Experimental Futures

Technological lives, scientific arts, anthropological voices

A SERIES EDITED BY MICHAEL M. J. FISCHER AND JOSEPH DUMIT

KAUSHIK SUNDER RAJAN

Pharmocracy

Value, Politics & Knowledge in Global Biomedicine

Duke University Press Durham and London 2017

CONTENTS

CHAPTER THREE

Constitutional Values

The Trials of Gleevec & Judicialized Politics

Two Histories of Gleevec

In the past few years, India has come to be seen as a site of deep vulnerability for multinational pharmaceutical interests. This is because of occurrences that suggest a less than favorable climate for intellectual property protection on drugs, in spite of having passed patent legislation in 2005 that is compatible with standards mandated by the World Trade Organization (WTO). Ironically, the 2005 Act was passed in order to make patent regimes more stringent, and indeed it does so, having replaced the earlier process patent regime (instituted in 1970) with a product patent one. The 1970 Act was a spur to India's generic drug industry, and led to India's drug prices becoming among the lowest in the world.

In 1995, as India became party to the WTO, it was allowed a ten-year transition period to change its patent laws to a product patent regime compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement (see introduction). This meant that as of 2005, any drug developed after 1995 would be subject to a product patent regime; any drug developed before 1995 would still be subject to a process patent regime under the 1970 Act. Hence, the 2005 Act has seen the harmonization of Indian patent laws with Euro-American ones, through multilateral free trade mechanisms, driven in large measure by the interests of the multinational, Euro-American pharmaceutical industry. Yet anxiety pervades the industry around the level and kind of patent protection companies will receive in India. This has to do with the ways in which new patent laws have been interpreted in India through the use of public health flexibilities that allow for a less-than-absolute monopoly under these product patent regimes. These flexibilities have resulted from allowances within TRIPS, especially the Doha Declaration on the TRIPS agreement and public health signed by member nations in 2001, which allowed national governments to use mechanisms that would allow for limitations on or work-arounds of patents in the case of public health emergencies.[1]

The emblematic case that provides precedent for such interpretation is the denial in 2006 of a patent on Novartis's anticancer drug Gleevec. Novartis took the Indian Patent Office to the Madras High Court to dispute the denial, and lost. Novartis then appealed, first to a newly constituted Intellectual Property Appellate Board (IPAB) and then to the Indian Supreme Court. It lost both appeals as well. Gleevec was a landmark case in and of itself, while also serving as a precedent for other cases that have seen the curtailment of intellectual property rights by drawing upon public health flexibilities incorporated into the 2005 Act.[2]

The legal history of Gleevec is vital to understanding contemporary intellectual property regimes and their relationship to pharmaceutical politics in India today. But this is in fact a tale of two histories. The first is the history of Gleevec's own development as a drug, and the place of patents in that history. The second is the history of patent regimes in India. The political is constituted within the relationship between these two otherwise independent histories that have come to be intertwined over the past decade. Gleevec is a drug that received a patent in over forty other jurisdictions before it was denied one in India; yet (perhaps because of this) Novartis felt it important to challenge the denial in India, and even to question the Indian patent regime under which this denial was allowed. Gleevec is just one drug out of thousands for which a product patent has been applied since India's TRIPS-compliant patent regime came into existence. Yet it is the most significant one, because the contestations around its patentability provided the first test case of how flexibilities contained in the new patent regime would be interpreted.

This chapter focuses on the legal history of Gleevec from 2005, when Novartis applied for a product patent on the drug in India, to 2013, when the Indian Supreme Court upheld the initial denial of the patent. First, I focus

on the actual dispute around the denial of the Gleevec patent by the Indian Patent Office under the terms of the 2005 Patent Act, followed by Novartis taking the Patent Office to the Madras High Court to litigate against the denial. This played out between 2005 and 2007. I then discuss Novartis's appeal to the Indian Supreme Court, which gave its final verdict in April 2013 upholding the denial of the patent.[3] I do this in order to think through the relationships between value, politics, and knowledge in the context of the judicialization of pharmaceutical politics. After outlining Gleevec's legal history, I consider the nature of the politics of access as it emerges in India in the aftermath of this case. Along with the HPV vaccine case (see chapter 2), this chapter also situates cancer as a disease that emerges within and through particular articulations of value, politics, and global biomedicine.

I provide a timeline of the historical trajectory of Gleevec below, adding certain other events that are relevant to its story in India (table 3.1). Alongside, I outline significant events in the history of Indian patent regimes over the past century, in order to point out that the legal history of Gleevec cannot be understood without reference to the simultaneous history of Indian patent law. Throughout the dispute, Novartis insisted—unsuccessfully—that it could, and that all that mattered was a purely abstract notion of invention, uncoupled from the historical and constitutional contexts within which such a notion would come to be rendered as legal and interpreted thus under national-state jurisdiction.

Alongside this trajectory, it is important to consider two questions. First: what kind of invention is Gleevec? And therefore, second: how does this question come to matter not just as a definitional philosophical question, but in legal and constitutional terms? Simply at the level of the outcome of this legal trajectory, what one sees is a curtailment of the scope of new product patent regimes. This has been celebrated by civil society groups fighting for access to medicines, and attacked by multinational corporate capital and its allies as a lack of proper respect and incentive for innovation. While I believe that the outcomes have been important not just for access to essential medicines, but for bringing into focus the monopolistic practices of the multinational pharmaceutical industry (for which see chapters 1 and 4), what I am interested in here is the mechanisms by which such outcomes are even possible. This involves considering, first, how a question of scientific invention can be rendered as a constitutional one, and therefore concerns the relationship between the technical and the constitutional; and second, how the constitutional itself comes to be rendered through complex and often contradictory forms of state mediation that reflect its own antinomies.

TABLE 3.1. Two Timelines—*Gleevec and Indian Patent Law*

History of Gleevec's Development	History of Indian Patent Law
	1911: Patent Act passed by British colonial regime. Product patents on drugs for 14 years.
	1950: Tek Chand Committee Report submitted to Indian Parliament, reviewing merits and demerits of the 1911 Act. First postcolonial Indian Patent Act passed.
	1959: Ayyangar Committee Report submitted to Indian Parliament, recommending a move from product to process patent regime.
1960: Link established between chromosomal defect and chronic myeloid leukemia (CML) (Nowell and Hungerford 1960).	
	1970: New Patent Act drafted, gets passed in Indian Parliament in 1972, replacing product patent regime with process patents on drugs for seven years.
1973: Mechanisms of chromosomal translocation in genesis of leukemias discovered (Rowley 1973).	
1980s: Screening of growth factor receptors by chemists at Ciba-Geigy leads to identification of compound with possible therapeutic effect for CML.	
	1986: Commencement of Uruguay Round negotiations of the General Agreements on Tariffs and Trade, bringing intellectual property into purview of free trade negotiations for first time.
1993: Ciba-Geigy files U.S. and Canadian patents on imatinib and "pharmaceutically acceptable salts" (Zimmermann patent).	

TABLE 3.1. Two Timelines—*Gleevec and Indian Patent Law* (contd.)

