## Framework

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

#### The value is morality since ought indicates a moral obligation

#### The value criterion is maximizing expected well-being which means causing the greatest amount of good for the greatest amount of people.

#### There are two main reasons for this:

#### Everyone does not like painful or emotionally harmful experiences, so naturally we should try to replace these things with good experiences.

#### Things like death and oppression are intuitively bad, and affect everyone, so we should try to prevent them.

#### In summary, if I can prove to you that reducing intellectual property protections would have a good impact on the world, then you should vote for the affirmative in today’s debate.

## Contention 1

#### The current WTO patent system is locking in global cannabis monopolies.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

B. How the Patent Has Become a Tool for Globalization

The trade-offs have been deemed beneficial by most of the international community, judging by the WTO’s TRIPS Agreement, whereby any signatory must institute a patent system to their national order.57 This requirement was seen to advance the benefits that intellectual property brings to markets and provide assurance for companies who depend upon intellectual property (for our purposes, patents) that they will be protected.58 Thus, investment and commercial activity can now more easily flow into countries where before the lack of protection rendered prospective costs of business prohibitive.59 The TRIPS Agreement imposed strong, uniform requirements upon signatory countries that went a long way towards its goal of globalization, and unlike most international treaties, required enforcement mechanisms with teeth.60 The most relevant requirement here is that the member patent office examining the patent may not discriminate “as to the place of invention, the field of technology and whether products are imported or locally produced.”61 This requirement allows great freedom to engage in business within member countries, and prevents a patent office from giving any advantage to its own citizens that it would not give to a foreigner, unless allowed under other treaties.62 Further, if a patent is secured in the relevant country, a business does not need to set up a subsidiary within that country to obtain protection.63 To assist actors whose businesses cross international borders, the PCT was enacted by the World Intellectual Property Organization (WIPO) to reduce barriers when seeking protection for inventions.64 The PCT, while a treaty in name, acts more like an organization; as the WIPO describes the PCT: The Patent Cooperation Treaty (PCT) assists applicants in seeking patent protection internationally for their inventions, helps patent Offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions. By filing one international patent application under the PCT, applicants can simultaneously seek protection for an invention in a very large number of countries.65 Importantly, filing an application to the PCT does not grant a patent international reach; the inventor must file a patent application and await approval in each jurisdiction they wish to pursue, and patents are still enforceable only in the countries where they are obtained.66 Rather, filing your invention to the PCT, and denoting the countries where you seek patent protection, means that the PCT will provide information on the timeframe and likelihood of a patent being granted in that jurisdiction, along with certain assistance that varies based on the jurisdiction sought.67 C. How Companies Can Utilize Patents Internationally Both the TRIPS Agreement and the PCT reduce barriers to transferring business across national boundaries by easing the transference of the intellectual property needed. The PCT acts merely as a helping hand and information collection tool, while the TRIPS Agreement acts to ensure that intellectual property will operate largely the same from jurisdiction to jurisdiction and, importantly, will be protected with uniform minimum standards. Without commenting on the desirability of this uniform treatment throughout varying economies, it has never been easier for businesses to use their intellectual property to enter international markets.68 In fact, under the TRIPS Agreement and PCT, companies can file a patent in a country where they have no connections,69 acquire a patent, and simply license the technology to (or bring infringement suits against) companies in the member country without needing to ever establish a presence.70 Notably, the PCT and many countries’ patent systems require you to file your patent application within a restricted timeframe after it is first disclosed.71 Thus, this transportation of patent rights must be loosely simultaneous throughout jurisdictions. However, the fact still remains that sophisticated actors who utilize the protections of the TRIPS Agreement can now acquire a monopoly to practice an invention in any country that is a signatory to the TRIPS Agreement or PCT. This usually reaches far short of global domination since companies generally file only in jurisdictions where they expect the benefit of using the patent to outweigh the cost of applying for one.72 However, if the inventor files a patent in every country that has a viable market for that invention, especially if only a few markets exist, the inventor could create an economic climate close to a global monopoly.

#### Thailand proves – the world is trending towards legalization but big pharma patents lock in cannabis monopolies and crowd out local growth.

Kellner 21 “Mitigating the Effects of Intellectual Property Colonialism on Budding Cannabis Markets” Hughie Kellner [Hughie Kellner came from the small farm town of Uvalde, Texas and received a bachelor’s degree in Physics from the University of Texas at Austin. Upon graduation from the Indiana University Maurer School of Law, Hughie will deploy his physics degree while prosecuting patents in the Frankfurt am Main, Germany office of Leydig, Voit, & Mayer. After Hughie’s first year at Maurer, he worked for a law firm in Thailand as a Stewart Fellow.] Indiana Journal of Global Legal Studies Vol. 28 #1 (Winter 2021) <https://www.repository.law.indiana.edu/ijgls/vol28/iss1/9/> SM

The reason the Thai public was so concerned over the cannabis patents filed by Otsuka and GW is that they represented the floor falling out from beneath them. The patents claimed both cannabinoid oil itself and a process for extracting the cannabinoid oil from the cannabis plant, which, based on the way they sought protection, was very likely not patentable anyway.88 However, if either Otsuka or GW received a patent, that patent would be an incredibly powerful tool in clearing competition in the upcoming market. Members of the Thai public saw their newly granted cannabis industry about to be swallowed up and taken from them by a foreign pharmaceutical company before they even had a chance to venture into it themselves. This more than questionable “emergency order,” which temporarily blocked the possible grant of patents to Otsuka or GW, paid lip service to the allowances under the TRIPS Agreement,89 but in reality discriminated based on the applicant’s nationality. The goal of the order was to avoid a scenario of foreign monopolization that could pop up in any market that is a signatory to the TRIPS Agreement and institutes some form of commercialization of cannabis. GW and Otsuka Pharmaceuticals did not do anything illegal; they had the right to apply for protection of their intellectual property and did so. The Thai government acted on legally questionable grounds,90 but had a just reason to do so: attempting to avoid the exportation of an upstart cannabis market that would provide a lucrative cash crop to a highly agrarian Thai population.91 The scenario of recreational cannabis markets being promptly secured by foreign interests grows more and more likely as cannabis companies grow larger and more countries look to liberalize cannabis laws.92 As of right now, Canada’s recreational cannabis market, the only recreational cannabis market open to privatization,93 supports the largest cannabis companies in the world with vast amounts of capital, competition, and the best incentives to research and develop products better than and before their competitors.94 The logic of the feared scenario is as follows: if there exists a jurisdiction that establishes a market that produces entities who innovate more than any other jurisdiction, then that jurisdiction will be state of the art by definition. When another jurisdiction opens up a market, until that market supports entities who are innovating on their own and at a level that surpasses or escapes the prior jurisdiction, all entities will either operate below state of the art or at the same level as the prior, more advanced jurisdiction. With that innovation comes the possibility for patent protection. As discussed in Part II, a patent is only enforceable in the jurisdiction (usually country) it is acquired in. However, with the binding rules of the WTO TRIPS Agreement and the helping hand of the PCT, a patent in one country can easily become a patent in another country. If a patent is acquired by the most innovative entities and exported to the less innovative jurisdiction, entities in the less innovative jurisdiction must pay to use that patent if they wish to operate at the state of the art or, alternatively, stop their business. Therefore, the monopoly of one jurisdiction can be imposed upon another jurisdiction, suppressing actors in the less advanced jurisdiction simply because the first jurisdiction got a head start.95 This fear was present at the time the TRIPS Agreement was signed and is still present today: [S]ome analysts interpret the growing concern of industrialized nations with intellectual property rights as an attempt to control the diffusion of new technologies . . . to freeze the existing international division of labor by way of the control of technology transfers . . . . [I]t is important to recognize that for a [lesser developed] country a reform designed to increase intellectual property rights protection will tend to generate a welfare loss at its initial stages. Because [lesser developed countries] are typically net importers of technology, a usual consequence of a more strict regime of intellectual property laws would be an increase in royalty payments to foreigners.96 As this plays out in today’s evolving cannabis industry, if someone is going to make advancements in the cannabis industry, most of those advancements will be from the Canadian actors before Thai actors, due to the head start and the stronger expected return on innovation in the Canadian recreational market. The Canadian actors’ innovations would be merely the product of the regulatory policies of their respective jurisdiction being amenable to innovation, and then importing those innovations into a jurisdiction that had not previously been amenable to innovation. Accordingly, the Canadian Patent Office has seen the effects of the innovative incentives: the Canadian market has produced and processed many patent applications.97 Further, even if Thailand prohibited any foreign actor from producing, importing, exporting, selling, or engaging with the Thai cannabis industry in any meaningful way, a foreign company could still force itself into the industry with the patent rights and structures available to it under the TRIPS Agreement.98 Without ever having a physical presence, business can be generated by filing a patent and forcing others to license the use of the patent or face an infringement lawsuit.99 Even if an action is not infringing, a patent could be used to threaten a lawsuit upon a new business 100 (every business in the Thai market will be new) that likely would not possess the resources to defend a patent lawsuit (one of the most expensive types of lawsuits)101 and would be forced to submit to a licensing arrangement or close its doors.102 This is so only because Canada decided to violate the terms of the UN Single Convention.103 Thus, Canada was able to safely internalize every first-mover benefit available because the other 184 countries party to the Single Convention, and all other G7 countries, would still be prevented from establishing a recreational cannabis market. Canada may not have had any malicious motives; after all, it did ensure that its regulatory scheme governed international trade as mandated by the Single Convention,104 and thus attempted to keep any acts that violate that treaty from causing other nations to violate it. This seems like the intention of a good neighbor who knows they have broken the rules, but the best intentions in the world do not alone alter the operation or availability of other global legal structures. A solution needs to be found whereby local actors, who did not have a chance to innovate, are given an opportunity to establish themselves so they can innovate while foreign business and investment is also allowed to participate in the market, bringing their advantage of experience rather than legal monopoly. In the following section, I argue that a solution, unique to the cannabis market, can be found by imposing a small and circumscribed amendment to the TRIPS Agreement, as a resolution to the Canadian recusal from the UN Single Convention.

