# 1AC v Scarsdale DH

### Definitions

#### I affirm the resolution resolved: The Member Nations of The World Trade Organization ought to reduce intellectual property protections for medicine.

#### Because the resolution involves international trade law, a notoriously complex topic, I would like to start this debate by offering the following definitions:

#### First, as financial analyst and writer Evan Tarver in 2021 explains:

Tarver, Evan. “How Best to Define the World Trade Organization (WTO).” *Investopedia*, Investopedia, 15 June 2021, www.investopedia.com/terms/w/wto.asp. // LHP PS

**Created in 1995**, **the World Trade Organization (WTO) is an international institution that oversees the global trade rules among nations**. It superseded the 1947 General Agreement on Tariffs and Trade (GATT) created in the wake of World War II. **The WTO is based on agreements signed by the majority of the world’s trading nations.** T**he main function of the organization is to help producers of goods and services, as well as exporters and importers, protect and manage their businesses. As of 2021, the WTO [with] has 164 member countries,** with Liberia and Afghanistan the most recent members, having joined in July 2016, and 25 “observer”countries and governments.

#### Second, intellectual property for medicine is explained best by Oxfam America as:

“Intellectual Property and Access to Medicine.” Oxfam, www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/.

**Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents**. **Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent**—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement.

#### Finally, The term “ought” in the resolution implies a moral obligation. Therefore, my value is morality.

#### My value criterion is maximizing societal well being. Prefer this for the following reasons:

#### [1] People give up some of their rights to the government in return for protection from that government. That’s called the social contract. Because the people agree to follow the law, the government is obligated to protect them.

#### [2] Real governments have an obligation to base their policy decisions on what will help the greatest number of people, as philosopher Robert Goodin explains

#### ROBERT GOODIN1

Consider, first, the argument from necgooessity. **Public officials are obliged to make their choices under uncertainty,** and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private **individuals** will usually **have more complete information on**the peculiarities of**their own circumstances and on the ramifications that alternative possible choices** might have for them. **Public officials**, in contrast, are relatively poorly informed as to what effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. **They know** **what will happen**most often**to most people as a result of their**various possible**choices**. But that is all. **That is enough to allow public policy-makers to use utilitarian calculus** – if they want to use it fat all – to choose general rules of conduct. **Knowing aggregates and averages, they** can proceed to **calculate the utility** payoffs from adopting each alternative possible **general rule**.

#### [3] Social welfare is a prerequisite for any other rights. If people are suffering, then freedom is meaningless.

#### Accordingly, my thesis is that reducing intellectual property for medicines is essential to societal well-being.

### Contention 1: Accessibility

#### In the status quo, innocent people are dying to diseases that can be easily prevented. However, these diseases continue to kill due to the lack of access to medicines and vaccines.

#### Subpoint a) Rotavirus

#### A prominent example of this is the rotavirus in Africa, as journalists Carmen Garcia and Philip Whiteside in 2019 explain

Garcia, Carmen, and Philip Whiteside . “Why 7,000 People Die Needlessly Every Day.” *Sky News*, 2019, news.sky.com/story/why-7-000-people-die-needlessly-every-day-11770982#. // LHP PS

