India and the Patent Wars

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The New Patent Regime

The Activists and Their Allies

After India changed its patent laws in 2005, I sounded an alarm because I was concerned that the new laws could dry up the supply of inexpensive Indian pharmaceuticals that much of the world depends on. Several activist groups had the same concern and rallied efforts to oppose these laws. Once the laws were implemented, they fought to ensure that public health interests were upheld in India and other countries under the current regime, often utilizing the flexibilities in India’s Patents Act in their efforts.

An organization of Mumbai- and Delhi-based lawyers known as the Lawyers Collective undertakes public-interest litigation on behalf of marginalized groups to ensure access to HIV medications and engages in other projects on women’s rights, drug policy, and LGBT discrimination. Founded in 1981 after the Indian courts began to allow third-party groups to move the court on issues of public concern, the Lawyers Collective has mounted what are known as “pre-grant oppositions” to drug patent applications at India’s patent offices. The group has also promoted access to affordable medications in other ways, such as rallying opposition to an
India-EU Free Trade Agreement, which may further expand patent protections. Pre-grant oppositions can be submitted to the court by any public groups that wish to state their objection to the awarding of a patent before it is granted. A key figure in the Lawyers Collective, Anand Grover, served from 2008 to 2014 as the United Nations Special Rapporteur on the Right to Health, during which time he called attention to health inequalities and warned of the effect of the new patent regime on global health.

Patent oppositions have also been mounted by the Indian Network for People Living with HIV/AIDS (INP+), a group that was founded in the 1990s by twelve HIV-positive men and women and has since expanded and developed connections to international AIDS organizations. INP+ engages in advocacy, network building, and providing services for people living with HIV/AIDS, and it has been assisted in filing ARV patent oppositions in India by a US-based group of legal activists, the Initiative for Medicines, Access and Knowledge (I-MAK). Made up of a team of lawyers and scientists, I-MAK provides technical advice, prepares licenses, and intervenes in court cases to challenge inappropriate patents and ensure access to medications.

The well-known humanitarian aid organization Doctors Without Borders/Médecins Sans Frontières has also been involved on the international level, raising awareness about the dangers of the new patent regime and assisting in maintaining access to essential medicines through various efforts, including creating guides for governments and NGOs on the prices of ARVs from various sources and developing a patent opposition database that includes information on how to build legal challenges to patents.

Concerns about an increase in the price of drugs for treating HIV/AIDS are well-founded. Production by Indian companies under the previous patent law significantly brought down the prices of essential medications, including ARVs. It is difficult to assess, though, how much these prices have fallen, since much of the reporting on price reductions makes untenable comparisons, claiming, for example, that the price of ARV treatment has come down from the $15,000 per person per year that big pharma companies charge buyers in high-income countries to the $200 per person per year that Indian companies charge in low-income countries. Such figures ignore the differential pricing system for different countries that big pharma and other foreign- and India-based pharmaceutical producers use in low-income countries. Indian company prices are generally around 20–25 percent less than the prices charged by big pharma—or more
precisely the “originator” company that developed the drug and owns the patent—in those same countries, and sometimes they are higher. For example, GlaxoSmithKline sells the ARV abacavir in low-income countries for $636 per person per year, and India-based companies Aurobindo and Cipla sell the same drug for $429 and $456 respectively. In the case of ritonavir, Abbott Laboratories sells this drug for $83 per person per year in low-income countries, while Aurobindo and Cipla charge $336 and $313.\textsuperscript{3} More importantly, it is competition from Indian companies that helped bring the prices originator companies charge in low-income countries down to these levels.

Comparisons that show dramatic decreases in prices brought by the Indian pharmaceutical sector also ignore the fact that the allegedly low cost “generic” prices are still too high for low-income countries. The involvement of Indian pharmaceutical companies did not so much make the drugs “affordable” as make them simply less expensive than before. Government programs, NGOs, and individual consumers in low-income countries cannot afford to provide ARVs to most people with HIV/AIDS at current prices.