#### Big pharma leverages cannabis patents to block out competition and secure monopoly – decks medical marijuana access

Barnett 20 Hailey A. Barnett [J.D. candidate 2020, Tulane University Law School; B.A. 2017, Communication, cum laude, Texas A&M University.], "High Risk, High Reward: Patent Law's Effects on the Medical Marijuana Industry," Tulane Journal of Technology and Intellectual Property 22 (2020): 125-164 <https://heinonline.org/HOL/LandingPage?handle=hein.journals/tuljtip22&div=8&id=&page=> SM

B. Cannabis Patents and Pharmaceutical Companies

Patent protection is a key component of the United States legal system. On principle, we should compensate and reward those who have rightfully invented something, as well as incentivize and stimulate further innovation. The marijuana industry has been historically composed of people who believe in the cause, the plant, and the health benefits it brings. Yet, many of the field's "new players" are getting involved with a specific 89 business purpose in mind. Cannabis patents are one way to normalize and bring the industry to the mainstream, but the winners in the patent system are often those who are first and have the most money.'90 It's no secret why everyone wants a piece of the marijuana industry pie: according to an April 2018 report by Grand View Research, Inc., the global legal marijuana market is projected to be worth $146.4 billion by 025.'9' The report additionally found that in 2016, medical marijuana emerged as the largest segment of the industry and is estimated to be valued at $100.03 billion by 2025.192 One way to obtain a monetary stake in the medical marijuana market is to use the patent process to acquire ownership over a particular strain and its seeds.' 93 This limited monopoly ensures that the patent holder "is the only one who can make or sell the product, or license other people to do so."'94 However, there are so many unanswered questions that surround IP protection of a federally illegal substance, it is unclear if the patents will be upheld.'9 5 If cannabis patents are upheld in federal courts, it is possible that a handful of companies could be in a position to demand licensing fees from the rest of the industry.1 96 This incentive is particularly appealing to major multinational pharmaceutical companies (Big Pharma) and is already being capitalized on today. For example, pharmaceutical firms are already seven of the top ten cannabis patent holders in Canada.' 97 These patents, filed prior to the country's full legalization of marijuana, would have been difficult to enforce prior to legalization.' 9 8 However, after Canada legalized marijuana on October 17, 2018, the patents became fully enforceable and gave the companies a key strategic advantage over non-patent holders in the ever- increasingly competitive market.' 99 The biggest concern is that Big Pharma companies will harness their powerful lobbies and seemingly bottomless payrolls to engage in patent blitzes. In other words, they will try to enlarge their patent portfolios and subsequent ownership of marijuana strains and their ancillary byproducts, such as oils, to marginalize competitors. In the United States, the FDA plays a crucial role in approving and 201 regulating medications for public use. Big Pharma requires the FDA's approval to bring their products to the public market, and it's no secret that Big Pharma's influence on the agency has accrued over many decades and billions of dollars spent.2 0 2 The current FDA Commissioner Scott Gottlieb recently slammed Big Pharma and accused drugmakers of using "gaming tactics" to stall the introduction of generic versions of biologic drugs, "a move that cost the U.S. healthcare system billions of dollars last year. "203 One of these tactics is to engage in patent blitzes, or evergreening, right before a drug's patent protection (and subsequent market exclusivity 20 4 period) expires. "In the pharmaceutical trade, when brand-name companies patent 'new inventions' that are really just slight modifications of old drugs, it's called 'evergreening. "'205 Evergreening occurs because once a drugmaker's patent on a particular drug expires, the door is open for other producers to bring generic versions of the drug to market.206 Patents in patent blitzes are often granted for even the most trivial improvements and innovations related to existing drugs.207 The purpose of evergreening is two-fold: first, to extend the commercial dominance of brand-name drugs, and second, to tie up producers of the generic drugs in 2 08 costly, time-consuming litigation. Evergreening prevents a generic drug's market entry and further extends Big Pharma's monopolies.2 09 A prime example of recent evergreening is when Mylan hiked the price of its life-saving epinephrine injectable drug, EpiPen, by more than 400%.210 After Teva Pharmaceuticals gained approval from the FDA for the first generic version of EpiPen, Mylan sued them for patent infringement, although epinephrine alone was already a generic drug.2 1 Mylan settled and kept "Teva off the EpiPen market until 2015."212 Much like AbbVie's battle with AmGen over a generic version of the former's costly biologic drug Humira, Big Pharma's inclination to place company profits over the needs and desires of patients could continue with cannabis strain patents. 2 13 This will ultimately affect cost and access to medical marijuana products. Thanks to shifting public opinion and state legalization, a growing number of cannabis patent applications have been filed with the USPTO and it is very likely they will be granted. Although marijuana remains illegal at the federal level, the premature filings signal hope that sometime in the near future, the federal government will reconsider its stance on cannabis, and make medical and recreational marijuana use legal from sea to shining sea.215 Companies with a large numb1er of cannabis strain patents, such as BioTech, could become an even bigger national player in the field of cannabis strain patents as they acquire more market share. Overall, if Big Pharma obtains exclusive rights to use, produce, and sell particular cannabis strains, together with their large influence over the FDA and other government regulatory bodies, they can control public access and maintain already robust profit margins.217 Not surprisingly, Big Pharma is not the only industry chasing profits from marijuana IP rights. Smaller breeders, including scientists who alter the plant for medicinal purposes, worry that large bioagricultural companies like Monsanto and Syngenta will hoard cannabis-based patents and deploy their massive economic power to position themselves as another dominant force in the market.218 in short, an open and accessible marketplace for cannabis products, especially for medicinal use, depends on tracking the patent activity of wealthy, powerful entities to ensure smaller entities are not marginalized.219

#### Monopolies kill cannabis biodiversity which throttles medical marijuana advances and industry innovation.

Barnett 20 Hailey A. Barnett [J.D. candidate 2020, Tulane University Law School; B.A. 2017, Communication, cum laude, Texas A&M University.], "High Risk, High Reward: Patent Law's Effects on the Medical Marijuana Industry," Tulane Journal of Technology and Intellectual Property 22 (2020): 125-164 <https://heinonline.org/HOL/LandingPage?handle=hein.journals/tuljtip22&div=8&id=&page=> SM