	1994: Uruguay Round concludes with signing of Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and the establishment of the World Trade Organization.
Mid-1990s: research to develop pharmaceutically active form of imatinib free base that has therapeutic effect in the treatment of CML (Druker et al. 1996).	
	1995: "Less developed" countries such as India given ten years to harmonize their patent regimes with requirements of TRIPS. Required to set up a mailbox whereby product patents could be filed in anticipation of a new patent regime in 2005.
1997: Swiss patent application on β-imatinib mesylate, a crystalline salt isoform of imatinib free base that shows potential effect in treatment of CML.	
1997–2001: Clinical trials to establish safety and efficacy of β-imatinib mesylate in humans. (None conducted in India.)	
1998: "Mailbox" application filed for patent on β-imatinib mesylate in India; to be opened and evaluated in 2005 on passage of TRIPS-compliant Patent Act.	
	1999: India amends Patent Act to allow for EMR on drugs for which mailbox applications have been filed, until TRIPS-compliant Patent Act passed.
2000: U.S. patent application on β-imatinib mesylate filed.	
2001: β-imatinib mesylate approved for marketing in United States as Gleevec. Indian companies start making generic versions of the drug for sale in India.	

TABLE 3.1. Two Timelines—*Gleevec and Indian Patent Law* (contd.)

2002: Novartis applies for and receives EMR on Gleevec in India.	**2002:** Further amendments to Patent Act, broadening definition of invention and addition of a chapter "Working of Patents, Compulsory Licenses and Revocation."
2004: Cancer Patients Aid Association (CPAA) files writ petition in Supreme Court opposing the grant of EMR on Gleevec to Novartis, on grounds of right to life and health.	
2005: Novartis applies for product patent on Gleevec. EMR (and writ petition opposing it) null and void because of passage of new Patent Act. Oppositions to Novartis's application, which is denied by Patent Office in Chennai. U.S. patent on β-imatinib mesylate granted.	**2005:** New, fully TRIPS-compliant Patent Act passed in India, granting product patents on pharmaceuticals for twenty-year period. Subsequent to intense debate in Parliament, public health flexibilities incorporated into this act, especially Section 3(d), which prevents pharmaceutical evergreening.
2006: Novartis files case in Madras High Court disputing patent denial and Section 3(d), one of the public health flexibilities based on which the denial was made.	
2007: Novartis loses case in Madras High Court, parts of the case relating to patentability of Gleevec transferred to Intellectual Property Appellate Board (IPAB).	
2009: IPAB upholds denial of patent on Gleevec, but only on grounds in Section 3(d). Novartis appeals IPAB decision to Supreme Court.	
2013: Indian Supreme Court upholds denial of patent on Gleevec.	

Gleevec Patent Denial and the Madras High Court Case, 2005–2007

By the time the new, TRIPS-compliant Indian Patent Act was passed in 2005, the question of the relationship between a product patent regime and access to medicines was already vexed. Gleevec was responsible for this because, before the product patent regime had been instituted, Novartis had been given exclusive marketing rights (EMR) on the drug (see chapter 4). This was in spite of the fact that generic capacity to make the drug existed; indeed, ten Indian companies were making generic forms of imatinib mesylate as soon as Gleevec was approved for sale in the United States. The cost of the generics ranged between 4,000 and 12,000 rupees (Rs.) per patient per month (approximately $100–300 at the time). Novartis's price for its patented medication, on the other hand, was Rs. 120,000 per patient per month (approximately $2,700). In other words, essential, life-saving anticancer medication that was already being sold to patients in a competitive marketplace was now being made potentially less accessible to them through a policy instrument that provided a market monopoly on the drug to a single company. The controversy surrounding the EMR led to active debate in the Indian Parliament about the implications of the new patent regime on drug prices, leading to provisions in the 2005 TRIPS-compliant Patent Act that would temper a product patent regime with public health protections. Thus, the politics around Gleevec were not simply a function of patent legislation that had already been set in place; such politics helped set the context within which the 2005 Act would be passed.

A crucial provision to mention here is Section 3(d). Section 3 of the Indian Patent Act specifies all the things that cannot be held to be an invention. This includes mere discoveries or inventions that might be contrary to the law and public order. But the 1970 Act also excluded, as part (d) of this section:

> 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.

This was amended in the 2005 Act to read as follows:

> 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 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.

The amended version of Section 3(d) therefore specified a criterion of enhanced efficacy as essential to qualify for the patentability of substances that were modifications of existing substances. This was done to curtail the practice of pharmaceutical evergreening, which is common in product patent regimes and involves the introduction of minor modifications to a drug that is coming off patent so that it can be claimed as a new drug under a new patent. How one might define enhanced efficacy was not, however, made clear in the amended act, and this ambiguity would come to be at the heart of the subsequent controversy around Gleevec.

Once the new Indian Patent Act had been passed, Novartis's EMR on Gleevec was no longer valid, but the company was eligible to file for a product patent, which it did. The Cancer Patients Aid Association (CPAA), a patient advocacy group that had been procuring generic β-imatinib mesylate and making it available to patients, filed a pregrant opposition to the Gleevec product patent application. Pregrant oppositions are another public health provision allowed by the 2005 Indian Patent Act, allowing anybody who feels that a patent application has been wrongly filed to oppose it before it is adjudicated upon. There were three major grounds in CPAA's opposition. The first ground was lack of novelty, based on the fact that a previous patent application had been made on imatinib and all pharmaceutically acceptable salts, including imatinib mesylate, in 1993 in the United States and Canada. Further, CPAA claimed that imatinib mesylate occurs spontaneously as a β-crystalline form. The second ground for opposition concerned the absence of an inventive step; CPAA claimed that for the reasons above showing prior art (a legal term signifying that any part of an invention is already known), imatinib mesylate was obvious to a person skilled in the prior art. The third ground of opposition was on the basis of Section 3(d), which as just mentioned does not allow a patent on a new form of a known substance unless the efficacy of the new form is significantly greater than that of the known substance. The question of significantly enhanced efficacy therefore became a crucial matter of adjudication.

In response to CPAA's pregrant opposition, Novartis claimed that Gleevec was a twofold improvement over prior art: first, because imatinib free base is converted to imatinib mesylate; and second, because the conversion of imatinib mesylate into its β-crystalline form occurs not spontaneously, but through human intervention. Hence, a basic question of molecular production came into being in this dispute—is the β-crystalline form of imatinib mesylate a spontaneous state of being of the salt or the product of human engineering? Novartis also made counterarguments regarding the question of efficacy. They pointed to a study conducted on rats which showed that β-imatinib mesylate is 30 percent more bioavailable than the core imatinib molecule. They therefore claimed that β-imatinib mesylate is more efficacious than imatinib. Hence, Novartis was making a direct claim that increased bioavailability implies increased efficacy. Next CPAA filed a rejoinder, stating that a study on rats is not relevant to a question of efficacy in humans. The organization also claimed that a 30 percent difference in bioavailability is not significant. In this way, CPAA was disputing Novartis's claims of significantly enhanced efficacy by unsettling the definitions of both efficacy and significance.

In January 2006, the Indian Patent Office in Chennai ruled that Gleevec is not patentable. The patent controller effectively accepted all the points in CPAA's opposition. Note that all three grounds on which the patent was opposed and denied are technical, even though Gleevec was already a high-stakes political battle. This in itself is not surprising—after all, the function of the patent office is to make technical determinations, not adjudicate matters of policy. However, the technical, far from providing universal, incontestable solutions, in fact remained entirely unsettled.

