## 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.

#### IP includes patents, copyrights, trademarks, etc.

**WIPO No Date** [World Intellectual Property Organization, UN agency that specifically deals with IP law, No date, "What is Intellectual Property (IP)?," WIPO, https://www.wipo.int/about-ip/en/]/Kankee

What is Intellectual Property? Intellectual property (**IP**) **refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce**. **IP is protected in law by**, for example, **patents, copyright and trademarks**, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

## Contention 1: Inequality

#### We’ve all been affected by COVID and know that a solution needs to occur. We have one. Reductions in IP protections are necessary for developing countries to make enough covid vaccines so that our situation gets better.

**Tai 21** Tai, Katherine. “A Patent Waiver on COVID Vaccines Is Right and Fair.” Nature News, Nature Publishing Group, 25 May 2021, www.nature.com/articles/d41586-021-01242-1./dhsNJ

**The core problem is that vaccine manufacturing, research and development is too heavily concentrated in a small group of high- and middle-income countries.** **Companies in these countries, which are also the main IP holders, have sold the majority of available vaccine doses to their own governments, and to governments of other high-income nations**. Some 6 billion doses out of the 8.6 billion confirmed purchases so far have been pre-ordered by governments in high- and middle-income countries. **It’s time to consider a patent reprieve for COVID vaccines** According to pharmaceutical-industry data, the industry expects to have made a total of about ten billion vaccine doses by the end of 2021. But on the basis of current trends, this is unlikely to happen, according to researchers at the International Monetary Fund in Washington DC. In a paper published on 19 May, they report that the industry is likely to have produced around six billion doses by the end of 2021 (see go.nature.com/2tchn13). This potential shortfall increases the risk that people in low-income countries will need to wait even longer for their first doses. As Nature went to press, the **number of vaccines given so far in Africa amounted to little more than one dose per person for some 2% of Africa’s 1.2 billion people.** This is, among other factors, because the continent currently imports 99% of its vaccines, and because African countries lack the pre-order purchasing capacity of richer nations. It is why the African Union has announced a plan for 60% of Africa’s vaccines to be manufactured on the continent by 2040. At the Global Health Summit in Rome last week, ahead of this week’s World Health Assembly in Geneva, Switzerland, European nations promised to share more vaccine doses with low- and middle-income countries. European Commission president Ursula von der Leyen is also proposing to ‘clarify and simplify’ the existing ways in which countries can implement compulsory licensing. And there is a strong possibility that the G7 group of the world’s biggest economies will pledge more funding for vaccination when member countries meet in the United Kingdom next month. These commitments are crucial in the race to end the pandemic. But they do not deal with the systemic issue — **countries backing the IP waiver are not asking for charity, but for the right to develop and make their own vaccines, free from the worry that they will be sued by patent holders.** Those backing the COVID IP waiver understand this core principle. The leaders of countries that are not currently in favour of the patent waiver must recognize it, too. As John Nkengasong, director of the Africa Centres for Disease Control and Prevention, says: they need to be on the right side when the history of the pandemic comes to be written.

#### While companies are monopolizing the vaccine in developed countries, people are increasingly becoming more and more affected by the disease in other countries like Bangladesh, India, and more. Many companies have the factories necessary, but they can’t afford to develop the vaccine due to the fear of being sued under a patent.

**Lerner and Fang 21** [Sharon Lerner, Investigative Reporter at The Intercept covering health, science, and the environment, Lee Fang, contributing writer at The Nation with a BA in government and politics from the University of Maryland, 04-29-2021, https://theintercept.com/2021/04/29/covid-vaccine-factory-production-ip/?utm\_campaign=theintercept&utm\_medium=social&utm\_source=twitter]/Kankee

