senior fellow at the Center for Global Development, a nonpartisan, nonprofit think tank in Washington and London; “*Big Pharma Is Not the Tobacco Industry*,” Barron, <https://www.barrons.com/articles/big-pharma-is-not-the-tobacco-industry-51620315693>] Justin

But here is the crux of the problem: The pharmaceutical industry is not the tobacco industry. They are not merchants of death. The companies are amoral and exist to make money, but their business is not fundamentally immoral. Big Pharma (mostly) develops and sells products that people need to survive and thrive. Their products improve health and welfare. Fights over access to medicines are possible because medicines exist in the first place—medicines that were usually developed by Big Pharma. And yes, the pharmaceutical industry benefits from public subsidy and publicly financed foundational research. But the companies also put their own capital at risk to develop new products, some of which offer enormous public benefits. In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen. But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita. It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize, preventable disease and deaths address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started. What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could? No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

#### Pharma Innovation prevents Extinction – checks new diseases.

Engelhardt 8, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

## 3

#### WTO consensus on fishing subsidies likely now but requires negotiations- consensus is key to solving overfishing- the brink is now.

Koop 21 [Fermin; Argentine journalist specializing in the environment with experience across diverse publications; “WTO Inches Towards a Deal to End Harmful Fishing Subsidies,” Maritime-Executive; 7/30/21; <https://www.maritime-executive.com/editorials/wto-inches-towards-a-deal-to-end-harmful-fishing-subsidies>] Justin

After more than 20 years of negotiations, the World Trade Organization (WTO) has moved a step closer to an agreement on ending harmful fishing subsidies. The deal would set new rules for the global fishing industry and limit government funding that contributes to unsustainable fishing and the depletion of global fish stocks. In a meeting with government ministers and heads of national delegations, WTO members vowed to finish the negotiations before the WTO’s Twelfth Ministerial Conference (MC12) in late November, and to empower their delegations in Geneva to do so. Members also said the negotiating text currently on the table can be used as the basis to strike a final agreement. “It’s been a successful day,” WTO chief Ngozi Okonjo-Iweala told reporters at the close of the meeting. “In 20 years of negotiations, this is the closest we have ever come towards reaching an outcome – a high-quality outcome that would contribute to building a sustainable blue economy. I feel new hope.” The talks’ chair, Santiago Wills, was also upbeat: “I believe that the answers today have given us the ingredients to reach a successful conclusion. Members now want to move to text-based negotiations. Twenty years has been long enough. If we continue [negotiating] for another 20 years, there won’t be any fish left.” Negotiators at the WTO had been tasked with eliminating subsidies for illegal, unreported and unregulated (IUU) fishing and prohibiting certain subsidies that contribute to overcapacity and overfishing. Talks have been going on since 2001 but differences between governments have hindered progress. 2020 had been set as a deadline to strike an agreement, but talks were delayed due to Covid-19 restrictions and the US presidential elections. A deadline was then set for this July, which was again missed. Now, Okonjo-Iweala, appointed as head of the WTO in March, aims to reach an agreement by year-end in what will be a key test for the organization’s credibility, with members deadlocked on other fronts. “In international negotiations of this type only two things are relevant. The nitty-gritty to make sure everybody is on the same page, and the spirit that prevails. If Ngozi and Wills reflected correctly what happened in the meeting, we can say there’s cautious optimism over an agreement,” Remi Parmentier, director of environmental consultancy The Varda Group, told China Dialogue Ocean. A potential agreement At the meeting, ministers discussed an eight-page draft agreement, which lists a range of subsidy bans and some conditions for exemptions for poorer countries, all of which are yet to be finalised. While some delegations like the EU were positive, several ministers expressed reservations over the content of the text. “Clearly, it will lead to capacity constraints for developing countries, while advanced nations will continue to grant subsidies,” Indian trade minister Piyush Goyal said at the meeting, regarding one part of the text. Pakistan described the draft as “regressive and unbalanced,” while the African coalition said “significant gaps” remain. Countries’ differences were acknowledged by Ngozi and Wills at the meeting. Nevertheless, they remain optimistic and said the issues would be resolved once countries move into text-based negotiations. The agreement on fishing subsidies will require a consensus among all member states, according to WTO rules. The draft deal essentially proposes three categories of prohibited subsidies; those that support IUU fishing, affect overfished stocks, or lead to overcapacity and overfishing. While this may sound simple, the political, economic and cultural complexities represent real challenges. One of the main issues has been the demand for developing countries and the poorest nations to receive so-called special and differential treatment. While this is widely accepted for the poorest countries, demands from self-identified developing countries to be exempt from subsidy constraints has proven to be difficult to accept. Many of the major fishing nations are considered developing countries by the WTO, including China, which has one of the world’s biggest fishing fleets. China’s minister of commerce, Wang Wentao, expressed China’s “support for the conclusion of [fishing subsidies] negotiations before the end of MC12.” Speaking at the meeting on 15 July, Wang stressed that concluding the negotiations would represent a major contribution from the WTO to the United Nations’ 2030 Sustainable Development Goals. “As a developing country and a major fishing power, China will take on obligations commensurate with our level of development," he said. At the meeting, Wang also introduced China’s emphasis on green development in future policies on fishing subsidies and its “zero-tolerance” policy towards IUU. Isabel Jarrett, manager of The Pew Charitable Trusts’ project to end harmful fisheries subsidies, told China Dialogue Ocean that an agreement “with too many loopholes” would undermine the WTO’s sustainability goals. The final text has to ensure that governments aren’t allowed to subsidize “irresponsible practices that can hurt fish populations,” she added. The scale of the problem Subsidies paid to the global fishing industry amount to around $35 billion per year (228 billion yuan). Of this, $20 billion is given in forms that enhance the capacity of large fishing fleets, such as fuel subsidies and tax exemption programmes, according to the European Parliament’s Committee on Fisheries. In 2018, the world’s top 10 providers of harmful fisheries subsidies gave out $15.4 billion in total, according to a report by Oceana. The EU, as a bloc, provided $2 billion, ranking third behind China and Japan. Research by Pew has found that eliminating all harmful subsidies could help fish populations recover. Specifically, it would result in an increase of 12.5 percent in global fish biomass by 2050, which translates into nearly 35 million metric tonnes of fish – almost three times Africa’s entire fish consumption in a single year. The need for progress on an agreement has gained new urgency during the last few years, as the world’s fish populations have continued to fall below sustainable levels. Around 60 percent of assessed stocks are fully exploited and 30 percent are overexploited, according to the latest figures from the UN Food and Agriculture Organization. The termination of harmful subsidies, which is embedded in the UN Sustainable Development Goals (SDGs), would be seen as key progress on ocean sustainability ahead of this year’s UN biodiversity conference in Kunming, scheduled for October, and the COP26 climate summit in Glasgow in November. “This is the year that the agreement has to be delivered. The WTO chief has made positive pronouncements of an agreement this year. There’s light at the end of this 20-year tunnel. The alternative of being in the tunnel shadows is a depressing prospect at the time ocean life is declining,” Peter Thomson,?UN special envoy for the ocean, said in a recent webinar.