The crucial point about this patent application, as earlier noted, is that it was for the β-crystalline form of imatinib mesylate. The opposition claimed that the β-form was simply a polymorphic form of a core molecule that had already been patented in 1993. Since Section 3(d) specifically excludes patents on polymorphs, the contention was that the β-form was hence not patentable, unless it shows significantly enhanced efficacy. So now, the question of adjudicating the ontological nature of a molecule (is the β-isoform of imatinib mesylate created through an inventive step or is its formation an inherent property of the salt?) had to shift to evaluating its efficacy. This, it turns out, meant evaluating what constitutes efficacy in the first place, and what constitutes a significant enhancement of it. It is worth quoting from the patent ruling in this regard:

> As regards efficacy, the specification itself states that wherever β-crystals are used the imatinib free base of other salts can be used. . . . As per the affidavit [submitted by Novartis] the *technical expert* has conducted studies to compare the relative bioavailability of the free base with that of the β-crystal form of imatinib mesylate and has said that the difference in bioavailability is *only 30%* and also the difference in bioavailability may be due to the difference in their solubility in water. . . . Even the affidavit submitted on behalf of the Applicant does not prove any *significant enhancement* of known efficacy.[4]

This ruling is made on purely technical grounds, apparently universal and value neutral. And yet there is no clear, universal understanding of what constitutes significantly enhanced efficacy. Further, the assistant patent commissioner inserts the value-laden word *only*. While the establishment of a 30 percent differential in bioavailability (and hence, it is claimed, in efficacy) was framed as a purely technical matter, the rendering of that difference as insignificant was the adjudication of the assistant patent commissioner. This is crucial, because Novartis pointed to the 30 percent difference in bioavailability as precisely being the significant difference. Therefore two moments of black boxing are seen here. First, efficacy was rendered in terms of bioavailability, a correlation that was itself questioned by the opposition and which would remain a significant point of contestation as the legal dispute over Gleevec unfolded in subsequent years. Second, it was deemed that a 30 percent increase is insignificant. A different adjudicator might well have seen that 30 percent in a different light. This verdict rested on such slender threads.

Novartis responded by taking the Indian Patent Office to the Madras High Court in May 2006 to challenge this decision. The company disputed both the denial of the patent and the very constitutional validity of Section 3(d), thereby splitting the case into two dimensions, one technical and the other constitutional. Novartis was not merely disputing the particularities of a single patent decision; it was challenging sovereign legislation of the Indian Parliament in a court of law, suggesting that nation-state sovereignty is not absolute but tempered by and subject to international agreements the state has signed. At this point, the case came to be about much more than the denial of a patent on a single molecule; it came to be about the very grounds upon which other such denials on other molecules could be made in the future. Therefore it also was about the possibilities of and limits to pushing back against trade agreements that constitute unequal relations of exchange

and development, the upper hand always going to the advanced industrialized nations of Euro-America and Japan.[5]

The basis of Novartis's opposition to Section 3(d) was twofold. The first claim was that Section 3(d) violated the TRIPS agreement. Novartis asserted that this noncompliance violated the government's constitutional duty to harmonize its national laws with its international obligations, and that the Indian state was constrained in its freedom of legislative action because of the contractual relations of international agreements that it had signed. The second claim was that it violated the Constitution of India. By not properly defining terms like "efficacy," "enhancement of efficacy," and "significant enhancement of efficacy," Novartis said that the provision was vague (though why vagueness should be a constitutional violation as opposed to merely imprecise wording of policy was not made clear). The defense meanwhile claimed that a domestic court does not have the authority to examine TRIPS compatibility. Rather, the exclusive forum for deciding such an issue would be the WTO's Dispute Settlement Board. Corporations cannot take an issue to the board; only member nations of the WTO can, and the Swiss government, which was the relevant member nation in this case, was not doing so. Second, it was claimed that there was no violation of the Constitution of India. Efficacy, the defense claimed, had a clear meaning in the pharmaceutical field. Further, in the field, a one-size-fits-all definition of efficacy could not be held as valid.

In June 2007, Novartis lost the case. The Madras High Court ruled that, on the specific matter of the denial of the Gleevec patent, it did not have the technical expertise to overrule the Patent Office, and it transferred the hearing on the specific merits of the patent denial to the IPAB (which subsequently upheld the original decision of the Patent Office to deny the patent on Gleevec). What the court did rule on was the constitutionality of Section 3(d). And here, the court effectively accepted the arguments of the defense. In doing so, the court further insisted that efficacy had to be understood narrowly, as meaning therapeutic efficacy. And so, while the court did not rule on whether Gleevec itself met the criterion of increased efficacy as required by 3(d), it did provide its interpretation of how that criterion should be defined. This would serve as important precedent for how efficacy would come to be read in the adjudication of subsequent appeals. The court also added a crucial insertion in its verdict. For the first time in the patent dispute, it went beyond technical considerations to bring in considerations of good health care. The judgment, in this regard, says, "We have borne in mind *the object which the Amending Act wanted to achieve*, namely . . . to provide easy access to the citizens of this country to life saving drugs and to discharge their *Constitutional obligation* of providing *good health care* to its citizens."[6]

There are three crucial points to emphasize regarding this verdict. The first concerns the court's willingness to engage in interpretation of legislative objectives in a high-stakes intellectual property case that has become a landmark verdict with implications for the precedents it sets. It is worth contrasting this to another such landmark intellectual property verdict in the life sciences that set a significant precedent allowing the patentability of multiple life forms in the United States, *Diamond v. Chakrabarty*, which allowed for a patent on a microorganism that could break down crude oil spills, in many ways providing the precedent that would open the floodgates to biotechnology patenting in the United States in and since the 1980s.[7] This well-known 1980 U.S. Supreme Court verdict is notable precisely for the majority's extension of plant patents to other living (in this case microbial) forms on the grounds that the U.S. legislature, in specifically coming up with laws that allowed patents on plant varieties, had not specifically excluded the patenting of other life forms. It was thus decided that an implied exclusion could not be assumed. The Madras High Court, however, read the 2005 Patent Act not just in its letter, but in its spirit; and the spirit that is being read concerns not the provisions that provide protection to capital, but those that provide exceptions to patentability in order to protect public health. Therefore, the second crucial point to consider is how the objective of the 2005 Act is read by the court in terms of access—a distributive justice-based interpretation. And the third point to consider is a set of key words—*constitutional obligation* and *good health care.*

What one sees in this case is an example of coproductions between law and the life sciences, a form of what Sheila Jasanoff (2011) has referred to as bioconstitutionalism. It is important to situate such judicial resolutions comparatively. The differences between the Madras High Court verdict on Gleevec and *Diamond* are in part likely to be a function of different kinds of relationships between the judiciary and the legislature in the United States and India, the deep American ambivalence toward perceived judicial activism in contrast to a readier willingness on the part of Indian courts to engage in legislative interpretation from the bench. They are also likely a result of different political imaginaries in relation to property, the deeply protectionist American attitude toward property (which has become almost sacred, especially since Reagan), a contrast to an Indian legal attitude toward property that has generally been much less reverent.[8]