**The figures, though improving, remain staggering: more than 2.6 million died from the diseases in 2017, the last full year for which figures are available. Children under the age of five, often in underdeveloped nations, are frequently the victims.** Analysis gathered exclusively by Sky News tells a complex story. And, while much progress has been made, **the struggle to reach remote corners of the globe and fight disinformation about vaccine-preventable diseases (VPDs) continues.** Robin Nandy, Principal Adviser and Chief of Immunisation for UNICEF, says: "Ten, 20 years ago, I could not have expected us to be in this situation **where we are today, with multiple outbreaks of measles in all different types of countries: You're seeing them in high-income countries like in Britain. "You're seeing them in middle-income countries... low-income countries."** "**If we take our foot off the pedal, things can regress pretty quickly.** **It's really important to drill the message** home," he added. "**Vaccination is not finished business.** **"As long as children keep getting born in the world, we need to continue to vaccinate."** Sky News has carried out exclusive analysis of data from international agencies. The figures, from the Global Burden of Disease Study, coordinated by the Institute of Health Metrics and Evaluation, tell a sad story. **After pneumococcal pneumonia, which kills 15 in every 100,000, the main cause of death is rotavirus - a gastric viral infection that causes severe diarrhoea, vomiting and dehydration.** T**he disease, which kills four in every 100,000, is extremely common: experts believe almost every child in the world gets infected at least once by the time they are five.** **Most of those who die are children killed by dehydration. In developed countries, deaths are rare because access to healthcare is widespread, but in African countries deaths are still common. But there is a vaccine that can protect against it - one said to be capable of preventing up to a third of all diarrhoea across the developing world.**

#### Subpoint B) COVID Vaccine

#### IPR is preventing the distribution of the COVID-19 Vaccine to low and middle income countries as Eccleston-Turner and Rourke in 2021 explain

[Mark, Lecturer of Global Health Law, Keele University, Michelle, CSIRO Synthetic Biology Future Science Fellow, Griffith University, Australia, American Society of International Law, "The TRIPS Waiver is Necessary, but it Alone is not Enough to Solve Equitable Access to COVID-19 Vaccines" 25(9) May 27, https://www.asil.org/insights/volume/25/issue/9

**High-income countries** have **dominated** the limited s**upply of COVID-19 vaccines, leaving low and middle-income countries** (LMICs) **with limited, if any**, supplies of these **life-saving countermeasures**.[[1]](https://www.asil.org/insights/volume/25/issue/9#_edn1) **The cause** of this **is two-fold: 1) insufficient doses of vaccine to meet** the global **demand**, and 2) **procurement of those limited doses which do exist has been dominated by a small number of high-income countries**. The result is a deep and growing inequality in access to vaccines for COVID-19. A potential solution is to empower manufacturers, particularly those based in LMICs, to begin making COVID-19 vaccines, to expand global supply. However, intellectual property rights create a clear barrier to this solution. **A dense web of intellectual property exists over the vaccines and** the manufacturing platforms used **to make them**.[[2]](https://www.asil.org/insights/volume/25/issue/9#_edn2) This web is both formal and informal; the manufacturing platform used to manufacture a vaccine is protected by numerous patents, while manufacturing methods and techniques (know-how) are protected informally as trade secrets.

#### Subpoint C) Reducing intellectual Property Solves

#### Billions of people lack access to these medicines that could prevent millions of deaths. High levels of IP protections like the status quo continue to make accessibility even harder as Oxfam America explains

“Intellectual Property and Access to Medicine.” Oxfam, www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/.

**Today, more than two billion people across the developing world lack access to affordable medicines**, including many patients in countries negotiating in the Trans-Pacific Partnership (TPP) free trade agreement. Two **critical factor**s **limit access to treatment: the high prices of new medicines, particularly those that are patent-protected**, and the lack of medicines and vaccines to treat neglected diseases, a consequence of lack of R&D. Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents. Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement. This trade-off underpins patent systems everywhere. **Governments need to maintain an appropriate balance between incentivizing innovation, on the one hand, and, on the other, ensuring that new products are widely available. High levels of IP protection in developing countries exacerbate, rather than help solve, the problem of access to affordable medicines. Extensive patent protection for new medicines delays the onset of generic competition.** And because **generic competition is the only proven method of reducing medicine prices in a sustainable way, such high levels of IP protection are extremely damaging to public health outcomes.**

### Contention 2: Evergreening

#### IP incentivize meaningless incremental changes that delay generics and competition for decades, journalist Nawrat in 2019 writes:

Nawrat 19 [Allie Nawrat, journalist with a BS in history and politics from the University of York, 11-12-2019, "From evergreening to thicketing: exploring the manipulation of pharma patents," Pharmaceutical Technology, https://www.pharmaceutical-technology.com/features/pharma-patents-manpulation/]/Kankee

The Initiative for Medicines, Access & Knowledge (I-MAK) argued in a 2018 report titled Overpatented, Overpriced that the current system is out of balance as “drugmakers have transformed the patent system in to a defensive business strategy to avoid competition in order to earn outsized profits on medicines for many years beyond what was intended.” University of California (UC) Hastings Center for Innovation director and distinguished professor of law Robin Feldman adds: “Patents are supposed to last for a limited period of time. After that, competitors should enter to drive prices down, but that’s not what is happening. Rather, drug companies pile new protections on to their drugs to extend the protection cliff.” The two most common practices employed by the industry to artificially extend protection, are ‘evergreening’ and ‘thicketing’, as Feldman describes them in a 2018 Journal of Law and the Biosciences research paper titled May Your Drug Price Be Evergreen. They involve making small changes to branded drugs – such as through modes of administration, new dosages and, as Scrip noted, even simply the colour of the drug itself – which sometimes do not confer more therapeutic benefit to the patients. Feldschreiber acknowledges “there are instances where it is very questionable as to whether slight changes to molecules do actually have an effect on safety and efficacy” and “there is something wrong with that”. It can also encompass protecting certain steps in the production and manufacturing process and recycling drugs for other similar indications. Some companies have also sought to find more creative loopholes in the law to extend their monopoly over a drug. For example, to fight legal challenges to its patents, Allergan transferred all patents for its eye drug Restasis to the St Regis Mohawk Tribe in September 2017, because the Native American tribe holds sovereign immunity against intellectual property lawsuits. The deal was subsequently defeated in the US courts, with the Supreme Court rejecting Allergan’s petition to appeal the case in April this year, but it’s a powerful example of the creative lengths some firms will go to extend patent protection. Scale of pharma patent manipulation Feldman’s research, which looked at all drugs on the market between 2005 and 2015 and every instance where a company added a new patent or exclusivity, concluded “stifling competition is not limited to a few pharma bad apples. Rather, it is a common and pervasive problem endemic to the pharmaceutical industry.” She found that 78% of drugs associated with new patents are not new drugs, but existing ones, and almost 40% of all drugs on the market had additional market barriers through further exclusivities. Although this manipulation trend exists across the industry, Feldman’s research found that manipulative extension practices were particularly pronounced among blockbuster drugs. More than 70% of the 100 best-selling drugs between 2005 and 2015 had their protection extended at least once, with almost 50% receiving more than one exclusivity extension. I-MAK’s 2018 report identified a similar trend among the 12 best selling drugs in the US in 2017; it found that the drugs have an average of 38 years of exclusivity – almost double the 20 year original patent protection – and an average of 125 patent applications. AbbVie and Humira: an example of bad behaviour One of the worst offenders according to I-MAK is AbbVie’s anti-inflammatory blockbuster Humira. Both Feldman and Dutfield picked out Humira as a particularly bad example of patent manipulation According to I-MAK’s 2018 report, AbbVie has filed 247 patent applications for the drug in the US with the aim of extending its exclusivity for 39 years – 137 patents have been awarded to date. This is in addition to 76 patent applications in the European Union and 63 in Japan. Humira is currently the world’s best-selling drug and the second best-selling drug of all time – it has generated around $100bn in sales for AbbVie since it was launched in 2002 and it is responsible for two-thirds of AbbVie’s total revenue. I-MAK concludes that “AbbVie’s pricing practices are protected by an aggressive evergreening patent strategy to extend the life cycle of Humira in order to deliberately delay competition.” These profits are also connected to other practices by AbbVie that have led to the price of the drug increasing 18% every year between 2012 and 2016; however, I-MAK concludes these are not consistent with rises in the price of manufacture or inflation. “Patents, like all good things, must come to an end” Although she acknowledges that drug development is expensive and patents are “important for creating the possibility of reward for that investment”, Feldman argues that these manipulations mean “the cycle of innovation, reward, then competition is being distorted into a system of innovation, reward, and then more rewards”. She calls for a focus on incentivising companies to focus on drug development through a “one-and-done approach, in which each drug invention receives one—and only one—period of exclusivity” as “patents, like all good things, must come to an end”, and not be allowed to be extended seemingly indefinitely. Dutfield suggests an alternative approach to incentivising drug R&D. “At the United Nations, there are proposals that the costs of research and development should not be recouped through high [drug] prices, but by other funding mechanisms in proportion either to the R&D costs, or to the global positive health impacts of the medicines in question,” he explains. While there are concerns about where exactly these ‘other funding mechanisms’ would come from, this approach could help to resolve an unbalanced patent system and ensure proper rewards for genuine innovation in disease areas or drug types where there is less potential profits, such as antibiotics and vaccines against healthcare crises primarily affecting developing countries.