#### Negotiations on IPR require tradeoffs- empirics prove.

DC = DEVELOPING COUNTRY

NET = NET EXPORTER OF TECH (advanced countries)

TNC = Trade Negotiations Committee

Anell = Lars Anell the Chair of the TRIPS negotiations

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016. SJMS

Regarding the provisions in the section on patents, including that on exclusions from patentability, another DC negotiator maintained that the stipulations should reflect ‘a well-balanced system’ (ibid: 3). Ironically however, he proceeded to categorise the texts as ‘reasonably satisfactory’, contending that a positive attitude of his delegation towards them would depend to a large extent on progress in other areas of the negotiation (ibid). This was the second time in the negotiations that a DC delegate made such an obvious attempt to concede in TRIPS while seeking bargains in other negotiating areas, suggesting that the real access-to-medicines implications of patents were not fully appreciated by all such participants (Abbott 2002: 43–4); and that such participants may have understood that the negotiations would not have culminated in their favour. Immediately after the April TNC of 1989 a similarly affiliated participant had also affirmed that if some participants were to be required to make sacrifices in the area of IPRs, there should be a readiness to make such sacrifices for their benefit in agriculture, natural resources or other negotiating groups (MTN.GNG/NG11/13: 5).10 This first declaration could be construed as a signal of a prejudged outcome that disfavoured DCs. Towards the end of this session another DC participant, supported by several others, pointed out that some other delegations had very high ambitions in the area of TRIPS and that the time had come to review the subject matter in the context of the Uruguay Round negotiations as a whole, particularly in relation to what was being offered in the more traditional areas of the GATT (ibid: 12). At these final stages in the negotiations, DCs were actively seeking trade-offs in other areas in return for agreeing to IPRs in the manner in which the NETs had anticipated (Adede 2003: 30 and Matthews 2002: 109). Anell’s informal consultations and his proposed bilateral bargaining strategies worked in tandem to consolidate the weakening position of DCs propagated during the April TNC meeting in 1989. Anell ended this final session by sharing concerns expressed about the need for results in all areas of the UR, explicitly urging delegations to manufacture consensus through concessionary bargaining. The effects would later be seen in Dunkel’s ‘Draft Final Acts Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations’.11

#### That collapses biodiversity.

Osmanski 20 [Stephanie; Freelance Journaler, Writer at GreenMatters; “How Does Overfishing Affect Biodiversity? Let's Do a Deep Dive,” GreenMatters; 12/29/20; <https://www.greenmatters.com/p/how-overfishing-affects-biodiversity>] Justin