The change from process patents to product patents, reflected in the change from India’s 1970 Patents Act to the WTO-compliant 2005 Patents Act described in the previous chapter, means that companies can now hold exclusive rights to a drug product itself, not just to a method of making a drug. If, for example, Pfizer, Merck, or Gilead comes out with a new AIDS medication, Indian companies can no longer produce a copy through reverse engineering without permission from the originator. Rather, they would have to obtain a license from the patent holder and pay royalties to produce the medication. This, critics felt, would reduce competition and increase the price of medications, which would in turn lead to major public health crises in the countries that depend on lower price pharmaceuticals from India, such as AIDS treatment programs in sub-Saharan Africa.\textsuperscript{4}

These effects would not be seen immediately, as the patent laws would affect only medications that come out after the new law came into force, though some applications have been in a patent “mailbox,” which is basically a queue, for years, waiting for approval under the new law. As more and more people become infected with forms of HIV that are resistant to the first-line drugs, the price of treating AIDS may go up, since the first-line drugs were developed before India’s new Patents Act, whereas the second-line drugs fall under the new regime.
Nine ARVs can be now be manufactured by generic producers through the United Nations’ Medicines Patent Pool, which allows non–patent holders to make products under certain restrictions, and some ARV patents have been defeated in the India Patents Office, which may help keep the price of medications down for now. A key early example of pricing under the new patent regime makes it difficult to tell what will happen in the future. California-based Gilead Sciences has voluntarily licensed tenofovir, an important AIDS drug it developed, and several other products to Indian generic producers, and the price has come down dramatically because of the scale-up of production from the Indian companies. The defeat of the patent on tenofovir in India, which came in the midst of developing this program, may be a factor in the drug’s accessibility. While the Gilead model of voluntary licensing has its limitations—as will be discussed in chapter 4—this drug is now available at a cost of $30 per person per year, a price that is relatively affordable, and this was achieved with all parties involved working within the new patent regime. This is an encouraging story that demonstrates the complexity and difficulty in predicting the effects of the new patent environment. Whether this scenario is replicable with other drugs has yet to be seen.

Efforts to oppose patents and otherwise make essential medicines affordable in the new patent regime were aided by certain flexibilities that existed in TRIPS, or that activists and government agents realized they could add to their TRIPS-compliant laws. The obscure-sounding and controversial “Section 3d” of India’s 2005 Patents Act was key in this effort.

Section 3d, Me-Too Drugs, and Coalition Politics

After the implementation of TRIPS, the member nations of the World Trade Organization met in Doha, Qatar, in 2001 for further negotiations. Delegates concerned about the effects of TRIPS on drug access in low-income countries demanded that TRIPS should allow for public health priorities. This resulted in the adoption by the WTO of the Doha Declaration, which affirmed:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the
Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. (WTO 2001:1).

The various parties agreed that patents could be overridden—or in the words of patent law, “compulsory licenses” could be issued allowing a non–patent holding company to produce a medication owned by another corporation—in the case of a public health crisis. A follow-up declaration in 2003 stated that countries with little or no pharmaceutical manufacturing capacity could import pharmaceuticals through compulsory licenses obtained by manufacturers in other countries.\(^5\) This became a crucial issue in the patent struggles in India because many countries in Africa that have been hard-hit by the AIDS crisis do not have their own production capacity and had been depending on exports of ARVs from India. At the same time, one of the main concerns of foreign-based multinational pharmaceutical companies regarding their patent interests in India has been the ability of Indian companies to export medicines to other countries.

Aware of flexibilities contained in TRIPS and bolstered by the mandate of the Doha Declaration, Indian lawmakers developed the now-controversial Section 3d of India’s 2005 Patents Act, which attempts to prevent evergreening and me-too drugs, where small modifications are made to existing drugs and other strategies are used to obtain new patents. These include “metabolite switching,” which involves patenting a drug and later patenting the metabolite the body makes from the drug as a new product when the expiration of a patent is approaching. For example, when the patent on loratadine (Claritin) was going to expire, Schering-Plough patented and put on the market desloratadine (Clarinex), which is the chemical created by the body when loratadine is ingested, initially at a lower price to encourage customers to switch to the drug with the new patent before older drug’s patent expired. Other methods are also employed, such as changing the way a drug is absorbed by the body to create a new product.\(^6\) Such products are marketed as new and improved, distracting consumers from the fact that an equally effective drug just became available as a generic because the patent has expired.
Section 3d has been important in defeating several patent applications on drugs that were awarded patents elsewhere, and its legality has been challenged by multinational pharmaceutical companies. The modification of the original Section 3d involved only a small change in wording, but the effects are significant. In the 1970 Patents Act, Section 3d read as follows:

3. What are not inventions
The following are not inventions within the meaning of this Act . . .

d. the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant (Government of India 1970)

This was changed in the 2005 Patents (Amendment) Act to the following:

In section 3 of the principal Act, for clause (d), the following shall be substituted, namely:—

“(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.” (Government of India 2005).

