**The Relationship Between Patents on Insulin, Drug Access, and Innovation in the United States**

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Noah Rushin
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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Signature _____ Date _____
Noah Rushin

Approved _____ Date _____
Bryn Seabrook, Department of Engineering and Society

**Overview of Insulin Accessibility:**

Research indicates that 45 percent of patients in the United States go without insulin (Rappold, 2019). A large part of this trend in the United States is due to the growing cost of insulin. Data indicates that the price of insulin has tripled from January 2002 to January 2014 (Rosenfeld, 2019). This lack of accessibility has led to drug rationing, and as a result patient deaths. Additionally, 90 % of the world's insulin market is owned by three companies; Eli Lilly, Novo Nordisk, and Sanofi (T1 International, 2019). This lack of accessibility has led to people rationing insulin, and as a result has caused death in the United States. In response to this growing problem this research paper focuses on the role that patents play on the accessibility, and innovation of insulin here in the United States. The two frameworks employed in this discussion include Political Technology, and The Technological Fix. These two frameworks are used in order to analyze the role that patents play in drug accessibility and drug innovation, with regards to insulin.

**Methods Used to Explore the Connection Between Insulin and Patents:**

The main STS research question that is explored is, how do patents influence people's access to insulin as well as, promote the innovation of insulin in the United States? This question is answered through methods that include an historical case study, policy analysis, and wicked problem framing.

The historical case study focuses on how insulin pricing, and accessibility has changed throughout time. This research method gives a better understanding of insulin prices. The political analysis of current laws surrounding insulin will be addressed. This political analysis

provides an in-depth description of current U.S laws surrounding patents and insulin to be understood. The impacts of U.S. laws surrounding intellectual property in its current state will be analyzed in order to gain a better understanding of how the government has influenced insulin accessibility, and innovation. The final method includes Wicked Problem Framing. This method is used to analyze if patents are the main problem when it comes to lack of access to insulin. Wicked Problem framing ensures that the problem that this paper is looking at remains clearly defined. Wicked problem framing is a problem that cannot be clearly defined or solved. Wicked problem solutions are not clear cut or concise as in math problems. The solution to creating accessible insulin while still encouraging its innovation is the wicked problem explored in this paper.

**Background Information on Insulin and Patents**:

Insulin is a hormone made by the pancreases that allows the body to use glucose (sugar) from carbohydrates in foods that are eaten for energy or to store glucose for future use (Hess-Fisch, 2019). Additionally, insulin helps to keep blood sugar levels from getting to high or low. Insulin attaches to the cells in order to absorb sugar from the bloodstream and use the sugar for energy (Hess-Fisch, 2019). If the body does not produce enough insulin or if the cells become resistant to the effects of insulin hyperglycemia (high blood sugar), which causes complication and even death if sugar levels stay elevated for long periods of time. This complication is called diabetes. Type I diabetes corresponds to individuals whose bodies do not produce insulin (Osborn, 2019). Type II diabetes corresponds to those individuals whose cells are not sensitive to

the insulin being released by the body, and therefore are not reacting to the levels of insulin present (Osborn, 2019).

Background knowledge regarding patents is also needed for this research paper. A patent is a right granted to an inventor by the federal government that allows the inventor to exclude others from making, selling, or using the invention for a period of time (United States Patent and Trademark Office, 2015). Patents are used in the government to encourage unique and useful inventions for society. The U.S. The Patent Trademark Office approves inventions, such as the drug Insulin. Insulin is a specific type of patent called a Utility patent (United States Patent and Trademark Office, 2015). A utility patent is granted to anyone who invents or discovers a new useful process, machine, drug, etc. Utility patents hold for 20 years from the date to which the patent was applied for. When a drug is under patent protection the inventor has the exclusive right to stop others from making, using, or selling the inventors product without their permission (Monosoff, 2005).

