Consortium on Law and Values in Health, Environment & the Life Sciences
2016-17 Student Proposal Cover Page

Applicant Information				
Applicant name(s):	Anindita Chatterjee		Email:	chatt051@umn.edu
Project title:	Bitter pill? Patent regimes, imitation, and innovation in the Indian pharmaceutical industry			
Department:	Geography, environment and society	College:	College of Liberal Arts	
Degree program:	PhD	Faculty advisor name & email:	Vinay Gidwani gidwa002@umn.edu	☐ NA
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☐ Consortium e-mail ☐ Graduate & Professional Student Update ☐ The Brief ☐ Advisor ☒ Dept. email/newsletter
☐ Consortium website ☐ Other

Funding

Total amount of funding requested: **$**

Executive summary (maximum 200 words)

India's significance in global pharmaceuticals stems from its historical role in articulating rules and precedents vis-à-vis pharmaceutical access, drug pricing, and patent law that challenged the hegemonic model skewed in favor of 'Big Pharma'. With the explicit aim of developing a nascent industry and serving a low-income national market, the post-colonial Indian state formulated a patent regime that protected drug manufacturing processes, but not drug molecules (i.e. the product), thereby allowing patented drug molecules to be reverse-engineered in India. This distinction between process and product patents powered the growth of the domestic industry, eventually making it the "economic backbone" of an ethically charged global access to medicines campaign, and also served as a policy model for developing economies. However, this foundation of the industry has come under strain with the operationalization of TRIPS mandated changes in India's patent law, which renders generics manufacturing theoretically impossible till a patent expires. This constitutes the starting point for my research. I examine the changing nature and role of patent law in the Indian pharmaceutical industry, their consequences, as well as resistance to these changes in patent law. I also situate these changes within the context of other emergent shifts in pharmaceuticals and analyze the coproduction and complex entanglements of legal, economic and scientific processes within the industry.

Approvals

Check all appropriate approvals required for your proposal. It is not necessary to have all approvals at the time of proposal submission; however, approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

IRB ☒ Yes ☐ No ☐ NA ☐ Application pending

Other ☐ Yes ☐ No ☐ NA ☐ Application pending Specify:

Checklist—for reviewer use

☒	The proposal is 1000 words or less excluding budget, biographies, references and citations.
☒	The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.
☒	The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.
☒	The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.
☒	The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check NA.
☒	All necessary approvals are pending or received.

Anindita Chatterjee
Consortium on Law and Values in Health, Environment & the Life Sciences

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

Background and importance

As the world's leading producer and exporter of generic drugs, the monetary value of the Indian pharmaceutical industry is substantial. Yet India's significance in global pharmaceuticals extends beyond such monetary value, and stems from its historical role in articulating rules and precedents vis-à-vis pharmaceutical access, drug pricing, and patent law that challenged the hegemonic model skewed in favor of 'Big Pharma'. With the explicit aim of developing a nascent industry and serving a low-income national market, the post-colonial Indian state formulated a patent regime that protected drug manufacturing processes, but not drug molecules (i.e. the product) (Ayyangar Report 1959). Under the Patents Act 1970 a molecule even if patented elsewhere, could be reverse-engineered and produced in India. This distinction between process and product patents not only powered the growth of the domestic industry, enabling it to develop a critical knowledge and technological base in the 'imitative' skill of manufacturing generics, but also served as a policy model for other developing economies (Chaudhuri 2005; Horner 2013).

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. TRIPS mandates both process *and* product patents, and guarantees legal monopoly over the patented subject matter for twenty years (which *de facto* includes the power to fix its price), thereby rendering the manufacturing of generics theoretically impossible till a patent expires. This attempt to forge a singular global IP script that benefits multinational pharmaceutical companies has been legally and judicially resisted in India. India therefore is an ideal site to analyze the changing nature and role of patent law in the industry and their consequences, while situating them within the context of other emergent shifts in the pharmaceutical domain.

Statement of problem

TRIPS has been widely criticized for attempting to freeze and perpetuate 'core-periphery' relations through the control of knowledge and technology transfers to the Third World (Braga 1990; Shiva 2007). Yet this linear narrative is unable to explain multiple and complex interactions, sometimes antagonistic and sometimes synergistic, between contingently situated actors and processes (Sunder Rajan 2006). Thus on the one hand Indian pharmaceutical companies and civil society organizations have mobilized the post-TRIPS law to challenge product patents of multinational companies, and have in the process argued to (re)define "public health" as well as what deserves commercial protection as "pharmaceutical innovation". On the other hand, the convergence of the ethical and the economic that made Indian companies the "economic backbone" (Roemer-Mahler 2013) of the HIV/AIDS campaign in the early 2000s by guaranteeing low cost alternatives to prohibitively expensive antiretrovirals produced by the multinational industry appears to be over. My preliminary research suggests that many Indian companies are looking to move up the pharmaceutical value chain through the discovery and development of new drugs- an activity with exponentially higher profit margins than generics manufacturing but requiring a 'strong' patent regime that guarantees product protection. Organizational changes in the industry through mergers, acquisitions, and research partnerships are also likely to have blurred the line between 'Big' and 'alternative' pharma. Further, scientific changes (shift away from the 'blockbuster drug' model, increasing

significance of biopharmaceuticals) are currently reorienting the geographies of innovation, production and value in the industry. My research aims to study the "coproduction" (Jasanoff 1995) and complex entanglements of these legal, economic, and scientific processes in the pharmaceutical domain.