Three out of seven people — about 260 million worldwide — rely on seafood as their primary source of protein, which means the environmental and health impacts of fishing are more relevant than ever. In fact, overfishing is becoming a huge problem; Conservation.org reports that one-third of the world’s wild-caught fisheries are depleted as a direct result of overfishing, pollution, and climate change. As fish populations decline, farmed fisheries have started supplying most of our seafood, which is often plagued with additives, growth hormones, genetically modified organisms, and even food dye. However, overfishing results in other issues, too — mainly, environmental issues. Overfishing significantly affects biodiversity, which in turn, changes the ecosystem. Keep reading to find out more on how overfishing contributes to biodiversity. What is overfishing? Overfishing refers to non-sustainable practices of fishing that result in the depletion of fish species. In layman’s terms, overfishing happens when fishermen catch fish faster than the fish can reproduce. Long ago, when fishing relied on more natural methods (instinct, word-of-mouth, and guesswork), fishing practices were more natural and therefore, sustainable. But due to modern technology, fishermen now get significant help from high-tech machinery that can detect and track schools of fish, enable fishermen to explore new areas of water they had not been able to access before, and also embark in deeper waters. According to the United Nations Food and Agricultural Organization (FAO), over 70 percent of the world’s fisheries are “fully exploited,” “over exploited,” or “significantly depleted” as a direct result of overfishing. What is biodiversity? Biodiversity refers to the variety of life on Earth, referring to our planet’s vast number of biological species and organisms. It's heavily impacted when certain species cease to exist, or become threatened at a rate that is faster than that species can reproduce. Ultimately, the number of plants, animals, and microorganism species on Earth determines biodiversity. According to Global Issues, varying genes in each of these species also contributes to more biodiversity. If ecosystems or species become threatened or cease to exist, biodiversity decreases — and ultimately, all walks of life are impacted — because of the degrading food chain and other necessary biological processes. How does overfishing affect biodiversity? Overfishing impacts biodiversity in more ways than one — per Marine Science Today, overfishing alters the food chain. If a certain species is wiped out due to overfishing, the animals that rely on that species as a food source could starve, or might resort to eating other species of fish, thus altering the ecosystem and food chain as a whole. On the other end of the spectrum, the population generally consumed by the extinct species would grow disproportionately, often making way for an influx of pests. Overfishing creates a domino effect that impacts all living organisms, therefore significantly affecting biodiversity. Why is biodiversity important? Biodiversity is necessary, because every organism plays a role in the eco-system. If one species is compromised, biodiversity becomes compromised as a whole: the food chain, ecosystems, and more. The more biodiversity there is on this planet, the more productive ecosystems are, contributing to a greater availability of biological resources. Apart from food, biodiversity impacts medicinal resources, wood products, and ornamental plants. Biodiversity also helps ecosystems recover in cases of disaster. If a weather event threatens natural disasters, healthy, biodiverse ecosystems have a better chance of bouncing back. It also ensures protection of water resources, soil formation, nutrient storage and recycling, and the necessary breakdown of pollution. Why is marine biodiversity is important to humans? Aside from assuring food security, marine biodiversity also provides social and socioeconomic benefits. Socioeconomically, many areas of the world rely on fisheries to survive. If fishermen cannot sell seafood, fisheries cannot purchase fish, and these ways of life are forced out of business. A side effect of that would be that so many populations that rely on fisheries would be out of their main source of protein. Biodiversity also brings many social benefits to human populations: the opportunities to research and educate about fisheries, natural habitats, ecosystems, and various species. It also increases tourism and recreational activities, while having a lasting cultural impact, too — if specific populations rely on a species for food, loss of that population would affect that population’s culture and food supply. Marine biodiversity is incredibly important — let's take a stand against overfishing to ensure it doesn't plague eco-systems and human populations alike. TBH, might be best to go fish-free. instead.

#### Biodiversity loss causes extinction.

Torres 19[Phil; Affiliate Scholar at the Institute for Ethics and Emerging Technologies, Founder of the X-Risks Institute, Writer Appearing in Skeptic, Free Inquiry, Bulletin of the Atomic Scientists, Salon, Truthout, Erkenntnis, Metaphilosophy; “Biodiversity Loss: An Existential Risk Comparable To Climate Change,” Bulletin of the Atomic Scientists; 4/11/16; <https://thebulletin.org/2016/04/biodiversity-loss-an-existential-risk-comparable-to-climate-change/>] Justin

Catastrophic consequences for civilization. The consequences of this rapid pruning of the evolutionary tree of life extend beyond the obvious. There could be surprising effects of biodiversity loss that scientists are unable to fully anticipate in advance. For example, prior research has shown that localized ecosystems can undergo abrupt and irreversible shifts when they reach a tipping point. According to a 2012 paper published in Nature, there are reasons for thinking that we may be approaching a tipping point of this sort in the global ecosystem, beyond which the consequences could be catastrophic for civilization.