**Background on the Political Technology and Technological Fix STS Frameworks:**

The first STS framework that is used is political technology. This framework looks at how technological systems are interwoven into politics (Winner, 1980). There are two main ways in which a technology is related to politics. The first way is that technology becomes a way of solving an issue for a particular community. The second way is where the technology is associated closely with a political relationship. This framework has been used in a wide variety of applications ranging from city planning, factory development, and farming technology (Winner, 1980). This framework looks at how politics influence the development and

implementation of the technology. The framework operates from the belief that in order to understand the impacts of technology we must look at the contexts in which these objects are placed in, especially when it comes to the policy and government surrounding the technology. Some critiques of this framework highlight that Winner's definition of politics is too broad resulting in his discussion taking into account more social, and cultural components as well (Donnelly, 1990)

The second framework in this analysis is the Technological Fix. This framework focuses on the assumption that technologies are best at solving specific well-defined problems. The technological fix framework also is used to describe the specific technologies that are used to respond to social problems (Newberry, 2020). More complex societal problems such as crime, public health, and poverty however, are harder to solve through Technological fixes. Social and systematic problems are more difficult to solve through Technological Fixes because human behavior is hard to change through technology, and goals are often not very clear (Newberry, 2020). This framework analyzes if a certain piece of technology can solve a societal problem, and if not what factors lead to the technology not being able to fully solve the problem. This framework has been used in a diverse set of applications such as when looking at the use of the desalination of water to improve the water supply in Cabo San Lucas in Baja California Sur (BCS), Mexico (McEvoy, 2014). This framework was used to see if the desalination of water would fix the problem of scarce water supply in the city, and its social implications. With this framework, an emphasis is placed on how the technology when implemented alleviates certain social problems while causing other social problems. The framework is used for its ability to

explore the social, and economic factors that can impact a technological fix and decrease its effectiveness.

**Background on the Historical Case Study, Wicked Problem Framing, and Political Analysis Methods:**

The main STS research question that is explored is, how do patents influence people's access to insulin, as well as promote the innovation of insulin in the United States? This question is answered through methods that include, an historical case study, policy analysis, and Wicked problem framing. Insulin's development, and accessibility as it has changed throughout time is the focus of this historical case study. The historical case study research method gives a better understanding of why insulin prices are what they currently are. The political analysis of current laws surrounding insulin is addressed. Analysis of these laws provide an in-depth description of current U.S laws surrounding patents and insulin to be understood. The impacts of U.S. laws surrounding intellectual property in its current state is analyzed in order to gain a better understanding of how the government has influenced insulin accessibility, and innovation. The final method is Wicked Problem Framing. This method is used to analyze if patents are the main problem when it comes to lack of access to insulin. Wicked Problem framing ensures that the problem that this paper is looking at remains clearly defined, and analyzes the root cause of insulin access in relation to insulin. These three methods will be combined to highlight the development of insulin access, innovation, and patent laws, to better understand the problem of insulin access and innovation.

**Insulin Pricing and Innovation Through the Lenses of Different STS Frameworks and Methods:**

Through the results of research the connection between has shown the development of insulin coinciding with patents, but also the decrease of consumer access to insulin as time has gone on. Evidence shows that large amounts of capital must go into producing drugs like insulin. These costs include both the cost of creating the drug, but also the amount of money the government needs from companies to approve of insulin. These governmental policies are needed to ensure that safe products are given to consumers. The policies, however, do cause the capital in order to produce and research drugs to increase, meaning that products like insulin will be more expensive. Conservative estimates for the drug range from 500 million to 1 billion of initial start up cost to gain approval for new drugs on the market (The Pharma Letter, 2018). Medical and legal professionals argue that without the patents there it would be economically infeasible for companies to invest in new drugs and solutions to certain diseases without intellectual property. The United State's Food and Drug Administration grants marketing rights for drugs like insulin for 5 years for a new small molecule and 12 years for biologics (The Pharma Letter, 2018). This grace period is given in order to encourage innovator companies to develop and seek approval for new drugs and after these years facilitate biosimilar competition (The Pharma Letter, 2018).

None of the patents on insulin are for the specific formulation for the drug. 53% of United States patents on insulin are directly correlated to delivery devices of insulin not for insulin specifically (Kaplan & Beall, 2017). As a result, the intellectual property does not bar early versions of insulin from entering the market or even the final formulation of the drug.