Bill Gates, the billionaire philanthropist whose foundations help manage the United States and Europe’s primary Covid-19 outreach efforts to the developing world, known as Covax, was even more blunt. “It’s not like there’s some idle vaccine factory, with regulatory approval, that makes magically safe vaccines,” Gates said last weekend by way of explaining to Sky News why he thought the recipe for making coronavirus vaccine should not be shared. Except it is exactly like that. **Factory owners around the globe, from Bangladesh to Canada,** have **said** **they stand ready to retrofit facilities and** **move forward** with vaccine production **if given the chance**. “**We have this production capacity and it’s not being used**,” said John Fulton, a spokesperson for Biolyse Pharma, a company based in St. Catharines, Ontario, that produces injectable cancer treatments. Fulton noted that **Biolyse** has **spent years buying equipment to produce biologics and is uniquely prepared to** start getting ready to **produce vaccines**. **The company**, which Fulton said is best suited for replicating the Johnson & Johnson vaccine, **could produce as many as 20 million vaccines per year**, he estimated. Abdul Muktadir, chair and managing director of **Incepta**, **a pharmaceutical firm based in** Dhaka, **Bangladesh**, has **told reporters that his firm has the capacity to fill vials for 600 million to 800 million doses of vaccine per year**. He has reportedly reached out to Moderna, Johnson & Johnson, and Novavax. “**Now is the time to use every single opportunity in every single corner of the world**,” Muktadir told the Washington Post. “**These companies should make deals with as many countries as possible**.” **Other firms in South Korea and Pakistan** have also reportedly **expressed an interest in producing vaccines or vaccine components**. So far, much of the pressure to share technology has centered on messenger RNA vaccines, such as those made by Pfizer-BioNTech and Moderna, which are approved in the U.S. and highly effective against Covid-19. The mRNA model also offers the advantage of having a production process that’s simpler than that of some other vaccines and may be quickly adapted to respond to emerging variants of the virus. But the **companies** **that** have **pioneered** the **mRNA** **vaccines** **have yet to offer to share their knowledge and expertise**. Earlier this month, the World Health Organization established the mRNA technology transfer hub, through which manufacturers of medical products and owners of patented vaccine technology have been invited to provide know-how, process training, and intellectual property rights so that low- and middle-income countries can produce their own vaccines. On Tuesday, Martin Friede, coordinator of the WHO’s Initiative for Vaccine Research, said that the hub had already received some 50 expressions of interest from companies, including some that have patents on components or processes involved in vaccine manufacturing. But **Moderna**; BioNTech, the German company that has developed an mRNA vaccine in partnership **with Pfizer**; and CureVac, another German company that has developed an mRNA vaccine with a longer shelf life, **have yet to respond to the call**, according to Friede. Friede emphasized that a lack of know-how, as opposed to patent protections, are the major barrier to expanding production. Others agree **sharing know-how is key** — and **getting cooperation from the companies that** **created the mRNA vaccines is necessary** before deciding to retrofit or build facilities to make them. “It’s useless to focus on that if BioNTech and Pfizer and Moderna are not going to surrender the information on how to do it,” Edward Hammond, an independent consultant who works on vaccine manufacturing, said in a recent online roundtable about vaccine production capacity. “If it is the case that we don’t have an open and cooperative and productive technology transfer environment, then the capacity situation looks a little bit different because you’re going to be relying on a different set of technologies.” Scaling up supply to meet the global need will also require overcoming shortages of various components, including the tiny fat droplets that enable the mRNA in the vaccine to enter cells, which may also slow the the process of upscaling production. Gates suggested that it could be unsafe to share the critical information that allows vaccines to be more widely produced: “There’s only so many vaccine factories in the world, and people are very serious about the safety of vaccines. And so moving something that had never been done — moving a vaccine, say, from a [Johnson & Johnson] factory into a factory in India — it’s novel — it’s only because of our grants and expertise that that can happen at all.” The delay in getting vaccines to low- and middle-income countries, he added, was shorter than expected. “Typically in global health, it takes a decade between when a vaccine comes into the rich world and when it gets to the poor countries.” Yet, in the past few months, **the danger of not transferring the knowledge more quickly has become painfully clear, with deaths climbing in India, Brazil, and other parts of the world** **that have been unable to procure** adequate supplies of **vaccines** **while richer countries stockpile them.** The **inequality is only increasing**. The state of **Florida, which has a population of 21.5** **million**, **has** now received some 20 million vaccine doses — **more than** Covax has delivered to **all of Africa, which is home to 1.2 billion** **people**. Worldwide, **Covax**, which is now supplying vaccines to over 100 economies, **has** only **delivered** 49 million doses so far, **less than** have been distributed in **California and Illinois**. Meanwhile, **wealthy countries are already in the process of purchasing booster shots**. **Canada** just **made a deal with Pfizer to get 35 million doses** **of boosters by next year, which means they will arrive before most people** around the world **receive their first shot**.

#### The impact of not voting affirmative is millions of people in developing countries dying due to vaccine inequality. It’s unethical to do nothing when we know that there is a solution to saving millions and millions of lives.