As the authors write, a planetary-scale transition could precipitate “substantial losses of ecosystem services required to sustain the human population.” An ecosystem service is any ecological process that benefits humanity, such as food production and crop pollination. If the global ecosystem were to cross a tipping point and substantial ecosystem services were lost, the results could be “widespread social unrest, economic instability, and loss of human life.” According to Missouri Botanical Garden ecologist Adam Smith, one of the paper’s co-authors, this could occur in a matter of decades—far more quickly than most of the expected consequences of climate change, yet equally destructive.

Biodiversity loss is a “threat multiplier” that, by pushing societies to the brink of collapse, will exacerbate existing conflicts and introduce entirely new struggles between state and non-state actors. Indeed, it could even fuel the rise of terrorism. (After all, climate change has been linked to the emergence of ISIS in Syria, and multiple high-ranking US officials, such as former US Defense Secretary Chuck Hagel and CIA director John Brennan, have affirmed that climate change and terrorism are connected.)

The reality is that we are entering the sixth mass extinction in the 3.8-billion-year history of life on Earth, and the impact of this event could be felt by civilization “in as little as three human lifetimes,” as the aforementioned 2012 Nature paper notes. Furthermore, the widespread decline of biological populations could plausibly initiate a dramatic transformation of the global ecosystem on an even faster timescale: perhaps a single human lifetime.

The unavoidable conclusion is that biodiversity loss constitutes an existential threat in its own right. As such, it ought to be considered alongside climate change and nuclear weapons as one of the most significant contemporary risks to human prosperity and survival.

## 4

#### Text: A nation appointed international panel of scientists including National Academies and corresponding organizations should [reduce intellectual property protections] and manage similar conflicts of interest between intellectual property.

#### International panel of science diplomats can rule over IP---that’s key to science diplomacy.

Hajjar and Greenbaum 18 [David; Dean Emeritus and University Distinguished Professor, and Professor of Biochemistry and Pathology at Weill Cornell Medicine, Cornell University. He is a Fellow of the American Academy of Arts and Sciences, Fellow of the American Association for the Advancement of Sciences, a Jefferson Science Fellow of the National Academies at the U.S. Department of State, and a recent Senior Fellow in Science Policy at the Brookings Institute; Steven; Professor and Chair of the Department of Physics and Astronomy at Hunter College of the City University of New York and a Fellow of the American Physical Society. He was a Jefferson Science Fellow of the National Academies at the U.S. Department of State; “Leveraging Diplomacy for Managing Scientific Challenges,” American Diplomacy; September 18; <https://americandiplomacy.web.unc.edu/2018/09/leveraging-diplomacy-for-managing-scientific-challenges-an-opportunity-to-navigate-the-future-of-science/>] Justin

At the global level, science diplomacy is defined as cooperation among countries in order to solve complex problems through scientific research and education (1). For example, science diplomacy plays an important role in resolving global issues related to the ecosystem (such as clean water, food safety, energy conservation, and preservation of the environment). It also addresses problems related to the healthcare industry. For example, scientists have served at the international level to forge the Middle Eastern Cancer Consortium a decade ago to facilitate better healthcare and improve cancer research in the region. Whether one considers science for diplomacy or diplomacy for science, international science collaborations benefit from allowing science diplomats (broadly defined as science envoys, science attaches, embassy fellows) to help establish positive international relationships between the U.S., Europe, Latin America, Africa or Asia, particularly when proprietary disputes arise (2, 3). These various types of science diplomats already exist; some, like embassy fellows and science envoys, have one-year appointments so their role may be limited, while attaches usually have two or three year appointments that may allow them to be more successful in long, protracted negotiations. In any event, we believe that scientists can play more of a role in advancing international scientific cooperation. A key point addressed here is how to balance security concerns against the need for free exchange of information needed for innovation and growth.

Both the National Science Foundation and the National Institutes of Health are already engaged in supporting American science and strengthening collaborations abroad. Such efforts take advantage of international expertise, facilities, and equipment. Here, we provide a rationale for the use of diplomacy to address scientific challenges. This approach allows some scientists working as diplomats to help manage complex and potentially conflicting situations that arise between scientific communities and their governments. Such issues include managing disputes such as licensing agreements for intellectual property (IP) and providing protection of IP.

International collaborations can not only support but also accelerate the advancement of science. However, collaborations may carry risk if IP is misappropriated for other purposes. International collaborations should have a basis in strategy and specific goals (for example, drug discovery) in order to justify the use of government and/or corporate funds.