They key difference is the addition of the clause requiring “enhancement of the known efficacy” for any product that is a new form of an existing medicine or chemical entity.

The requirement to demonstrate increased efficacy to get approval for a slight modification of an existing drug is not present in US patent law. This provision has limited the approval of me-too drugs, representing an effort that should earn praise by critics of the pharmaceutical industry. In her exposé of the pharmaceutical business, the former editor of the New England Journal of Medicine Marcia Angell (2004) explains that there is little true innovation in commercial pharmaceuticals, since
pharmaceutical companies mostly produce me-too drugs. Sometimes it is only the dosage that is changed. And of the few true innovations that result in New Molecular Entities (NME), most are derived from government or university research that is then licensed to drug companies. For example, from 1998 to 2002, only 14 percent of new drugs approved by the United States Food and Drug Administration (FDA) were “truly innovative,” in Angell’s view, while 86 percent were for already existing drugs. Seventy-seven percent of the newly approved drugs did not show any more efficacy than current standards of treatment. A major problem, Angell argues, is that the FDA only requires drugs to be effective against a placebo, not more effective than the existing standard of care. Thus me-too drugs can be patented and brought to market if they are merely as good as or even less effective than the standard treatment, as long as they beat the placebo. This was the case with GERD—an advanced kind of “heartburn”—treatment Nexium (esomeprazole), which Angell says is not as effective as the earlier Prilosec (omeprazole), and the several statins on the market that are slight modifications of Merck’s original statin, Mevacor (lovastatin), which Angell says was truly innovative. Companies claim, however, that me-too products have advantages, and they are sometimes tested against the standard of care but not for the same uses. This situation, Angell insists, highlights the poor enforcement of the requirement of novelty and non-obviousness in patent law in the United States.

If a provision like Section 3d were introduced into US patent law, it would eliminate the majority of pharmaceutical patents recently awarded and create more incentive for “true” innovations through finding NMEs or more effective modifications of existing drugs.

The story of the development of Section 3d is a complex one involving political maneuvering and eleventh-hour negotiations. The Communist Party of India (Marxist) [CPI (M)] and other left allies joined a coalition government in which the Congress Party, the mainstream party made famous by Jawaharlal Nehru and Indira Gandhi, was the largest constituent. While the communist parties of India are not in the political mainstream, they have millions of followers, and sometimes the Congress Party needs their support to form a government and get legislation passed. The leftists thought the language originally in the new Section 3d was overly friendly to multinational drug companies and that the government should raise the bar of patentability by including language that requires a new drug to show
increased efficacy or by allowing patents only for new chemical entities. Mainstream members of the coalition government, however, thought this might deviate too much from the requirements of TRIPS, but since they needed the support of their leftist allies to get the bill through parliament, they allowed the bill to go forward with the language that required increased efficacy. As the *Times of India* explained, “Thus, the legislative breakthrough happened as a concession that a coalition government was forced to make. The history of Section 3(d) shows that if the ruling party had enough strength to push the Bill through Parliament, the government would have stuck to the MNC [Multi-National Corporation]-friendly scheme of the ordinance.”

Thus one of the reasons the new patent regime has not had as negative an impact on global drug prices as anticipated is that leftist parties dug in their heels to preserve this change in legislation.

Section 3(d) is not the only legislative tool for limiting the applicability of patents in India. Certain other flexibilities exist in patent law based on earlier international treaties, such as the Paris Convention of 1883, which allows for the overriding of patents and awarding of compulsory licenses if a patent is not worked in a particular locality. This continues to apply in the contemporary patent environment. For example, in 2013 Indian producer Natco was able to obtain a compulsory license to manufacture and sell Bayer’s anticancer drug Nexavar (sorafenib), since the courts decided Bayer was not working the drug—that is, it was not sufficiently making it available in India.

