Consortium on Law and Values in Health, Environment & the Life Sciences
Award Report for the 2016-17 Academic Year

"Bitter pill? Patent regimes, imitation,
and innovation in the Indian pharmaceutical industry"

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Project Summary

Internationally, legal and policy trends promote expansion of patent rights as *the* mechanism to foster innovation in the pharmaceutical industry. Patent rights grant the "innovator company" monopoly over production of a drug for a limited time, and power to fix its price, while barring generic versions during such period. However, universalization of this regime skewed in favor of 'Big Pharma', has been contested in and by India. Indian pharmaceutical companies are among the world's leading producers and exporters of generic drugs, and over the last two decades have provided cheaper substitutes for many prohibitively expensive products of the multinational pharmaceutical industry. This ability to address economically and geographically uneven pharmaceutical markets was achieved on the back of a patent law regime explicitly formulated by the post-colonial Indian state to develop the capabilities of a nascent industry and serve a national consumer base with low purchasing power. The Patents Act 1970 allowed patent protection to drug manufacturing processes, but not to drug molecules. Thus a molecule even if patented elsewhere, could be reverse-engineered and produced in India. This distinction between process and product patents powered the growth of India's pharmaceutical industry, enabling it to develop a critical knowledge and technological base in the "imitative" skill of manufacturing generics.

However, this foundation of the industry has come under strain with the operationalization of the Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS) in India in 2005. Seeking to harmonize geographically differentiated intellectual property (IP) regimes, TRIPS mandates both process *and* product patents, and guarantees legal monopoly over the production of the patented subject matter for twenty years, thereby rendering generics manufacturing impossible until a patent expires. Given that patent law seeks to regulate life itself through its shaping of drug pricing and pharmaceutical access, there are urgent ethical and policy reasons to investigate the impact of TRIPS-mandated changes on generics manufacturing in India, as well as the legal battles being fought in the country that offer ways to articulate alternative relationships between law, health, and science policy.

In order to examine the above issues, I ask the following questions:

1. How has the introduction of product patents impacted the production of generics manufacturing by Indian pharmaceutical companies, and what strategies have such companies adopted to navigate the post-TRIPS terrain?
2. How has law defined and understood patentable pharmaceutical innovation under the amended patent law in India? What relationships between law, health and science have been articulated in and through these legal battles?
3. What are the emergent shifts in drug innovation and production globally, and where do Indian companies lie in this landscape?

Results

The Consortium grant helped support fieldwork for my PhD dissertation. In particular, I was able to travel to Delhi, Bombay, Bangalore, Chennai and Himachal Pradesh to interview persons who have worked in the pharmaceutical industry, as well as patent law specialists and researchers. The interviews with pharmaceutical industry insiders proved challenging: many were unwilling to talk, and those who agreed to interviews often gave generic responses. However, I was able to speak with people who had recently retired from the industry, who were relatively more willing to expand on thoughts and questions.

Over the course of the last year, I have been able to attend some key conferences and workshops on intellectual property as well as public health, which provide the broader framework for my research questions. I have also collated a range of documents like newspaper reports, policy/consultancy/industrial reports, and case laws pertinent for my research. Listed below are some of my outcomes over the past year:

Presentations ***(planned or completed)***

1. Bitter pill? Scattered thoughts on law, development and intellectual property in the pharmaceutical industry, Young Scholar Series, Ambedkar University Delhi, March 2017
2. Multiple presentations, The Politics of Health: Towards Sustainable and Empowering Health Care (Workshop), Sambhaavnaa Institute, Himachal Pradesh, March 2018
3. A tale of two cases: intellectual property battles and the jurisprudence of access to knowledge in India (Tentative title, Accepted for the South Asia Conference, Madison, October 2018)

Grant proposals (planned or submitted)

1. Recipient, Mark & Judy Yudof Fellowship, 2018-19
2. Mellon ACLS Dissertation Completion Fellowship, 2019-20 (planned)

Future project plans

Based on the fieldwork I have conducted over the past year, I am currently writing a paper which I will present at the upcoming South Asia Conference, Madison, but which will also form the basis for a chapter in my dissertation. I plan to apply for the Mellon ACLS Dissertation Completion Fellowship, 2019-20 this fall and (other writing fellowships) so that I am able to defend by the end of Spring 2020.