About a decade ago, a group of academics from the University of Manchester in the United Kingdom assembled the “Manchester Manifesto,” subtitled “Who Owns Science” (6). This document addressed the lack of alignment between commercial interests, intellectual rights, and credit to the researcher. In our (and commonly held) view, the groups representing these disparate values could benefit from diplomatic mediation. More recently, it has become increasing apparent that managing China as a science and technology superpower represents another challenge for the U.S. Resolution of issues such as ownership of IP, rights to reagents, or use of skilled laboratory personnel from international collaborations may require the efforts of science diplomats. There are few international offices or “guardians” to protect junior and senior scientists in corporate or academic sectors from misuse of reagents or piracy.

China’s failure to respect IP rights, and the resulting piracy, has drawn much attention. The media have also focused on the failure of watchdog government agencies to detect and manage these unwanted activities. Industrial espionage compromises U.S. interests. Moreover, Chinese and Russian hackers have cyberattacked U.S. technology companies, financial institutions, media groups, and defense contractors. In 2018, industrial spying was even reported in a major medical school in New York City where scientists were alleged to have illegally shared research findings with Chinese companies.

The U.S. has a long history of hiring research personnel from other countries to staff its laboratories and industrial R&D centers. These scientists and engineers have made critical contributions to our nation’s well-being and security. These young Chinese and South Asian graduates of U.S. programs a generation ago now staff our research enterprise. However, recent trends in U.S. graduate school applications in science, technology, engineering and mathematics (STEM) reflect a downturn in foreign applicants, particularly from China. It is becoming increasingly apparent that the number of American-born students seeking STEM degrees is not sufficient to satisfy future demands of our high-tech workforce. While our own educational reforms must be augmented, we cannot ignore the need to continue to recruit overseas talent.

We believe that foreign scientists can continue to make critical discoveries in the U. S. provided that their talent is nurtured, developed, and harnessed for the common good. At the same time, American companies cannot hire foreign scientists if they take the ideas they generate in U.S. laboratories back to their home countries without proper credit or permission. If the advancement of science is to succeed, greater diplomatic cooperation is needed to solve and manage proprietary issues for the benefit of all (5, 6).

So, how does one strike the proper balance between security and growth? Science is a universal social enterprise; international conferences lead to friendships and productive collaborations between nations. Given that the U.S. and Chinese governments recognize the need for international communication and collaboration then surely there should be a mechanism for adjudicating anticipated conflicts. One approach would be for government, industrial, and academic stakeholders to form an international panel of scientists and engineers to manage any conflicts of interest between the need to protect proprietary information crucial to a company’s competitive edge, and the need for students and young faculty members to publish their findings. Smaller scale efforts along these lines have recently given rise to unique global partnerships, such as fellowship support by major pharmaceutical companies, which aim to address these conflicts to the benefit of both parties. An added feature of such arrangements is that they often provide corporate financing for research (9). Can this corporate-academic partnership model be adapted to multinational joint R&D efforts while protecting IP? This question falls squarely within the purview of international science diplomacy, whereby science diplomats can establish rules of conduct governing joint global technology development with proper IP protection.

Despite the highly publicized and legitimate piracy allegations against China, at least some data indicates that the Chinese legal system is responding positively to worldwide pressure to honor foreign IP. A 2016 study by Love, Helmers, and Eberhardt, for example, found that between 2006 and 2011, foreign companies brought over 10 percent of patent infringement cases in China, and won over 70 percent of those cases (10). Today, “win rates” average around 80 percent, and “injunction rates,” around 98 percent (10). As Chinese scientists and engineers increasingly enter the top tier of the innovation space, their growing awareness of their own need for IP protection could be a powerful motivating force for the protection of all IP. As stated earlier, science diplomats could catalyze this progress even further by direct negotiations with those parties involved in the conflicts. An obvious flaw in this optimistic outlook is that scientists in the U.S. wield more influence with their government than scientists in China wield with theirs. And to the extent that the Chinese government could be encouraging IP theft, this must be addressed first by those international companies/firms who want to do business with the Chinese. Chinese investments, as well as tech incubators and targeted acquisitions, can enable access to U.S. technologies for commercial development. Although this conveys a level of risk to the developers, it may provide valuable opportunities for U.S. companies as well. In many respects, the extensive engagement and collaboration in innovation between the U.S. and China, often characterized by open exchanges of ideas, talent, and technologies, can be mutually beneficial in enriching and accelerating innovation in both countries.