#### Insulin price gouging makes an essential medicine 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

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

#### Excessive insulin costs are due to patent exclusivity causing monopolies with customers that have no choice but to buy

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

A. Economics-Based Justifications Effective federal regulation will alleviate at least two causes of high insulin prices: patents preventing competition from manufacturers of "generic" insulins, and the failure of normal market forces due to the lack of competition.4 5 U.S. patent law provides patent-holders with twenty years of patent exclusivity for the development of new drugs.46 Exclusivity permits patent-holders to set prices and control the market for at least twenty years.4 7 Currently, there are three primary pharmaceutical companies manufacturing insulin in the U.S. market: Eli Lilly, Novo Nordisk, and Sanofi. 4 8 These three pharmaceutical companies "minimize competition by patenting incremental changes" to their insulin formulas, making it extremely difficult for other manufacturers to develop affordable, effective generics known as biosimilars. 49 For example, even though Sanofi's primary patents for the insulin Lantus expired in 2015, Sanofi has filed around seventy patents for incremental changes since 2000.s0 These secondary patents will allow Sanofi to receive patent protection over the formula for Lantus through at least March 2028. Thus, the three pharmaceutical companies that manufacture insulin have developed what is essentially a monopoly over the insulin market through this patent-based barrier to potential competitors. 52 Because it is so difficult for other manufacturers to create biosimilar insulins due to patents, there is currently very little room for competition from other drug manufacturers." In fact, Eli Lily and Sanofi produce the only two biosimilar insulins currently on the market, meaning these manufacturers can maintain the monopoly.54 In a typical market, product price usually falls as time goes on. Common causes of a decrease in market value include competitors entering the market and introducing similar, cheaper alternatives, or a current manufacturer making an advancement that lowers the value of older versions of a product.5 6 Consumers can choose to either purchase a cheaper alternative or upgrade to the newer, more advanced product-either choice would lower demand for the original product, thus lowering the market value of the older version.5 7 Insulin is not a typical consumer product." Not only do patents prevent competitors from entering the market, but type 1 diabetics cannot exert pressure on the pharmaceutical companies to lower prices by simply choosing to not purchase insulin.59 Instead, "[tlype 1 diabetics without adequate insurance coverage are vulnerable to price increases because they can't live without the drug . . . . 'People have to buy insulin no matter what the cost is . .. [giving] a lot of strength to the people selling insulin."' 0 When the marketplace is unable to self-regulate a monopoly through competition, the traditional solution is the passage of regulation rather than leaving the monopoly free within "the unregulated marketplace or to the antitrust laws for correction."61 When determining the most appropriate type of regulation, there are several options available, the most viable of which are discussed below. 6 2 B. Regulations Available to Increase Competition

#### Reducing IP protection for insulin increases innovation – it stops redundant research and competition

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, does 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 industry207 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