# **1AC – WTO**

Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

# **Value: Justice**

#### **Our value today is justice because people impacted by health issues need more access to medicine and without this access injustice will be perpetuated.**

# **Criterion: Minimizing Structural Violence**

#### **Minimizing Structural violence key**

**Bobichand 12’** July 30, 2012 Rajkumar Bobichand (Rajkumar is a Conflict Transformation and Peacebuilding Practitioner with over 10 years experience conducting workshops, trainings, and facilitation and action research; documenting and disseminating human rights and conflict situation. Educator with over 15 years experience. Journalist with over 17 (seventeen) years experience reporting and writing on human rights violations, political situations and social affairs in India’s North-Eastern Region. Working for Conflict Transformation and Peacebuilding; and Development. Specialties: Facilitation of Conflict Transformation and Peacebuilding Trainings and Workshops, Working with grassroots and civil society leaders in conflict situations, Non-profit management, Action Research on Ethnic Conflicts, Evaluation, Writing and editing etc. “Understanding Violence Triangle And Structural Violence” URL: http://kanglaonline.com/2012/07/understanding-violence-triangle-and-structural-violence-by-rajkumar-bobichand/)

We understand that Violence is any physical, emotional, verbal, institutional, structural or spiritual behaviour, attitude, policy or condition that diminishes, dominates or destroys others and ourselves. Violence is one of the possible responses to specific conflict situations. This does not imply that violence is unavoidable. **Violence is not inevitable and it must not be confused with conflict.** In other words, **Violence consists of actions, words, attitudes, structures or systems that cause physical, psychological, social or environmental damage and/or prevent people from reaching their full human potential** (Fisher et al. 2000). **Violence can be deeply structured into the system of relationships, within socio-economic and political arrangements, and** even in the **culture of a society and** **of a global system. Therefore, systemic violence can in turn be a root causes of conflict,** **as well a behavioural response to a specific conflict situation.** **Johan Galtung** (1969), **made a clear distinction between Structural Violence, Cultural Violence and Direct Violence.** These ideas are connected to his distinction depending on how it operates between three inter-related forms of violence (Structural-Cultural-Direct) where Structural Violence is at the left end and Cultural Violence is at the right end of the base of a Triangle invisibly while Direct violence is on the vertex visibly. According to Galtung’s Violence Triangle (1969), Cultural **and Structural Violence cause Direct Violence. Direct Violence reinforces Structural and Cultural violence.** **Direct Violence, Physical and/or verbal, is visible as behaviour in the triangle. However, this action does not come out of nowhere; its roots are cultural and structural.** **Direct violence can take many forms.** In its classic form, it involves the use of **physical force,** like **killing** or **torture, rape and sexual assault, and beatings.** Further, we understand that **verbal violence, like humiliation or put downs, is also becoming more widely recognised as violence.** Johan Galtung, further, describes direct violence as the “avoidable impairment of fundamental human needs or life which makes it impossible or difficult for people to meet their needs or achieve their full potential. Threat to use force is also recognised as violence.” **Cultural violence is the prevailing attitudes and beliefs that we have been taught since childhood and that surround us in daily life about the power and necessity of violence.** **We can consider the example of telling of history which glorifies records and reports wars and military victories rather than people’s nonviolent agitation, movements, rebellions or the triumphs of connections and collaborations. Almost all cultures recognise that killing a person is murder, but killing tens, hundreds or thousands during a declared conflict is called ‘war’ or killing of innocent people by the security forces are often declared as caught in the crossfire.** **Structural violence exists when some groups, classes, genders, nationalities,** etc are assumed to **have,** and in fact do have, **more access to goods, resources, and opportunities than other groups, classes, genders, nationalities**, etc, and this unequal advantage is built into the very social, political and economic systems that govern societies, states and the world. These tendencies may be overt such as Aparthied or more subtle such as traditions or tendency to award some groups privileges over another. Constitutional privileges of Job reservations and financial supports in the name of the welfare of the “tribes or backwards” and non-uniform land law, which bans one group to own landed property in their own land while other groups are free to own landed property wherever they want are also examples of structural violence. **Theories of structural violence explore how political, economic and cultural structures result in the occurrence of avoidable violence, most commonly seen as the deprivation of basic human needs** (will be discussed later). Structural theorists attempt to link personal suffering with political, social and cultural choices. Johan Galtung’s original definition included a lack of human agency; that is the **violence is not a direct act of any decision or action made by a particular person but a result of an unequal distribution of resources.** Here, we must also understand “institutional violence”. “Institutional violence” is often mistaken for structural violence, but this is not the case. “Institutional violence” should be used to refer to violence perpetrated by institutions like companies, universities, corporations, organisations as opposed to individuals. The fact that women are paid less at an establishment than men is an act of direct violence by that specific establishment. It is true that there is a relationship with structural violence as there is between interpersonal violence and structural violence. And Structural violence is the most problematic area to be addressed for conflict transformation.