In summary, we believe that science diplomats could help address the increasingly complex issues that arise between accelerating scientific and engineering advances, and the need to protect national security and corporate IP. We also propose that this might be accomplished by asking the National Academies to **recommend** academic, corporate, and government scientific leaders to serve on an international scientific advisory board, and for the corresponding organizations in other countries to do the same. Access to the free flow of information promotes new knowledge and innovation. A return to a more restrictive intellectual environment is not only harmful to progress, but also nearly impossible to manage in the current internet age. A good place to start would be to engage the newly appointed head of the White House Office of Science and Technology Policy (the Science Advisor to the President of the United States), and working groups within established organizations. These organizations include the American Association for the Advancement of Science (AAAS) or the National Academies of Science, Engineering and Medicine, and corresponding international organizations. What incentive is there for a busy and successful scientist to serve in such capacity? It is the same altruism that motivates us to accept assignments as journal editors, manuscript reviewers, or funding agency panelists for the advancement of science toward the greater good.

#### Solves every existential threat.

Haynes 18—research associate in the Neurobiology Department at Harvard Medical School (Trevor, “Science Diplomacy: Collaboration in a rapidly changing world,” <http://sitn.hms.harvard.edu/flash/2018/science-diplomacy-collaboration-rapidly-changing-world/>, dml) // Re-Cut Justin

Today’s world is extremely interconnected. Most of us take this fact for granted, but its implications cannot be overstated. The rate at which information, resources, and people are able to move from one part of the world to another continues to accelerate at an alarming rate. Undoubtedly, this development has done society immense good. In the last century, global life expectancy has doubled, the percentage of people living in extreme poverty has dropped by about 60%, and world literacy rates have increased by a similar margin. But while these statistics paint a promising picture of human civilization, human progress rests on a fragile foundation of international cooperation; the challenges presented by an interconnected world are immense. War, natural disasters, and economic collapse now exert their effects globally, creating economic and ecological disasters and mass human migrations on an unprecedented scale. And with the US pulling out of major multilateral agreements on trade, climate change mitigation, and denuclearization, you might wonder if our ability to collaborate across borders productively is really up to the task.

Global challenges require global solutions, and global solutions require collaboration between countries both big and small, rich and poor, authoritative and democratic. There are few human enterprises capable of providing continuity across these differences, and as technological solutions are becoming available to some of our most pressing issues, two in particular will be necessary to getting the job done: science and diplomacy. While science has long been utilized as a means to reach political ends—think of British explorer James Cook’s mapping of unexplored continents or the United States’ Manhattan Project—a more formal integration of scientists into the diplomatic process is being undertaken. This effort, which has led to scientists and academics playing a direct role in foreign policy development and international relations, has given birth of a new branch of diplomacy: science diplomacy.

What is science diplomacy?

As both the term and concept of science diplomacy have only recently gained traction in scientific and diplomatic circles, it’s been given a variety of definitions. But common to them all is the focus on applying scientific expertise to an international effort. The focus of these efforts is to solve international problems collaboratively while balancing economic prosperity, environmental protection, and societal wellbeing. The challenge of reaching this balance in the face of a booming global population cannot be understated, but this new branch of diplomacy is already at work and is producing results. International agreements such as the Paris Climate Agreement and the Iran Nuclear Deal are two famous examples, and science diplomacy is also establishing international collaboration in many other important arenas. While these lesser known efforts may not dominate the headlines, they are quietly tackling the global issues of today and preparing us for those of tomorrow.

Natural disasters don’t respect national boundaries (and neither does the aftermath)

In 2013, the number of refugees displaced by natural disasters—hurricanes, droughts, earthquakes—outnumbered those displaced by war. Current projections estimate as many as 1 billion people may be displaced by natural disasters by the year 2050. That would mean 1 in 9 people on the planet displaced and looking for a home. Compare this to the estimated 12 million refugees displaced by the war in Syria, and a frightening picture begins to form. As natural disasters continue to increase in both their frequency and intensity, solutions for mitigating the risk of total catastrophe will be underpinned by science, technology, and the ability of the international community to collaborate. Many organizations are starting to tackle these problems through the use of science diplomacy. The center for Integrated Research on Disaster Risk (IRDR) is composed of ten national committees—a network of government sponsored research institutions across the world in countries ranging the political and economic scale. These working groups have committed to improving disaster-risk-reduction science and technology while providing guidance to policy makers charged with implementing disaster prevention and mitigation strategies.

IRDR is governed by a committee comprising experienced scientists and natural disaster experts. Its members come from all over the world—the US, China, Uganda, Norway, Mexico, Venezuela, and more. The diversity of this organization starts at the top and is crucial to developing comprehensive risk-reduction strategies. Data and insights from countries with varying areas of expertise are being shared and built upon, facilitating more accurate natural disaster forecasting and better strategies for mitigating their destructive power. And by including representatives from countries of varying political and economic power in its leadership, IRDR ensures that its work will consider the needs of the global community at large, rather than just nations with considerable wealth and political standing.

The results of this type of international collaboration speak for themselves. Although humanity is grappling with more natural disasters than ever before, deaths related to these incidents continue to trend downward. Operating outside of the typical political framework that dominates foreign relations, IRDR provides a model for effective collaboration across the geopolitical spectrum in the face of a major global issue.

