India and the Patent Wars

Pharmaceuticals in the New Intellectual Property Regime

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INTRODUCTION

We live in a world where more and more ideas and experiences are becoming forms of property. Intellectual property laws have expanded throughout the globe, and a broad range of creations and realms of human experience have been cordoned off, with legal fences being put around the sharing of innovations and cultural practices. Yoga routines, genetically engineered mice, French gastronomy, and the cultural practices of Afro-Brazilians have all been subject to ownership claims under a new global regime of intellectual property protections. We are also seeing extensions of laws that protect more familiar forms of intellectual property. Copyright laws now keep vast collections of film and literature out of the public realm, while new patent laws make it harder both to share medical knowledge and to produce generic versions of medicines. United States court decisions, multinational corporations, and the World Trade Organization (WTO) are major contributors to this new regime in which knowledge that was once considered part of the public domain has become the property of individuals, corporations, and communities.[1] At the

same time, counterefforts such as the Access to Knowledge movement, Creative Commons licensing, and Doctors Without Borders' Access to Essential Medicines program struggle to keep artistic creations, medications, and scientific knowledge in the public realm.[2]

In this new property regime that spans the globe from Indonesia to Brazil to the United States, India has been the site of some of the most fraught battles over the ownership of pharmaceutical knowledge. A center of medical knowledge for centuries, India is home to several non-Western medical systems that are taught in colleges and practiced in hospitals, and the country provides many of the world's Western, biomedical drugs through its growing pharmaceutical sector.

Over the last ten years, as I spoke to people in the United States about the research I had been doing on controversies over patents in India, some would make comments about Indian companies "stealing" products from US companies or "violating" patents by producing "copies" of medications that were patented elsewhere. What most people who knew a little about this controversy did not know was that nothing illegal was going on. Before the WTO implemented its global patent rules, each country created its own patent laws tailored to its own priorities and concerns. India's pre-WTO patent law had a provision stating that, for medications, *only the process for making the medication, but not the medical product itself, could be patented.* Thus, different companies could make the same medicine if they could find a different way to manufacture the drug, and, until recently, Indian companies were free to create their own versions of drugs that were patented elsewhere, whether antidepressants, treatments for AIDS, medications for erectile dysfunction, or the various statins, such as Pfizer's Lipitor, that have been making huge profits for multinational drug companies.

The Indian government included this special product patent exception back in 1970 because it wanted to avoid monopoly control of medicines. Medications, because they could save a life or cure a disease, were not like other kinds of inventions in the minds of Indian lawmakers. In the United States, on the other hand, medicines have long been protected by product patents, and laws have conformed more closely to the interests of pharmaceutical corporations, allowing what some critics today consider to be frivolous patents on slight modifications of drugs, known as "me-too" drugs, that offer no increase in efficacy. Over the course of the 1990s and

2000s, the WTO required member nations to change their laws and conform to a single, United States–style intellectual property regime. In other words, India had to make its patent laws more like those of the United States because of the WTO's mandate. The deadline India and other developing countries were given was 2005, and India met this requirement when it passed its 2005 Patents (Amendment) Act.

One employee of a multinational pharmaceutical corporation whom I spoke to about this topic displayed the usual disdain for Indian companies "stealing" other companies' ideas. National autonomy did not matter. India's earlier law with its product patent exception was simply wrong in the view of this employee. If an Indian company made the same drug this person's company patented, it should be illegal, and the 2005 law made it so. It was only later that I learned that the company this person worked for was one of several that produced products based on knowledge from India's ayurvedic medical system for which no royalties or other compensation were ever paid. While corporations have become more vigilant about safeguarding what they feel to be their intellectual property, the Indian government has been shoring up protections for what it considers to be Indian proprietary knowledge, such as the pharmacopoeia of ayurvedic medicine. This book examines the new world of increased restrictions on the use of medical knowledge, and on the production of the drug products that derive from this knowledge, and asks what is gained and lost in this new system of control.

While the WTO mandate, known as the Trade Related Aspects of Intellectual Property Agreement, or TRIPS, limited the sharing of Western pharmaceutical knowledge and production by expanding patents, some were concerned that it would also enable what is known as "biopiracy," which is the plundering of local or indigenous knowledge to create commercial products for multinational companies. Indigenous peoples and practitioners of non-Western systems of medicine in India, Brazil, and elsewhere became concerned that multinational companies would come prospecting for their knowledge about medicinal plants. They would learn of, say, a tropical shrub that treats stomach disorders used by the Ka'apor people in the Amazon or a tuber that has anti-inflammatory properties well known to practitioners of ayurvedic medicine in India, and they would then isolate the active ingredient in the plant to create a new product for which they would acquire patent rights. These concerns were not far-fetched, as

the first effective antipsychotic in Western psychiatry was derived, and patented, by isolating the active ingredient in *Rauwolfia serpentina,* a plant used in Ayurveda to treat mental disorders. And an important early anesthetic was derived from an extract, curare, used by indigenous people in South America and made into a medication by a US company. These innovations were developed by pharmaceutical laboratories that eventually became, respectively, part of Novartis and Bristol-Myers Squibb, and both of these companies have been recently involved in patent disputes in India, asserting property rights for their own innovations. More recently, US and European patents have been issued based on knowledge from India of the properties of turmeric and the neem tree.[3] There are numerous other examples of treatments derived from local or indigenous knowledge around the world, from birth control pills to cancer treatments. In fact, the legal scholar Ikechi Mgbeoji, in his study of biopiracy, estimates that "over one-quarter of modern drugs prescribed all over the world are directly derived from plant life forms, and most of them are products of . . . traditional knowledge of the uses of plants."[4] If Mgbeoji's assessment is correct, the struggle between corporate and indigenous knowledge of the medicinal effects of plants could be quite extensive.