**Lennard 21** [Natasha Lennard, educator of Critical Journalism at the New School for Social Research and Contributing Writer for the Intercept, 6-11-2021, "The G7 Upheld Vaccine Apartheid. Officials From the “Global South” Are Pushing Back.," Intercept, <https://theintercept.com/2021/06/17/vaccine-g7-covid-internationalism-summit/>]/Kankee

IF **THE** **G**ROUP of **Seven** summit in the United Kingdom last week made anything clear, it is that those powers **cannot be trusted to end the urgent crises facing life on Earth** — for humans and nonhumans alike. **When it comes to the Covid-19 pandemic**, the **G7** nation-**states reaffirmed their commitment to** **global vaccine apartheid** **through** **neoliberal governance**, **only** slightly **obscured under a guise of charitable** **offerings**. The **concessions** **are insufficient at best**. **Amnesty International condemned** **the G7’s pledge to provide 1 billion doses to** middle- and **low-income countries as a** “**drop in the ocean**.” **G7 leaders failed to agree to waive vaccine intellectual property rules** and commit to knowledge and technology sharing. **Under the current medicine** **monopoly** **regime**, **it is projected to take until 2078** **for the world’s poorest countries to vaccinate their** **populations**. **G7 countries are expected to** **vaccinate their populations by** January **2022**. Later this week, **government ministers** from many of the countries **that** will suffer most — and **have** already **suffered** — **from** **this** **abhorrent** **vaccine inequality** are convening online alongside scientists and global health advocates to forge a different path out of the pandemic. The summit, hosted by Progressive International, recognizes vaccine internationalism as the necessary order of the day. Politicians from states including Cuba, Venezuela, Vietnam, Kenya, Kerala — which is in India — and Argentina will attend, alongside Western parliamentarian progressive allies like the U.K.’s Jeremy Corbyn and Greece’s Yanis Varoufakis. The question is whether a solidarity-based bloc can be established with sufficient power and cooperation to undo vaccine apartheid. The stakes could not be higher. **Covid-19 is all but assured to shift from a pandemic into an endemic disease, with the victims of historic and ongoing colonialism left to die by the millions**. “**We do not have a system that protects against unequal access**,” Varsha Gandikota-Nellutla, an India-based coordinator with Progressive International, told me by email. She pointed to the disparities between the European Union and countries in Africa. “Consider this: **the EU** has **already made a deal** **with** BioNTech/**Pfizer for 1.8 billion booster shots even as the entire continent of Africa** **has vaccinated less than 2 percent of its population** with the first and second doses.” Gandikota-Nellutla noted that at current rates, **it will take nearly six decades for the world to be vaccinated** — a statistic echoed by the People’s Vaccine Alliance, a coalition of organizations including Amnesty International, Health Justice Initiative, Oxfam, Stop AIDS Campaign, and UNAIDS. She said, “**We’re witnessing the ills of** nationalism, **imperialism**, and racial capitalism all **play out** in the most grotesque of ways in the vaccine race.” WE KNOW WHAT vaccine nationalism looks like: **Powerful countries, aided by World Trade Organization regulations, make deals with** leviathan **pharmaceutical companies** **to** buy up and **hoard vaccines**. **Poorer countries are forced into positions of dependence on insufficient charity**; Big Pharma gets bigger. Meanwhile, intellectual property fetishist Bill Gates asserts, despite evidence from international scientists to the contrary, that poorer nations are per se incapable of developing, regulating, and distributing vaccines safely and efficiently. **A system of health care scarcity is developed by design, with results no less than genocidal**. **The** basic **means of surviving a pandemic are held as a political cudgel** **by the richest countries over the poorest.