Thesis Project Portfolio

Design of an mRNA Vaccine Manufacturing Platform to Target *M. Tuberculosis*

(Technical Report)

Analyzing the Effect of Patents on Innovation and Drug Accessibility Within the Pharmaceutical Industry: A Case Study on Bedaquiline

(STS Research Paper)

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Sociotechnical Synthesis

mRNA Vaccine Manufacturing and Pharmaceutical Patent Equity

The development of mRNA vaccine technology and the pharmaceutical patent systems highlights the crucial balance between healthcare innovation and accessibility to life-saving treatments. My technical capstone, which involves designing an mRNA tuberculosis vaccine production facility, and an STS analysis of Johnson & Johnson's (J&J's) patent strategies for bedaquiline, highlight the importance of balancing technical efficiency in medical innovation with equitable access to life-saving therapies. These projects illustrate that engineering solutions carry ethical responsibilities influenced by past policy failures, necessitating the integration of technical design with an awareness of sociopolitical factors.

My technical capstone addresses the resurgence of tuberculosis as the leading infectious disease killer by designing a modular mRNA production facility aimed at increasing vaccine availability. The facility is designed to produce 10 million annual doses at a capital cost of $3.8 million, with the aim of providing approximately 75% of doses at low costs to low- and middle-income countries (LMICs), while the remaining doses will be sold to U.S. healthcare workers and international travelers. The facility encapsulates the produced mRNA in lipid nanoparticles (LNPs) to allow for efficient delivery to the cell. Key innovations include a confined impinging jet mixer (CIJM) for LNP encapsulation and an in-vitro transcription (IVT) reactor for mRNA production, both of which are highly specific to mRNA manufacturing. However, this technical solution exists within a pharmaceutical landscape where patent systems, as demonstrated in the STS analysis, often prioritize corporate profits over patient access.

This tension requires a detailed examination of how engineering decisions are influenced by and interact with existing legal and economic frameworks. While mRNA technology enables

rapid response to global health crises, patent strategies like J&J's "evergreening" strategy for bedaquiline display how innovation incentives can become access barriers. The technical capstone's transparent cost structure, with an estimated cost of $0.50 per dose, responds to such abuses by directly disclosing manufacturing costs, which reduces the ability to perpetuate cost narratives to justify inflated prices, much like J&J did.

My STS research paper analyzes how J&J extended bedaquiline's market exclusivity through patent evergreening, delaying generic production until 2023 in high-TB-burden countries. Using Actor-Network Theory, the study reveals hybrid agencies between human actors (corporate executives) and non-human actants (Hatch-Waxman Act provisions, salt formulation patents). This framework exposes how J&J's tiered pricing ($30,000 vs. $67 per month) interacted with WHO prequalification requirements to exclude LMICs, despite public-private partnerships with TB Alliance. The analysis reveals three systemic flaws: (1) secondary patents enabling 17-year monopolies, (2) R&D cost narratives obscuring public sector contributions, and (3) stakeholder incentives prioritizing shareholders over patients.

When considered together, these projects show that vaccine manufacturing systems operate as sociotechnical compromises, balancing technical innovation with policy and ethical considerations. Through the alignment of technical features like modular design and high-throughput capability with policy reforms like price restrictions on patented therapies, this synthesis models how engineering can advance both innovation and equity. Future work must expand such hybrid solutions, ensuring medical breakthroughs remain protected as public goods rather than corporate commodities.