A. Biodiversity Implications for Cannabis Strain Patents

Biodiversity, or biological diversity, is an ongoing controversy in the marijuana patent industry. Like comprehensive research on the benefits and drawbacks of medical marijuana, "empirical analysis on biodiversity in the patent system is limited."2 2 2 Biodiversity is a broad term but is generally defined as "biological diversity in an environment as indicated by numbers of different species of plants and animals." 23 Increasingly, however, countries and companies are asserting IP rights in native flora, 224 impacting global biodiversity. "Historical documents from around the world, some dating as far back as 2900 B.C., tell us that cannabis has lived alongside humans for thousands of years, cultivated for food, fiber, and fodder, as well as for religious and medicinal purposes." 2 5 The fear is that without a wide variety of cannabis strains available for breeding and growing, production and processing of the plant will inevitably consolidate into the hands of large conglomerates.22 6 The United States and Thailand are signatories to the Convention on Biological Diversity (Biodiversity Convention), a multilateral treaty committed to sustainable development. The Biodiversity Convention's goals include "conserving biological diversity, promoting the sustainable use of its components, and the fair use and equitable sharing of benefits from biological resources."228 The Biodiversity Convention requires signatories to enforce regulations on plant patent applications and mandates that new patent applications include the plant's genetic resources and evidence of local use if they seek to patent the plant in a certain country. This is the chief reason behind the Biodiversity Sustainable Agriculture Food Sovereignty Action Thailand's (Biothai) call for careful scrutiny of recently filed foreign cannabis patents in the country, as discussed in greater detail in the next Section. Since medical marijuana is now legal for use and manufacture in Thailand, the mere implication that fabled Thai marijuana strains, such as "Northern Lights," could be available on the global market has generated 23 much buzz. 1 Like Cuban cigars or French champagne, Thai marijuana is known for its potency and quality.232 Thailand's marijuana is apure sativa landrace strain, meaning it is a local strain of cannabis that has adapted to Thailand's native environment and conditions over time. Environment plays a key role in the THC, CBD, and terpene quality and quantity and is part of what makes landrace strains so unique. For example, the marijuana plants and seeds that are indigenous to the tropical jungles of Thailand are bred to preserve their naturally occurring high THC levels.235 As more cannabis strain patents are granted worldwide, it is possible that growers will be increasingly dependent on seed makers that hold patents on certain types of seeds and methods used to produce them. As a result, growers will be subject to agreements and royalties and will be charged licensing fees for use of the seeds. A healthy number and variety 236 of available cultivars are vital for advancing cannabis legalization and the industry’s continued growth. From an agricultural perspective, the patent system encourages a consolidation and reduction of variety in order to enhance and maximize profits. This can be seen in today's staple crops, such as com, soy, and wheat, where fewer cultivars exist than they did decades ago.23 9 Other crops globally consumed today, such as fruits 240 and vegetables, are likely grown from patented varieties or cultivars. As a result, agricultural biodiversity has diminished due to the introduction and consolidation of genetically modified, patented varieties, and it is highly likely the cannabis industry could see a similar fate.24 1 Cannabis biodiversity will be threatened if there are fewer available cultivars and, thus, fewer strain options.2 42 Fewer available strains could also lead to limited consumer experiences and patient treatment options. This notion, coupled with already limited clinical and scientific research, could significantly throttle advances in medical marijuana availability and use.2 43 The corporatization of the industry, thanks to patent law, could see smaller growers and businesses merging into giant conglomerates, with 2 the profits being held in the hands of a very few. 4 In short, the "winners" of the cannabis patent wars will dominate the industry post-prohibition.2 45 Some argue that expanding strain patents could have the opposite effect and allow researchers and physicians to "correctly identifty], dos[e], and perhaps even personalize prescriptions for particular strains in the future" to treat specific ailments.24 6 Patents are a hallmark of innovation, and with wide access to more and better cannabis strains, there could be innovation advances in the industry as a whole.2 47 However, the reality is that cannabis patents are likely to be held by large corporations, given what we have seen before with the United States government and the FDA's involvement.24 8 Both medical marijuana patients and recreational marijuana users are strain-driven. While the current cannabis landscape is rich with hundreds of different varieties, strain patents could lead to a "locked genetic landscape where innovation becomes rare and costly."2 4 9 Further, a monopoly on the local strains of one country could have disastrous effects on that country's biodiversity and its rights to that biodiversity.2 50

#### Monopolies kill market growth and disincentivize innovation.

Gunelius 20 “How Big Business, Monopolies and Stacked Licenses Impact the Marijuana Industry,” February 7, 2020, Originally published 3/4/17, Susan Gunelius is President & CEO of KeySplash Creative, Inc. <https://www.cannabiz.media/blog/how-big-business-monopolies-and-stacked-licenses-impact-the-marijuana-industry> SM

However, the continued growth and development of big businesses with deep pockets in the cannabis industry has many people worried that the result of continued mergers and acquisitions will be monopolies, lower quality products, and a shift of revenues away from mom and pop businesses in local communities to out-of-state (or out of country) corporations. The Start of Monopolies and Oligopolies in the Cannabis Industry Monopolies and oligopolies are already developing in the cannabis industry — not just in terms of big businesses usurping smaller businesses but also in terms of state regulations that allow vertical integration, which leads to markets dominated by one or a few players that control the cultivation, processing, and sale of cannabis products.To clarify, all but two states (Louisiana and Washington) with active medical or recreational cannabis programs allow or require vertical integration of the cannabis supply chain. Cannabiz Media defines the related cannabis license structures as follows: Fully stacked licenses: A single licensed business can or is required to handle all operations from seed to sale in a fully vertically integrated structure. Partially stacked licenses: A single licensed business can or is required to handle more than one operation but not all operations from seed to sale. Unstacked licenses: Different businesses handle different operations across the supply chain from seed to sale. For example, in Minnesota, the state’s medical marijuana program requires full vertical integration with only one type of license – the Medical Cannabis Manufacturer license. Currently, only two of these licenses are allowed in the state to grow, process, and sell (at four dispensaries each) cannabis. Other states, like Colorado and Oregon, have ceased to award additional licenses to some cannabis businesses in the past thereby creating oligopolies. In California, oligopolies are forming in a different way. Regulations passed leading up to opening the state’s adult-use market in 2018 allowed large businesses to exploit a loophole and obtain as many cultivator licenses as they could afford. Across the country, smaller cannabis businesses are struggling to compete with other bigger cannabis companies. In Maryland, large out-of-state companies (including several well-known cannabis companies that are publicly traded on the Canadian Securities Exchange) have been quietly taking control of multiple marijuana dispensaries through management agreements or acquisition plans that circumvent the state’s regulations limiting ownership to one dispensary. The concern about monopolies and oligopolies in the cannabis industry was in the Florida news extensively throughout 2019 when a Florida court ruled that the state’s required vertical integration was unconstitutional. The Future of Marijuana and Big Business Bottom line, whenever every business that wants to be in an industry cannot enter the market, competition will not flourish. The result is the same whether businesses are shut out due to state regulations or because big businesses have deeper pockets and force smaller players to leave. Either way, the result is the same. Fewer players equals less competition which usually leads to higher prices and limited market growth.As Sean Williams of The Motley Fool warned back in 2017, “The culprit for the substantial drop in marijuana prices appears to be big businesses infiltrating the industry and flooding the market with product. As with any industry, if big business can push the little guy out, they’ll have considerably more liberties down the road to raise their prices back up and capture a juicier margin, along with greater market share.” Only free competition ensures fair prices and market growth over the long-term as well as ongoing innovation and product accessibility.