Explore or Exploit? Managing international spaces

Over the last few decades the polar ice cap that covers much of the Arctic Ocean has been shrinking. So much so, that during the warm season vast areas of previously solid ice have become open waters, creating opportunities for new trade routes and exposing the Arctic’s enormous reserves of oil and natural gas. Depending on your values, this will sound either like an opportunity for huge economic development of the region or the inevitable exploitation of one of the last untouched natural territories on the planet. And if you live there, like the half a million indigenous people who currently do, how this territory is managed will determine where you can live, how (and if) you can make a living, and what the health of the ecosystems that have supported Arctic life for millennia will look like.

Luckily, such a scenario was predicted decades ago. In 1987, Mikhail Gorbachev, then leader of the then Soviet Union, delivered a speech outlining his aspirations for the arctic to be explored rather than exploited—to radically reduce military presence, create a collaborative multinational research effort, cooperate on matters of environmental security, and open up the Northern Sea Route for trade. This speech laid the foundation for the Arctic Council (Figure 1), which is one of the most successful examples of science diplomacy at work. Composed of the eight Arctic nations, including geopolitical rivals US and Russia, and numerous groups of indigenous peoples, the Arctic Council was established to maintain Gorbachev’s vision for the region while giving the indigenous peoples a seat at the negotiating table. The council’s activities are conducted by six scientific and technology-based working groups who conduct research in the area and provide knowledge and recommendations to the council members. As a result of this research, and allowing scientists to take part in the negotiations, the Arctic council has enacted several legally binding agreements regarding the sustainable development and environmental protection of the Arctic Ocean. These agreements have facilitated cooperation on a number of important issues including search and rescue operations, prevention and containment of maritime oil pollution, and, most recently, enhanced data sharing and scientific research collaborations. Against a backdrop of rapidly deteriorating diplomatic relations, the US and Russia have co-chaired task forces that laid the foundation for these agreements, proving to the world that meaningful results can be achieved through the avenue of science diplomacy, regardless of geopolitics.

Science diplomacy going forward

The technical expertise that characterizes science diplomacy will continue to be in demand across many realms of foreign policy. For example, synthetic biology and gene-editing technology continue to factor into matters regarding agriculture and trade. Also, digital currencies, such as bitcoin, have changed the way economists and businesses are approaching markets. Finally, machine learning and artificial intelligence are being used by governments as a means for population control, giving rise to a new type of governance—digital authoritarianism.

While this expertise will be necessary for managing such issues, building international coalitions can’t be done through a purely scientific and technical lens. Convincing others to cooperate means providing them with a convincing argument to do so, and in terms they understand and find compelling. To achieve this, scientists must be trained to communicate their expertise in a way that moves stakeholders in policy discussions to act. This means appealing to motivations they have been largely taught to put to the side—whether they be political, economic, or emotional in nature—without obscuring the data and insights they have to offer.

For our leaders, policy makers, and diplomats to effectively understand issues underpinned by science and technology, experts in these fields must continue to be integrated into the mechanisms of governance. With scientists in the US running for elections in numbers like never before, we can expect this trend to continue. And in the face of a rising wave of nationalism across the world, it is crucial that we do everything we can to foster collaboration. The future of human civilization depends on it.

## 5

#### Interpretation: affirmative debaters must delineate what intellectual property they reduce in the 1AC.

#### Four types of IP that are vastly different.

Ackerman 17 [Peter; Founder & CEO, Innovation Asset Group, Inc; “The 4 Main Types of Intellectual Property and Related Costs,” Decipher; 1/6/17; <https://www.innovation-asset.com/blog/the-4-main-types-of-intellectual-property-and-related-costs>] Justin

Intellectual property protection isn’t as simple as declaring ownership of a particular product or asset. In most countries, there are four primary types of intellectual property (IP) that can be legally protected: patents, trademarks, copyrights, and trade secrets. Each has their own attributes, requirements and costs.

Before narrowing your focus on which form of protection to use, know that these forms of protection are not mutually exclusive. Depending on what you’re doing, you might be able to use a “belt & suspenders” approach and apply multiple forms of protection, or one approach might be the most sensible. Read the descriptions below to get some of the basics.

Used to protect inventive ideas or processes – things that are new, useful and nonobvious - patents are what most often come to mind when thinking of IP protection. **Patents** are also used to protect newly engineered plant species or strains, as well.