### The Activists and Their Oppositions

The Lawyers Collective has filed several oppositions to HIV drug patents, including an attempt by Novartis to patent a second-line protease inhibitor, atazanavir, in India. The opposition to Novartis’s application claims that the compound is among those identified in an earlier patent and that the use of this compound as a protease inhibitor is obvious to anyone experienced in drug development. In addition, the Lawyers Collective argues that the knowledge that the protease enzyme can be used as a therapeutic agent in treating HIV, which is the basis of the effectiveness of this treatment, was discovered through research funded by the US government’s National Institute of Allergy and Infectious Diseases (Lawyers Collective
2006: 5, citing the 1996 NIAID AIDS Agenda). Thus, according to the Lawyers Collective, Novartis cannot claim that the treatment using this compound is sufficiently based on the company’s own innovative efforts, and the invention is not sufficiently novel to warrant a patent. The opposition also urged the court to take into account the negative effect on public health due to the high cost of this medication that would result if the patent were awarded.

In its arguments to the Chennai Patent Controller in charge of this case, the Lawyers Collective further advised that while India met its WTO obligations by passing the Patents Act of 2005, “India retains full sovereignty in determining the standards that must be met with respect to patentability” (4), urging that the patent be denied under Section 3(d), which prohibits patents on “a new form of a known substance” (15). In this case, the Lawyers Collective works within the new patent regime to oppose patents by arguing that the innovation does not meet the standards of Section 3(d) and by defending India’s sovereignty to determine such standards. Novartis eventually withdrew its application on atazanavir in the face of opposition to this patent.

Meanwhile, the Lawyers Collective and other groups have successfully opposed other patent applications on similar grounds. For example, the Initiative for Medicines, Access and Knowledge (I-MAK) assisted the non-profit Indian Network of People Living with HIV/AIDS (INP+) and the Delhi Network of Positive People (DNP+) in opposing Gilead Science’s application for a patent on tenofovir, which is both a second-line drug and a recommended less toxic first-line drug, on the same grounds. The opposition from INP+ and DNP+ states:

Section 3 (d) sets out that a “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” does not amount to an invention and is not patentable under the Act. The ‘Explanation’ for s3(d) provides further clarification in that “salts, esters, ethers, polymorphs . . . combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

21. Based on a plain reading of s3(d), it is quite clear under that [sic] any new discovery of an ester for a known compound is not patentable as an invention. (I-MAK 2014a, emphasis in original)
Note how the opposition makes use of the language inserted at the behest of the left allies in the passage of the new Patents Act. The India-based pharmaceutical company Cipla also filed an opposition to tenofovir claiming the product lacked an inventive step and invoking Section 3d. This drug is already patented in the United States, but its application for an Indian patent was denied.

The Lawyers Collective in the atazanavir patent opposition was able to tap into the fact that the innovations claimed by the pharmaceutical companies had been discovered by government-funded research. Often drug development by pharmaceutical companies depends on knowledge developed from publicly funded research carried out by government agencies and universities. This legal strategy involves what the critiques of the myth of autonomous invention, mentioned in the previous chapter, point out: that invention is normally incremental and dependent on prior knowledge. What pharmaceutical companies often do is not so much invent new drugs but buy IP rights from innovators—such as university researchers and small companies—and scale up their discoveries into a marketable product. This includes investing money in clinical trials and the mass production of the product, which many innovators cannot do on their own. Some have critiqued pharmaceutical company claims that they need to recover profits from patents to invest in the discovery of new drugs, arguing that most truly innovative drugs come from publicly funded research.10 Angell gives the examples of paclitaxel (Taxol), the anticancer drug that was developed by National Cancer Institute research at a cost of $183 million to US taxpayers and then licensed to Bristol-Myers Squibb, and Novartis’s leukemia treatment imatinib mesylate (marketed as Glivec and Gleevec), which were based on the discoveries of university researchers in, respectively, Pennsylvania and Oregon.11 In both cases, the company made significant investments in supplying and testing the drug, but the innovative steps came from public research. In the John Moore cell line case in the previous chapter, we also saw an instance of corporate licensing of a university innovation. UCLA doctors and the Regents of the University of California made an agreement with Sandoz and Genetics to market products based on cells from the body of UCLA patient John Moore. It seems that while corporations do not develop much in terms of innovation, they are trying to recover money for scaling up production and paying for clinical trials. Thus what patent law often protects is the transferability
of intellectual properties rights, or the ability to buy someone’s rights over their innovations and make that innovation into a marketable product. It does require a substantial investment of capital to bring a new drug to market. An often-cited study by a research group at Tufts University that has received funding from the pharmaceutical industry puts the price of research and development for a new drug (a real innovation in Angell’s and the new Indian Patents Act’s definition—a new chemical entity, not a me-too drug) at $802 million in 2000 (projected, in the 2003 article, to be $2.16 billion in 2012). Other analysts, however, have critiqued assumptions used in the development of this figure and calculated the cost to be about one-tenth this amount.