** At present, for example, **Venezuela has been shut out of receiving** any of the half a billion **Pfizer vaccine doses** President Joe **Biden pledged to donate** to COVAX, short for COVID-19 Vaccines Global Access, the initiative purportedly committed to equitable international vaccine distribution. **Despite Biden stating that vaccine donations** “**don’t include pressure for favors or potential concessions**,” **Venezuela has been shut out** of COVAX access **due to ongoing**, brutal **U**.**S**. **sanctions against the country**. “**No country has the right to obstruct the access to health of any other**,” Venezuelan Foreign Minister Jorge Arreaza, who will be attending the Summit for Vaccine Internationalism, said in a statement. “**Obstructing a people’s access to vaccines during the pandemic is a crime against humanity** and **the free peoples of the world must unite** and design mechanisms **to avoid this medical apartheid, where a few have access to vaccines and others are excluded**.” **ANY** SORT OF robust **vaccine internationalism** — in which collective potentials for vaccine production and distribution are truly unlocked — **has** so far **been off the table**. Yet we have seen a number of recent examples of production and sharing outside the top-down control of powers like the U.S. and the EU. At the end of May, Mexico received its first batches of locally produced AstraZeneca vaccines and sent half the consignment to its production partner, Argentina. Alongside establishing a stronger political bloc to put pressure on Western nation-states and the WTO, the upcoming summit could see agreements made for future vaccine production and sharing partnerships, which eschew precarious dependence on the world’s richest countries. “This is not going to be another talking shop,” David Adler, general coordinator for Progressive International, tweeted, referring to the summit. “These governments are really coming together to build something new — a system based on South-South cooperation, a serious plan to end the pandemic where the G7 refused to find one.” As Gandikota-Nellutla told me, inspiration for the “New International Health Order” that the summit aims to create can be found in the New International Economic Order first proposed in the 1970s. The plan, introduced by a number of poorer nations to challenge the post-war economic colonialism of the West, was adopted by the United Nations in 1974. As with vaccine internationalism, the idea of the New International Economic Order was to foster greater cooperation between heavily exploited countries, while ensuring states’ sovereignty over their resources, and a dramatic overhaul of the rules and procedures of unequal international trade, particularly as related to commodities. Nearly half a century later, and aside from a few concessions, the plan has never been even close to fully realized; U.S. hegemony and the neoliberal order of corporate globalization and extractivism won the day. The prospect of a New International Health Order may seem equally beyond reach, yet the extraordinary circumstances of this pandemic have, in a number of ways, created openings for previously foreclosed political economic shifts. In the U.S. alone, although too short-lived and too temporary, pandemic exigencies led to eviction moratoria and fair unemployment benefits. The government leaders and advocates meeting to build vaccine internationalism are all too aware of the urgency of the project. “**Our very survival is at stake**,” Gandikota-Nellutla told me. “Not only are we set on resolving vaccine access in our countries in the present pandemic, but strengthening the foundations of a world order that will not allow such injustices to ever occur again.”