Procedure For most companies, patents result from the following stages: Conceptualization Typically, innovation teams work to address a common problem facing their organization, industry, or the world at large when developing their idea. When they’ve arrived at a solution or concept, they’ll draw up plans and gather the resources necessary to make it a reality. Prototypes or drawings can be created to provide a more accurate description of the end product or process. Invention Disclosure An internal review process often occurs with every invention. The innovation team consists of internal counsel and an invention review panel of varying disciplines. The reviewers assess, rate, rank, score, and highlight potential flaws in the supporting documents and descriptions for the invention, which are then addressed by the inventor. These reviews can and often do take place multiple times for a single invention. Patent Application If the invention is deemed meritorious enough for the pursuit of patent protection, some organizations prepare their own provisional or nonprovisional patent applications. Others will farm this stage out. There may be more tweaks as an application is prepared, and then submission to the appropriate patent office and the prosecution stage begins (the back & forth with the government patent office). Typically it is outside counsel that manages this process and related docketing activities. Docketing is the overarching name for activities that include management of paperwork and meeting filing deadlines specified by the government patent office. Because the application process is often very complicated, patent offices highly recommend working with experienced patent attorneys to handle this process. Maintenance Once a patent is approved, it has a finite lifetime. Patent holders are responsible for maintaining and tracking the usage of their patents and paying the appropriate periodic government renewal fees. If a given technology or other patented asset is collecting dust, you might not want to renew it. Instead, you can try and sell, license or donate it. Conversely, if a patented asset is performing well through product sales or licensing activities and its life is getting shorter, you might think about innovating ahead and maintaining competitive momentum. Costs Costs will vary depending on the country or countries where you file an application, and can run into tens of thousands of dollars depending on the invention’s complexity, plus attorney fees. Maintenance fees over the lifetime of the patent can run into thousands more per patent, per country where patent rights have been granted. You have to keep your eyes on these costs.

Trademark

A trademark is unlike a patent in that it protects words, phrases, symbols, sounds, smells and color schemes. Trademarks are often considered assets that describe or otherwise identify the source of underlying products or services that a company provides, such as the MGM lion roar, the Home Depot orange color scheme, the Intel Inside logo, and so on.

Procedure Trademarks do not necessarily require government approval to be in effect; they can apply through abundant use in interstate commerce. Still, registration of a trademark affords far superior protection and is gained by filing an application with the proper government office. A trademark application requires the company or user to provide a clear description and representation of the mark and its uses in conjunction with associated products or services. As with patents, it’s a good idea to partner with outside counsel that specializes in trademark applications and/or search services so they can help ensure there is a clear path for your desired mark. Costs Trademarks are generally quite less expensive to obtain. According to the US Patent and Trademark Office, trademark registration currently costs between $225 and $325 for each class code you use per mark. Attorney and search fees are extra. There are also periodic (and relatively inexpensive) government maintenance fees for trademarks.

Copyrights do not protect ideas, but rather the manner in which ideas are expressed (“original works of authorship”) - written works, art, music, architectural drawings, or even programming code for software (most evident nowadays in video game entertainment). With certain exceptions, copyrights allow the owner of the protected materials to control reproduction, performance, new versioning or adaptations, public performance and distribution of the works. Procedure Copyrights in general attach when the original works become fixed in a tangible medium, but should be registered with the government copyright office for optimal protection in the form of damages, injunctions and confiscation. Copyright registration applications are much simpler than patents or trademarks, and typically can be obtained by the author alone. The US Copyright Office encourages use of their online application system, and requires a sample of the work to be protected and some background information about the author. Costs Depending on the type of work being protected, currently fees vary between $25-$100 in the US. The most frequent copyright registration sought is for one work by one author, and costs about $35.

Trade Secret

Trade secrets are proprietary procedures, systems, devices, formulas, strategies or other information that is confidential and exclusive to the company using them. They act as competitive advantages for the business. Procedure There actually isn’t a federally-regulated registration process for trade secrets. Instead, the onus is on the company in possession of the secret to take necessary precautions to maintain it as such. This is an ongoing, proactive process and can include clearly marking relevant documents as “Confidential,” implementing physical and data security measures, keeping logs of visitors and restricting access. The issuance of nondisclosure agreements or other documented assurances of secrecy can also be employed. One of the first defenses typically put up when you assert that someone misappropriated your trade secret is that you failed to adequately treat it as a trade secret. Costs Though there are no official registration costs, there are costs associated with taking appropriate precautions and security measures. You must weigh the competitive significance of your secrets against the cost of protecting them.

#### Violation:

#### Negate:

#### 1] Shiftiness- they can redefine what intellectual properties the 1ac defends in the 1ar which decks strategy and allows them to wriggle out of negative positions which strips the neg of specific IP DAs, IP PICs, and case answers. They will always win on specificity weighing.

#### CX can’t resolve this and is bad because A] Not flowed B] Skews 6 min of prep C] They can lie and no way to check D] Debaters can be shady.

#### 2] Real World- policy makers will always specify what the object of change is. That outweighs since debate has no value without portable application. It also means zero solvency since the WTO, absent spec, can circumvent aff’s policy since they can say they didn’t know what was affected.

#### This spec shell isn’t regressive- it literally determines what the affirmative implements and who it affects