However, these patents that are related to insulin bar the development of competition in the insulin production industry. Competition is barred because patents give company's exclusive rights to produce a product, like insulin, in order to entice companies to innovate. However, companies extending these periods of exclusive production by patenting minute changes on products can abuse this system. Additionally, in the U.S. and globally, insulin patent manufactures indicate that a majority of the insulin in the United States is sold by brand name manufactures long after the patents expire (Kaplan & Beall, 2017). A large reason for is the large start up cost to produce and legal measures to ensure drug quality in the United States.

The historical history of insulin access, innovation, and patents also help to display the link between insulin and patents. For the past 30 years since insulin was first introduced to the market there has been numerous technological developments. Fredrick Banting and Charles Best created insulin in 1922 from purified insulin from cows and pigs for use in humans (Kowalski, 2019). They sold their patent for three dollars at the time. For the 50 years animal-derived insulin was the only one that was used. During the late 1970s the use of recombinant DNA changed the way in which insulin was used. Recombinant DNA allowed for insulin to be synthesized and more easily mass-produced. The first drug of this kind was Humlin, which was patented in 1982. The price of insulin early on was $21 for a vial in 1996 to now that same insulin being $375 for a vial (Kowalski, 2019).

Insulin is connected to U.S. politics, making insulin a political technology. Based on the information described above, Insulin has been shaped by the U.S. government policies, by impacting the way the drug is developed, sold, and distributed across the country. The rising cost of insulin has also led to political impacts, and debate. Discussions on whether there should

be a cap on the insulin have started to happen. Different states such as Illinois, Virginia, and Colorado have all placed caps on insulin to respond to its growing pricing (Williamson, 2020). Insulin has impacted politics and the social atmosphere surrounding consumers and pharmaceutical companies. More states are pushing towards improving access to insulin for their constituents in order to ensure that they are re-elected. This shift in focus of state legislatures shows that citizens are becoming more aware and engaging politically to ensure that drug products are accessible to them. In this way insulin has made the general public more politically engaged and emphasizes which set of technologies governments are regulating.

Through the Wicked problem framing the root cause of what is causing insulin to be inaccessible to many consumers in the United States and the symptoms of this are analyzed. This works with the technological fix framework to understand why insulin is not effectively reaching consumers even though its formulation has been off patent. When looking at the root cause of insulin access as it relates to patents many people question whether pharmaceutical companies are extending their patents on insulin. With each improvement on insulin there is a new patent that follows suit. These improvements result in a landscape where insulin formulation by itself is not what is being patented but rather the technology surrounding the drug. The change in the insulin market highlights that once patents end on a drug there may not necessarily be a great amount of competition or bio-similar that comes to market. Based on the wicked problem framing, drug patents are not clearly linked to lack of access on the drug insulin. Analyzing the data through a Wicked Problem framing lens emphasizes that the root of the problem may not be with the patent system itself, but other factors that limit potential competition from entering the

insulin market. Some of these barriers such as government regulation and approval make it harder for new businesses to enter the market and produce a biosimilar.

Many manufactures also point out that in order to allow for insulin access, rebates must be paid to the government. Lily argues that they also must pay discounts to payers and other supply chain entities. From this perspective the government and other organizations are hindering the technological fix of insulin curing diabetes for those in the United States. Less access to a drug makes the drug less effective at treating the general population in the United States (Eli Lilly, 2020). Using the Wicked problem framing method and the opinions of Eli Lilly, insurance companies not Lilly's patents are the root of the issue concerning insulin inaccessibility. Lilly claims that as time goes on patients are more responsible for cost sharing, and more Americans are forced to pay for their medicine without a co-pay (Lilly, 202). From this perspective wicked problem framing makes it apparent that lack of competition may not be the reasons why insulin is so inaccessible but lack of access to medicines like insulin via insurance is likely to play a role. Lilly also points out that almost half of adults in the United states have high deductible health plans forcing people to spend thousands of dollars before their coverage plan comes into effect.

