

Thesis Project Portfolio

Production of Adalimumab: A Humira® Biosimilar

(Technical Report)

**Evaluating Why Intellectual Property Cannot be *Stolen*, and Why *Violation* is a Better
Replacement Term**

(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

John Patrick Kilduff

Spring, 2022

Department of Chemical Engineering

Table of Contents

Sociotechnical Synthesis

Production of Adalimumab: A Humira® Biosimilar

Evaluating Why Intellectual Property Cannot be *Stolen*, and Why *Violation* is a Better Replacement Term

Prospectus

Sociotechnical Synthesis

Humira, a drug designed to treat arthritis, was the highest grossing pharmaceutical in 2020 at \$20.4 billion in revenue, yet it was only the 152nd most commonly prescribed product. Finding medication at an affordable price has become increasingly difficult for many citizens. In this report, I delve into the technical and ethical aspects involved in providing drugs to patients. My capstone project covers the technical process and development of Humira while my STS research focuses on the ethical dimensions of patenting drugs and determines whether intellectual property can be *stolen*. While the process of drug production and the patent system have entirely different forms and functions, they both cooperate in the vast network of delivering drugs from the manufacturer to the patient. In order for good engineering practice, I not only must have knowledge over the technical aspects of the drug production process, but also understand how the product relates to the organizational and social structures of other networks such as the patent system.

In our capstone project, we designed a process to produce a biosimilar of Humira. Biosimilars are drugs with similar structure to brand-name products, but with the same quality, safety, and efficacy standards. AbbVie, the manufacturer of Humira, can sell their product at a high price due to the patent which gives AbbVie exclusive production rights. However, AbbVie has reached settlements with six companies to allow the production of Humira biosimilars in 2023. The release of new biosimilars have the potential to increase accessibility by decreasing the price of treatment by 30% (Blackstone & Fuhr, 2013, p. 471). My group designed a process for one of these six companies that would supply product for 10% of the market share of Humira. We designed our process to operate continuously, when possible, to lower operating costs and increase time efficiency. We also selected most of our equipment to be compatible with single-use technologies in order to minimize water and cleaning chemical usage. We hope that our process

can alleviate the financial burden for patients, and do so in a way that is more efficient and less harmful to the environment.

In my STS research, I focus on the ethics of the patent system which allows Humira to be sold at a higher price. I question whether intellectual property (IP) can be *stolen* if multiple people can share possession of the IP at the same time. I argue in my research that the appropriate term to describe intellectual property is *violation* because it removes physicality from the definition and it also conveys the same essence of wrong doing. To support these results, I look at the justifications and critiques of the patent system using three philosophical frameworks: personality theory, utilitarianism, and Locke's theory. I use these frameworks to determine that information cannot be considered property and that utilitarian ethics justify the protection of intellectual property. While changing the terminology from *stealing* to *violating* may seem trivial at first, it adds clarity to the concept of intellectual property and helps paint a more consistent definition.

By focusing on both the technical aspect of biosimilar manufacturing and the social perceptions of the patent system, I have a better understanding of the drug production process as a whole. Both the technical and social networks are equally important to the drug production system. There would be no product without the technical knowledge, and the product would be poorly priced without considering the social perceptions of patents. Next year, I will be working as an engineering consultant for MPR Associates, and I believe the capstone project and STS research have prepared me well by allowing me to research meaningful solutions to unsolved problems and communicating my results in an effective manner.

I would like to thank Taylor Bloom, Susan Furlough, William Gawrylowicz, and Brandon Hudson for being fantastic team members in the development of our capstone project. I would also like to thank Professor Eric Anderson for advising our group in weekly meetings, as well as

Professors Giorgio Carta, Michael King, George Prpich, and Ron Unnerstall for being available to consult with questions on our project. Finally, I'd like to thank Professor Kay Neeley for her guidance and feedback on the STS research.