The High Court verdict opened up at least three sets of stakes that would come to matter in significant ways as the legal history of this case subsequently unfolded. The first concerns the purification of technical and constitutional regimes in adjudicating the Gleevec patent. While the technoscientific purports to be universal, it turns out to be contingent, with the means of establishing, defending, and contesting relations of production being actively constructed. While the constitutional always already limits itself to national and civic issues, it does so through the invocation of values that are, if not universal, then at least for the public good. The second concerns the question of comparison. If one looks at the Madras High Court judgment not in isolation but next to landmark judgments in other national contexts, then one can potentially see different relationships to legislation as well as different imaginations of the value of property rights, their sanctity, and their weight relative to the public good. At stake here are comparative questions of judicial cultures, technoscientific imaginaries, and legal histories of property.[9] And the third concerns questions relating to the kinds of social contract that are at stake—between state and citizen on the one hand, and between consumer and corporation on the other—through the imagination of different biomedical economies that presume different definitions of health. In the process, it becomes important to consider how the notion of invention itself is put into question, and how its scientific understanding intercalates with the history and politics of patent law in postcolonial India. These questions emerged as central to the Gleevec case as it further enfolded in the Supreme Court of India.

The Supreme Court Case, 2009–2013

In 2009, Novartis appealed to the Indian Supreme Court. This was not an appeal against the High Court verdict, and hence no longer a questioning of the constitutional validity of Section 3(d), but was rather about its interpretation.[10] Novartis sought to enforce an interpretation that would allow 3(d) to remain on the books, but effectively as a dead letter. First, it disputed the restricted meaning given to the term *efficacy* in terms of therapeutic efficacy by the Madras High Court. Second, Novartis asked that since 3(d) contained no specific guidelines for what constitutes enhanced efficacy, how could bioavailability be rejected as a basis for its evaluation?

This led to a broader disputing of whether or not a 30 percent increase in bioavailability was consequential for the purpose of evaluating efficacy. As mentioned, the Patent Office held that it was not, a point that the IPAB reiterated by making reference to the Madras High Court's insistence that efficacy be narrowly understood as therapeutic efficacy. Novartis claimed that it was impossible to establish therapeutic efficacy in relative terms without clinical studies on humans, since therapeutic efficacy was not an inherent property of a molecule but always dependent on context—the clinical setting, patient population, form of drug, or dosage. Such a context-dependent evaluation of therapeutic efficacy, it argued, was the purpose of a clinical trial for regulatory approval of a drug to market. It could not be a reasonable requirement for a patent claim. Conducting clinical studies as a prerequisite for a patent claim, which is an early-stage claim made long before regulatory preclinical studies, would, according to Novartis's submission, be "highly unethical" (Novartis Supreme Court SLP, 5(F)). Therapeutic efficacy in a clinical setting, it was stated, was only shown for β-imatinib mesylate, and not for any molecular form obtained prior to that. In making this argument, Novartis sought to uncouple the requirements of a patent regime that evaluates invention and a regulatory regime that evaluates the safety and efficacy of a drug. Given that the clinical efficacy of a research compound could not possibly be ethically determined, a proxy was required as a marker of efficacy. Bioavailability constituted such a proxy. Therefore, Novartis moved away from earlier arguments before the High Court that claimed bioavailability as implying increased efficacy, to now suggesting that bioavailability was a necessary surrogate marker for increased efficacy, the best that could exist in the absence of actual clinical studies.

I return to some of these questions in the course of reading the Supreme Court's judgment on this appeal. Before doing so, it is worth considering the modality of adjudication employed thus far in relation to the validity of the Gleevec patent by the Patent Office (and subsequently the IPAB). This concerned asking the question of patentability in relation to the existing legislation, but also in relation to the patent claim itself. These were the two authoritative sources that had to be reconciled. Section 3(d) rendered this reconciliation challenging, because it introduced an additional standard for patentability beyond the establishment of inventiveness and nonobviousness, and therefore legally uncoupled the definition of invention from that of patentability. Nonetheless, what was at stake was the reconciliation of the letter of the law with the letter of the claim. Novartis's appeal sought to effect this reconciliation in a manner that rendered the former effectively worthless as an enhanced standard of patentability beyond invention.

The Supreme Court, however, insisted upon a different kind of reading of the law, one that was hermeneutic as opposed to literal. The court's attempt was not just to reconcile two statements, but to interpret the legislative context

within which a patent claim should be evaluated. This meant that the court insisted upon reading legislative intent into Section 3(d).[11] The way in which it arrived at its interpretation of legislative intent was through historical context. In the process, the judgment provided a tour-de-force account of patent history in postcolonial India. The two histories of Gleevec that I set up at the start of the chapter do not just serve analytic purposes; it was precisely by insisting upon the situation of the history of Gleevec's development in the context of the history of Indian patent law that the court arrived at its final denial of a patent on Gleevec.

Writing for the court, Justice Aftab Alam explained the reasons behind such a reading.[12] The patent application for β-imatinib mesylate was filed in India in 1998, when the country was in a transitional period between two patent regimes, and in which the primary change to be enacted was the institution of a product patent regime. This involved important changes in Sections 2 and 3 of the Patent Act (which described the criteria for patentability and specified what does not qualify as a patentable invention respectively). According to the court, "it is necessary to find out the concerns of Parliament, based on the history of the patent law in the country, when it made such changes in the Patent Act. *What were the issues that the legislature was trying to address?*" (Supreme Court verdict, 14, emphasis added). This is a clear statement that the court understood judicial function to involve the reading of legislative intent, thereby setting up the dialogic relationship between different arms of the state as the foundational context for adjudicating a particular patent claim. This understanding was itself based on judicial precedent, from the verdict of *Utkal Contractors and Joinery Pvt Ltd and others v. State of Orissa and others*, which also provided a method for interpreting legislative reasoning:

> A statute is best understood if we know the reason for it. The reason for a statute is the safest guide to its interpretation. How do we discover the reason for a statute? There are external and internal aids. The external aids are statements of Objects and Reasons when the Bill is presented to Parliament, the reports of committees which preceded the Bill and the reports of Parliamentary Committees. Occasional excursions into the debates of Parliament are permitted. Internal aids are the preamble, the scheme and the provisions of the Act. Having discovered the reason for the statute and so having set the sail to the wind, the interpreter may proceed ahead.[13]

Interpretive method was further articulated on the basis of the verdict in *Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd. and Others*, which stated, "Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context is what gives the colour."[14]

It is again worthwhile comparing this to the U.S. Supreme Court in *Diamond v. Chakrabarty*, cited earlier in reference to the Madras High Court verdict, to suggest the unwillingness of the U.S. court in that instance to similarly speculate upon legislative objectives in relation to a landmark intellectual property decision. Perhaps the most significant decision in American patent law relating to the life sciences was made by purifying the patent claim away from legislative context, rendering it as a separable and separate object that needed to be adjudicated in its own terms.[15] It was precisely such purification that was assumed by Novartis in all its submissions, but that the Indian Court refused at the outset. The comparative question of judicial cultures is in part a question of the way in which the relationship between the technoscientific and the political comes to be differentially interpreted. Both the Madras High Court and the Indian Supreme Court insisted upon the coproduction of the two, such that the question of what constitutes invention could never avoid recourse to the legal definition of invention and the legislative intent behind such definitions. The interpretive formula that was employed could be summarized as follows:

Is Gleevec an invention?
To answer this question, we must ask:
What is invention?
↓
What is invention *in the law*?
↓
What is the *legislative intent* behind such a legal definition of invention?
↓
What is the *history* behind the passage of legislation
that might reveal said intent?