It was unclear, however, how the WTO's new provision on intellectual property would affect non-Western medical systems, since it was oriented toward protecting corporate products and individual inventors and did not seem to change any rules that pertain to indigenous knowledge.[5] Still, many in India, Brazil, and elsewhere were wary of the potential exploitation of local knowledge, and in light of these concerns, India implemented laws based on the Convention on Biological Diversity, which was signed at the 1992 Rio Earth Summit, to provide protection for and benefit-sharing of indigenous knowledge. The Indian government also established the Traditional Knowledge Digital Library (TKDL) to codify knowledge and practices it considers national property, from yoga to the arts to treatments from Indian medical systems.

The most prized aspect of India's local knowledge that the government is trying to protect is Ayurveda, a contemporary, institutionalized medical system that has ancient roots. Ayurvedic medicine has grown in popularity in the West, but it is not quite the "holistic," "natural," or "spiritual" healing system that many people in the West believe it to be. Those outside of South Asia tend to imagine Ayurveda as akin to other "alternative" healing

systems. These views are often shaped by a New Age outlook that sees all non-Western medicines as having something in common and as being holistic, natural, or spiritual, whereas in fact these healing systems vary greatly and are often as material and pragmatic as they are holistic or spiritual.

Ayurveda actually has a lot in common with Western biomedicine; both systems intervene in the physiology of the body through the use of pharmaceuticals and other therapeutic modalities. One could argue that Ayurveda is more holistic than Western biomedicine in the sense that it takes into account diet, the season, and other environmental factors more often than biomedicine does. But a typical ayurvedic medical consultation will focus on symptoms and physiology as understood in ayurvedic terms. The patient will describe symptoms, and the doctor—or *vaidyan,* as ayurvedic practitioners are often known—will palpate the patient's body, perhaps listen with a stethoscope (since Ayurveda has adopted some tools of Western biomedicine), and ask the patient questions. Then the vaidyan will make a diagnosis, using one of the Sanskritic terms for diseases in Ayurveda, such as *asmari* or *kapha unmada*, and assess the effect on the three *dosas*, or bodily characteristics, *vata, pitta,* and *kapha*, and other factors. Sometimes the diagnoses have clear correspondences to Western medical diagnoses, such as *asmari*, which is kidney stones, and sometimes they are harder to translate, such as *kapha unmada*, which resembles depression but has different characteristics.[6]

Though its earliest texts date back about two thousand years, Ayurveda is a contemporary, thriving practice. It is taught in ayurvedic medical schools throughout India, and it features schema for understanding health and illness, such as the dosas, bodily substances known as *dhatus,* and myriad other factors. These schema help practitioners understand the effects of food and environmental factors on health and illness and are the basis of an extensive pharmacopoeia of ayurvedic plant-based medicines that some fear will be copied and patented. Research journals present new clinical studies in Ayurveda, but the issue of whether Ayurveda offers new inventions or is based on past truths of medical insight is unclear and, as we shall see, a problem for how ayurvedic knowledge relates to patent law. Ayurvedic medications are produced in factories that process and refine raw plant materials, but ayurvedic pharmaceutical producers do not isolate active chemical entities as is done in Western biomedicine.

Thus Ayurveda is arguably more "natural" than biomedicine, even though plant ingredients are pulverized, evaporated, cooked, and otherwise processed by machines in factories to make ayurvedic drugs. Some ayurvedic doctors prefer not to prescribe factory-produced medicines and instead mix medicines, which they tailor to specific patients' problems, in their own offices. Thus minor innovations are constantly created in the practice of ayurvedic medicine. Sometimes individual doctors' formulations have been kept secret, but no legal ownership rights have been claimed for these creations—that is, until the WTO upped the ante in the world of intellectual property by creating an environment that led practitioners to be more protective about their innovations.

India is also a major producer of pharmaceuticals of Western medicine, or what is referred to as "biomedicine" in this book. Medical anthropologists prefer the term "biomedicine" partly because this medical system is no longer, and rarely has been, exclusively "Western." Also, there are other medical systems that derive from the same Western—specifically Greek—origins of biomedicine, such as India's *Unani* medical system. In India, "biomedicine" is known as "English medicine," "modern medicine," and "allopathy." The term "alternative" medicine is not used because several medical systems, including biomedicine, Ayurveda, and homeopathy, are considered mainstream, but biomedicine is the dominant system in terms of government and private financial and institutional support.

The Indian biomedical pharmaceutical sector is huge, and India-based companies, many of which operate in countries all over the world, have been a source of inexpensive medications for individual consumers and public health programs, supplying low-cost antiretrovirals for AIDS treatment programs in sub-Saharan Africa, which has 70 percent of the global burden of HIV/AIDS, and cost-saving generic drugs to US consumers. While the role of Indian pharmaceutical companies in supplying affordable medications for the international AIDS crisis has received media attention, the degree of consumption of Indian pharmaceuticals in the United States and other high-income countries is less well known. Eighty percent of the active ingredients in all drugs consumed in the United States are produced in India and China.[7] In addition to active ingredients, many of the final drug products are produced by Indian companies. US consumers may not be aware that 40 percent of the prescription medicines they pick up from their pharmacies come from India, even though a company

name such as Aurobindo, Ranbaxy, or Sun Pharmaceuticals appears on the label.[8]

Indian pharmaceutical companies, however, have had to rework their business practices after the World Trade Organization enacted TRIPS, and India had to change its Patents Act to allow product patents for medications. Now drug products can be patented in India and can only be produced with permission, usually in the form of a license from the patent holder, and an accompanying payment of royalties.