After opposition from the Lawyers Collective, INP+, I-MAK, and Indian pharmaceutical companies, some patents were defeated. In other cases, companies withdrew their applications. Novartis withdrew its application for atazanavir in 2007 in the face of opposition under Section 3d, and GlaxoSmithKline backed off its claim for the second-line ARV abacavir later in the same year after it was opposed by INP+ with the help of I-MAK and Doctors Without Borders. The application appears to have been withdrawn out of concern that it was a slight modification of an existing medication and would not pass the standard of Section 3d. Meanwhile, patents have been awarded for compounds whose novelty does meet the standards of Section 3d, such as the second-line AIDS medication maraviroc, owned by Pfizer, and it is such patents that leave cause for concern about the future prices of second-line ARVs. Pfizer has announced in the UN Medicines Patent Pool its intention to license this product, allowing other manufacturers to produce maraviroc for low-income countries, but this drug has not been recommended by the WHO and no licenses have been issued so far.

The standards for the approval of patents under India’s new law is at the heart of a controversial case that went to India’s Supreme Court. An Indian patent office denied Novartis’s application for its anticancer drug imatinib mesylate (Glivec, Gleevec in India), which provides effective treatment for some forms of leukemia, since it found that the drug represents an incremental step, not a novel innovation. Indian pharmaceutical companies had been producing their own versions of Gleevec, selling the drug in India for $2,500 per person per year, while the cost of this treatment can be as much as $70,000 elsewhere. Novartis sued
the Indian government, claiming the 2005 Patents Act was overly restrictive and Section 3d contains an overly narrow view of innovation for modifications of existing chemical entities. On April 1, 2013, the Indian Supreme Court ruled against Novartis in this case, affirming that Gleevec “did not represent a true invention” and supporting Section 3d. In commenting on this ruling, Anand Grover, a member of the Lawyers Collective who represented the Cancer Patients Aid Association in India in the Novartis case and who was at the time Special Rapporteur to the UN on the right to health, contrasted the effect of India’s law to the patent system in the United States, where incremental changes are more easily patented: “‘What is happening in the United States is that a lot of money is being wasted on new forms of old drugs.’ . . . Because of Monday’s ruling, ‘that will not happen in India’” (Harris and Thomas 2013).

Large pharmaceutical companies claim that such a law restricts their ability to recover their research and development investments, which is necessary to invest in developing new medications. This is at least their rhetoric since, as mentioned earlier, most new drug products do not come from companies’ own R&D, and the large financial outlays they do engage in are for clinical trials, compliance, marketing, legal fees, and other costs. Big pharma does have some sympathizers in India who feel that Section 3d of the Patent Law is an obstacle to better United States–India business ties and to Indian pharmaceutical companies’ own transition to becoming innovators and not just generic producers. Because of Section 3d, the United States placed India on a watch list of countries considered to have inadequate intellectual property enforcement. The business journalist Arvind Subramanian suggests removing Section 3d of the Patent Law to boost India’s stature in the eyes of the US trade office, and he proposes that in exchange the United States return to the WTO, a multilateral forum, to settle trade disputes. In the last few years, the United States has been resorting to bilateral negotiations with individual nations, feeling that the WTO has too often ruled against US interests. The European Union has done so as well, pursuing an India–European Union Free Trade Agreement, which has stalled partly because of proposed patent extensions that favor EU-based pharmaceutical companies and go beyond the requirements of TRIPS.