#### Shifting away from corporate cannabis monocultures is key to organic weed.

Russo 19 “MARIJUANA NOT MONOCULTURE!” Sarah Russo [writer, cannabis consultant, and a social media and content manager. She got her degree in environmental studies and social justice, with a focus in plant medicine from the Evergreen State College], May 2, 2016 updated April 2, 2019, <https://www.projectcbd.org/es/node/494> SM

We have a pesky, non-organic thorn in our side. Our current agricultural system is not based on sustainable means of cultivation and, unfortunately, this also applies to much of cannabis farming today. While the “organic” marijuana movement is gaining momentum, the vast majority of cultivators grow cannabis as a monocultural crop, which often entails the use of toxic pesticides and plant growth boosters to maximize profit.A monoculture, or “monocropping,” involves growing one type of crop to the exclusion of others. There are virtually zero examples of monocropping in nature. Unlike monocropping, sustainable growing practices mimic what is done in nature and seek to recreate it in a controlled setting. As interest in medical cannabis has increased, the terms “organic” and “sustainably grown” have become trendy buzzwords within the industry. There is obviously a need to propagate more cannabis to supply a large consumer demand, but the “more for your money” approach to growing has not been conducive to healthy stewardship of the land. Our corporate-dominated agricultural system is broken, and the cannabis industry should not emulate its worst features.Some cannabis farmers have adopted sustainable, alternative practices, including a technique known as companion planting or “multicropping.” Companion planting is a method of cultivation where various plants are grown together in ways that promote a dynamic, flourishing ecosystem. Companion planting improves the land’s resilience and also increases the yield and health of the plants within the garden. The science of intercropping cannabis is still in its infancy. Presently, there is little scientific study of companion planting in general, and research and development efforts in the area of cannabis cultivation face additional obstacles due to the plant’s historical stigma. But the absence of hard science doesn’t discredit the ancient cultivation methods that utilized permaculture techniques as the standard. Human beings were growing sustainably long before the advent of toxic, soil-depleting industrial agriculture. “Companion planting is a method of cultivation where various plants are grown together in ways that promote a dynamic, flourishing ecosystem.” A classic example of companion planting is the “Three Sisters Method” used by indigenous peoples in the Americas for food production. Various tribes planted beans, corn, and squash—the golden crop trio—in proximity. This practice reflects an understanding of plant mutualism, wherein each cultivar has one or more functions that benefit the botanicals growing around it. In the Three Sisters model, the beans act as a nitrogen-fixer, which is essential for plant growth; the corn feeds off the nitrogen; the beans use the corn to climb on; the squash provides a source of shade and natural mulch, which conserves moisture in the soil and aids the growth of beans and corn. The plants are engaged synergistically in positive ways, and this contributes to a dynamic, thriving agricultural environment. The ancient practice of companion planting has been resurrected by modern-day permaculture farmers and to a lesser extent by cannabis growers. According to permaculturist Kate Miller of Alpine Botanicals in Nederland, Colorado, companion planting is “even more important now that we see what’s happening to the planet, to soil fertility or lack thereof, and to our pollinating insects. Pollinators such as honey bees, butterflies, bats, and other insects simply do not thrive in a monoculture.” Miller’s medicinal garden includes cannabis and various companion plants with therapeutic properties of their own. Sometimes, these botanical companions can be combined with cannabis to create artisanal herbal formulas for healing. MULTIPLE BENEFITS Miller says that comfrey offers significant benefits as a botanical companion, functioning simultaneously as a cover crop and dynamic accumulator. Comfrey is also a natural remedy for external wounds, rashes, repairing tissue, and other skin issues. “The only downside of growing comfrey,” Miller explains, “is that it can take over and its large leaves can also shade out other plants. This is not a bad thing if you’re trying to prevent weeds. You can chop up the comfrey leaves and use it as living mulch throughout the season, or even as animal fodder.” Alfalfa is another example of a companion plant with therapeutic as well as other benefits. Alfalfa acts as a nitrogen-fixer and it also stabilizes terraces to prevent soil erosion. A cultivator can harvest alfalfa for making compost. Or it can be brewed and consumed as a mineral-rich medicinal tea. Image Cameron, another Colorado-based cannabis cultivator, maintains that intercropping techniques enable his plants to reach their greatest potential. “As far as ganja farmers are concerned,” he asserts, “a high diversity of organic soil offers all the nutrients for the plant to bloom into its fullest expression. This enhances both the flavor profile and resin content.” A well-fed plant is more likely to be disease-resistant. Permaculture techniques can build a plant’s resilience, making it stronger and healthier. Some cannabis cultivators utilize mycorrhizal fungus as a soil topping at the base of a marijuana plant to increase nutrient availability. “When all ecological niches are intentionally filled with beneficial organisms, there is little space for pests to take hold,” says Cameron. Cannabis is a highly adaptable and durable plant, but diseases and pests pose ongoing risks in both indoor and outdoor cultivation. Monocultures are major targets for problematic insects and pathogens like powdery mildew. By diversifying their crop spectrum, farmers are less likely to lose plants to disease and insect infestation. Companion planting also helps to create a stable, diverse habitat for a myriad of birds, bees, and small animals, which interact in positive ways with their botanical counterparts. OUTDOORS AND INDOORS For outdoor grows, crop rotation can help an ecosystem flourish by diversifying the earthly terrain. It’s more difficult but not impossible to implement companion planting techniques when growing indoors. This can be accomplished by placing various companion plants—like basil to deter pests—around cannabis pots. Cover crops with shallow roots can also be placed at the base of a marijuana plant to promote nutrient availability in the soil. You can also get creative by planting aromatic herbs for cooking and for medicinal purposes when growing indoors. “Throughout modern U.S. history, we have seen farmers falling victim to the monoculture cash crop mentality,” says Casey O’Neill, owner of Happyday Farms in Northern California. He grows 47 different kinds of veggies amongst his outdoor cannabis varieties. This enables Happyday to maximize space and harvest as much as possible from the same garden. O’Neill says that companion planting lowers cultivation costs and mitigates risk by providing economic protection that is lacking in monoculture farming. In the event of a theft or a raid, his food crops are left untouched and he is still able to sell vegetables at the local farmer’s market.

#### Organic weed key to climate change – removes CO2 from the atmosphere and reverses harms of corporate farming.

Bronner 8/23 “Opinion: Cannabis industry needs regenerative organic farming, not modified seeds,” August 23, 2021, David Bronner [Cosmic Engagement Officer (CEO) of Dr. Bronner's, BA Biology from Harvard] <https://hempindustrydaily.com/opinion-cannabis-industry-needs-regenerative-organic-farming-not-modified-seeds/> SM

As the legal cannabis industry continues to expand, it’s urgent that we understand the consequences of placing too much reliance on large industrial cannabis grown indoors under artificial lighting. Now is the imperative time to acknowledge natural farming as one of the solutions for mitigating the impacts of climate change.We should be looking for ways to be kinder to the Earth and to reject harmful chemical-intensive agricultural practices. We should embrace organic farming methods that improve soil health and build resilient, regenerative supply chains that nurture both people and planet.I’m disturbed by reports that seed breeders are using gene-editing technology to develop varieties that no longer contain THC but have the addition of herbicide-resistant genes so growers can spray weed killer on their plants. Two years ago, I founded the cannabis brand Brother David’s, the first cannabis brand to become Sun+Earth Certified — the regenerative organic certification for cannabis that guarantees the cannabis is grown under the sun, organically in soil, and that farmers and farmworkers are fairly paid. Brother David’s, and our ally Sun+Earth, along with other advocates and experts in the industry share a common mission to move the cannabis industry away from chemical-intensive farming practices. Because official organic certification from the U.S. Department of Agriculture remains off-limits to high-THC cannabis producers, Sun+Earth provides validation for cannabis consumers who want to know how their cannabis is produced. Cannabis is a bio-accumulator that relies on the richness of the soil in which it’s grown and pulls toxins from the soil. But those toxins eventually get passed on to the consumer in the cannabis products they buy.And the vast majority of cannabis currently sold in the United States has no labeling that explains how it’s grown and whether chemicals used in its production are harmful to people, the soil and the natural environment. According to the market research group TrendSource and its 2019 Cannabis Industry Report, more than 53% of consumers are willing to pay more for organic cannabis products. In order to bridge the gap between consumer preference and the actual supply of cannabis in the market, Sun+Earth aims to shift the industry toward healthier, more sustainably and ethically-grown cannabis. Just as genetically modified seeds are not the answer to our agricultural industries, finding ways for cannabis to be more easily sprayed with toxic chemicals is also counterproductive to the cannabis and hemp industry.Sun+Earth is also committed to reducing the impacts of climate change in an industry that uses excessive amounts of energy to grow plants indoors. Industrial cannabis production in the U.S. uses the same amount of energy it takes to power 1.7 million U.S. homes. It generates greenhouse gas emissions equivalent to that of 3 million cars, on an annual basis.According to a report from 2012, indoor cannabis production uses 1% of all electricity consumed in the US at a cost of $6 billion per year. More recently, the 2021 report from Colorado State University found that indoor cultivation in the U.S. produces up to 5,184 kilograms of greenhouse gas emissions for each kilogram of harvested flower. Regenerative organic cultivation standards encourage the planting of cannabis alongside food crops with strategic use of cover crops, composting, mulching, and reduced soil tillage — methods that have been shown to sequester carbon from the atmosphere and are championed as a part of the solution to global warming by groups like the Rodale Institute, a pioneer of organic agriculture research and consumer education.The regenerative organic model for cannabis grown under the sun, in the soil, without chemical fertilizers or toxic pesticides can drastically reduce the carbon footprint of cannabis, and indeed build networks of food and flower production that are themselves more resilient to the impacts of climate change.Sun+Earth stands as an ideal model and a beacon of hope for the cannabis industry and the broader agricultural sector. This innovative certification relies not on new genetic technology, but on farming methods that work with the natural world instead of suppressing it. Such tried and true methods have been used for millennia and represent more of an answer to producing cleaner cannabis and for building healthy, vital soil that can better address our current environmental and agricultural crises.