# **Contention 1: Insulin**

#### **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

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

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

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

#### **Reducing IP protection for insulin 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

#### **Newer insulin isn’t better then old insulin**

**Belluz 19** [Julia Belluz, Vox's senior health correspondent and Knight Science Journalism fellow at MIT with a MSc from the London School of Economics, 4-3-2019, "The absurdly high cost of insulin, explained," Vox, https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive]/Kankee

“As solutions to the insulin-cost crisis are being considered,” a new New England Journal of Medicine editorial argues, “there is value in remembering that when the patent for insulin was first drafted in 1923, Banting and Macleod declined to be named on it. Both felt that insulin belonged to the public. Now, nearly 100 years later, insulin is inaccessible to thousands of Americans because of its high cost.” Most patients with diabetes remain vulnerable to the whims of drug company pricing, since companies can still set whatever prices they wish. And no drug is better for understanding how that happened than insulin. How the companies justify their price increases With Type 1 diabetes, which affects about 5 percent of people with diabetes in the US, the immune system attacks the insulin-producing cells in the pancreas, leaving the body with little or none of the hormone. In Type 2 diabetes, the pancreas still makes insulin, but the body has grown resistant to its effects. In both cases, patients rely on insulin medication to keep energy from food flowing into their bodies. The US is a global outlier on money spent on the drug, representing only 15 percent of the global insulin market and generating almost half of the pharmaceutical industry’s insulin revenue. According to a recent study in JAMA Internal Medicine, in the 1990s Medicaid paid between $2.36 and $4.43 per unit of insulin; by 2014, those prices more than tripled, depending on the formulation. The doctors and researchers who study insulin say it is yet another example — along with EpiPens and decades-old generic drugs — of companies raising the cost of their products because of the lax regulatory environment around drug pricing. “They are doing it because they can,” Jing Luo, a researcher at Brigham and Women’s Hospital, told Vox in 2017, “and it’s scary because it happens in all kinds of different drugs and drug classes.” In countries with single-payer health systems, governments exert much more influence over the entire health care process. In England, for example, the government has an agency that negotiates directly with pharmaceutical companies. The government sets a maximum price it will pay for a drug, and if companies don’t agree, they simply lose out on the entire market. This puts drugmakers at a disadvantage, driving down the price of drugs. The US doesn’t do that. Instead, America has long taken a free market approach to pharmaceuticals. Drug companies haggle separately over drug prices with a variety of private insurers across the country. Meanwhile, Medicare, the government health program for those over age 65 — it’s also the nation’s largest buyer of drugs — is barred from negotiating drug prices. That gives pharma more leverage, and it leads to the kind of price surges we’ve seen with EpiPens, recent opioid antidotes — and insulin. Insulin manufacturers say the increases are just the price tag that comes with innovation — creating more effective insulin formulations for patients. According to a 2017 Lancet paper on insulin price increases, “Older insulins have been successively replaced with newer, incrementally improved products covered by numerous additional patents.” The result is that more than 90 percent of privately insured patients with Type 2 diabetes in America are prescribed the latest and costliest versions of insulin. But soaring prices for these newer formulations is out of step with how much they improve treatment for patients, said Yale endocrinologist Kasia Lipska. For Type 1 diabetes, newer formulations appear to be more effective at controlling blood sugar than older formulations. “For Type 2 diabetes, it’s less clear — the benefits are not as strong.” So, Lipska asked, “Are [the new insulins] 20 times better? I’m not sure.” Luo, the Lancet paper’s lead author, doesn’t find the “cost of innovation” argument very convincing. In his research, he’s come across many examples of the same insulin products that have been continuously available for years without improvements, yet their price tags have gone up at a much higher rate than inflation. “The list price of these products are already out of reach for most Americans living with diabetes — in some cases, over $300 a vial,” he said. “It is also strange to see Humulin still priced at over $150 a vial considering this product was first sold in the US in 1982.” Drugmakers do this because they can So insulin’s drug pricing problem is much bigger than anything one state — or drug company — alone can fix. But more changes in the market may be on the horizon. The three major insulin makers — Eli Lilly, Novo Nordisk, and Sanofi — testified before the House Energy and Commerce’s oversight subcommittee last April, focusing more attention on the issue. Lawmakers, including Sens. Chuck Grassley (R-IA) and Ron Wyden (D-OR), have also been investigating the problem and sending letters to drug companies asking them to account for their outrageous price hikes. But while the pressure around insulin may be mounting, we’re also seeing the terrible impact of rising insulin prices on patients: people being forced to taper off insulin so they can pay their medical bills, and winding up with kidney failure, blindness, or even death. Some are forced to head to Canada, where drug prices are more heavily regulated and, according to the new NEJM editorial, where a carton of insulin costs $20 instead of the $300 patients often pay in the US. “Of course, there isn’t enough insulin in all of Canada to make large-scale importation feasible,” the editorial authors wrote. One real solution to the problem, however, would be to bring a generic version of insulin to the market. There are currently no true generic options available (though there are several rebranded and biosimilar insulins). This is in part because companies have made those incremental improvements to insulin products, which has allowed them to keep their formulations under patent, and because older insulin formulations have fallen out of fashion. But not all insulins are patent-protected. For example, none of Eli Lilly’s insulins are, according to the drugmaker. In those cases, Luo said, potential manufacturers may be deterred by secondary patents on non-active ingredients in insulins or on associated devices (such as insulin delivery pens). There’s also “extreme regulatory complexity” around bringing follow-on generic insulins to market, Luo added. And that’s something regulators, such as the Food and Drug Administration, have been working to streamline. History has shown that their efforts are worthwhile: When cheaper generic options are introduced to the market, overall drug prices come down. A century after insulin was discovered, it’s about time we had one.

