Design of an Amgen Trastuzumab Manufacturing Facility to Continuously Produce Kanjinti, a HER2+ Breast Cancer Treatment Biosimilar
(Technical Report)

An Actor-Network Theory Analysis of the Threat of Evergreening to the U.S. Trastuzumab Biosimilar Market
(STS Research Paper)

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Table of Contents

Socio-Technical Synthesis

My technical project and STS project addressed aspects of the socio-technical problem of limited monoclonal antibody (mAb) drug accessibility due to the high cost for patients. In what follows, I will describe each project and explain the benefit of considering them together rather than as isolated fixes. My technical project aimed to decrease the manufacturing costs of trastuzumab, a mAb breast-cancer treatment, brand named Herceptin and made by Genentech. My project was from the perspective of Amgen, a biopharmaceutical company that produces the Herceptin biosimilar Kanjinti. My STS project analyzed how evergreening is threatening the US trastuzumab biosimilar network, which was created to allow competitive pricing of biologics. Evergreening allows the original manufacturer to maintain high prices, despite advances in technology lowering their costs. Both projects addressed aspects of drug cost, and both aimed to help patients receive lifesaving medicines.

My technical project involved designing a manufacturing facility in the United States to continuously produce Kanjinti with minimized operating costs. My group designed the entire manufacturing process starting with CHO cells and ending with purified protein product. The process is split into upstream and downstream manufacturing. Upstream is responsible for growing cells and forcing them into fermentation to produce the mAb product. My group used the latest continuous manufacturing technologies to have lower costs than traditional batch manufacturing. We focused design around a perfusion bioreactor to increase product yield and reduce contamination risk. Downstream is responsible for purifying the fermentation broth from upstream into the protein product. This involved many filtration and chromatography steps to assure the product is safe for patients and aligns with strict FDA regulations.

My STS project analyzed the US trastuzumab biosimilar market network. I used Michael Callon's Actor-Network Theory (ANT) to show evergreening threatens to destabilize the network, which is responsible for competitive pricing of mAb drugs. Evergreening is a method biopharmaceutical companies use to extend the life of their drug's patent, which prevents other companies from selling their own biosimilar versions of the drug. ANT examines complex relationships between both human and nonhuman actors that come together to create a dynamic network. ANT was useful in this analysis because the US biosimilar market network is constantly changing and has many interconnected actors. Recognizing evergreening as a rogue actor in the network showed the complex nature of biologic drug pricing. Evergreening in the US biologic market must be understood to fully address limited drug accessibility due to high prices.

By working on both projects simultaneously, I realized that improved technology and processes alone cannot fix the real problem of limited drug accessibility. Without competitive pricing, the only incentive for biopharmaceutical companies to lower their drug prices is purely altruistic. Even with lowered manufacturing costs, a company can continue to charge a high price. Competitive pricing forces manufacturers to lower their prices or risk losing their customers. Although Genentech's patent for trastuzumab has expired and other biosimilars are on the US market, Genentech evergreening will destabilize existing progress in accessibility that has occurred from biosimilars, such as Kanjinti. The biosimilar market will close, and Genentech will be able to charge whatever price they want. It is important to continuously improve the manufacturing process to decrease the base price biopharmaceutical companies charge, but my STS project has shown me that unless there is competitive pricing from the biosimilar market, companies can continue to charge any price. Drug prices will stay high, and patients will continue to struggle to afford the medicines they need.