This seemingly slight change from process patents to product patents in 2005 confers exclusive market control of medications to single companies and could have major international public health effects if this causes prices of essential medicines to rise. Already, controversy has stirred over the effects of the new patent regime, with court cases mounted in opposition to new patents and applications for licenses to override patent rights in the name of public health submitted in India, Brazil, and other places. Meanwhile, some multinational drug companies have voluntarily licensed the right to produce some of their medications to Indian companies, keeping the prices of certain treatments for HIV/AIDS relatively low for now. These trends need careful monitoring, since thirty-seven million people in the world are living with HIV, and only 46 percent of them have access to these lifesaving medications.[9]

Practitioners of Ayurveda have been concerned by the new patent regime but uncertain about how it would affect them, since Ayurveda relates ambiguously to the provisions of patent law. Patents protect innovations that are useful, novel, and non-obvious and that are individually created rather than the product of collective, shared knowledge. Innovation in Ayurveda is both individual and collective, novel yet always in dialogue with classic principles. It is based on knowledge about the physiological effects of plants but does not involve isolating active ingredients, which would make their therapies patentable since one cannot patent plants (unless they have been genetically modified). In some ways, biopiracy does not seem to threaten the practice of Ayurveda directly, since biomedical products, which use chemically isolated ingredients rather than plant materials, would not be used by ayurvedic practitioners, and ayurvedic pharmaceutical producers should be able to continue to use medicinal plant materials even if active chemical ingredients extracted from them were patented by others. But this patent system seems unjust to Ayurveda's

defenders, since it protects rights for biomedical products but does not defend ayurvedic innovation in the same way—confirming that science and the law, like any other social practices, are culturally inflected.[10] For example, reserpine, the antipsychotic drug developed from ayurvedic insights, which is now used as an antihypertensive, continues to make over $200 million a year in sales for the biomedical drug companies that produce it, but no ayurvedic practitioners have seen a share of these profits.[11] In response, ayurvedic activists are digitizing ayurvedic knowledge through the TKDL as a resource to use in opposing patents while some ayurvedic practitioners are developing products that they think are patentable, possibly changing the practice of Ayurveda in the process.

In exploring controversies over the ownership and control of medical knowledge in a post-WTO world, this book highlights the vicissitudes and dangers of this new environment while revealing moments of opportunity for a more equitable future in this regime of ownership that may affect access to medicine for a large portion of the world's population. To do so, the book takes into account actors that have much at stake in the new patent environment, including activists concerned with the price of essential medicines, United States– and India-based pharmaceutical companies, and ayurvedic practitioners and producers.

Overextending Intellectual Property

The idea of intellectual property and its application in the new patent regime are not wholly nefarious, oppressive, and without productive consequences. Like the legal scholar and critic of the current IP regime, James Boyle (2008), I do not object to intellectual property in principle. The idea of giving an innovator a temporary monopoly over an innovation conditional on the public disclosure of how the innovation works balances individual and public interests and was an improvement on an earlier system where innovators simply kept the formulations behind their creations secret. This secret often died with the innovator rather than becoming part of the public domain as innovations now do after twenty years under patent law. What is problematic is the overextension of intellectual property law and the use of obfuscating myths of individual invention that justify it. Scholars have examined myths that support principles of intellectual

property showing that claims of individual invention obscure the collective and incremental nature of innovation in medicine, science, and the arts.[12] Patents, for example, protect the collective invention of employees of a corporation only because a corporation is legally, though not actually, an individual, while the collective knowledge of a community or an indigenous medical system is not patentable.

Before the WTO, when nations crafted their intellectual property laws with greater autonomy, people around the world were freer to borrow, share, or appropriate each others' knowledge and creations. Today, because patent cordons are being reinforced mostly at the behest of powerful commercial interests, less privileged forms of knowledge are also being cordoned off, leading to a loss of creativity, a reluctance to share knowledge, and a shrinking of the public domain. This reinforces observations by critics who lament the loss of an intellectual commons that comes from both sides of intellectual property struggles, the powerful interests that advocate for expansive IP law and the groups that resist these expansions by establishing defensive claims.[13]

In Indonesia, the government's defenses of indigenous knowledge and arts—from contemporary theater to textiles to classical dance—through new intellectual property laws limit the borrowing of ideas from Indonesian cultures by outside artists. This restricts the possibility of cultural exchange and works against the interests of the artists the Indonesian government claims to be defending, who want their products to be used and circulated by outsiders.[14] Likewise, people in India and the Indian state often celebrate how their cultures, medicines, and sciences have been adopted around the world—from yoga to Gandhian nonviolence to the concept of zero in mathematics and even ayurvedic medicine—but such contributions to global patrimony, and even the discovery of new treatments for diseases, may be threatened by the Traditional Knowledge Digital Library and other attempts to encode and protect knowledge systems.

