

Thesis Portfolio

**Design of a Monoclonal Antibody Manufacturing Facility in the United States to
Continuously Produce Trastuzumab, a HER2+ Breast Cancer Treatment**
(Technical Report)

**Analyzing Accessibility Issues to Monoclonal Antibody Treatments in the United States
using Actor Network Theory**
(STS Research Paper)

An Undergraduate Thesis

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Bachelor of Science, School of Engineering

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Sociotechnical Synthesis

Breast cancer is a disease that has detrimental impacts on the patients, friends, and families affected. In addition to the emotional and physical hardships associated with breast cancer diagnoses, there are severe financial burdens that the patients face. Depending on a patient's social and economic background, treatment accessibility can be an overwhelming concern. To address this issue, we will be designing a pharmaceutical manufacturing facility to continuously produce trastuzumab (biosimilar of Herceptin), a monoclonal antibody (mAb) treatment for HER2+ breast cancer. We will design the complete upstream and downstream processes, from mammalian cell culturing through final filtration, to produce purified mAb product. By incorporating perfusion bioreactors into the upstream design, this portion of the process will become continuous and make the overall production more efficient and timelier. In the technical portion of this thesis, I will outline the technical process and motivation for designing a biopharmaceutical manufacturing facility to continuously produce trastuzumab.

While optimizing the drug manufacturing process helps reduce production costs and increases revenue for the pharmaceutical company, this does not necessarily reduce costs to the patients. Patent protection prevents competing pharmaceutical companies from producing a generic version of the drug which drives up prices for the name-brand product. In order to lower HER2+ breast cancer treatment costs to patients of all backgrounds, I will be investigating the technical and social aspects of the drug's pricing. There are a number of different actors and non-human actants that contribute to this complex network. In the STS portion of this thesis, I will use actor-network theory to analyze biologics patent policy and political factors that contribute to the accessibility issues associated with mAb treatments.