# **Contention 2: Innovation**

#### **Medical innovation in crisis – rarely do new drugs improve health outcomes due to new patents being only marginally better than older drugs**

**Naci et al. 15** [Huseyin Naci, assistant professor of health policy at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science , Alexander W Carter policy fellow, at the Institute of Global Health Innovation, Imperial College London, Elias Mossialos, professor of health policy, , at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science, 10-23-2015, “Why the drug development pipeline is not delivering better medicines,” BMJ, https://sci-hub.se/https://www.bmj.com/content/351/bmj.h5542.full]/Kankee

Many in the pharmaceutical sector suggest that the industry is in crisis. Industry analysts fret that financial rewards are no longer sufficient for companies to maintain the investment needed to develop clinically useful drugs.1 Despite these concerns, regulators in the US and Europe granted marketing authorisations to a record number of new medicines in 2014. However, the majority of new medicines offer few clinical advantages over existing alternatives. We discuss how both government and drug company practices contribute to the ongoing innovation deficit in the sector. Paucity of clinically superior medicines Patients and clinicians commonly understand innovation to mean a medicine that has transformed management and treatment,2 either by providing treatments for conditions with no current (satisfactory) remedies or by offering meaningful improvement over existing options. In recent years, however, industry analysts have adopted other definitions to measure innovation (box 1).3 Currently, the most common approach to measure innovation is to count the number of new drug approvals.3 The number of drug approvals has increased over the past five decades, culminating in 41 approvals in the US and 40 in Europe in 2014 alone; this compares with a 50 year average of 20 approvals a year.4 5 Large numbers of new drugs have been taken as a proxy for the innovative capacity of the industry. Unfortunately, rather than new breakthroughs, most of the new drugs are relatively minor modifications of existing treatments.6 Studies evaluating the clinical importance of new drugs over the past decades consistently report a negative trend.7-11 Regardless of differences in analytical approach and time period, all characterise only a minority of new drugs as clinically superior to existing alternatives.3 Luijn found that 10% of 122 new medicines on the European market between 1999 and 2005 were superior to drugs already on offer.12 Among drugs reviewed by German authorities between 2012 and 2013, about 20% were concluded to offer some benefit over existing alternatives and none was deemed to offer major benefit.13 Between 1990 and 2003, only 6% of 1147 drugs approved in Canada provided a substantial improvement over existing drug products,14 and Canadian authorities considered 10% of new drugs approved between 2004 and 2009 as highly innovative.15 Despite the paucity of clinically superior drugs, the pharmaceutical market grew by a factor of 2.5 in real terms between 1990 and 2010 (fig 1⇓). Much of the increased expenditure on drugs was the result of increasing industry investment in “me-too” medicinesrather than clinically superior medications.14 Drug companies have remained profitable over this period while the proportion of health spending on drugs has increased and drugs have become less affordable.16 17 Over the past 30 years, firms lost their number one position in the Fortune 500 ranking of US companies only in 2003, coming third behind oil and financial companies. In 2012, the top five pharmaceutical companies included in the Fortune 500 earned over $50bn (£30bn; €40bn) in net profits.

#### **Repatenting old drugs wards off competition through endless monopolies and deterring generic entry to the market – both harm innovation**

**Gurgula 20** [Olga Gurgula, lecturer of intellectual property law at Brunel University London, 10-28-2020, "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?," IIC - International Review of Intellectual Property and Competition Law, https://link.springer.com/article/10.1007/s40319-020-00985-0]/Kankee

Strategic Patenting Impairs Originators’ Incentives to Innovate While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish. Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84 the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share. In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85 Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92 Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93 A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly. Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns. Strategic Patenting Impairs Follow-on Innovation of Generic Companies Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators: The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97 Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100 As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns. Strategic Patenting is Considered Lawful Under the Current Approach

#### **Incremental changes increase average patent expiration dates, delaying generics and competition for decades**

**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.

#### **Squo innovation doesn’t help patients as monopolies remove incentives for improvements**

**Feldman et al. 8-10** [Robin C. Feldman, researcher at University of California Hastings College of the Law, David A. Hyman, researcher at Georgetown University Law Center, W. Nicholson Price II, University of Michigan Law School researcher, and Mark J. Ratain, researcher at The University of Chicago, 8-10-2021, "Negative innovation: when patents are bad for patients," Nature Biotechnology, https://www.nature.com/articles/s41587-021-00999-0]/Kankee