It is on the basis of this methodological principle that the court outlined the legislative history of Indian patent law as outlined in table 3.1.[16] This began with the British colonial Patent Act enacted in 1911, which allowed product patents on pharmaceuticals for a fourteen-year period. This was the law of the land at the time of Indian independence in 1947. In 1949, a committee under the chairmanship of Justice Bakshi Tek Chand was constituted to look into the merits and demerits of this act. The committee gave its recommendations the following year and led to the first postcolonial Indian Patent Act passed in

1950, which insisted that inventions needed to be "worked" in India (i.e., the product on which a patent was obtained had to be manufactured in India and could not simply be imported from abroad), and included provisions for the issuance of compulsory licenses (which would allow the government to force the patent holder to license its invention) and revocations of patents in the public interest. The more substantial modification was based on the report of a committee headed by Justice N. Rajagopala Ayyangar, delivered in 1959, which recommended abandoning the product patent regime for a process patent regime. This formed the basis of the 1970 Patent Act. A process patent regime insisted upon the distinction between invention and patentability: even if something might philosophically be considered a technoscientific invention in its own terms, it did not necessarily imply that it was legally an invention that could be granted a patent. The Ayyangar Committee was centrally concerned with pharmaceuticals in its recommendations, both in terms of ensuring affordable access to medicines by preventing monopoly and in terms of stimulating national political economic competitiveness through creating a market terrain that would allow Indian pharmaceutical companies to compete with their multinational counterparts. This was the legislative intent behind the 1970 Act which, the Supreme Court noted, was met in subsequent decades. India's drug prices became among the lowest in the world, and its generic industry became nationally and globally competitive.

The change away from this regime, the court understood, was entirely a function of the demands of the TRIPS agreement. But even this agreement included the subsequent provisions of the 2001 Doha Declaration, which allowed signatory national governments to enact public health flexibilities within their now-mandated product patent regimes. There were three amendments to the Patent Act as India transitioned fully to TRIPS compliance: in 1999, when provisions for exclusive marketing rights were included; in 2002, when the definition of invention was broadened but certain flexibilities relating to public health such as compulsory licensing were included in Chapter XVI, Section 83; and then in 2005, when the law became fully TRIPS compliant with the inclusion of provisions for product patents (which included further flexibilities, including the amended Section 3(d)). The court read the Doha Declaration as entirely constitutive to the formulations and requirements of TRIPS and read the public health flexibilities enacted in 2002 (and 2005) as central to the legislative intent behind the amendments. Section 83 explicitly claimed that patents needed to be in the "public and national interest," and made reference to the importance of affordable pricing in relation to a patent regime.[17]

There was context to the passage of the final 2005 Act that the court paid particular attention to. The initial draft bill introduced in 2004 had not been legislated into an act by the end of the year. Worrying about the possibility of defaulting on its international obligations under TRIPS, the government passed an ordinance at the end of December 2004 that instituted a product patent regime. The ordinance was, however, only valid until March 31, 2005, by which time it needed to be replaced by an act of Parliament. The passage of the act was preceded by spirited parliamentary debates on March 18, 21, and 22, 2005, in which opposition parties voiced concerns about the impacts of a new product patent regime on drug prices. Gleevec was responsible in significant measure for this concern, given the politics that had already developed around the granting of exclusive marketing rights on the drug in 2002, which curtailed the capacity for generic manufacture (see chapter 4), and given that the price at which Novartis was selling its patented medication was up to thirty times higher than what Indian companies were charging for their generic versions. This was echoed by global concerns that were made clear to the Indian government, for instance by the World Health Organization and UNAIDS.[18] Hence, Indian patent legislation was entangled not just in global trade politics but also in a global politics of access to essential medicines. The terrain of globalization here is not simply constituted as an opposition between global free trade and sovereign national interest, but also through challenges between forces of capital and of public interest and public health that play out at both national and global levels of governance and advocacy. The politics around Gleevec was not just a consequence of the legislative history of patents in India; it actively helped shape that history.

The parliamentary debates emerged as a major source for the court to read legislative intent, because of the explicit concerns about product patent regimes in general that were voiced in these debates, specific concerns that were voiced about the extension of monopolies through evergreening, and suggestions that emerged in the course of the debates regarding the various public health flexibilities that could be introduced. The amendments to Section 3(d) were a response to these concerns. The court established a direct relationship between concerns about public health and access to medicines in Parliament, and the incorporation of 3(d) amendments as a response to those concerns. This was fundamental to the court's refusal to read Novartis's arguments about the interpretation of 3(d) simply with reference to the patent claim itself, and its insistence that this technical concern necessarily had to be interpreted constitutionally, with reference to legislative intent.

What one sees in the court's hermeneutic strategy is the coproduction of the technical with the constitutional, but also an interruption of logics of monopoly capital by creating its own interpretive dialogue with other arms of the state. Novartis's assumption in its submissions was that the critical issue in rendering a favorable interpretation of Section 3(d) was to argue for a broader definition of efficacy than therapeutic efficacy, a technical matter. But the court refused to accept it as such. Yet there was a further implicit assumption on Novartis's part, which has largely been unchallenged in the functioning of patent regimes in (especially) the United States (though also in Europe)—which is that the purpose of the patent (certainly in the arena of pharmaceuticals) is the securing of corporate monopoly. That assumption was nipped in the bud by the court through its reading of the parliamentary debates around Section 3(d). One level at which state dialogues operate here is between the judicial and legislative arms as the former reads the intent of the latter. But the voicing of concerns within Parliament, and the accommodation of those concerns by the government, speaks to another level at which they operate, within legislative and representative party politics in a multiparty parliamentary democracy, a point that I return to and detail in the next section.

The actual interpretation of Section 3(d) involved establishing its relationship to Section 2(1)(j), which defined what constitutes invention for the purposes of granting a patent, as the earlier debates in the IPAB about the relationship between molecular production and pharmaceutical efficacy now came to be reframed in terms of the relationship between two sections of an act of Parliament.[19] Counsels for Novartis contended in their arguments that Section 3(d) was not meant to nullify the criteria for invention as stipulated in 2(1)(j). They wished for an interpretation that would render 3(d) a derivative extension of 2(1)(j). Through a reading of legislative intent, the court established that Parliament clearly intended a distinction between invention and patentability. Even if Novartis could show that Gleevec was an invention that satisfied the criteria of Section 2 of the Patent Act, it would have to meet the higher standard of patentability demanded in the act, especially through Section 3(d). Meeting a philosophically intuitive definition of what constitutes invention would not be enough; it would be necessary for Gleevec to meet the legal definition of invention, which required satisfying 2(1)(j) and 3(d) independently. As Justice Alam stated in his verdict, 3(d) could not be read as subordinate to 2(1)(j) because it was "the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable" (Supreme Court verdict, 56).

