structures of global pharmaceutical political economy. What interests me is precisely the fact that in the same place (India), at the same time (the 2000s), in the same industrial sector (concerning pharmaceuticals and health), one can have such different trajectories of political contestation, which intersect and interact with globally hegemonic movements in political economy.

This is the empirical conundrum that allows me to enter into a further discussion of how I conceptualize the emergent phenomenon of pharmocracy. This is a complex phenomenon, operating across scales, locales, histories, and events. I do not wish to present a simplified picture of this phenomenon for the sake of analytical clarity; but I also do not want to allude to the massive complexity of this phenomenon without a concerted attempt to unpack it.[13] This will necessarily be partial, following certain threads that I feel are significant, and focusing largely on Indian events and circumstances. But through a multiplicity of such partial perspectives, juxtaposed and set in historical, geographical, epistemic, and sectoral relationship to one another, I hope to generate elements of a broader and more comprehensive structural elucidation of contemporary biomedicine, contemporary capital, contemporary globalization, and contemporary Indian politics.

I enter into an empirically grounded analysis of pharmocracy through the case: significant events in India that have structured terrains of global biomedicine even as they highlight elements of that terrain. The two cases that are central to this book concern clinical studies of vaccines against human papilloma virus (HPV) infection conducted in the Indian states of Andhra Pradesh and Gujarat (the focus of chapter 2), and patent disputes in India around an anticancer drug, Gleevec, developed by the Swiss pharmaceutical company Novartis for the treatment of chronic myelogenous leukemia (the focus of chapter 3). Alongside that, I unpack the critical concepts of value, politics, and knowledge, to show how complex and multifaceted each one is. I next elaborate these two parallel routes through which I elucidate elements of pharmocracy as they have materialized in contemporary India.

Elements of Pharmocracy (1): A Tale of Two Trials

The year 2005 saw the coincidence of critical pieces of legislation being passed in India in the domains of clinical trials and intellectual property rights respectively. These changes must be located within larger trajectories and contexts of global harmonization/hegemony that facilitate capital flows. How does one think of the relationship between these *longue durée* institutional reconfigurations and the particularity of a legislative event? Or more

simply: how might we see structures of pharmocracy through the lens of these esoteric and coincidental regulatory moments?

One way I do so is by focusing on two significant events that played out over a longer time horizon (months and years) rather than a single moment of policy formulation. The first event concerns a scandal that erupted consequent to the death in 2010 of seven teenage girls who had been enrolled in a clinical study of vaccines against HPV, developed by the American multinational company Merck (whose vaccine was called Gardasil) and the British multinational GlaxoSmithKline (which developed a comparable counterpart, Cervarix). The second concerns the Indian Patent Office's denial in 2005 of a patent on the anticancer drug Gleevec, developed by the Swiss multinational pharmaceutical company Novartis, and the long judicial appeals and judgments that followed in Indian courts.[14] The former case exemplifies the politicization of clinical trials in India through public scandal, while the latter exemplifies the judicialized politicization of intellectual property rights and issues concerning access to essential medicines.

The scandal of the deaths of seven girls in the HPV studies unfolded as follows. The new vaccines were considered revolutionary advances in the prevention of cervical cancer, for which HPV is a primary causal agent.[15] Phase 3 clinical trials for these vaccines had already been conducted (though never in India), so these were not studies to demonstrate the safety and efficacy of the vaccines. Rather, they were demonstration studies being conducted by the Seattle-based Program for Appropriate Technology in Health (PATH), a global health nonprofit whose major donor is the Bill and Melinda Gates Foundation, in collaboration with the Indian Council of Medical Research (ICMR), which is the apex public body for the formulation, coordination, and regulation of biomedical research in India. The purpose of the studies was to consider inclusion of these vaccines in India's national immunization program. It could not eventually be established that the girls had died because of the vaccines, but the controversy that arose subsequent to the deaths provided an impetus for civil society mobilization against unethical clinical trials in India.

The second case I discuss relates to Gleevec, a revolutionary treatment for chronic myeloid leukemia. It directly targets the protein *bcr-abl*, known to cause the cancer. Therefore it provides a more targeted, less dangerous therapy than the possibilities that had existed earlier (either treatment with interferon or bone marrow transplantation). In this regard, Gleevec provides one of the earliest examples of rational anticancer therapy that directly addresses the cause of the disease and not just the symptoms of out-of-control cell

division.[16] The basis of the Gleevec patent denial in India was a public health flexibility incorporated into the amended, WTO-compliant 2005 Patent Act, which prevented what is known as pharmaceutical evergreening. Evergreening is a common practice in the United States and Europe, whereby a patent holder on a drug modifies it slightly as it approaches the end of its patent term and claims a new twenty-year product patent for the new drug that is thus produced. The Indian legislation by contrast included a provision under Section 3(d) that prevented a patent on a modification of an already known substance unless it conferred significantly enhanced efficacy on the prior molecule. The core molecule that would subsequently be developed by Novartis, imatinib, was patented in the United States and Canada in 1993. A crystalline salt isoform of this molecule, β-imatinib mesylate, was the subsequent marketed iteration of this molecule for which patent protection was being sought in India. It was determined that this was not a new molecule, simply a modification of an existing patented molecule, which came under the purview of the 1970 Act since it had already been patented prior to 1995 and hence was not eligible for a product patent. Novartis disputed this denial by embarking upon a seven-year legal battle, first in the Madras High Court (2006–2007) and then in the Indian Supreme Court (2009–2013). It lost both cases and the denial of the Gleevec patent stands in India.