Incentives in patent law have driven innovation into spaces that are affirmatively harmful to patients, and patentees are discouraged from taking steps to improve the product so as to prevent adverse health outcomes. Patent law in the United States is historically premised on advancing the interests of society. From the store of productive activity available to all, the government restricts some activities for a limited time in hopes this will redound to the benefit of all by incentivizing innovation1. The law thereby restricts competition, forgoing the concomitant advantages of the free market, but only during the patent period. After that time, the law expects that competition will enter, driving down prices and spurring new innovation. From this perspective, US patent law centers on the benefit to the public, with the inventor’s reward providing the vehicle for accomplishing this jurisprudential goal. In the health care space, these incentives have resulted in extraordinary success stories, but the same incentives can also result in a range of undesirable consequences, including excessive development of similar (but not better) products (‘me-too drugs’), the focus on drugs for diseases that affect wealthy people and wealthy countries rather than diseases that disproportionately affect the poor and developing nations, and a lack of innovation for types of medicines that may return fewer profits, such as antibiotics2,3,4. Similarly, drug companies will not research the utility of a known (and hence unpatentable) chemical, since the ability to obtain patent protection is central to their business model5. Past literature has highlighted these problems but has largely overlooked the problem of ‘negative innovation’, in which patent law drives innovation into spaces that are affirmatively harmful to patients. By this, we mean scenarios whereby patents create incentives to bring a product to market in a way that is relatively harmful to consumers, and the existence of a patent (and the associated rents) discourages the patentee from taking steps to improve the product so as to prevent the adverse health outcomes. Of course, there are other patent-driven situations of problematic utility, including scenarios that result in purely financial harms, such as drugs that are no better than existing options but are more expensive; scenarios where a small, heightened risk of direct physical harm is offset by lower prices for the drug in question6; and scenarios where there is no existing product on the market and inadequate incentives to develop such a product, so any physical harm is the result of the underlying disease or illness7. Finally, there is a general concern that inadequate new information about existing products is generated in the current system8. All of these scenarios are different in kind from negative innovation, which results in a harmful (but profitable) product. We focus on this dangerous but overlooked space of the patent landscape, wherein patents themselves lead fairly directly to patient harm. What does negative innovation look like? We highlight a particularly pernicious example, the case of Imbruvica (ibrutinib); suggest the likelihood of broader problems; and outline various strategies for preventing such outcomes going forward. The case of ibrutinib

#### **Patents don’t cause innovation – secrecy and corruption thump any benefits**

**Zink 18** [Julie E. Zink, Professor at University of Dayton School of Law that has taught courses on Intellectual Property Law, Trade Secret Law, and Patent Litigation, 2018, “When Trade Secrecy Goes Too Far: Public Health and Safety Should Trump Corporate Profits,” Hein Law, https://heinonline.org/HOL/P?h=hein.journals/vanep20&i=1183]/Kankee

III. THE NEGATIVES OF SECRECY Not surprisingly, there are also negatives involved in protecting trade secrets-namely, providing a legal shield that corporations can use to conceal nefarious activities. According to Bok, "[t]rade secrecy is the most frequent claim made by those who want to protect secrets in business"; corporations may assert such claims to protect legitimate secrets and, in some cases, to abuse or exploit their trade secret protections. 41 Trade secrecy can cause harm. First, trade secrecy does not always promote one of its stated policy goals-innovation. 42 Rather, it encourages companies to engage in duplicative investment in research and development. 43 It also frustrates the disclosure goals of the patent system when companies opt for trade secrecy rather than patent protection.44 Second, secrecy debilitates judgment.45 If only a select few know the trade secret, then they are the only ones who can make decisions regarding the information at issue. This postpones discovery of errors and effectively shuts out criticism from others who may be able to provide valuable feedback.46 As a result, faulty assumptions about risk may mean that little to no deliberation takes place regarding whether to continue, modify, or cease use of the trade secret. 47 Third, secrecy has the capacity to corrupt and to invite abuse. 48 Due to others' lack of knowledge regarding the trade secret, those with knowledge operate in a system free from oversight.49 This lack of accountability coupled with the desire for higher profits (for which they are held accountable) results in a loosening of moral constraints.50 When no one is present to hold a mirror up to their faces, they can downplay the consequences of their actions and disregard any negative impacts the trade secret may have on their employees, their consumers, the general public, or the environment. IV. HISTORICAL EXAMPLES OF TRADE SECRECY ABUSE

# **Contention 3: IPR Fake News**

#### **We can’t choose which ideas we create – any creative thought is a recombination or variation of previous memes an inventor holds no right to**

**Gunten 15** [Andreas von Gunten, philosopher with an MA in Philosophy, 2015, “Intellectual Property is Common Property,” Philosophy Archive, https://philarchive.org/archive/VONIPI]/Kankee