Even before the rise of modern globalization, cultural hybridity was commonplace, and the adoption and sharing of different cultural and scientific ideas—borrowing that today might be considered forms of piracy—was the norm. We take for granted that, until recently, we had been living in a world where an open public domain was maintained, often simply because there were fewer laws limiting the circulation of innovations. Europeans did not have to pay royalties to China every time they

made pasta, brewed tea, or set off fireworks because of the Chinese origins of these innovations. Mathematicians and engineers did not have to figure out which numerical concepts came from Indian, Greek, or Arab sources and get the necessary permissions to continue their work.[15] While restrictions on the sharing of knowledge and innovation, whether artistic or scientific, represent a loss to human creativity and scientific discovery, researchers who examine recent IP controversies argue that we need to be wary of the ideal of an open public domain, which, like many rational-actor or level-playing-field ideals, ignores social inequalities that give more powerful interests a greater ability to extract and benefit from communal resources.[16] It is also not appropriate to suggest that both sides—the corporate interests and the defenders of local knowledge—share equal blame for the current partitioning of the world's knowledge. The defenses of Ayurveda, yoga, and the arts in India, Indonesia, and elsewhere are best seen as a reaction to the corporate actors who initiated this standoff.

Reacting to Globalization: Power, Complexity, and Vulnerability

In analyzing the struggles between activist, corporate, and government actors, this book provides an example of how people react to and resist forces of globalization. Global initiatives and agreements constantly reshape the socioeconomic world we live in today, and understanding and reacting to these forces—or what I call "constellations" of power to refer to their multilayered nature and their complexity—can be daunting. WTO mandates, such as TRIPS, free trade agreements, such as NAFTA and the proposed Trans-Pacific Partnership (which contains new IP protections), and the constant movement of industrial production in pursuit of low-cost labor regularly remake our world, but it can be difficult to discern what will be their effects.

Thus, this examination of the current struggle over intellectual property claims considers the legibility of power, which refers to how difficult it is to understand a system of power, such as the new patent regime, for people whose lives it affects and even for the journalists, researchers, and activists who assess such systems and decide what to do about them. For a long time, analyses of power and resistance considered power relations

that were relatively easy to read or where the threat, and who was behind it, was clearer. For example, labor exploitation of peasants and indigenous people and the seizure of land by Hispanic elites led to the Mexican Revolution and similar uprisings in the twentieth century.[17] The threat of fascist and authoritarian leaders like Mussolini and Suharto was also relatively easy to perceive.[18] The political scientist James Scott famously argued that often resistance does not result in open revolt but takes place through what he called "everyday forms of resistance" such as foot dragging, work slowdowns, pilfering, and other methods, but the conditions people were reacting to were relatively clear to those who were affected: landlords were raising the rent, mechanization was putting people out of work.[19]

Today, amorphous "forces of globalization" are harder to decipher. They are mysterious, daunting, and difficult to figure out how to resist. These networks of power are also like rhizomes, to use a popular metaphor proposed by social scientists and philosophers for analyzing science, technology, and social networks.[20] A tree is hierarchical and centralized, with a trunk from which branches break off and divide into smaller branches, ending up at the smallest level like capillaries in the human body, and all dependent on the center. The rhizome, on the other hand, is a mostly subterranean structure of roots that goes out in every direction, constantly forming new junctions and networks from which plant shoots pop up at various intervals. Unlike the tree, there is no center in the rhizome. The structure continuously reproduces itself as it moves out through space in multiple directions. There is no trunk, stem, or root structure that, if severed, affects the whole organism. If one were to cut the roots of the rhizome, it would continue to send out new branches and shoots in different directions as long as there were space and nutrients. The new global intellectual property regime is in some ways like the tree, since the WTO was central in its implementation, but it has taken on the structure of a rhizome, sending shoots up in different countries as laws are changed and new supporters or adherents are added to the network. Some supporters at new nodes in the network appear at first to be resistors, as in the case of those in India who are working to protect Ayurveda through the TKDL. Although this effort is aimed at protecting knowledge from misappropriation, it at the same time affirms the principles of intellectual property of the new regime by preparing to mount oppositions to patents using provisions of patent law—specifically by proving that biomedical

pharmaceuticals derived from Ayurveda are based on prior knowledge and therefore not patentable. This amounts to an agreement to the principles of patent law that are central to the new IP regime.

In trying to understand what she calls "the state of globalization" today, the social anthropologist Shalini Randeria speaks of the unwieldy and complex nature of contemporary forces that involve webs of corporate and government actors and multiple legal regimes.[21] In earlier studies of power and resistance mentioned above, people objected to policies of their landlords, bosses, or government leaders. Today, the government and local officials are as likely to be allies as adversaries, since the "law today transcends state boundaries in complex and significant ways due to a proliferation of actors, arenas, methods and forms of rulemaking and dispute resolution located at different sites around the world."[22] Randeria considers the multiple legal regimes that India must negotiate, including TRIPS and the Convention on Biological Diversity, and concludes that "in the new architecture of global governance, power is diffuse and elusive."[23]

Francis Gurry of the United Nations World Intellectual Property Organization (WIPO) similarly points to the growing complexity that international policies and agreements have taken on in the wake of TRIPS, where organizations, such as the Convention on Biological Diversity, the Food and Agriculture Organization, and UNESCO, have suddenly had to work intellectual property positions into their agendas, when they did not have to do this in the past. The dynamics of power and resistance have been a major focus of social science research for several decades now, but this diffuse character of power—which renders it illegible and makes strategies of resistance difficult to devise—has not been central to that research.[24]

Thus global constellations of power, like the new intellectual property regime, are multilayered and constantly changing, and attempts to resist them can lead to unanticipated results. A rhizomatic structure is difficult to dismantle or resist. In the case of the effect of the new IP regime on ayurvedic medicine, the threat is hard to decipher, and ayurvedic practitioners and activists have engaged in a variety of reactions, which include deliberate inaction, hoping that by "lying low" and not engaging with the new regime there will be no threat. Defenders of Ayurveda must deal with an extra layer of complexity, since they are trying to understand how their system of medicine relates to patent law and whether and how their knowledge needs to be defended, but few people have the legal, political,

and ayurvedic expertise to assess these issues. For biomedical pharmaceutical production, there is a little more clarity.