#### Warming causes extinction

**Pester 21** (Patrick, staff writer for Live Science. His background is in wildlife conservation and he has worked with endangered species around the world. Patrick holds a master's degree in international journalism from Cardiff University in the U.K. and is currently finishing a second master's degree in biodiversity, evolution and conservation in action at Middlesex University London. Citing **Luke Kemp, a research associate at the Centre for the Study of Existential Risk at the University of Cambridg**e in the United Kingdom AND **Michael Mann, PhD, distinguished professor of atmospheric science at Penn State**. “Could climate change make humans go extinct?” [https://www.livescience.com/climate-change-humans-extinct.html August 30](https://www.livescience.com/climate-change-humans-extinct.html%20August%2030), 2021)DR 21

According to Mann, a global temperature increase of 5.4 degrees Fahrenheit (3 degrees Celsius) or more could lead to a collapse of our societal infrastructure and massive unrest and conflict, which, in turn, could lead to a future that resembles some Hollywood dystopian films. One way climate change could trigger a societal collapse is by creating food insecurity. Warming the planet has a range of negative impacts on food production, including increasing the water deficit and thereby reducing food harvests, [Live Science previously reported](https://www.livescience.com/58891-why-2-degrees-celsius-increase-matters.html). Food production losses can increase human deaths and drive economic loss and socio-political instability, among other factors, that may trigger a breakdown of our institutions and increase the risk of a societal collapse, according to a study published Feb. 21 in the journal [Climatic Change](https://go.redirectingat.com/?id=92X1590019&xcust=livescience_us_1191050396230939400&xs=1&url=https%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs10584-021-02957-w&sref=https%3A%2F%2Fwww.livescience.com%2Fclimate-change-humans-extinct.html). Related: [Has the Earth ever been this hot before?](https://www.livescience.com/65927-has-earth-been-this-hot-before.html) Past extinctions and collapses Kemp studies previous civilization collapses and the risk of climate change. Extinctions and catastrophes almost always involve multiple factors, he said, but he thinks if humans were to go extinct, climate change would likely be the main culprit. "If I'm to say, what do I think is the biggest contributor to the potential for human extinction going towards the future? Then climate change, no doubt," Kemp told Live Science. All of the major [mass-extinction events](https://www.livescience.com/mass-extinction-events-that-shaped-Earth.html) in Earth's history have involved some kind of climatic change, according to Kemp. These events include cooling during the Ordovician-[Silurian](https://www.livescience.com/43514-silurian-period.html) extinction about 440 million years ago that wiped out 85% of species, and warming during the [Triassic](https://www.livescience.com/43295-triassic-period.html)-[Jurassic](https://www.livescience.com/28739-jurassic-period.html) extinction about 200 million years ago that killed 80% of species, Live Science previously reported. And more recently, climate change affected the fate of early human relatives. While [Homo sapiens](https://www.livescience.com/homo-sapiens.html) are obviously not extinct, "we do have a track record of other hominid species going extinct, such as [Neanderthals](https://www.livescience.com/28036-neanderthals-facts-about-our-extinct-human-relatives.html)," Kemp said. "And in each of these cases, it appears that again, climatic change plays some kind of role." Scientists don't know why Neanderthals went extinct about 40,000 years ago, but climatic fluctuations seem to have broken their population up into smaller, fragmented groups, and severe changes in temperature affected the plants and animals they relied on for food, according to the [Natural History Museum](https://www.nhm.ac.uk/discover/who-were-the-neanderthals.html) in London. Food loss, driven by climate change, may have also led to a tiny drop in Neanderthal fertility rates, contributing to their extinction, [Live Science previously reported](https://www.livescience.com/65594-neanderthal-fertility-led-to-extinction.html). Climate change has also played a role in the collapse of past human civilizations. A [300-year-long drought](https://www.livescience.com/38893-drought-caused-ancient-mediterranean-collapse.html), for example, contributed to the downfall of ancient Greece about 3,200 years ago. But Neanderthals disappearing and civilizations collapsing do not equal human extinction. After all, humans have survived climate fluctuations in the past and currently live all over the world despite the rise and fall of numerous civilizations. Homo sapiens have proven themselves to be highly adaptable and able to cope with many different climates, be they hot, cold, dry or wet. We can use resources from many different plants and animals and share those resources, along with information, to help us survive in a changing world, according to the [Smithsonian’s National Museum of Natural History](https://humanorigins.si.edu/research/climate-and-human-evolution/climate-effects-human-evolution). Related: [How would just 2 degrees of warming change the planet?](https://www.livescience.com/58891-why-2-degrees-celsius-increase-matters.html) Today, we live in a global, interconnected civilization, but there's reason to believe our species could survive its collapse. A study published on July 21 in the journal [Sustainability](https://www.mdpi.com/2071-1050/13/15/8161/htm) identified countries most likely to survive a global societal collapse and maintain their complex way of life. Five island countries, including New Zealand and Ireland, were chosen as they could remain habitable through agriculture, thanks to their relatively cool temperatures, low weather variability and other factors that make them more resilient to climate change. New Zealand would be expected to hold up the best with other favorable conditions, including a low population, large amounts of good quality agricultural land and reliable, domestic energy. So, even if climate change triggers a global civilization collapse, humans will likely be able to keep going, at least in some areas. Turning on ourselves The last scenario to consider is climate-driven conflict. Kemp explained that in the future, a scarcity of resources that diminish because of **climate change could** potentially create conditions for wars that threaten humanity. "There's reasons to be concerned that as water resources dry up and scarcity becomes worse, and the general conditions of living today become much, much worse, then suddenly, the threat of potential nuclear war becomes much higher," Kemp said. Put another way, climate change impacts might not directly cause humans to go extinct, but it could lead to events that seriously endanger hundreds of millions, if not billions, of lives. A 2019 study published in the journal [Science Advances](https://advances.sciencemag.org/content/5/10/eaay5478) found that a nuclear conflict between just India and Pakistan, with a small fraction of the world's nuclear weapons, could kill 50 million to 125 million people in those two countries alone. Nuclear war would also change the climate, such as through temperature drops as burning cities fill the atmosphere with smoke, threatening food production worldwide and potentially causing mass starvation. What's next? While avoiding complete extinction doesn't sound like much of a climate change silver lining, there is reason for hope. Experts say it isn't too late to avoid the worst-case scenarios with significant cuts to greenhouse gas emissions. "It is up to us," Mann said. "If we fail to reduce carbon emissions substantially in the decade ahead, we are likely committed to a worsening of already dangerous extreme weather events, inundation of coastlines around the world due to melting ice and rising sea level, more pressure on limited resources as a growing global population competes for less food, water and space due to climate change impacts. If we act boldly now, we can avoid the worst impacts."