Research questions

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 their ability to serve economically and geographically differentiated pharmaceutical markets? 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 (Section 3d of the Patents Act)? What relationships between law, health and science have been articulated in and through these legal battles?
3. What are the emergent scientific shifts in processes of drug innovation and production globally, and where do Indian companies lie in this landscape?

Methodology and work plan

A grant from the Consortium would support three months of fieldwork towards my dissertation in India from June-August 2017. My research will use semi-structured interviews with industry insiders, drug research and development specialists, pharmaceutical patent law specialists, health activists and public commentators, to examine the above questions. I will also study policy documents and industry reports to gather statistical data on industrial trends, and attend relevant conferences as an observer to understand key challenges, achievements, and priorities as articulated by professionals. Finally, I will analyze select cases filed under the post-TRIPS Indian Patents Act to mine the legal arguments made, and understand the imbrication of law and scientific knowledge in the determination of patent-worthy pharmaceutical innovation. Apart from comprising a chapter of my doctoral dissertation, I anticipate this research resulting in a journal article.

I will be based in Delhi where some of the biggest IP law firms and practitioners, and health activist organizations are located, and which sees frequent conferences on IP, health and the pharmaceutical industry. I will also travel to Hyderabad and Mumbai, which house some of the largest Indian pharmaceutical companies. I will use my prior contacts (particularly among the legal community in Delhi and elsewhere) to facilitate my research.

Contribution

My research will contribute knowledge useful to several fields and is by nature interdisciplinary. First, my research contributes an empirical foothold to interrogate and assess the complex consequences of TRIPS, widely considered a historic departure in global control of knowledge. Second, my research traces the increasingly significant "global institutional ecology of pharmaceuticals" produced by emergent international and national regulation and law (Petryna and Kleinman 2006). Third, by foregrounding the changing nature and function of patent law within the pharmaceutical industry, I address the curious absence of systemic reflection on the role of law in economic restructuring and (re)regulation within literature on state theory and globalization (Barkan 2011). Finally, it will be useful to legal and policy practitioners interested in understanding the complex relationship between law, health and science.

References

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Biography

Anindita Chatterjee is a graduate student in the Department of Geography, Environment and Society at the University of Minnesota. She grew up in Delhi, India and holds a Bachelor's degree in law and socio-legal studies. After graduating from law school she worked with a not-for-profit organization, Samavesh- Society for Development and Governance, for two years. She was an Associate in the Education Program which addresses various aspects of elementary education in government schools in inner city and rural districts of Madhya Pradesh, India. She then went on to pursue an M.A. in Development Studies from Ambedkar University, Delhi. Her Master's thesis explored and analysed experiences of labour market participation and migration among security guards in the city in order to understand the nature and dynamics of the 'informal economy' as well as of identity in the labour market. This eclectic background finally led her to geography, a discipline whose boundaries are attractively fluid and which allows a lot of space for interdisciplinary work. Anindita received an Interdisciplinary Centre for the study of Global Change (ICGC) fellowship in 2012. She is currently pursuing her PhD which brings together her interests and training in law and geography.

Consortium on Law and Values in Health, Environment the Life Sciences
Proposed Budget

Project Title:

	Provide justification along with costs.		**Requested funding**	**Matching/other funding** *Provide this information is you have other funding sources for this project.*	
	Category& instructions	**Justification**	**Amount**	**Amount**	**Source**
1	Your stipend *Maximum of $5,000*	*200 hours at $18.38/hour (current graduate assistant rate in the Geography department)*	$3,676		
2	Speaker honoraria (for colloquia)	___ speakers x $ _____ honorarium	$0		
3	Supplies & Services *Identify and explain use here or in the body of your proposal.*	*Cellular phone service ($120 for 3 months)*		$120	Savings
4	Equipment *Identify and explain use. Allowable only if the equipment is necessary for this project. All equipment must be given to your dept. at the completion of your project.*		$0		
5	Travel *Indicate the purpose of the travel, estimated dates of travel, transportation, housing and allowable per diem costs (see travel.umn.edu).*	Flight tickets: MSP-DEL (one way) $900 DELHI-BOMBAY round trip $100; DELHI-HYDERABAD round trip $120; intracity travel $150 at $50/month for 3 months; Housing in Delhi $350/month for 3 months; Accomodation for 1 week each in Bombay and Hyderabad ($100/day for 14 days)	$2,820	$900	Savings
		The precise dates of the Bombay and Hyderabad trips will be planned after contacting the interviewees once I am in India. Ticket prices are estimated from Expedia, with small allowance for variability. Rent and accomodation rates are based on my experience of living in Indian cities. Both are less than housing and per diem costs listed at travel/umn.edu	**$2,820**	**$1,020**	
	TOTAL BUDGET		$6,496	$1,020	