If one severs the roots of a rhizome, there will be little effect on the plant network. Similarly, creatures of mythology, such as the hydra or the cyclops, seemed daunting, but they always had some vulnerability that the hero could find to subdue the creature. This is somewhat like what activist groups and government representatives in India have managed to do through legal maneuvering within the new patent regime, notably by adding an obscure-sounding provision to the country's new patent law, Section 3d. While they have not actually "subdued" the new regime, we might say these efforts have "domesticated" it by limiting its negative effects in India and for places that depend on India's low-cost drug supply. This story of heroism is not well known, most likely because it involves legal technicalities that seem complicated and obscure, but basically, small activist groups in India, such as an organization of HIV-positive people assisted by a handful of activist lawyers, have been able to defeat patent applications by multinational companies in the India Patent Office, and their efforts are aided by Section 3d's rigorous standard for patents to be awarded in India.

Section 3d creates a more balanced patent law that resembles the original principle of intellectual property as a temporary and limited social contract that protects real innovation, rather than what IP has become today, a tool for expanding the reach of private property. The oppositions based on Section 3d prevent what some have seen as frivolous patents that have been awarded in other places, such as the United States, for me-too drugs. Section 3d requires that new versions of drugs show greater effectiveness than the older versions to obtain a patent. While this does not sound like an unreasonable requirement, it has brought the ire of the pharmaceutical industry. This provision prevents Indian patents of several medications that were profitable for pharmaceutical companies elsewhere, and it was added, at the behest of leftist parties, to India's new intellectual property laws. Corporations got what they wanted in the WTO with TRIPS, but they did not anticipate India adding this section that would limit its effects. Needless to say, "big pharma" did not see the creation of Section 3d as heroic, but rather as an unfair restriction on their property rights. Swiss-based multinational giant Novartis challenged Section 3d in India's Supreme Court, but in a decision handed down in 2013, the court ruled this provision was legal and allowable under TRIPS.

The metaphor offered earlier of trying to defeat a mythical beast is appropriate because it calls attention to the fact that global constellations of power such as the new patent regime are complex and intimidating. The metaphor's weakness is that it depicts a uniformly dangerous and malign threat whereas the new patent regime is not so simple, and, unlike a mythical beast, it has its allies. Enthusiasts of the "free market" model believe that increasing corporate profitability through strict property controls will float all boats and spur economic growth in many sectors, and strong IP protections will create incentives for corporate innovation in all WTO member states. There are many problems with such "free market" ideals—and one of them is that TRIPS is more about WTO and government intervention in favor of corporate interests than freeing markets—yet the new patent environment is not wholly nefarious, and it has led to unexpected opportunities that have some benefits, such as development of new products by Indian pharmaceutical companies. These products do not merely add more drugs to the overly medicated privileged strata of society in India and high-income countries; they also show promise in addressing neglected diseases of low-income areas that large, multinational pharmaceutical companies ignore.

Finally, this book takes pharmaceutical companies seriously as important, and unavoidable, actors with legitimate concerns. Without a doubt these corporations have an unfair share of power to conform economic policy to their interests, but we will see how the caricature of an all-powerful "big pharma," often found in social science and public health research, ignores the complexities and varied agendas of pharmaceutical producers.

Studying Pharmaceutical Producers

This book builds on other work that has explored the expansion of intellectual property rights in the last few decades.[25] Most of those studies focus on Europe or North America and explore these issues from legal and textual sources. Less attention has been paid to the most significant sites of current patent struggles, such as India, one of the world's largest pharmaceutical producers with a history of sharing medical knowledge with the West, and we have not learned much about how actual people

in pharmaceutical production respond to the new legal regime.[26] I chose to follow these issues over an extended period of time, tracking the maneuvers of the WTO, pharmaceutical corporations, and Indian government protections of indigenous medical knowledge in the media from the period before 2005, when India implemented the new intellectual property rules, and for several years after. Like other work on the new patent regime, this book depends on documentary and legal sources, but I supplemented these observations with insights from pharmaceutical producers involved in the struggles and opportunities created by the new patent environment by speaking with individuals involved in the protection of ayurvedic knowledge and employees of ayurvedic and biomedical pharmaceutical companies in India and the United States.

The issues considered in this book are constantly emerging and evolving, making it challenging to offer definitive pronouncements on them. As I was including genes in the list of objects that are now subject to IP claims in this introduction, the United States Supreme Court ruled that naturally occurring, unaltered genes could not be patented, striking down Myriad Genetics' claim to own the BRCA breast cancer genes but affirming that synthetic genes could be patented.[27] Meanwhile, legal precedents continue to emerge from India, such as the 2013 Indian Supreme Court decision upholding Section 3d of the 2005 Patents Act. While the terrain is always shifting, it is valuable to try to make an accounting of where we are and where we are heading.