Scholars and activists have regularly depicted the WTO as the central, hegemonic power that dominates the global economy on behalf of
powerful corporate and national interests that shape its agenda. While there is a lot of truth to this, efforts by the United States and European Union to avoid the WTO forum in trade negotiations and the effective use of Section 3d to oppose patents show that policies of the WTO are not seamless and all-powerful. The situation is somewhat ironic and shows that the deployment of global hegemony is not as straightforward as the shapers of the WTO agenda anticipated. Big pharma representatives probably did not foresee India introducing a provision like Section 3d when they framed the TRIPS agreement, which aimed to impose a pro-corporate, pro-IP agenda around the globe. They probably also did not imagine that they would have to go to court in India to change India’s TRIPS-compliant patent law—or that they would fail in this effort.

Taking a position somewhere between the anti-patent activists and the business journalist Subramanian, two IP experts from an Indian pharmaceutical company, Vijayaraghavan and Raghuvanshi (2008), claim the new patent law will spur innovation in the Indian pharmaceutical sector, but they also strongly defend Section 3d as protecting against “frivolous inventions” whose “aim is not to protect a product but prevent anyone else from coming up with an alternative.”

Section 3d is important and should be maintained because a rigorous patent standard returns patent practices to the fairer ideals of a temporary and balanced contract between innovators and society as described by James Boyle (2008), the legal scholar discussed at the outset of the last chapter, and advocated by others such as the Initiative for Medicines, Access and Knowledge (I-MAK).

Other actors involved in negotiating the new patent terrain include a variety of NGOs such as I-MAK, which disseminates information about patent cases around the world and, like the Lawyers Collective, intervenes in Indian cases to oppose what it feels are unwarranted claims, including several applications for patents on drugs that treat HIV/AIDS. I-MAK’s general position on patents is similar to the position of this book and Boyle’s perspective, finding merit in some of the basic premises of IP law but claiming that IP protections have been overextended. I-MAK explains that “the patent system was designed to balance innovation in medicines and the dissemination of new treatments to society” but feels that the system has gotten to the point where it “upholds private interests over the public good” (I-MAK 2014b). The staff at I-MAK worked successfully to oppose Abbott Laboratories’ patent application for lopinavir/ritonavir,
which the Clinton Foundation has been involved in procuring at lower prices. They were joined in the opposition by three Indian pharmaceutical producers, Cipla, Okasa, and Matrix.

The Indian Network for People Living with HIV/AIDS (INP+) is an organization that employs a variety of interventions to improve the quality of life of people living with this diagnosis in India. These have included joining in some of the legal oppositions to patents on ARVs mentioned earlier. Meanwhile, claiming that “the existing system of health care is not geared towards the needs of the majority of the people, the poor and the rural segments of our society,” an organization of India-based doctors, researchers, and activists known as the Medico Friend Circle engages in research and advocacy on the connection between health problems and political and economic factors, and it has been involved in legal action related to drug pricing and patent policies.21

Other actors from outside India are also involved in fighting what they see as unwarranted patents in India and elsewhere. Doctors Without Borders/Médecins Sans Frontières established a website (patentoppositions.org) to facilitate patent oppositions by patient and civil society groups around the world, such as pre-grant opposition cases in India, and it regularly offers critiques of patent policies through mainstream media outlets. Gilead’s application for a patent on tenofovir in India was opposed in court by INP+ and the Delhi Network of Positive People (DNP+). Later, the Brazilian Interdisciplinary AIDS Association (ABIA) joined another Indian NGO, SAHARA, in filing an opposition to the tenofovir application:

because a patent in India would not only restrict generic competition in India, but would also directly impact Brazil being able to import and access affordable generic versions of the drug.