What was at stake in the legal adjudication of the Gleevec patent was not just the patentability of a single drug, but the very question of how the new Indian patent legislation would be interpreted, especially as intellectual property rights had to be balanced against considerations of public health. The 2005 Act came to be rendered an interpretive matter, even as the politics of intellectual property and access to essential medicines came to be judicialized. Indeed, subsequent to Gleevec becoming a subject of legal contestation, a slew of drugs have had their patent status questioned in India through judicial and quasi-judicial appellate procedures. The law has provided a terrain by which intellectual property rights have become politically contestable. Meanwhile, following the HPV vaccine controversy, the capacity building for global clinical trials that had been envisaged in the 2005 Schedule Y amendments has come to be mired in controversy and scandal, as further cases of possibly unethical clinical studies have come to light and the general absence of adequate regulation of experimentation on human subjects has been questioned. This controversy has become a nodal point around which the conduct of clinical trials in India more generally has come to be politicized, largely through the register of public scandal. At the same time, the gendered dimensions of biomedical intervention came to be especially evident

through this case, as connections were explicated between emergent regimes of clinical research and longer histories of reproductive politics.[17]

Just as the ways in which the two cases have become politically contested have been different, so too has the configuration of actors involved in each.[18] The Gleevec case saw Novartis pitted against a host of Indian pharmaceutical companies that had started manufacturing generic versions of the drug; the patient group Cancer Patients Aid Association (CPAA), which was involved in procuring generic medication and subsidizing its availability to poor cancer patients; an Indian legal advocacy group, Lawyers Collective, which represented CPAA throughout the legal trajectory of Gleevec; and the Access to Medicines and Treatment Campaign of Médicins sans Frontières (MSF), which had been established with Nobel Peace Prize money in 1999 and emerged as a major global advocate for affordable medication. These legal actors were joined by other civil society actors, especially HIV-AIDS groups in India and global civil society groups involved in battles around access to knowledge and access to medicines, in the terrain of popular and policy advocacy around Gleevec.

Meanwhile, mobilization against the HPV vaccine studies was initially orchestrated by feminist groups, including the All India Democratic Women's Association, which is affiliated with the Communist Party of India (Marxist), and Sama, an advocacy group for women and health based in Delhi. They joined together with medical ethicists, people's health movements, and advocates concerned with the proper regulation of scientific and medical activities in India. It was less clear in this case who the adversaries were: even though the vaccines in question belonged to Merck and GlaxoSmithKline, their responsibility for the studies seemed to have been outsourced along with the vaccine itself. Questions were asked of PATH, which was notably absent in answering any of them. Much of the immediate ire therefore ended up being directed at the Indian state, specifically the ICMR. If the Gleevec case targeted the multinational corporation as the hegemonic global capitalist adversary, the HPV case showed how difficult identifying such an adversary could be in situations where global capital flowed through dispersed and multiply outsourced brokerage economies operating under the sign of public-private partnerships.

I elaborate upon the controversy surrounding the HPV studies in chapter 2 and upon the Gleevec case in chapter 3. These speak to two distinct meanings of *trial*, one biomedical and the other legal. The first is concerned with movements of pharmaceutical clinical trials and concomitant politics consequent to their progressive privatization and globalization, while the second refers

to the judicialization of pharmaceutical politics, which describes the playing out of politics of access to essential medicines in the courts (see Biehl and Petryna 2011).[19] I situate these in relation to a third, everyday use of *trial* to describe any kind of problem, difficulty, or trouble, in the sense of the structure of constitutive crisis under which both the Euro-American R&D-driven pharmaceutical industry and the Indian generic industry operate. Taken together, the HPV and Gleevec cases become emblematic of and signify a broader political terrain in their own right, and are therefore events that function beyond themselves.[20] They demand conceptualization that goes beyond just pointing to the contingency of their own happening, and allow for a thicker insight into the structural trajectories informing the legislative moment of 2005 while also signifying this moment as a site for the theorization of value, politics, and knowledge. But what do these terms mean, and what are these structural trajectories? I next discuss how I analyze value, politics, and knowledge in this book. This involves disaggregating them into multiple registers through which they operate, and thinking about the articulations and contradictions between these registers.

Elements of Pharmocracy (2): Theorizing Value, Politics, and Knowledge

This book traces the hegemonic structures and operations of pharmocracy. One of the nuances of Gramsci's notion of hegemony is that while it refers to a state of (naturalized or legitimated) domination, it is fluid. Hegemonies can be established, contested, overturned, or reconfigured. Battles over hegemony constitute politics, while politics comes to be the means of establishing hegemony. I argue that the establishment of regimes of value becomes a means through which hegemonies can be naturalized or reconfigured, such that value itself becomes the ground upon which further politics plays out. Value and politics become mutually constituting and reinforcing. Further, questions of knowledge often come to be at stake or mediate various articulations of value and politics. Yet none of value, politics, or knowledge is a singular thing, and each requires disaggregation and conceptualization in its own right.

Certain elements of value, politics, and knowledge have emerged as constitutive to contemporary global biomedical economies as they have materialized in India. I consider value in four registers: as an abstraction that has material consequences; as surplus value for capital; in terms of norms and ethics; and as an antinomy, something that is in contradictory relationship