Based on a hearing in the Senate for the House special Committee regarding insulin access; the role that the U.S, Legislature had on insulin, and the effect that insulin itself has on government organizations can be clearly understood. A congressional committee researched and found companies who did not invest in drugs like insulin for innovative purposes, but still chose to raise the price on these drugs (Collins & Hatch, 2018). The congressional documentation gave clear indications that many members of congress directly blame pharmaceutical companies

for the lack of access to insulin, and that even past the patent period companies are still not facing enough market completion. When using the Wicked problem framing method from the viewpoint of many in the U.S. state legislature the root cause of the inaccessibility problem lies directly on the pharmaceutical companies, that officials like Elizabeth Warren, think are overcharging for the drug.

Both the companies like Eli Lilly, and members of the state government agree that the main functions of patents to promote innovation have been realized. But through political analysis and wicked problem framing it is clear that the two entities have differing views as to what is happening to drugs like insulin in the market place after they go off patent. The government focuses more of the problem on lack of competition against pharmaceutical companies, while pharmaceutical companies are focused on high regulatory rates, and insurance companies implementing higher co-pays. From the research analysis the symptom of this problem is that insulin prices have not gone down even though the drug has been off patent for quite a long time, showing that the grace period for a patent may be being extended through means other than patent protection.

The Technological fix framework answers why Insulin is not stopping deaths in the United States when it has been on the market for over 100 years. This research focuses on patent protection that has led to innovation and improvements to insulin, as well as insight into how despite these improvements people still die yearly from diabetes. An in depth historical analysis looks into how patents have aided in the development of insulin throughout the years. After the first iteration of insulin was created in 1922 from animal extract, in the 1930's H.C. Hagedorn lengthened insulin action by adding protamine, and Scott and Fisher were able to lengthen

insulin's action by adding zinc (Quianzon & Cheikh, 2012). Due to the high amount of funding of research these drugs were patented and put on the market. On the first recombinant DNA human insulin was put on the market in 1978 Greentech and Lily were able to create and patent Humulin in 1982 (Quianzon & Cheikh, 2012). Later on in 1996 short acting insulin was developed and in 2006 Pzifer developed insulin that could be inhaled. As a result, major and clear developments in insulin production and delivery have been realized. This clear historical development of insulin shows that the current relationship between insulin and patents allows for an environment where insulin can be developed. However according to recent data 1 in 4 patients are rationing insulin in the United States (Caffrey, 2019). Additionally, insulin rationing can lead to more heart disease, more blindness, and more disability for diabetic patients rationing insulin. Furthermore, three people in 2017,and three people in 2018 died from rationing insulin (Right Care, 2019) With knowledge of the STS framework the Technological Fix if the fix for curing diabetes among the American population should be realized especially with the stark advancements in insulin described above. Innovation for insulin has clearly flourished but patients with diabetes still suffer major health risks simply because they do not have access to the drug. Through this evidence it is clear that simply having effective insulin present in the marketplace is not enough to treat the general population, and minimize the harmful effects of diabetes.

**Final Connections between Patents to Insulin Access and Innovation:**

From the research conducted it is clear that the current patent system has helped foster the innovation of insulin. Through historical case study the development of insulin was tracked.

From this data it is clear that the current U.S. Patent system provided enough capital for companies to develop and improve the drug. However through the STS frameworks of political technology and the Technological fix, as well as the Wicked Problem framing method access to insulin and patents was not so easy to correlate. After analysis it is clear that the time limit on patents for drugs is legally set up to ensure that competition is present and drug accessibility is ensured. Despite this insulin prices have continued to rise. From my research there seems to be a systematic reason for this that includes increasing cost of governmental regulation for drugs, lack of coverage for certain drugs, and high copays from insurance companies. From the research it is clear that patents play a role in the accessibility argument but other forces especially once patents on drugs have expired play a large role in decreasing accessibility. Governmental intervention such as price caps and initiatives to promote completion outside of patents in drug manufacturing business are required to solve this problem. This research tackles the larger issue of drug accessibility for drugs other than insulin.

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