The court used this insistence on a legal definition of invention that required the independent satisfaction of 2(1)(j) and 3(d) as the foundation for its reading of the invention claimed by Novartis for β-imatinib mesylate over that claimed for imatinib and its pharmaceutically acceptable salts in the original 1993 patent application filed in the United States and Canada (this was referred to as "Zimmermann patent" throughout the hearing, after Jurg Zimmermann, the lead author on the 1993 application).[20] But once again, it made a significant departure from the process followed by the Patent Office and the IPAB and from the mode of argument made by Novartis, all of which kept referring to the Zimmermann patent as the original point of reference with respect to which subsequent comparisons could be made, thereby rendering the patent claim the singular material signifier of the invention.[21] Beta-imatinib mesylate had to be established as an inventive, nonobvious modification of the substance claimed in the Zimmermann patent, and further as one that showed significantly increased therapeutic efficacy.

In contrast, the court looked not at the singularity of the patent claim, but at how that patent claim was deployed in the history of Gleevec's development and marketing in order to arrive at its judgment. And it noted a singularly important fact, which was that the U.S. patent for β-imatinib mesylate was filed in 2000 and only given to Novartis in 2005.[22] Yet Gleevec was approved for market in the United States in 2001, and protected in the U.S. market on the basis of the Zimmermann patent itself. The court further looked at the relationship between the patent claim and regulatory approval by studying the New Drug Application (NDA) filed by Novartis with the U.S. Food and Drug Administration (FDA).[23] In the NDA, the active ingredient was stated as imatinib mesylate, and the active ingredient and its composition and formulation were said to be covered by the Zimmermann patent.[24] The court further cited Gleevec's package insert, which describes the drug as follows: "GLEEVEC™ capsules contain imatinib mesylate equivalent to 100 mg of imatinib free base. Imatinib mesylate is designed chemically as 4-[(4-Methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamind methanesulfonate."[25]

Nowhere was β-imatinib mesylate mentioned in the NDA or the package insert. Furthermore, once the drug was approved for market, Novartis filed for an extension of the patent term of the Zimmermann patent, which was granted, again suggesting that this was the patent that covered the drug. The court also looked at Novartis's own history of enforcing its patent monopoly on Gleevec. Natco Pharmaceuticals had started selling its generic version of the drug, Veenat, in the United Kingdom. This was successfully challenged

by Novartis, yet again on the basis of the Zimmermann patent. This history suggested to the court:

> It [is] clear that the drug Gleevec directly emanates from the Zimmermann patent and comes to the market for commercial sale. Since the grant of the Zimmermann patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann patent. It obtained drug approval for Gleevec on that basis. It claimed extension for the term of the Zimmermann patent for the period of regulatory review for Gleevec, and it successfully stopped Natco Pharma Ltd. from marketing its drug in the UK on the basis of the Zimmermann patent. (Supreme Court verdict, 68)

The parenthesis in this statement is particularly important: "Gleevec (that is, Imatinib Mesylate)." Based on Novartis's own claims throughout the social life of the drug, the court decided that Gleevec was, chemically, imatinib mesylate and not β-imatinib mesylate. In addition to its regulatory and patent enforcement history, the court looked at the publication history around the drug, noting a 1996 publication in *Cancer Research* that included Jurg Zimmermann as an author, which discussed the antitumor properties of imatinib and imatinib mesylate; and a 1996 *Nature Medicine* article, also with Zimmermann as author, showing imatinib as the compound that inhibits Abl protein tyrosine kinase (Buchdunger et al. 1996; Druker et al. 1996). And imatinib mesylate, according to the court, was already covered by the Zimmermann patent, which covers all pharmaceutically acceptable salts of imatinib (a conclusion consonant with that arrived at by both the Patent Office in its initial denial of the patent on grounds of lack of inventive step, and by the IPAB). In the court's judgment, the question of whether the conversion of imatinib mesylate to β-imatinib mesylate was inventive or nonobvious or not was irrelevant, because it was imatinib mesylate, not its β-isoform, which was functioning as a drug commercially. Even if chemically, Gleevec was β-imatinib mesylate, legally and from a regulatory standpoint, Gleevec was, simply, imatinib mesylate, based on Novartis's own submissions. Justice Alam made his thoughts on β-imatinib mesylate's legal status clear during the hearing of the case, when he stated that "the β-crystal form is the same person [as imatinib mesylate] in fancy dress."[26]

At stake here are two different modalities of reading the authority that resides within a patent claim. The arguments of Novartis's counsel rested upon the structure of anticipatory knowledge embodied within the claim, as something that covers all potential modifications of the invention that is

claimed, but does not disclose any particular one. This allows for a broad scope of coverage (allowing for a broader monopoly from a patent) alongside a narrow scope of disclosure (allowing for subsequent separate patent claims on specific modifications of the initial invention, also thereby allowing for a broader monopoly from a patent).[27] It also presumes broad conceptual and temporal authority of the initial claim, while dissociating it from the specific deployments of that claim in the world.

It is precisely such a presumption that was refused by the court in its reading that rendered the initial claim accountable to its subsequent deployments. This reflected different understandings of the relationship between the monopoly conferred by the patent and public interest. Novartis adopted a Schumpeterian perception of the monopolistic function of the patent, which is that providing the inventor with an absolute monopoly as an end in itself serves public interest by providing incentives to innovate (Schumpeter 1942). In the case of Gleevec, Novartis would maintain that these incentives were repaid to the public through the company's charitable drug donation program, the Gleevec International Patient Assistance Program (GIPAP), which provided the drug free to eligible patients unable to pay for it.[28] In contrast, the court read the patent as an instrumental monopoly in the public interest. In such an understanding of a patent regime, the boundary between the scope of coverage and disclosure that Novartis was arguing for was rendered untenable, because it would allow the initial patent to function as a blocking patent.[29]

By refusing this distinction, the court restricted the authority of the patent claim as an instrument to secure future monopoly as an end in itself. The implications of this go beyond the specifics of the Gleevec case, even beyond the specifics of the interpretation of Section 3(d), to providing judicial precedent for the rationale of the patent system itself. The court made this clear as it stated, "We certainly do not wish the law of patent in this country to develop on lines . . . where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its *claims* by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent" (Supreme Court verdict, 81, emphasis in original).

By situating Section 3(d) within the broader history of patent law in India, the court had determined that it was a criterion that had to be satisfied in its own right, and not simply as derivative of Section 2(1)(j). By reading the Zimmermann patent not just as a discrete claim with its own authority but as a strategic instrument that was deployed in the world toward particular

ends, the court questioned whether the patent on β-imatinib mesylate would even matter given Gleevec's legal and regulatory history as imatinib mesylate in the United States and elsewhere. And by refusing to accept the distinction between scope of coverage and disclosure, the court made clear that it saw imatinib mesylate as already covered by the Zimmermann patent, which was not enforceable in India, while also clarifying that it saw the patent as an instrument of public interest that had to be interpreted and enforced as such. Through these lines of reasoning, the court established that Gleevec did not meet the criteria for legal invention established in Section 2(1)(j).