THE CREATOR AS A MEME COPY MACHINE We usually think of every cultural expression as a result of one or more person’s labour. But it is more than just ‘labour’ that we attribute as the input factor for the result of a creative process. It is a kind of extraordinary creativity, which not every person is fortunate enough to have. For some it is even the divinity which talks to us, through the creator. Our perception of the artist is often that of a genius. But is the creator then really a creator in the sense of being a creative agent, or is he just a means to represent and reproduce what the ‘Zeitgeist’, God or his unconsciousness creates? Is the inventor really an inventor or is he just an explorer of what is already there? In other words, is creativity something where we act as active agents, or is it something which just happens unconsciously inside our neural system? In the closing chapter of his 1976 book, The Selfish Gene, Richard Dawkins introduces his postulate of the meme (Dawkins 2006).2 In 1991 Daniel Dennett used this concept as an important building block for his account of how human consciousness can be understood from a materialist perspective (Dennett 1993). The term “meme” is an abbreviation of the ancient Greek word “mimeme” which stands for ‘imitator’. A meme is a cultural expression, or a behaviour which reproduces itself while jumping from brain to brain. This happens through human imitation. Imitation is the building block of human culture and tradition. The brain is the copy machine for the memes. Cultural evolution occurs, like biological evolution, as soon as there is information which shows variation, selection and heredity. Memes get copied by imitation. During this copy process they are sometimes changed only slightly, and sometimes they are recombined with other memes, which leads to variation. Some memes are more successful in getting copied than others, which gives us selection. For example the idea of nations and states was more successful than the idea of a society without authorities; the idea of a person-like God was more successful than the pantheistic or animistic world views, or the story of two lovers who are not allowed to come together and eventually commit suicide is told in different variations and settings over centuries, and so on. The concept of the meme is important for our analysis of intellectual property because it gives us a framework to explain cultural evolution as an interpersonal process from which we cannot postulate one individual as the exclusive creator of a creative work. Ideas cannot realise themselves without brains, but brains are not the creators of ideas, they are just the hosts for the replication process. Even if an individual person recombines different memes, which is more common than the simple copying from one meme, it is still a copying process, which we cannot really operate ourselves actively. It just happens with us, inside our brains. As I am writing this text, I am not really in charge in the sense that I decide which memes I am taking and combining with others. I do of course have the experience of ‘thinking myself,’ but this is not what actually happens inside my brain according to Daniel Dennett (1991).3 Everything I write here is the result of a continuous meme copying and recombination process. One association leads to another. The river of consciousness is full of surprises which I cannot claim myself as an active agent to be responsible for, in the sense that I can insist on an exclusive property right for what comes out of my brain.4 Artists also often talk about having the sense of not being in charge while creating their artwork. They emphasise that they don’t know how it comes about that they are creative. They usually are not aware of what is going on in their consciousness while creating a piece of art, or at least are not able to explain it. It is common that they talk about inspiration on which they depend and that one has to wait until it arrives. Sometimes it does not arrive at all. The idea of the need to be inspired by outside forces to be able to be creative can be traced back to the Muses of Greek mythology. The romantic concept of art, which emphasises that the genius has the benefit to let the divine express itself through the artist, also leads to the idea that the genius himself is not in charge here, but something else is. Human beings and their memes are living in a symbiotic system. Cultural expressions seem to be continuously replicated inside brains, and from brain to brain, so to speak. Each copy is slightly different from its original and is at the same time another original for the next replication procedure. This is important because it shows that all expressions are equal in the sense that they are all copies and originals at the same time. We should not imagine memes as singular representations of expressions or ideas in our brain though. They are rather complex compositions of many different aspects and attributes of them in different places and at different times as Daniel Dennett explains in his multiple drafts model (Dennett 1991:111ff). THE CREATIVE PROCESS AS A COLLECTIVE PROCESS Because ideas jump from brain to brain in the form of memes the creative process has to be seen as a collective process. Every piece of art, every patent, every musical pattern, every behaviour is always the end- and starting point of a continuous collective process of human creativity and innovation. Ideas are represented through expressions. These can be words, images, music melodies, behaviours and so on. There are no ideas without representation, which means that we cannot communicate or experience ideas without them being expressed somehow. The ideaexpression relationship is far more complex and controversial than we can discuss in this paper, but for our purpose (to point to the mechanism of cultural evolution through copying) it should be sufficient to understand its general aspects. Every expression of a human being is the result of the recombination of what has been expressed by someone else and of the meme copying process inside his neural system. We have evidence for the collective aspects of creativity from Ludwik Fleck’s philosophy of science. According to Fleck it is not correct to assume that human beings think individually. We should accept the fact that ‘cognition is a collective process’ (Sady 2012). ‘A truly isolated investigator is impossible… An isolated investigator without bias and tradition, without forces of mental society acting upon him, and without the effect of the evolution of that society, would be blind and thoughtless. Thinking is a collective activity… Its product is a certain picture, which is visible only to anybody who takes part in this social activity, or a thought which is also clear to the members of the collective only. What we do think and how we do see depends on the thought-collective to which we belong.’ (Fleck 1935b, cited in Sady 2012) Fleck is stressing here that without mental content from other members of the thoughtcollective we belong to, we would not be able to give meaning to our thinking. We could also say that Fleck describes some of the cultural effects of the meme-replication-process. This becomes even more apparent when we look at how Wojciech Sady describes the definition of Fleck’s thought collective: ‘A thought collective is defined by Fleck as a community of persons mutually exchanging ideas or maintaining intellectual interaction (Fleck 1935a, II.4). Members of that collective not only adopt certain ways of perceiving and thinking, but they also continually transform it—and this transformation does occur not so much “in their heads” as in their interpersonal space.’ (Sady 2012) The continuous transformation of ideas in ‘their interpersonal space’ is what we could also call cultural evolution. And even if Fleck has provided his account in the special context of the question of how scientific research works, we can easily adapt it to the creative process as such. Not only in science but in every aspect of creativity, cultural evolution is at work. Let us imagine in a short thought experiment a human being born on an island, where his parents have died right after his birth. Somehow he has managed to survive and he is living now as an adult alone on this island. It is rather unlikely that he has started to paint images in his leisure time, but for the sake of the argument, let us assume he did. But what seems to be rather implausible is that he paints images in the style of cubism without any social interaction or cultural heritage. Cubism is a typical example of a phenomenon of cultural evolution and at the same time an example of how our society tends to attribute cultural innovations to individuals even if there is much evidence that it is more an emergence of the “Zeitgeist” than a creative event by a single genius. Pablo Picasso and Georges Braque are usually said to be the inventors of cubism, while at the same time it is considered as a fact in art history that there were different pre decessors and influences which prepared the ground to let the new movement arise. We can consider the members of the cubist movement as a thought collective in Ludwik Fleck’s sense and adapt his findings to the process of art production. Even if we consider Pablo Picasso to be one of the most important artists of cubism it does not seem very probable that he would have created the same type of paintings had he lived in the eighteenth century or had he been raised by a worker family in Manchester around 1850. And it also does not seem very likely that cubism would not have evolved if Pablo Picasso had never lived at all. Nevertheless, it cannot be denied that it was Picasso who painted Les Demoiselles d’Avignon and not some thought collective. There is at least a substantial individual part in the creative works of artists of any kind. There is no artwork without the decision of the artist to start working on it. If he decided to plant trees instead of creating a piece of art, there would be no painting, song or text we could enjoy and analyse. This is definitely true, but the question is, is this enough to consider him as the only source of the result and to provide him therefore with the rights to exclusively exploit the benefits from it? It is undeniable that there lies labour in every cultural artefact, and this labour can usually be attributed to the creators. It was Pablo Picasso who moved the paint brushes to create his Les Demoiselles d’Avignon and not Paul Cézanne. But the fact that this picture looks how it looks cannot be attributed to Picasso alone. Let us assume the meme model and the thought collective are adequate conceptual descriptions for how human expressions and ideas evolve interpersonally. It still can be said that what we call being creative is what is new or original, and that this is exactly what the individual aspect of creativity represents. The problem here lies in the question: what is to be considered as new or original? As we have seen in the case of cubism, even when we can assign a new category to an artistic style, it has not evolved out of nothing. The borders of such categories are always blurred and arbitrary, and they fade away as soon as we try to find them. And even what we consider as radically new and original in the history of our culture, like cubism, or as another example the theory of relativity formulated by Albert Einstein, can be traced back to former works by other individuals which were necessary foundations for Picasso or Einstein to make their discoveries. There is never anything radically or totally new in human culture. Every cultural expression evolves slowly from its predecessors. Evolutionary steps are very small: so small that they usually are not detected. It is the last straw that breaks the camel’s back. The famous big theories, the so-called new inventions in art or the great discoveries in science are always results of long-lasting interpersonal creative and evolutionary processes. It looks as though it is mere luck that the memes are combined in a particular way inside a neural system from a specific individual and not through someone else’s. Of course, the artist or the scientist has often contributed a lot of personal education and work to bring themselves into the position to be able to make this very last important step for a new discovery or a new kind of cultural work. But it remains a small step compared to the whole process which was needed before he could take this step. Albert Einstein knew this as well. He said at a meeting of the National Academy of Science in 1921: When a man after long years of searching chances on a thought which discloses something of the beauty of this mysterious universe, he should not therefore be personally celebrated. He is already sufficiently paid by his experience of seeking and finding. In science, moreover, the work of the individual is so bound up with that of his scientific predecessors and contemporaries that it appears almost as an impersonal product of his generation. (Einstein 1921:579) The creator or author is far from being passive in this process. As we have seen above, it was Picasso who painted his paintings and it was Einstein who wrote his papers. So there is definitely an important individual part in every cultural work. But when we take the collective aspect of the creative process we have sketched so far into consideration, it looks like it just does not seem to be justified to attribute the originality to the individual by whom it was expressed. The person who creates a work should not be seen as its author or creator but more as its source. This kind of attribution gives respect to the individual part without stressing it too far. There are many practical reasons to attribute the work to a source. It helps others to refer to it, it may help to understand it better, it may even help to give some other kind of reward (e.g. money) to its source. But just because we are the source of a piece of work, we cannot thereby claim that we are the single author or creator and therefore the owner of it. Such a treatment of the work is also in line with Kant’s account of the person ality rights of an author. While attributing the source of an expression, we esteem the individual part one has on the creation of a cultural expression without making him the sole creator and exclusive owner. Both the postulation of a meme theory and the concept of the thought collective may lead to several objections. The most important is that the concept of free will may not be compatible with these views. Meme theory as proposed by Daniel Dennett has to be considered as a materialistic theory of the mind. Materialistic theories of the mind and the concept of the thought collective can be called deterministic in their character. It is disputed whether free will is compatible with determinism or not, and we cannot discuss this question in this paper. And it is true that if we hold the view that free will exists and that it is not compatible with determinism we have to reject meme theory and maybe Fleck’s thought collective as well. But we could still accept that creativity and innovation are more to be perceived as interpersonal than individual processes; we just have to find another theory which is not in conflict with free will. Anyone who insists on the view that ideas and expressions are naturally owned by the individual from whom they occur, must also provide a plausible theory as to how minds produce ideas independently from their social environment. I do not assert that such a theory does not exist, but I have not come across one yet. But if we accept that we are merely a source rather than a creator of cultural expressions, and if the only thing which we can take into account for intellectual property rights is the labour we have contributed and not the creativity itself, there seems to be little ground for any personality-based account of intellectual property rights. The only hope for the justification of the personal property of cultural expressions and inventions lies now in the utilitarian arguments, which are the ones we are going to examine in the following chapter