My own assessment of the effects of the patent regime has changed over the course of my research on this issue. In an earlier analysis of the emerging patent environment, I raised the concern that the new regime will have a dire impact on global public health because it will most likely raise the price of medications that have been developed since the new regime came into effect, such as treatments for new forms of HIV/AIDS that are becoming resistant to the first line of antiretroviral drugs (ARVs). This could have a devastating effect on ARV programs in low-income countries.[28] Yet in the case of tenofovir, one of the most important first- and second-line AIDS treatments that has come out under the new patent regime, the price in low-income countries has come down dramatically, from $200 per person per year to $26 per person per year, because of voluntary licensing agreements that the patent owner, Gilead Sciences, issued to multiple Indian generic pharmaceutical manufacturers, allowing them

to produce the medications. Thus one of the earliest and most well documented examples of pricing under the new patent regime was not what I, and others, anticipated. This raises the possibility that the effects of the new patent laws may not be as dramatic as expected. As we will see later, such voluntary licensing practices have their limitations, and we will have to monitor whether the tenofovir scenario is repeated with other essential medicines as drug production under the new regime continues.

Also, some were concerned that the new patent environment would result in Indian pharmaceutical companies being acquired by multinational producers and becoming a source of cheap scientific labor for making medications. This has not happened—or not happened yet—and this concern assumes a simplistic opposition between multinational "big pharma" and a vulnerable Indian generic sector. Many India-based companies are large and multinational. Meanwhile, some foreign-based companies are generic producers, and some India-based companies have developed and marketed their own branded products. The first pharmaceutical developed and patented under India's new law by an India-based company is Ranbaxy's Synriam (arterolane maleate and piperaquine phosphate),[29] an antimalarial that will help treat a disease that has been neglected by other multinational companies.

Despite my training in anthropology, this book is not heavily ethnographic, although it uses ethnographic methods and presents ethnographic perspectives not typically offered in other assessments of the new intellectual property regime. I based some of my claims on following institutions, the implementation of laws, and efforts by activists over the last twelve years through information I gathered from the media and other public records such as press releases and documents available on interest-group websites. The analysis of the emergence of a new legal regime and its impacts on public health, practitioners, and corporations does not easily lend itself to the fly-on-the-wall orientation of participant observation, the signature method of anthropology, which in this case would ideally involve observing people in the workplace. Still, I gained important insights from doing field research. Discussions with ayurvedic practitioners and producers who were not directly working on projects such as the TKDL but who were concerned about patent issues were the easiest to initiate and provide an important perspective. Fieldwork around ayurvedic practitioners working on the TKDL or inside pharmaceutical companies was

not as feasible, although it was attempted with limited success. I did also manage to meet with, and interview, other important stakeholders and activists in India and the United States. This blend of methods is an effective way—but not the only way—to study the emergence of a new legal regime. It enabled me to take account of slowly evolving processes along with the views of local actors, and it is appropriate when one is "studying up" powerful institutions as I did in examining pharmaceutical company policies and practices.

In the 1970s, the anthropologist Laura Nader urged researchers to "study up," which refers to doing ethnographic work on powerful institutions, not just marginalized people, everyday practices, or exotic others.[30] Efforts to study up have become increasingly popular, but as Hugh Gusterson points out, based on his ethnographic studies of nuclear weapons scientists, people in powerful institutions or elite positions usually do not welcome scrutiny and they often have the means to avoid it. This difficulty in studying up Gusterson labeled the "Roger and Me syndrome," a reference to the Michael Moore documentary where Moore tries to interview the CEO of General Motors, only to be turned away repeatedly by security personnel. Gusterson thus advocated "polymorphous engagement" with powerful subjects, which involves a variety of methods, including interviewing where possible, conducting ethnographic observations in peripheral spaces, such as workplace cafeterias and waiting areas, and doing research based on news and other textual sources.[31]

The research in India was conducted during brief fieldwork in Kerala in 2004 and 2005 that focused on meetings with ayurvedic practitioners and producers and legal and public health experts. In a subsequent visit in 2012, I conducted interviews with ayurvedic practitioners, legal analysts, and pharmaceutical company representatives in Hyderabad, Delhi, and Kerala. Hyderabad, a historical, multicultural city that was once the center of a large kingdom ruled by a succession of Nizams, is now the pharmaceutical hub and a high-tech boomtown of southern India. Delhi is one of the nation's megacities, home to several pharmaceutical companies as well as government workers who analyze national policy, including intellectual property provisions. Kerala is a state in southern India where I have conducted ethnographic research on a range of issues related to medical anthropology and public health. The state is, in essence, the ayurvedic pharmaceutical hub of India, the lesser-known counterpart to Hyderabad,

and Kerala is renowned for its concentration of ayurvedic physicians and institutions, including clinics, hospitals, and even psychiatric facilities. Many have come to Kerala seeking the region's local knowledge about medicinal plants, starting with Hendrik Adriaan van Rheede, a Dutch official stationed in Cochin, who, in the seventeenth century, compiled the famous *Hortus Malabaricus*, an encyclopedia of botanical knowledge from this part of India that aided the development of biological science in Europe.