This still left the question of the specific applicability of Section 3(d): was β-imatinib mesylate a modification that conferred significantly enhanced therapeutic efficacy over the known substance? And what was the known substance, imatinib free base or imatinib mesylate? Recall that this was the primary question in Novartis's appeal to the Supreme Court. It therefore was a question that still needed to be adjudicated. However, the hermeneutics employed by the court rendered it a tertiary question as far as the Gleevec patent itself was concerned: whatever its verdict on 3(d), Gleevec could not be granted a patent because it did not satisfy 2(1)(j). Nonetheless, the stakes of the court's interpretation of 3(d) were high in terms of the precedent it would set in the long term regarding how efficacy would be interpreted. Novartis was attempting in its appeal to force the issue of defining significantly enhanced efficacy by revisiting the question of the relationship between bioavailability and efficacy, with the hope that this would lead to a broader interpretation of efficacy than that allowed by the Madras High Court and upheld by the IPAB.

In the Supreme Court, Novartis's case was supplemented by an independent brief submitted by legal expert Shamnad Basheer, who argued against the narrow definition of efficacy as therapeutic efficacy granted by the High Court.[30] Basheer's brief was an attempt to lend legal and regulatory clarity to Section 3(d), by establishing a consistent definition on the basis of which it could be enforced, which he felt was important for "the robust development of sound patent jurisprudence for India" (Basheer intervention, 8).

Basheer argued that the U.S. Orphan Drug Act (ODA) should provide the basis for a definition of efficacy in terms of "therapeutic advantage."[31] This would be a broader criterion than therapeutic efficacy, and would explicitly allow physical properties of a molecule such as bioavailability to be taken into account while evaluating enhanced efficacy. This was a peculiar line of argument. For one thing, Basheer was arguing for an interpretive guideline for 3(d) that did not even include the word *efficacy*, which appears not once

but twice in the section. For another, the ODA is not even patent legislation, and its intent is to incentivize research into rare or neglected diseases for which there might not be a sufficient market incentive; the intent of 3(d) is to prevent pharmaceutical evergreening. This means that 3(d) is specifically an instrument to reduce monopoly, whereas the ODA provides extra market exclusivity and monopoly to companies as reward for developing orphan drugs. Rather than clarifying the legislation, Basheer seemed to be rewriting it in terms of categories that existed in neither the wording nor the intent of 3(d).

The ODA provides complete market exclusivity of seven years to the originators of orphan drugs. But it does allow a competitor to market a structurally similar drug that is "clinically superior." The question of what constitutes clinical superiority then becomes a crucial interpretive question, which Basheer suggested was a problem similar to that confronted in the evaluation of efficacy with respect to 3(d). Clinical superiority is defined under the ODA as showing "a significant therapeutic advantage over and above that provided by an approved orphan drug" (as cited in Basheer intervention, 13). The grounds upon which therapeutic advantage can be established include not only greater therapeutic effectiveness of the competitor drug, but also superior safety. Basheer argued that in principle, increased bioavailability could lead to increased therapeutic advantage by leading to lower dose requirements and thereby reduced toxicity, which could lead to improved safety. He was not claiming increased therapeutic advantage in the specific case of Gleevec by virtue of the 30 percent increase in bioavailability of the crystalline isoform over free base, which he said needed to be independently established. But he was arguing for a lower threshold for establishing efficacy than the establishment of therapeutic efficacy.

Basheer's intervention did not turn out to be significant to the verdict in the case (except ironically, as indicated below, to Novartis's detriment), though it did cause anxiety among Novartis's opponents given that it was providing a persuasive alternative to therapeutic efficacy as the definition of efficacy. But it is important to point to the conceit behind it. If Novartis sought to enforce a narrowly technical definition of invention purely with respect to the patent claim, then Basheer's attempt was to enforce a narrowly legal one, in which the letter of the law would transparently and without reference to history or context provide a clear definition of efficacy that could be uniformly enforced. Both Novartis and Basheer were pushing technocratic interpretations of patent law that could consistently isolate and purify inventive criteria in ways that did not allow for the interpretive license taken by patent adjudicators and the courts as they attempted to establish the applicability of 3(d)

to Gleevec. For the court, however, such license was essential to allowing the kinds of thick interpretation necessary to situate a molecule's patentability not just along a linear imaginary of romantic invention that materializes through a patent claim, but also in relation to the legislative intent to prevent monopolistic corporate practices at the expense of public health and access to affordable medicines.

The court established that β-imatinib mesylate needed to meet the test of Section 3(d) since it was derived from a "known substance" that had already been patented. To this end, it referred to the Indian patent application for β-imatinib mesylate, which states that "all of [its] indicated inhibitory and pharmaceutical effects are also found with the free base . . . or other cells thereof" (cited in Supreme Court verdict, 84). This statement alone, according to the court, made it clear that β-imatinib mesylate could not qualify for a patent under 3(d), since "when all the pharmacological properties of beta crystalline form of Imatinib Mesylate are equally possessed by Imatinib in free base form or its salt, where is the question of the subject product having any enhanced efficacy over the known substance of which it is a new form?" (85).

However, what was the known substance? The court pointed to the ambiguities of Novartis's own position in the matter. Its patent application pointed to imatinib free base as the original molecule from which β-imatinib mesylate had been derived. Yet its claims for the inventive nature of the crystalline form claimed that it was two steps removed from the free base, suggesting that the known substance preceding it was not the free base but imatinib mesylate. The court had already established that both freebase and imatinib mesylate were disclosed in the Zimmermann patent and therefore not eligible for a product patent in India; but the question was which one of the two would serve as the reference with respect to which the efficacy of the β-crystalline isoform would have to be established?

To answer this, the court referenced two affidavits submitted on behalf of Novartis before the controller of patents at the Chennai Patent Office in 2005, by the chemists Paul Manley and Giorgio Massimini, in order to show that Gleevec met the requirements of Section 3(d). Manley's affidavit pointed to the greater stability, flow, solubility, and hygroscopicity of β-imatinib mesylate, while Massimini's described the rat study showing 30 percent increase in bioavailability—in both cases, the point of comparison was to the free base. The court could not find any submission that showed the efficacy of β-imatinib mesylate over noncrystalline imatinib mesylate. It wanted to know: does noncrystalline imatinib mesylate have equivalently higher solubility relative to free base as the β-crystal? The assumption was that it probably

did, given that "one does not have to be an expert in chemistry to know that salts normally have much better solubility than compounds in free base form" (Supreme Court verdict, 88). And if so, then how could the β-form be an improvement over its immediately preceding substance, imatinib mesylate?

The relationship between chemical ontology and legal reasoning is worth unpacking here. The reason that imatinib mesylate does not appear as an entity in any of Novartis's submissions is likely because it is chemically a transitional or interstitial entity. The patent claim on the β-crystalline isoform suggests that methanesulfonic acid salts of imatinib tend to crystallize. A common crystal form is the α-crystal form, which is less thermodynamically stable, needle-shaped (and therefore less easy to absorb), and difficult to reproduce. The β-form is more thermodynamically stable, non–needle shaped, and can be reproduced. Yet legally, imatinib mesylate was an entity that needed to exist in order for Novartis to claim a two-step improvement over imatinib free base, and did exist in its regulatory submissions and package insert. For β-imatinib mesylate to satisfy Section 3(d) legally, the court demanded a comparison with imatinib mesylate, a comparison that was chemically untenable. Imatinib mesylate was deemed to be a known substance for the purposes of comparing efficacy because it was anticipated by the Zimmermann patent claim, which included "all pharmaceutically acceptable salts" of imatinib, rendering it legally a real substance and a relevant standard of comparison.