The Brazilian activists were aware that, should the patent be rejected, local production would take some time to start. During this delay, if no other source were available, Brazil would still have to pay monopoly prices for a short time. (Patent Opposition Database 2014)

The Brazilian activists had met members of India’s Lawyers Collective at the International AIDS Conference in Toronto in 2006, and the two groups shared their experiences with opposing patents. ABIA adopted some of the claims the Lawyers Collective had raised in their patent
oppositions in India, and eventually the Indian tenofovir application was defeated, since, in the words of the patent office, it “does not constitute an invention as it lacks an inventive step” and it “does not result in the enhancement of the known efficacy of that substance,” citing, respectively, section 2(1)j of the 1970 Patents Act and section 3d of the 2005 Patents (Amendment) Act.  

On visits to India in 2004 and 2005, I met with organizations and activists working on HIV/AIDS and learned about the problems that India, and in particular the state of Kerala, was confronting in trying to expand access to treatments for this disease. Drug prices and the emerging patent regime were very much on the mind of individuals working in these areas, such as staff members I met from the state-run Kerala AIDS Control Society and private NGOs. Tapping into my knowledge of drug access and drug prices from earlier fieldwork on mental health in Kerala, I published an analysis of the potentially alarming public health effects of India’s 2005 Patents Act. India and other “less developed” or poor countries have had trouble scaling up their AIDS treatment programs in part because of drug costs, and increases in prices for essential medicines could only make matters worse. In addition, programs that have been intervening in the international AIDS crisis, such as Doctors Without Borders, the US President’s Emergency Plan for AIDS Relief (PEPFAR), and the Clinton Foundation, had been obtaining medications from Indian sources and would be negatively impacted by such increases.  

Certainly, factors other than the new patent regime are involved, and it is important that we not leave the context of poverty out of the picture. Blaming poverty is a double-edged sword, however, in debates about patent policies. Big pharma points to poverty as the culprit to explain problems of access to essential medicines. Pharmaceutical company representatives I spoke to also pointed out that many countries that complain about the price of drugs and problems of access to essential medicines choose to spend huge sums of money on military technology. Such accusations have the effect of obscuring the contribution of patent laws to these problems. The context of poverty, however, and the priorities of government spending in low-income countries cannot be ignored. As mentioned earlier, AIDS services in low-income countries are unable to obtain sufficient quantities of ARVs at current and pre-TRIPS “low” prices offered by India-based pharmaceutical companies. We need to take into account
poverty, government spending priorities, and patent policies as we assess how best to promote access to essential medicines.

**ARVs and Affordability**

In an effort to increase access to second-line AIDS drugs under the new patent regime, the Clinton Foundation negotiated price reductions for some ARVs: for example, bringing down the cost of lopinavir/ritonavir, a key second-line treatment, from $1,000 to $695 per person per year for lower- and lower-middle-income countries, including India and China. This is an important achievement, although, as will be discussed later, this price is more than the average annual per capita income in India. The Clinton Foundation is procuring lopinavir/ritonavir from Indian manufacturers Cipla and Matrix, which have been able to produce this drug since Abbott Laboratories was denied an Indian patent for the product in 2010.

People in low-income settings cannot afford the price of patent-protected ARVs, and often generic ARVs are out of reach as well. Although multinational pharmaceutical companies offer reduced prices to developing countries, these prices are usually significantly higher than the reductions negotiated by the Clinton Foundation and the prices Indian generic manufacturers offer, and they are far out of the range of affordability for people living with HIV/AIDS in poor countries. Multinational pharmaceutical companies are not going to sell these drugs to 90 percent of people with HIV/AIDS in low-income countries regardless of patent enforcement. In India, the cost of antiretroviral therapy for HIV/AIDS using grandfathered drugs that are exempt from the patent regime has dropped from $795 to $23 per person per month. This was a dramatic decline, but it is rarely acknowledged that even this “low” price of $23 per month is close to the total average monthly per capita income in India. Most people in India who take ARVs get them free from government programs, and how many people the government programs can serve is dependent on the price of medications. Likewise, the price charged by Indian companies for the generic version of Novartis’s anticancer drug Gleevec is also still out of range for almost everyone in India (Ecks 2008), so generally people do not have access to this drug unless they get it through a government or
NGO program or are among the thirty thousand in low-income countries who get this medication free from Novartis.