Observations about ayurvedic medical practices are based on these visits as well as fieldwork conducted since the early 1990s on ayurvedic treatments for psychopathology, and I continued to monitor developments related to the new IP regime in the Indian media during an eight-month stay in India in 2013–2014 that was focused on a different research topic.[32]

The process of trying to speak to representatives of pharmaceutical companies that were key players in the new patent regime was fraught with challenges characteristic of the "Roger and Me" syndrome. I believe that pharmaceutical companies in the United States and India want to avoid direct interaction with researchers. They prefer to control what is said to the public through press releases and presentations on their websites, but those pharmaceutical employees I was able to speak with were forthcoming and helpful in discussing how they respond to the new patent environment, although they were, no doubt, a self-selected group. Thus in addition to analyzing pharmaceutical company perspectives on patent controversies and presenting an encouraging example of price reductions through partnerships between United States–based Gilead Sciences and several India-based companies, I will examine corporate obfuscation showing how companies' preference for one-way communication contributes to the difficulty in deciphering systems of power today.

The History of Intellectual Property and the Current Regime

The next two chapters examine the development of intellectual property law in Europe and the recent expansion of this type of property relation around the world while also highlighting features of India's changing

patent laws and activists' attempts to use these laws to oppose patents. The book then moves on to examine the perspective of pharmaceutical producers, showing how ayurvedic practitioners and producers, United States–based pharmaceutical companies, and Indian pharmaceutical companies navigate the new terrain of intellectual property.

Chapter 1 sketches the history of the concept of intellectual property from its emergence in fifteenth-century Europe through its expansion in the late twentieth century with the World Trade Organization TRIPS agreement. Chapter 2 considers the public health effects of the change from a process to a product patent regime in India, the primary supplier of essential medicines for low-income countries, and examines how activists in India, such as the Lawyers Collective and the Indian Network for People Living with HIV/AIDS, have defeated recent patent applications.

Chapter 3 highlights the history of the sharing of medical knowledge between India and the West and analyzes the divergent reactions of practitioners and producers of ayurvedic medicine to the new patent regime, some of whom oppose the regime and some of whom try to create proprietary ayurvedic medicines. Chapter 4 presents the perspective of multinational pharmaceutical companies, with a special focus on Gilead's voluntary licensing program that has allowed Indian companies to make several of Gilead's antiretroviral products, bringing down the price of important medicines for AIDS in low-income countries. We will learn that for these companies, the main priority under the new patent regime is to protect their markets in wealthy and middle-income countries, and the main problem of drug access may turn out to be for the poor who live in middle-income countries such as Brazil and China. Chapter 5 critiques the distinction between "multinational" pharmaceutical companies, or "big pharma," and "Indian" pharmaceutical companies used in many analyses, and presents discussions with representatives from two Indian pharmaceutical companies, which address patent licenses, economies of scale—the special capacity of the Indian pharmaceutical sector—and prospects for research and development in India, which has recently produced new drugs for cancer and malaria.

Before further examining the role of these actors involved in pharmaceutical creation and production, it will be necessary to understand where the concept of intellectual property came from. Intellectual property does

not really exist until innovators create this concept starting in fifteenth-century Venice. This is a particular European view about property relations built largely on romantic ideals of individual innovation, and it is remarkable that these culturally specific ideas about ownership have spread to the point where most of the globe is conforming to a single intellectual property regime.

1

The Invention and Expansion of Intellectual Property

In a compelling study of our shrinking creative and cultural commons, *The Public Domain* (2008), the legal scholar James Boyle alerts us:

> We are in the middle of a second enclosure movement. While it sounds grandiloquent to call it "the enclosure of the intangible commons of the mind," in a very real sense that's just what it is. . . . Once again things that were formerly thought of as common property, or as "uncommodifiable," or outside the market altogether, are being covered with new, or newly extended, property rights. (45)

The first enclosure movement, which developed over the course of the fifteenth to nineteenth centuries in England, involved the privatization of what were once common lands, while this second enclosure movement involves the privatization of creative and intellectual realms through intellectual property laws. Despite sounding the alarm about the new enclosure movement, Boyle's book opens with a defense of the basic principles of intellectual property law.

In the case of patent law, Boyle explains that this kind of protection is preferable to the previous method of gaining a commercial advantage through the maintenance of secrecy that was used, for example, by medieval guilds. The problem with secrecy is that the invention does not get broadly produced so that the greater society can enjoy its benefits, and its usefulness to society may die with the death of the innovator. Some ayurvedic doctors use this method of keeping their formulas to themselves to control the use of their innovations. Most ayurvedic practitioners I spoke to were not, however, enthusiastic about this method. They explained that they preferred that knowledge be shared, and they complained that formulations that were kept secret died with their "owners." A patent, which is a time-limited contract between the innovator and society, and not a guarantee of enduring ownership, ensures that innovations remain as public resources after the expiration of a patent and after the death of an inventor. Boyle explains that through this contract, society is assuring innovators that if they publically disclose their invention—in enough detail so that others will be able to recreate it—the state will give them a temporary monopoly to produce the invention or transfer the rights to benefit from its production. After the term of the patent expires, the invention will become part of the public domain, available for anyone to produce. Should the inventor not wish to divulge how the invention works after the expiration of the patent or if the inventor dies, society will have an explanation of how the invention works "on file," even though the form of the record of the patented invention has changed over time.[1]

Boyle goes on to explain the other key forms of intellectual property, copyrights and trademarks that protect artistic works and symbols of trade, and then asks:

> But does intellectual property work this way now, promoting the ideal of progress, a transparent marketplace, easy and cheap access to information, decentralized and iconoclastic cultural production, self-correcting innovation policy? Often it does, but distressingly often it does the reverse. The rights that were supposed to be limited in time and scope to the minimum monopoly necessary to ensure production become instead a kind of perpetual corporate welfare—restraining the next generation of creators instead of encouraging them. (8–9)

Boyle adds that through extensions of the life of copyrights to, in many cases, over a century, at least in the United States, "most of twentieth century culture is under copyright—copyrighted but unavailable. Much of this, in other words, is lost culture" (9). This is because books, films, and music are often not made available to the public because of fear of infringement.