#### **IPR’s abstract status means usage by others doesn’t harm your own property rights**

**Gunten 15** [Andreas von Gunten, philosopher with an MA in Philosophy, 2015, “Intellectual Property is Common Property,” Philosophy Archive, https://philarchive.org/archive/VONIPI]/Kankee

EGALITARIAN JUSTIFICATION FOR INTELLECTUAL COMMONS A just society from an egalitarian point of view gives individuals, in addition to equal rights to maintain and develop a life according to their own desires, equal access to worldly resources, such that the rules for distributing the resources equally amongst its members can overrule the personal freedom of the individual14 . As we have seen above, intellectual property rights are monopoly rights which grant a temporary privilege to exclusively exploit income rights from abstract objects which are created collectively. Nevertheless there are several possible arguments to justify these rights on egalitarian grounds. First, it could be argued that these privileges are not arbitrary. They are granted to individuals who deserve them, because they are the creators or inventors. It is not individuals with the most money who get the monopoly rights from the state, but those who are willing to bring their ideas into existence in form of expressions. If a privilege for creators serves the goal of getting a more equal distribution of wealth, it can be justified. A second point is that social justice from the egalitarian point of view needs state-enforced redistribution of goods, and therefore the state needs an intellectual property rights framework to redistribute the profits which can be raised from abstract objects. And a third argument would be that intellectual property rights are rights which help the individual creator against exploitation by powerful corporations or other organisations. While discussing these arguments, we should be aware that we tend to apply distribution problems from physical objects to abstract objects. And in the world of physical objects and a private property rights-based society, we do in fact face the problems which come with unequal appropriation of worldly resources. An individual who has more talent may be able to appropriate resources faster than others, so that in the end there is nothing left. Today, there is not one square foot of land on our planet which is not ‘owned’ by someone. Whether the owner is an individual or a collective of some sort, there is always someone who claims ownership. Land and every other worldly resource are finite15 and therefore there is always a struggle about the question of to whom they belong. But in the case of abstract objects, the situation is totally different. The use of abstract objects like cultural expressions, ideas, inventions and so on is not limited simply because someone else is using them, as we have discussed already. If I build my house on a piece of land, and someone wants to do the same on the same piece of land, he has to send me packing. He then has the land and I don’t. If I invent a wheel and use it for my convenience, I can share this invention without reducing its value for me. In fact any invention and any expression can be shared by anyone without dimin ishing its utility for others. The value for me also does not reduce if someone who has more capital at his disposal than I do is able to produce wheels to sell them on a market. I can still use my own wheel, which I have created. There is even a chance that the producer of the wheels innovates on it and makes it better, and as he cannot claim intellectual property rights either, I am able to use his ideas to upgrade my wheel as well. If there is a demand for wheels, chances are high that I will still be able to find my market for my handmade wheels, even if a lot of other ‘wheel makers’ are producing them at lower costs. Buyers do not value only monetary aspects; a lot more is often taken into account for a buying decision. In a world with private intellectual property rights the rights holder can exploit the income exclusively; in a world with intellectual commons everyone has the chance to do so. From an egalitarian point of view this fact raises the problem that the more talented and/or the more powerful may be able to exploit the profits from the cultural expressions of any kind much more effectively than the less talented, whether this is the creator or someone else. This is partly true, but it is true in any world, whether there exists a legal framework for intellectual monopoly rights or not. We can see this very well in the actual situation in our world. Most of the income from intellectual property rights is concentrated around a few big players in every market. The main difference is that the powers are more stable in a world with intellectual property and more dynamic in a world without. In a world without intellectual property rights, monopolies could still occur but they would be de facto monopolies, and these types of monopolies will not last long. The abolition of intellectual property rights would lead to a more fragmented and decentralised economic situation as no one can be prevented from copying inventions and cultural expressions. Profits will be near zero for those who just copy and will be higher for those who innovate on the copy. Intellectual property rights are not an effective instrument for redistribution of income or wealth. From an egalitarian point of view the problem of inequality persists, and as intellectual property rights are monopoly rights they create even more inequality on one part between the “winners” and the “losers” inside the system, but also between rights holders and users. If we consider the situation that without intellectual property rights, the use of any expression or invention is open to everyone, we can easily see that in such a world a much more diverse market would evolve. As there are no monopoly rights, probably many more individuals and smaller groups would use the cultural expressions which are free to use, and remix them with their own ideas to create new products and services to make a living. With the system of intellectual property rights which we have in place now, the exploitation of the inventor or the creator through big corporations is the reality. Only for a few ‘superstars’ might the situation be the other way around. There are two main reasons for this. First, it is expensive to get and even more expensive to enforce intellectual property rights; and second, the big money lies in the portfolio of rights and not in the single expression. Even if there are blockbusters which generate a multiple of the income from the average ‘product’ for the rights holders, it is usually the backlist, the sum of thousands of single products, which is the important source of a permanent revenue stream for the big rights holders. But isn’t it the case that the creator gets at least his share from the revenue stream and without intellectual property rights these companies could take everything for themselves without even thinking of letting the creator or inventor participate? This is true, but for most creators the share is so small that it does not contribute to enhancing their economic situation. In many cases they would be in a better situation to generate income with their creations if they had not exclusively sold the licences for the exploitation of his work to a single company. From an egalitarian perspective, the most important question is: how can wealth be distributed equally amongst the people? The intellectual property rights regime obviously does not contribute much to solving this problem; it rather looks like it does the opposite. I do not argue here that the absence of individual intellectual property solves the general distribution problem, but it leads to a situation where many more people can benefit from cultural expressions, scientific research and inventions than now, and therefore less redistribution is needed.