## Contention 2: Insulin

#### Current patent protection makes insulin, an essential drug for many, unaffordable – that causes diabetics to skip/ration doses, skimp on necessities, or die trying.

**Barker 20** [Erin M Barker, Executive Editor at the Campbell Law Review with a JD, 2020, "When Market Forces Fail: The Case for Federal Regulation of Insulin Prices," Campbell Law Review, [https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331]/Kankee](https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331%5d/Kankee)

INTRODUCTION Today, a single vial of insulin can cost more than $250 in the United States, and most patients use between two and four vials each month.' Consequently, if a diabetic patient is without insurance, or if insurance does not cover a specific brand of insulin, that person could pay upwards of $500 to $1,000 per month out-of-pocket for an essential medication.2 These costs are astronomical and unacceptable-the federal government must step in to regulate pricing. On January 11, 1922, fourteen-year-old Leonard Thompson faced the end stages of a terminal illness: diabetes mellitus, otherwise known as type 1 diabetes.3 Thompson weighed only sixty-five pounds after living with diabetes for three years.' His attempt to control his diabetes with a starvation diet failed to keep him from slipping in and out of a diabetic coma.5 Desperate for any chance to save his son, Thompson's father agreed to let the hospital inject the boy with a recently-discovered drug-insulin.6 Thompson would be the first human subject to receive the injection,' and the results were nothing short of miraculous.' His blood sugar lowered to a normal level, and the glucose and ketones' present in his urine also lowered to a tolerable level.10 Four men discovered this "wonder drug"": Frederick Banting, Charles Best, James Collip, and John Macleod.12 Following Banting's and Best's initial publication of their results,13 the discovery of insulin and its successful application to human subjects landed on the covers of newspapers worldwide.14 Insulin provided life-saving treatment for people who previously faced a death sentence; the drug brought diabetic patients out of comas, allowing them to end their starvation diets and eat carbohydrates." For their discovery, Banting and Macleod won the 1923 Nobel Prize in Physiology or Medicine and split their winnings with Best and Collip.16 Banting, Best, and Collip acquired an American patent on insulin and its method of creation on January 23, 1923.17 When applying for their patent, the trio maintained that "their goal was not profit, but ensuring the speedy and safe availability of their discovery to the public.""8 They then sold their patent rights to the Board of Governors of the University of Toronto for $1.00 each.1 9 In a letter to the University's president, the trio wrote, "The patent would not be used for any other purpose than to prevent the taking out of a patent by other persons. When the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."20 Banting, Best, and Collip stated a clear goal: their lifesaving invention was to remain available to all. That goal has failed. This Comment analyzes how federal regulation of insulin prices will correct failed market forces, leading to a stabilized market for the indispensable medication. Part I of this Comment will provide a brief overview of the current state of the insulin market in the United States. Part II of this Comment will explain economics-based justifications for adopting federal legislation to regulate the insulin market. It will also provide an overview of the types of regulatory schemes that the government could utilize in this market. Part III of this Comment will describe and critique legislation that two states-Nevada and Colorado-have already acted to regulate the cost of insulin and will then examine currently proposed federal legislation that aims to lower insulin prices. Lastly, Part IV of this Comment offers a solution: the addition of language to the proposed federal legislation, incentivizing competition and positively affecting market prices through the nationalization of patents. I. THE STATE OF THE INSULIN MARKET IN THE UNITED STATES TODAY A. Economic Impact ofRising Insulin Prices From 2002 to 2013, the cost of insulin nearly tripled.21 Then, from 2012 to 2016, the cost of insulin rose dramatically again, nearly doubling. 22 In the first month of 2019 alone, insulin manufacturers Sanofi and Novo Nordisk raised some of their insulin product prices as much as 4.9% and 5.2%, respectively. 23 As of 2017, diabetes treatment and complications cost the United States ("U.S.") more than $327 billion per year, making it the most expensive chronic illness in the country.24 This cost is a combination of $237 billion in direct medical costs, including $15 billion for insulin, and $90 billion in indirect costs. 25 The American Diabetes Association reports: While much of the cost of diabetes appears to fall on insurers (especially Medicare) and employers (in the form of reduced productivity at work, missed work days, and higher employer expenditures for health care), in reality such costs are passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.26 Government insurance, including Medicare, Medicaid, and insurance through the military, provide for a majority (67.3%) of the cost of diabetes care in this country.27 Private insurance pays for 30.7%, and the uninsured pay for 2% of the cost of diabetes care. 28 Uninsured diabetics visit the doctor 60% less and receive 52% fewer prescriptions than insured diabetics, yet uninsured diabetics account for 168% more emergency department visits than insured diabetics.2 9 Accordingly, because of both the direct and indirect costs of diabetes care, it is not just diabetics who are paying-all of society shoulders the financial burden of the increasing cost of diabetes. 30 B. Social Impact ofRising Insulin Prices Rising insulin prices induce "negative health and financial burdens on the population." 3 1 Of the 30 million diabetic Americans, approximately 7.4 million require daily doses of insulin to survive.32 Rising insulin prices have forced some to cut back on or skip doses of insulin. 3 Others elect to forgo other necessities such as food or rent in order to afford insulin. 3 A 2018 study found that almost 26% of diabetics in the U.S. had rationed their insulin the previous year.35 Recently, poignant stories have emerged detailing the tragic societal consequences of these negative health and financial burdens, including deaths due to an inability to afford insulin. 6 One such story is that of Alec Smith, a twenty-six-year-old who died less than a month after his mother's health insurance plan removed him as a beneficiary.3 7 Smith, who worked a full-time job and earned more than minimum wage, could afford neither new insurance nor the monthly $1,000 out-of-pocket cost of his insulin. 38 Another story is that of Meaghan Carter, a forty-seven-year-old woman who died alone on her sofa on Christmas night because she could not afford insulin.3 9 Carter, a nurse, was between jobs.4 0 She planned to start a new nursing position with health insurance benefits only a week after her death.4 1 Carter's family found empty vials of insulin among Carter's nursing supplies in her home.42 According to Carter's sister-in-law Mindi Patterson, "[s]he had gauze, bandages and all her nursing supplies"-"plenty to take care of others but not enough to take care of herself." 4 3 The stories of Alec Smith and Meaghan Carter demonstrate that there is more than just money at stake here-people's lives are on the line because of insulin prices in the U.S. Almost a hundred years after the discovery of insulin, diabetics should not be forced to ration an essential drug or face death due to excessive costs. Banting, Best, and Collip's goal was to make insulin affordable for all," but that is not the case today. The current price of insulin in the U.S. is unacceptable and must be addressed. II. THE FEDERAL GOVERNMENT SHOULD REGULATE THE INSULIN MARKET BECAUSE OF THE FAILURE OF TYPICAL MARKET FORCES

#### Patents allow a “government sanctioned monopoly” on insulin – Studies prove that looser IP laws would substantially decrease the cost of insulin and that research and manufacturing costs are extremely low right now

**Johnson 18** [Judith A. Johnson, Specialist in Biomedical Science Policy at Congressional Research Service with an MS in molecular biology from Yale, 11-19-2018, “Insulin Products and the Cost of Diabetes Treatment,” Congressional Research Service, https://fas.org/sgp/crs/misc/IF11026.pdf]/Kankee