Although the life of a copyright has been extended to over a hundred years, in most cases the life of a patent remains at twenty years. It is the enforcement of patents that has been extended, along with the application of United States–style patent law through the WTO, which includes product patents for medications and overrides much local variability in patent provisions. A key rationale of patent law, the assurance that after investing in research and bringing a new drug to market others cannot come along immediately and copy it, is now used as "a kind of blackmail" where "industry leaders and lobbyists routinely warn that lower prices will reduce funds for R&D and result in suffering and death that future medicines could reduce."[2] Such appeals to the importance of recovering investments, however, obscure the significant amount of public money that goes into innovations for which corporations claim exclusive rights. Nonetheless, pharmaceutical companies have effectively mobilized the ideology of intellectual property and the threat of diminishing future drug development to advocate for the expansion of their property claims.

The Invention of Intangible Property

Anthropologists have tried to determine whether intellectual property or similar protection for intangible forms of property exists outside of European societies or before capitalism and its sanctification of private property became the global norm. Their findings have, however, been ambiguous. In 1928, Robert Lowie claimed something like intellectual property, or "incorporeal property," to use his term, existed in precapitalist societies in the form of rights to songs and secrecy of certain kinds of knowledge. He cites, for example, research on the Eskimo, among whom "a communistic trend as to economic necessaries is coupled with strict individualism as to the magical means of securing food," and describes the process by which ritual knowledge and songs may be "purchased" among Blackfoot

Native Americans.[3] A. Irving Hallowell retorted that this indicates something like mere possession, which is not equivalent to formal property rights, since such claims do not have the "commercial flavor" seen in contemporary property claims.[4] Countering those who argue that non-Western peoples do not have principles that resemble intellectual property and believe only in communal ownership, Michael Brown offers examples of Kiowa and other Native American practices of individual ownership of songs, designs, and other forms of intangible property. He adds that "the rules controlling the flow of ideas and information are often hard to reconcile with Western practices and, perhaps more significantly, with the replicative technologies spawned by the Industrial Revolution."[5]

It is difficult to determine whether practices such as secrecy about knowledge and "owning" songs constitute predecessors to what we know as intellectual property. If Michael Brown is right, it may be the "replicative technologies," such as mass printing and mass manufacturing, that spur the creation of actual legal protections for intellectual property. Doctors of ayurvedic medicine speak about the maintenance of secrecy of some doctors' formulations as if it is similar to intellectual property law. This practice may predate the commodification of medical products that developed with colonialism and capitalism, or it may be a more recent response to commodification, a defense against the practice of making and selling medical products for a profit.

The emergence of modern intellectual property law can be more distinctly defined. The granting of patents as privileges to market inventions—but not as ownership of the concept behind the invention—dates back to fifteenth-century Venice. The elements of modern patent law—which protects the information that is the basis of an invention—can be traced to transformations in claims of ownership and ideas about mental and physical labor in eighteenth-century Europe and the United States.[6]

The science historian Mario Biagioli highlights a shift that occurred around 1790, when the state stopped conceiving of patents as privileges and began protecting patents as rights. New specification requirements for patents replaced the principle that the invention was a material thing the inventor presented before representatives of the state to claim ownership. Patent laws adopted in France and the United States in the late 1700s required a precise description of the invention on paper and resulted in the protection of the idea behind the invention as property: "Allowing for

the emergence of the idea as a distinct entity, specifications made possible for that idea to become the immaterial 'essence' of the invention."[7] This is the basis of the social contract behind patent law that we have today, where the state gives the innovator a temporary monopoly on his innovation in exchange for the innovator's public disclosure of the invention in enough detail so that others can reproduce it after the patent expires or the inventor dies.

Similar principles emerged in the development of copyright law after the passage of the Statute of Anne in England in 1710. The statute claimed that "printers, booksellers, and other persons have of late frequently taken the liberty of printing, reprinting, and publishing, or causing to be printed, reprinted, and published, books and other writings, without the consent of the authors or proprietors of such books and writings, to their very great detriment, and too often to the ruin of them and their families." "For the encouragement of learned men to compose and write useful books," it awarded exclusive rights to print books to their authors and to those booksellers and printers to whom the authors assigned their rights.[8] Thus the book trade's "claims of proprietorship extended not only to the particular books they published, but to the content of those books."[9]

Starting in the late 1700s, Wordsworth and other Romantic authors promoted the ideas that creative works came from an individual wellspring of creativity and that writers could be said to own these works. Before then:

> Writers, like other artisans, considered their task to lie in the reworking of traditional materials according to principles and techniques preserved and handed down to them in rhetoric and poetics—the collective wisdom of their craft. In the event that they chanced to go beyond the state of the art, their innovation was ascribed to God, or later to Providence. Similarly, in the sphere of science, invention and discovery were viewed as essentially incremental—the inevitable outcome of a (collective) effort.[10]

References to the romantic myth of the individual inventor in this book thus invoke two meanings of "romantic": it is "romantic" in the sense that it is an ideal and not a reflection of the actual practice of innovation, and it is "Romantic" in that it evokes a literary movement that inspired the idea of individual creativity in literature which is, in turn, linked to the notion of individual creativity in science.[11]