Thesis Portfolio

Design of a Pembrolizumab Manufacturing Plant in Ireland Using Continuous Bioprocess Technology and Single-Use Bioreactors

(Technical Report)

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

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Fulfillment of the Requirements for the Degree
Bachelor of Science, School of Engineering

Noah Rushin
Spring, 2020

Department of Chemical Engineering

Table of Contents

Sociotechnical Synthesis

Protein therapeutics is a class of drugs where proteins are engineered in the laboratory for pharmaceutical purposes. They are an extremely effective class of drug because of their high specificity, far reaching patent protection, as well as faster clinical approval and development from the FDA. As a result, the demand for protein therapeutics is increasing over time (Creative Proteomics, 2020). The global protein therapeutic market was 140,109 dollars in 2016, and is predicted to grow to 217,591 million in 2023 (Sumant & Shaikh, 2017). Both the technical work and the STS research in this portfolio focus on two different types of protein therapeutics. The technical portion focuses on the drug Keytruda, and building a manufacturing facility to expand Merck's production of the drug. The STS research focuses on the protein therapeutic insulin, and how patent influence the innovation and access of the drug. Both the technical and STS research focuses on engineering ways to increase the production of these drugs due to their growing demand, as well as better understanding the access to and innovation of these drugs respectively. Both the technical and STS research help to better understand the science behind and social implications of protein therapeutics as they become more prevalent.

The technical portion of the research focuses on building a facility in Dublin, Ireland in order to increase the production of Keytruda. Keytruda is a type of immunotherapy that works by blocking the PD-1 pathway, preventing cancer cells from hiding. This as a result allows the immune system to detect and kill cancer cells in the body (Merck, 2020). The plant design was focused around continuous bioprocessing which has been shown to lead to greater efficiency and product quality (Kakes, 2018). In order to limit the impact to the environment the plant was also designed using single use systems throughout the plant. The benefits of this design was too decrease the environmental impacts that come with multiple use systems associated with

cleaning and sterilizing these components. A single use perfusion bioreactor was used in order to provide continuous bioprocessing upstream, while downstream multiple filters, protein A chromatography units, and diafiltration steps will be used to ensure a continuous downstream processing within each plant campaign.

The STS research focused on the protein therapeutic Insulin. The research focused on analyzing the connection to patents on insulin to the innovation and access of the drug in the United States. The STS research used the frameworks of Political Technology and the Technological fix to analyze the role that patents have played in the increasing innovation of the drug insulin and the lack of access to the drug. The political technology framework was used to analyze how U.S. laws and regulations surrounding patents influenced the development of insulin and how consumers purchase the drug. Additionally, the technological fix framework examines the economic, social, and political implications that lead to people not having access to insulin and dying of diabetes. Overall, the STS research provides a better understanding of how the U.S. patent system influences and impacts the drug insulin. The methods that were included in this research was a historical case study, political analysis, and wicked problem framing looking at past and current laws regarding patents and how that influenced insulin's development and access throughout history.

Working with both projects simultaneously has emphasized how the increasing demand for protein therapeutics, has led to a greater need to understand the social implications of these drugs. Both projects highlight how lack of access to a drug is not totally limited by the production rate of that specific drug. The political, economic, and social system in place influence how protein therapeutics like Keytruda and Insulin will be distributed in the future, and how they are developed and improved. These projects emphasized how drug pricing effects who

can receive treatment, as well as emphasizing the large amount of capital necessary to create and innovate on drugs. To ensure access to protein therapeutics companies must expand the amount of drugs produced per year, but government officials must also ensure that those in their jurisdiction who need those drugs can reasonably afford them. Working with both projects simultaneously highlighted that government regulations, including those with patents, are important to ensure and provide incentive for innovation, and must be in balance with consumer needs for access to protein therapeutics. The study of Insulin access ties in directly with Keytruda as the demand for the drug is projected to grow substantially. As a result, a similar situation leading to the lack of access to insulin in the United States could occur in the near future with drug Keytruda. As a result, better understanding the innovation and access of insulin and how that is linked to patents could help to ensure that the drug Keytruda continues to be developed and remains accessible to consumers in the future.

References:

Creative Proteomics. (2020). Protein Therapeutics Analysis. Retrieved March 15, 2020, from https://www.creative-proteomics.com/application/overview-of-protein-therapeutic-analysis.htm

Kakes, E. (2018, October 29). Continuous Processing's Benefits within Biopharma's Reach. Retrieved March 15, 2020, from https://www.genengnews.com/magazine/324/supplement-continuous-processings-benefits-within-biopharmas-reach/

Merck. (2020). HOW DOES KEYTRUDA WORK? (n.d.). Retrieved March 15, 2020, from https://www.keytruda.com/how-does-keytruda-work/?src=google&med=cpc&camp=Keytruda+Pan+Tumor_Brand_BRND_NA_ENGM_EXCT_TEXT_NA&adgrp=What+Is+Keytruda_General&kw=what+is+keytruda&utm_kxconfid=sq7irm3mh&gclid=EAIaIQobChMIob_5tZui6AIVgpOzCh1iVwHrEAAYASAAEgLAzfD_BwE&gclsrc=aw.ds

Sumant, O., & Shaikh, S. (2017, November). Protein Therapeutics Market Size, Share: Industry Analysis - 2023. Retrieved March 15, 2020, from https://www.alliedmarketresearch.com/protein-therapeutics-market