Insulin is a hormone that regulates the storage and use of sugar (glucose) by cells in the body. **When the pancreas** **does not make enough insulin** (**type 1 diabetes**) **or it cannot be used effectively** (**type 2 diabetes**), **sugar builds up in the blood**. **This may lead to serious complications, such as heart disease, stroke, blindness, kidney failure, amputation of toes, feet, or limbs**. **Prior to** the discovery of **insulin** treatment, **type 1 diabetics usually died from this disease**. **There were 23.1 million diagnosed cases of diabetes in the United States** in 2015 **according to the** Centers for Disease Control and Prevention (**CDC**). **Adding an estimated 7.2 million undiagnosed cases brings the total to 30.3 million** (**9.4% of U.S. population**). **People** with type 1 diabetes, about 5% of U.S. cases, **must have insulin injections** to survive. For those with type 2 diabetes, about 95% of cases, many can control their blood glucose by following a healthy diet, losing weight, maintaining regular physical activity, and taking oral medications, but some require insulin injections **to control their blood glucose levels**. Data collected in the 2010-2012 National Health Interview Survey from diabetics aged 18 or older indicate that 14% are treated with insulin alone, 14.7% are treated with both insulin and oral medication, 56.9% are treated with oral medication alone (not insulin), and 14.4% are not treated with either medication. **The price of various insulin products has risen significantly**. **From 2001 to 2015, the price of** one type of **insulin** (insulin lispro) **increased 585%** (from $35 to $234 per vial). **One vial might last a patient less than two weeks**. Given the number of Americans dependent on insulin, Congress may be interested in considering whether consumers have access at a reasonable cost. Insulin Discovery and Development Insulin was discovered nearly a century ago, in 1921, by researchers at the University of Toronto; their U.S. patent was later sold to the university for $1. Manufacturing challenges resulted in collaboration with Eli Lilly in 1923 in order to make enough insulin for the North American market. They also licensed the right to produce insulin to other firms including a Danish company which eventually became Novo Nordisk. Insulin is a small protein composed of 51 amino acids. Because it is made from a living organism, it is considered to be a biologic, or biological product. Like many other biologics (such as drugs or vaccines), insulin was obtained in the past by extraction from animals. Production has changed over the years as researchers have made alterations to insulin, easing its use by the patient. The ideal treatment regimen for diabetics would closely mimic the way insulin secretion occurs in the body. This would involve a consistent insulin level between meals combined with a mealtime level of insulin that has a rapid onset and duration of action to match the glucose peak that occurs after a meal. The original insulin, also called regular insulin, is a short-acting type of product with a duration of action of about 8 hours, making it less suitable for providing 24-hour coverage. In the late 1930s through the 1950s, regular insulin was altered by adding substances (protamine and zinc) to gain longer action; these are called intermediate-acting insulins. One such advance (neutral protamine Hagedorn, or NPH) was patented in 1946 and is still in use today. It allowed for the combination of two types of insulin in premixed vials (intermediate-acting and regular insulin), making a single daily injection possible for some patients. In 1982, recombinant DNA technology allowed for the replacement of animal insulin extracted from cattle and pig pancreases by human insulin (Humulin R) made in a laboratory fermentation process using microorganisms. These advances still did not mirror the normal release of insulin. Over the past few decades, slight modifications of the insulin molecule—called insulin analogs—have been developed. This has resulted in five types of insulin products on the market: long-acting, rapid-acting, intermediate-acting, short-acting (regular insulin), and premixed. In the early 2000s, the long-acting insulin analogs, Lantus (insulin glargine) and Levemir (insulin detemir), entered the market. In addition, the rapid-acting insulin analogs Humalog (insulin lispro) and Novalog (insulin aspart) were developed to allow for quicker absorption and shorter duration of action at mealtime. The insulin analogs more closely replicate normal insulin patterns in the body and resulted in a greater number of patients using these new products. In 2000, of privately insured adults with type 2 diabetes using insulin, 19% were using analog insulins; by 2010, 96% were using these products. **Studies indicate that** the **more expensive analogs do not seem to provide any advantage over regular insulin** in controlling glucose levels or preventing diabetes-related complications, but they are more convenient for the patient. Insulin Regulation and Production In the past, all biologics, including insulin, were regulated by the National Institutes of Health (or its precursors) under the Public Health Service Act (PHSA). In 1941, Congress gave the Food and Drug Administration (FDA) authority over the marketing of insulin. As a result, insulin has been regulated as a drug under the Federal Food, Drug, and Cosmetic Act (FFDCA) rather than as a biologic under the PHSA. In the United States “generic” insulin products are referred to by FDA as “follow-on” products and are not called biosimilars (which are regulated under the PHSA). However, under a provision of the Biologics Price Competition and Innovation Act (BPCIA) of 2009, biologics approved as drugs under the FFDCA will transition to biological licenses under the PHSA in March 2020. BPCIA was enacted as Title VII of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148). Currently, **three firms**—Eli Lilly, Novo Nordisk, Sanofi Aventis—**account for over 90% of the global insulin market and produce the entire insulin supply for** diabetic patients in **the United States**. For the most part, **insulins** produced by these companies are brand-name drugs. In general, brandname drugs **cost more because the drug manufacturer has free rein in setting the drug price due to a government sanctioned monopoly** for a defined period of time. Branddrugs are protected from market competition by (1) patents issued by the U.S. Patent Office and (2) a regulatory exclusivity period granted by FDA under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), also called the Hatch-Waxman Act. According to some analysts, **lack of price competition in the U.S. insulin market is a contributor to the high cost** of this vital drug. The price of a drug is directly affected by the number of different manufacturers marketing the drug. According to an FDA analysis of generic chemical drugs, “the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, **the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price**. **As additional generic manufacturers market the product, the prices continue to fall**, but more slowly. **For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower**.” One “generic” insulin product—or what FDA calls a “follow-on” product—is being marketed in the United States. Eli Lilly received tentative approval for Basaglar from FDA in August 2014. Final approval occurred in December 2015 following resolution of patent issues with Sanofi-Aventis, maker of the brand product, Lantus (insulin glargine). The Basaglar application was submitted to FDA under Section 505(b)(2) of the FFDCA and relied on the FDA’s finding of safety and effectiveness for Lantus. Eli Lilly began marketing Basaglar in the United States in December 2016; by the end of December 2017, Basaglar had captured about 17% of the U.S. Lantus volume share. Because three firms manufacture all the insulin used in this country, the market behaves differently from the usual case in pharmaceutical markets where generic competition results in price reductions following patent expiration and the end of the exclusivity period granted by FDA under Hatch-Waxman. Basaglar, the only follow-on insulin available in the United States, is made by one of the three insulin-making firms, Eli Lilly. Basaglar’s approval has not resulted in a new insulin manufacturer on the U.S. market. Industry observers believe that as other pharmaceutical companies enter the insulin market, price reductions may begin to occur. In July 2017, FDA granted tentative approval to a second insulin glargine product, Lusduna Nexvue, made by Merck. However, in October 2018 Merck announced that it is discontinuing Lusduna. Some industry analysts believe Merck’s decision was due to the drug rebates offered by the three manufacturers of insulin products. For drugs such as insulin with a high list price, manufacturers may use a high rebate to gain placement on an insurance company formulary. This results in making the drug more affordable for insurance plans, but **the drug remains expensive for the uninsured, as well as for those with high cost-sharing insurance plans.** Price of Insulin, Cost of Manufacture, and Profit **The price of a drug** often **has very little basis in the cost of manufacturing a drug**. Also, it is very rare to find data on manufacturing costs; this is considered to be proprietary information. However, a 1995 paper in Biotechnology and Bioengineering focused on the process used by Eli Lilly in the commercial production of insulin using E. coli bacteria. The authors found that **the total cost involved in making enough insulin to treat one patient per year is $33.60**. This amount would be altered by inflation, but would be offset by process improvements. Most of the manufacturing cost (94.2%) is associated with the recovery and purification of insulin; the remainder (5.8%) is the fermentation process using E. coli. The economic analysis includes the cost of raw materials, product separation materials, facility overhead (depreciation and maintenance of the facility), treatment and disposal of waste materials, and labor of plant operators and laboratory scientists who perform analysis of the process and product (quality control/quality assurance). It does not account for other costs, such as the cost of vialing and quality assurance of vialing, distribution costs, promotion and advertising costs, and briefly mentions research and development cost recapture. In the case of insulin, however, much of the initial basic **research**—**original** **drug discovery and patient trials**—**was performed 100 years ago**. Other more recent costs, such as developing the recombinant DNA fermentation process (over 35 years ago) and the creation of insulin analogs (about 20 years ago) may account for some portion of the current price of insulin products, but exactly how much is known only by the manufacturers. The pricing of insulin could also reflect accounting for research costs of other drug products, both the past costs of drugs that were not successful as well as future products that are currently under development. A September 2018 study published in BMJ Global Health calculates that **a year’s supply of human insulin could be $48 to $71 per person** and between $78 and $133 for analog insulins; **this amount would cover production costs and still deliver a profit to the manufacturer**. How much profit is fair is another piece of the drug pricing puzzle. A November 2017 Government Accountability Office (GAO) report found that the average profit margin was 20% in 2015 for the largest 25 drug companies, compared with 6.7% for the largest 500 companies in general. The three insulin manufacturers are among the largest 25 drug companies.