## Contention 2: Innovation

#### While patents first-glance may seem like a good idea, the problem is that many corporations use them to get rid of rivals, functionally monopolizing the market. As a result, medical innovation has slowed down tremendously.

**Gubby 19** [Hellen Gubby, professor at the Rotterdam School of Management at Amarus University with a PhD in law, 9-6-2019, "Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective," Wiley Online Library, https://onlinelibrary.wiley.com/doi/10.1111/1758-5899.12730]/Kankee

As the economy has largely shifted from industrial manufacturing to high-tech, life science and information processing industries, intellectual property has become more and more important. **Corporations have become increasingly aware** **of the potential of the patent**, **not just as a shield to protect against imitation, but as a strategic tool to block competition** **and dominate markets**. Patents have come to have a broader strategic function in which **innovation may only play a small part**. Although many patents do not produce any income: ‘In terms of strategy, though, the patent can be much more valuable’ (Macdonald, 2004, p. 143). Patent strategy is directly related to the business context. The Carnegie Mellon Survey of the US manufacturing sector in 1994 revealed that **firms often used patents as strategic tools, rather than** as simply **a means of protecting an invention from wrongful imitation** (Cohen et al., 2000). In their examination of motives to patent, Blind et al. (2009) recognised that, although protection from imitation was still the most important factor, ‘the importance of the strategic motives to patent are confirmed’ (Blind et al., 2006, p. 671). Patent strategies **The decision to patent has become** in part uncoupled from the original core purpose of the patent: **to protect an invention from unfair imitation by other market participants**. **Larger firms, with the capital assets to pay for the cost of patenting, use their patent portfolios strategically**. **Patents have become** useful as **bargaining chips; they provide leverage**. **Large patent portfolios are a means to get access to important co-operations or cross-licensing arrangements** (Blind et al., 2009, p. 431). Yet while building **the portfolio** requires enormous legal costs, it **contributes little to research incentives**. Furthermore, **these** **portfolios** can be used not just to oblige competitors to take licences, but also the terms of these licences can **restrict competitors to certain areas of technology** (Barton, 2000). **Larger firms** **can** afford to play the ‘wrap around’ strategy. Instead of **apply**ing **for** a single patent to cover an invention, other **patents** are filed **around the main patent**. **These** **related** **patents lock down the discrete features of an invention**. **The tactic hinders entry to the market**. **Competitors will be put to time, effort and cost to fight their way through all the relevant patents covering the technology**. Furthermore, **the chance** that **the competitor's invention may infringe one of the many claims in one of the many patents is high**. Not only can **damages be awarded for infringement, but also an injunction**. **Injunctions prevent the party accused of infringement from producing any products that require the use of the tech**nology **covered by the infringed patent and all infringing products are removed from the market.** Patents may be used simply to block competitors. **Using a patent as a blocking strategy is common practice** (Neuhäusler, 2012). **Defensive blocking is used to protect a firm's own freedom to operate**: **it does not want to be shut out by the patents of its rivals**. An offensive blocking strategy is where **patents are filed to cover products or processes that the firm does not intend to practice itself, but which could be viable alternatives to competitors**. **By patenting all conceivable alternatives, research by competitors that might threaten their own technological lead can be thwarted**. As in general **a patentee is under no obligation to license out its technology to another, the strategy can deter market entry or new product launch.** This offensive blocking of competitors by means of **patents**, ‘is clearly a case of the patent system being used for purposes other than for which it was originally intended’ (Blind, 2009, p. 436). However, both defensive and offensive **blocking** should be a policy concern, as they **can reduce economic** **efficiency**. **Defensive patenting increases cost to firms without necessarily producing any benefit and offensive patenting can reduce technological progress and increase consumer costs by reducing competition** (Thumm, 2004, p. 533). Using data from a large-scale survey of patent applications, Torrisi discovered that **a substantial share of patents remained unused and a substantial number of patent applications were filed to block other patents**. There were institutional differences; there were more unused patents in Japan and the EU than in the USA. Although cautious to make generalisations about unused patents, as some unused patents are there to ensure freedom to operate or simply because of management inefficiency, Torrisi et al. did conclude that: ‘[**o**]**ur results highlight that there might be substantial benefits that patent owners draw from being able to keep patent rights unused**. These would have to be balanced against possible harm imposed on other economic agents’ (Torrisi et al., 2016; , p. 1384). These strategies show a disconnect with the original purpose of the patent system. Patent strategies impact on innovation, and this in turn impacts on society. Concern was already expressed quite forcibly some years ago by Turner: Surely when the framers of the [US] Constitution empowered Congress to grant monopolies to ‘promote the progress of science and the useful arts’, they did not envision the beneficiaries of this grant would use it to bury new technologies to protect market share or capital investments. (Turner, 1998, p.209) Administrative failures Patent offices have been struggling to cope with the increasing number of patent applications: in 2017, more than 3 million patent applications were filed worldwide (WIPO, 2018). This influx has resulted in substantial application backlogs, with an increasingly long time between the patent filing and the patent grant: five years is not unusual. Complaints of poor quality control have been made concerning the US Patent and Trademark Office as well as the European Patent Office (Abbott, 2004; Mabey, 2010). The WIPO recognised a consistent upward trend in patent filings is putting patent offices under enormous pressure (WIPO, 2017, p. 13). Why are these administrative failings dangerous from a societal perspective? **Patents** **grant a monopoly that can impact innovative processes for 20 years or more**. **Patents have been granted that should not have been granted**. **When an overly broad patent is granted, this can block further innovation by others**. **Broad patents may mean** that **access to vital research is not available because** the **results** of that research **are covered by patent claims**. In particular, **broad** basic **patents on fundamental research** **can block and deter follow-on** **research**. **The incentive to innovate is reduced** (Barton, 2000; Henry and Stiglitz, 2010).1 Back in 1966, the societal implication of overly broad grants was expressed clearly by the US Supreme Court when it rejected a broad claim covering a group of chemicals: ‘**Such a patent may confer power to block off whole areas of scientific development** without compensating benefits to the public.’2

#### Empirics prove our thesis– up to 80% of all new patents are not new drugs but old ones.

**Feldman 2** Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—**drug companies are focusing their time and effort extending the patent life of old products.** **This**, of course, **is not the innovation one would hope for**. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, **78% of the drugs associated with new patents** in the FDA’s records **were not new drugs** coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost **40% of all drugs** available on the market **created additional market barriers by having patents or exclusivities added** to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

## Contention 3: 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

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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