#### **IPR has no material basis and arbitrarily infringes on actual (property) rights – all patents are expressions of publicly available laws of nature**

**Long 95** [Roderick T. Long, American professor of philosophy at Auburn University with a PhD in philosophy from Cornell, 1995, “The Libertarian Case Against Intellectual Property Rights,” Free Nation, http://freenation.org/a/f31l1.html]/Kankee

The Ethical Argument Ethically, property rights of any kind have to be justified as extensions of the right of individuals to control their own lives. Thus any alleged property rights that conflict with this moral basis — like the "right" to own slaves — are invalidated. In my judgment, intellectual property rights also fail to pass this test. To enforce copyright laws and the like is to prevent people from making peaceful use of the information they possess. If you have acquired the information legitimately (say, by buying a book), then on what grounds can you be prevented from using it, reproducing it, trading it? Is this not a violation of the freedom of speech and press? It may be objected that the person who originated the information deserves ownership rights over it. But information is not a concrete thing an individual can control; it is a universal, existing in other people's minds and other people's property, and over these the originator has no legitimate sovereignty. You cannot own information without owning other people. Suppose I write a poem, and you read it and memorize it. By memorizing it, you have in effect created a "software" duplicate of the poem to be stored in your brain. But clearly I can claim no rights over that copy so long as you remain a free and autonomous individual. That copy in your head is yours and no one else's. But now suppose you proceed to transcribe my poem, to make a "hard copy" of the information stored in your brain. The materials you use — pen and ink — are your own property. The information template which you used — that is, the stored memory of the poem — is also your own property. So how can the hard copy you produce from these materials be anything but yours to publish, sell, adapt, or otherwise treat as you please? An item of intellectual property is a universal. Unless we are to believe in Platonic Forms, universals as such do not exist, except insofar as they are realized in their many particular instances. Accordingly, I do not see how anyone can claim to own, say, the text of Atlas Shrugged unless that amounts to a claim to own every single physical copy of Atlas Shrugged. But the copy of Atlas Shrugged on my bookshelf does not belong to Ayn Rand or to her estate. It belongs to me. I bought it. I paid for it. (Rand presumably got royalties from the sale, and I'm sure it wasn't sold without her permission!) The moral case against patents is even clearer. A patent is, in effect, a claim of ownership over a law of nature. What if Newton had claimed to own calculus, or the law of gravity? Would we have to pay a fee to his estate every time we used one of the principles he discovered? "... the patent monopoly ... consists in protecting inventors ... against competition for a period long enough to extort from the people a reward enormously in excess of the labor measure of their services, — in other words, in giving certain people a right of property for a term of years in laws and facts of Nature, and the power to exact tribute from others for the use of this natural wealth, which should be open to all." (Benjamin Tucker, Instead of a Book, By a Man Too Busy to Write One: A Fragmentary Exposition of Philosophical Anarchism (New York: Tucker, 1893), p. 13.) Defenders of patents claim that patent laws protect ownership only of inventions, not of discoveries. (Likewise, defenders of copyright claim that copyright laws protect only implementations of ideas, not the ideas themselves.) But this distinction is an artificial one. Laws of nature come in varying degrees of generality and specificity; if it is a law of nature that copper conducts electricity, it is no less a law of nature that this much copper, arranged in this configuration, with these other materials arranged so, makes a workable battery. And so on. Suppose you are trapped at the bottom of a ravine. Sabre-tooth tigers are approaching hungrily. Your only hope is to quickly construct a levitation device I've recently invented. You know how it works, because you attended a public lecture I gave on the topic. And it's easy to construct, quite rapidly, out of materials you see lying around in the ravine. But there's a problem. I've patented my levitation device. I own it — not just the individual model I built, but the universal. Thus, you can't construct your means of escape without using my property. And I, mean old skinflint that I am, refuse to give my permission. And so the tigers dine well. This highlights the moral problem with the notion of intellectual property. By claiming a patent on my levitation device, I'm saying that you are not permitted to use your own knowledge to further your ends. By what right? Another problem with patents is that, when it comes to laws of nature, even fairly specific ones, the odds are quite good that two people, working independently but drawing on the same background of research, may come up with the same invention (discovery) independently. Yet patent law will arbitrarily grant exclusive rights to the inventor who reaches the patent office first; the second inventor, despite having developed the idea on his own, will be forbidden to market his invention. Ayn Rand attempts to rebut this objection: "As an objection to the patent laws, some people cite the fact that two inventors may work independently for years on the same invention, but one will beat the other to the patent office by an hour or a day and will acquire an exclusive monopoly, while the loser's work will then be totally wasted. This type of objection is based on the error of equating the potential with the actual. The fact that a man might have been first, does not alter the fact that he wasn't. Since the issue is one of commercial rights, the loser in a case of that kind has to accept the fact that in seeking to trade with others he must face the possibility of a competitor winning the race, which is true of all types of competition." (Ayn Rand, Capitalism: The Unknown Ideal (New York: New American Library, 1967), p. 133.) But this reply will not do. Rand is suggesting that the competition to get to the patent office first is like any other kind of commercial competition. For example, suppose you and I are competing for the same job, and you happen to get hired simply because you got to the employer before I did. In that case, the fact that I might have gotten there first does not give me any rightful claim to the job. But that is because I have no right to the job in the first place. And once you get the job, your rightful claim to that job depends solely on the fact that your employer chose to hire you. In the case of patents, however, the story is supposed to be different. The basis of an inventor's claim to a patent on X is supposedly the fact that he has invented X. (Otherwise, why not offer patent rights over X to anyone who stumbles into the patent office, regardless of whether they've ever even heard of X?) Registering one's invention with the patent office is supposed to record one's right, not to create it. Hence it follows that the person who arrives at the patent office second has just as much right as the one who arrives first — and this is surely a reductio ad absurdum of the whole notion of patents. The Economic Argument