#### Reducing IP protection for insulin also increases innovation – it stops redundant research and competition by allowing other companies to innovate similar medicines and sell them for a lower cost which makes it affordable to many.

**Emily 20** [Emily Hanson, JD Candidate at the University of Georgia School of Law, 2020, “Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States,” Journal of Intellectual Property Law, https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1457&context=jipl]/Kankee

The discussion above paints a grim picture. The abbreviated pathway to approval provided for under federal law has not achieved its goal of increasing competition and lowering prices in the insulin market. As progress stalls, **many people with diabetes** continue to **struggle** **to pay for the medication they need as insulin prices continue to rise.** It should be noted that **some steps have been taken** in 2019 by both corporations and governments **to alleviate the insulin pricing crisis**. For example, the three major insulin manufacturers, Eli Lilly, Sanofi, and Novo Nordisk, have each announced that they will lower the list prices of their insulin products.180 Furthermore, pharmacy benefits manager, Express Scripts, announced a price cap of twenty-five dollars per month for its members.181 Colorado recently passed legislation capping the price of insulin at $100 per month for insured patients.182 **These efforts** have one thing in common: they illustrate the fact that attention is increasingly being directed at this issue. The increase in attention, however, **do**es **not mean that the issue is solved**. Unfortunately, **all** of the **measures** identified above **are too limited** in scope **to serve as a complete solution** to the problem. After all, **Novo Nordisk or Express Scripts**, for example, **may decide tomorrow that the price guarantees they make today are no longer economically viable**, which will leave diabetic patients in much the same place they are now. Many diabetics with health insurance in Colorado are seemingly out of immediate danger, but Colorado is home to only a very small percentage of all diabetics in the U.S.183 This is why legislation at the federal level is necessary to correct this issue for good. As discussed in section III(C) infra, trade secret is one of the three forms of intellectual property protection available to pharmaceutical innovators. In order for an innovation to qualify for this protection, it must: (1) confer economic benefit upon the holder, (2) not be generally known, and (3) be the object of reasonable steps by the holder to maintain its secrecy.184 Makers of pharmaceutical products, and biologic drugs in particular, avail themselves of trade secret protection quite liberally.185 **Trade secret** **is** particularly **attractive for protecting the manufacturing processes for insulin** and other biologics, which has a major impact on competition.186 Biologics like **insulin differ considerably from chemical medications in terms of the difficulty of manufacturing them**.187 Small-molecule chemical medications are relatively simple to describe scientifically,188 and a generic manufacturer can use any of a number of methods to synthesize the compound, all of which produce a result easily proven to be identical to the reference product.189 **Insulin** and other biologics, by contrast, **have much more complex chemical structures**.190 **Small differences** in the method of synthesis **can lead to broad variation in the final result**.191 This means that **showing biosimilarity is very difficult unless the manufacturer uses the same method that the maker of the reference product used**.192 Furthermore, **the precise molecular identity** of some biologic drugs **is not known** because the analytical techniques needed to make that determination do not yet exist.193 Crucially, to qualify for abbreviated approval under the Biosimilars Act, the maker of the biosimilar must make a product that not only is biosimilar, but can be shown to be biosimilar.194 **Because trade secret protection can** theoretically **last indefinitely**,195 **makers of would-be biosimilar insulins may never have access** **to** **manufacturing** process **information**, all but **foreclosing the possibility of producing a follow-on insulin** that the maker is able to prove is biosimilar to the reference.196 **A claim that X is the same as Y is impossible to prove or disprove when Y’s identity is not known**. **A scaling back of trade secret protection for pharmaceuticals would ameliorate this problem**. The Biosimilars Act does not require the maker of a reference product to disclose manufacturing information to any greater extent than is required under Hatch-Waxman, which means that it is unlikely to be successful in increasing competition in the insulin market now that insulin is within its scope.197 Insulin will likely continue to be more trouble than it is worth to biosimilar manufacturers. The Defend Trade Secrets Act of 2016 provides an extremely broad scope of the type of information that may be eligible for trade secret protection: [A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing.198 The breadth of the protection available under the DTSA means that makers of follow-on insulins will have an extremely difficult time showing that their products are biosimilar. Statutorily eliminating biologics manufacturing process information from trade secret eligibility (as an amendment to the Biosimilars Act, for example) would force pharmaceutical companies to choose among three alternatives. They could: (a) include process information in their patent application, (b) apply for separate patent protection for the process and the product, or (c) leave the process information with no protection at all. Acknowledging choice (c) to be in all likelihood the least popular of these, the net effect would be that the process by which biologics like insulin are manufactured would become part of the public omain once the patent expires, rather than remaining secret indefinitely as it does today. This change would naturally have downstream effects, both positive and negative. The first advantage would be that **insulin** and other biologics **would become more attractive** to makers of follow-on products. **Armed with the knowledge needed to create a biosimilar without** going through **the costly process of additional research and development, follow-on firms could produce biosimilar** **insulins** **more cheaply**. The second advantage would be that **the growing fund of public knowledge** **about insulin** and other biologics **would facilitate greater innovation** in the field **over time**.199 **By keeping critical information about their discoveries secret, pharmaceutical companies prevent other companies, universities, and private research firms from benefitting from it**.200 **Trade secret law** **is** often **criticized for its tendency to cause redundancy and duplication of effort**,201 **and repetition of clinical trials to prove** that **a follow-on is biosimilar** or interchangeable **can cost hundreds of millions of dollars**.202 **A free flow of information** about process in a field where process has a tremendous influence on the identity and quality of the final product203 **would have substantial value** to society.204 To that end, the third advantage to reducing trade secret protections would be a rebalancing of the public and private interests at stake in the market for insulin. The free-market approach to drugs and other medical products that operates in the U.S. presumes that the same forces at work in the markets for CocaCola and iPhones are at work in similar ways in the markets for insulin and other healthcare products.205 As discussed previously, the free-market approach has undoubted advantages,206 but **the ethical implications of letting the market decide** **who can afford insulin and who cannot should not be ignored**. **A reduction of** **protection for an already immensely profitable industry**207 **would ease the burden on people who rely on insulin for survival**. On the other hand, this approach does have drawbacks. For example, as **with any limitation on intellectual property protection, there is the concern** that **this** **would** **decrease incentives to innovate**.208 Insulin makers may decide to slow or halt development of costly new products if they fear that they will not be able to recoup their losses.209 However, **this** particular **issue seems to be of less concern** here than in other situations in which cutting edge biologics are not yet on the market. **Insulin’s age and long history in the market will** likely **shield it from this negative effect because** **several** **safe and effective varieties** **already** **exist**. Thus, while reducing trade secret protections for biologics may have the effect of making some drug manufacturers more reluctant to develop entirely new biologic drugs, it will likely have the opposite effect of improving competition for drugs that are already on the market. Furthermore, a compromise might be made to restrict the scaling-back of trade secret protection to insulin alone, rather than to all biologics. Using insulin as a sort of pilot for a broader scheme of reducing trade secret protections in the pharmaceutical industry would provide lawmakers and the public with some context for the effectiveness of such a scheme. A second potential drawback to this proposal is the possibility of a chilling effect on insulin production in general. Once information about manufacturing insulin enters the public domain, regulatory agencies like FDA will have the ability to set manufacturing standards accordingly.210 The more that is known about a substance, the easier it is to regulate.211 An increase in the minimum standard may raise production costs, thus deterring current producers from continuing to make insulin, and discouraging new firms from entering the insulin market in the first place. **Trade secrecy** has **kept** the **barriers to entry high for competitors in the insulin market**.212 There is no question that, in general, insulin and other biologics are more difficult and more expensive to produce than chemical medications.213 Thus, the U.S. is unlikely to see drastic price reductions for these products such as those that resulted from the enactment of Hatch-Waxman.214 However, the current situation is clearly untenable for patients, and **a scaling back of trade secrecy** in the insulin market **would** likely help **facilitate price reduction**. VI. CONCLUSION