Multinational pharmaceutical companies are concerned about their public image in relation to these issues. Pfizer, Merck, and other companies prominently display their global access programs on their websites. Novartis devoted a substantial portion of its website to defending its position in its Gleevec/Section 3d lawsuit in India while also spending money on television ads in the United States to celebrate its programs to subsidize American consumers who are unable to pay for their prescriptions.\textsuperscript{29} Medical anthropologist Stefan Ecks has tracked pharmaceutical company efforts to develop a positive image among the communities and customers they interact with.\textsuperscript{30} This undertaking is known as “corporate citizenship,” and it includes drug access and health programs aimed at underserved populations. While corporate drug donation programs and other corporate citizenship efforts do benefit patients, they also distract from profits made elsewhere, according to Ecks. In the case of Novartis’s experiences in India—in its Supreme Court case and its Gleevec donation program—it was not Novartis’s goal to make money off Indian consumers but to maintain their high prices in developing country markets by reducing the supply of inexpensive drugs made in India that may leak into markets in Europe and North America. They also aimed to reduce another kind of leakage that Ecks calls “information spillover,” which refers to the awareness of the existence of lower-price drugs in these markets and how this may affect the willingness of people in high-income countries to continue paying high prices.\textsuperscript{31} From speaking to pharmaceutical company representatives in the United States and India, as we will see in chapter 4, I too saw that the priority for multinational pharmaceutical companies was not so much to charge high prices in poor countries but to keep low-priced medications out of their more lucrative markets in middle-income and wealthy countries.

A Double Standard in the Concerns of Pharmaceutical Companies

A case of hypocrisy was overlooked in the media coverage of Novartis’s challenge to Section 3d of India’s Patents Act, and it is worthy of note
since it encapsulates what some see as a key injustice of the new patent regime. At the time that Novartis led the legal challenge to make India’s new patent law more amenable to what they saw as their intellectual property, this company was producing several products containing reserpine, a medication based on knowledge from ayurvedic medicine, India’s largest indigenous medical system. The development of reserpine stemmed from ayurvedic knowledge about the antihypertensive and antipsychotic characteristics of the plant *Rauwolfia serpentina*, which ayurvedic doctors use in treating mental disorders. Ciba Pharmaceuticals originally patented the drug in the 1950s after isolating the active ingredient, reserpine, from *Rauwolfia serpentina*, and Ciba was later acquired by Novartis. The patent on reserpine has expired, and Novartis and several other companies continue to use this substance in a variety of products. However, no Indian entities ever received compensation for the insights that were the basis of this “invention.” Novartis seems to hold a double standard about whose innovations are worthy of legal protection and whose should be available for free sharing and replication. The same could be said about Bristol-Myers Squibb, a subsidiary of which created early anesthetics based on indigenous South American people’s knowledge of curare, and which, like all big pharma companies, actively defends what it considers its innovations in courts around the world.

Patent struggles in India thus take on an extra layer of complexity and intrigue because India is home to several indigenous medical systems whose products might potentially be patentable and which have already been an inspiration for new medical therapies and innovations in the West. The physician and anthropologist W. H. R. Rivers in 1924 presented a brief survey of what was known of the world’s medical systems at the time. In discussing the native healing practices of many places, such as Australia, Africa, and the Americas, he is somewhat condescending, assuming that his own European system of medicine is far more advanced. In discussing India, however, his tone changes, and he says, “We find in India an extensive pharmacopoeia and a surgery from which that of Europe has taken more than one lesson.” He then explains that Europeans adopted the practice of rhinoplasty and of conducting surgery under hypnosis from India. Since then, other medical practices from South Asia have been adopted and also patented in Europe and the United States.
In my early investigations into the emerging patent regime in the late 1990s and early 2000s, there was concern about these forthcoming changes from interests other than AIDS activists and legal NGOs. The United States had granted a patent for the wound-healing properties of turmeric, and the European Union approved a patent for fungicidal uses of products from the neem tree, both “innovations” having their basis in knowledge of plant uses in India. Dismayed by these decisions, practitioners of India’s indigenous ayurvedic medical system began to worry about the effect the new patent regime would have on their knowledge and practices. Under TRIPS, they wondered, could foreign entities patent products based on ayurvedic knowledge? If so, could such patents prevent ayurvedic doctors from using these treatments themselves? And did ayurvedic practitioners therefore need to compile information on the ayurvedic pharmacopoeia to defend against cases such as the patents on turmeric and neem?