The final question concerned efficacy—how was it to be defined for the purpose of interpreting Section 3(d)? The court concurred with the Madras High Court that it had to be in terms of therapeutic efficacy, using as its basis the linguistic definition of efficacy as stated in the *New Oxford Dictionary of English* (1998 edition), which describes it as "the ability to produce a desired or intended result" (cited in Supreme Court verdict, 90). The court deemed that, in the case of medicines, this had to imply the ability to cure a disease, and hence necessarily suggested therapeutic efficacy.[32] What then would be the parameters by which therapeutic efficacy could be defined?

The arguments for Novartis's counsel echoed Basheer's interventions, suggesting that these parameters had to be broad enough to include attributes such as bioavailability, which could confer therapeutic advantage by leading to reduced dosage requirements and hence decreased drug toxicity. In opposition to this position, Anand Grover, lead counsel for CPAA, insisted on the basis of pharmacological textbooks that therapeutic efficacy had a clear meaning in the field and was established in terms of pharmacodynamics (what the drug does to the body), not pharmacokinetics (what the body does to the drug, which is relevant for considering attributes such as bioavailability).

The court accepted the fact that bioavailability of a drug is necessary for its effectiveness, but cannot in itself be regarded as an indicator of therapeutic efficacy. Ironically, it drew upon Basheer's intervention to disregard bioavailability as a criterion for therapeutic efficacy, since he had stated (citing another commentator) that "a determination that a drug product is bio-available is not in itself a determination of effectiveness."[33] On this basis, the patent was denied on the basis of 3(d) as well, and precedent was set for the interpretation of the section on narrow grounds of therapeutic efficacy.

The Science and Politics of Gleevec

The Supreme Court verdict led to predictably polarized responses from those supporting and opposed to Novartis's position. For instance, a *Wall Street Journal* article cited Novartis's executives and representatives of the multinational pharmaceutical industry making straightforward and oft-cited correlations between a favorable patent environment, innovation, and public health. Ranjit Shahani, vice chairman and managing director of Novartis India, said, "This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options." A Novartis spokesman linked this to the threat of reduced investment in India as a market: "If innovation is rewarded, there is a clear business case to move forward [in India]. If it isn't rewarded and protected, there isn't." The Pharmaceutical Research and Manufacturers of America, the major U.S.-based lobbying group for the multinational pharmaceutical industry, stated that the ruling "marks yet another example of the deteriorating innovation environment in India" (Krishna and Whalen 2013).

In contrast, those involved in advocacy for access to medicines celebrated the ruling as an important victory. A collection of essays in the *Economic and Political Weekly* provides various legal and civil society perspectives and contexts on the case, and the stakes and consequences of the verdict, from this oppositional position.[34] Particularly important in this collection is an essay by K. M. Gopakumar (2013), who argues that while important, this was nonetheless a limited victory, and that what was needed was legislation that would prevent patenting on all known substances, regardless of improvements in efficacy, as existed in the 1970 Act. Such positions are also taken in the interests of innovation but more stringently defined, with an insistence that practices such as evergreening in fact reflect the lack of innovation in an industry that often protects its monopoly through minor modifications to existing drugs.

It is perhaps ironic that such an argument could effectively be made against Gleevec, widely regarded as one of the most innovative and revolutionary anticancer medications ever developed. Indeed, much has been written about Gleevec as a magic bullet in the treatment of cancer, and as an exemplar of translational research that sees basic research into mechanisms of disease translate into medically available treatments. Some of these accounts, such as the one written by Novartis CEO Daniel Vasella (2003), provide a linear and romanticized model of scientific invention. More reflexive and sociologically intricate accounts of Gleevec's development have been provided by Siddhartha Mukherjee (2011), and by Peter Keating and Alberto Cambrosio (2012). It is worth constructing some of the complexities of Gleevec's story from these accounts; but even they are not attentive to how the political gets constituted if one recognizes that Gleevec's is a global story, not just one that plays out in Euro-American research laboratories, clinics, and corporate boardrooms.

Mukherjee's account of Gleevec's development is part of his magisterial account of the history of cancer research and treatment (what he refers to as a "biography of cancer"), *The Emperor of All Maladies*. It is exemplary of a move that began in the 1980s toward targeted cancer therapy, which developed out of a mechanistic understanding of cellular and molecular triggers for particular cancers that then serve as therapeutic targets. The breast cancer drug Herceptin (trastuzumab, developed by Genentech) and Gleevec are the two early success stories of targeted cancer therapy. The histories of both drugs indicate the importance of corporate involvement in biotechnology research toward therapy. This involvement is not politically straightforward. On the one hand, it is unlikely to imagine the translation of basic research on molecular mechanisms involved in cancer into therapeutic development without the pull of corporate investment in capital and human resources. On the other hand, these investments are always predicated on strategic market calculations, which means that the developmental trajectory of a drug is always dependent upon how potentially valuable that investment seems in terms of financial rather than therapeutic benefit. Both the Herceptin and Gleevec stories involved particular researchers (Dennis Slamon at UCLA in the case of Herceptin; Brian Druker at the Oregon Health and Science University and Nicholas Lydon at Novartis in the case of Gleevec) having to fight against corporate market calculations to push ahead with their research programs.

A second common thread in the two histories concerns the importance of cancer patient activism for access to medicines and putting pressure on

researchers and regulatory agencies to speed up clinical trials. In the case of Herceptin, Mukherjee traces the history of breast cancer activism that led to an expanded access program to the experimental drug even before it was approved for market.[35] Therefore, access politics was imbricated in the politics of clinical trials, in ways radically different from a context such as India's where clinical trials for these drugs did not take place, and where the political resonances of experimental subjectivity emerge quite differently. Questions of such differential constitutions and resonances of the political across different locales are precisely what concern me here, as I will elaborate.

Any account of the scientific developmental trajectory of Gleevec must be located in these two contexts, of corporate involvement and of a politics that was about speedier access through greater investment in novel drug development and quicker approval to market. But the purely scientific trajectory is itself complex and involves the serendipitous intersection of two independent histories—of basic research and of corporate screening for potential drug targets—that merge and continue into a third: of clinical trials. I briefly describe this trajectory for Gleevec, by summarizing accounts from Mukherjee and from Keating and Cambrosio's account of the history of cancer clinical trials, *Cancer on Trial*.

The basic research trajectory did not begin with the search for a drug. It was, rather, perhaps like all basic research in biology, full of moments of discovery that could retrospectively be reconstructed into a linear trajectory toward a drug. Some elements of this include the discovery of a particular chromosomal abnormality (the Philadelphia chromosome) in patients with chronic myeloid leukemia (CML) in 1960 (Nowell and Hungerford 1960); the discovery of translocation between fragments of chromosomes 9 and 22 as the mechanism causing this abnormality (Rowley 1973); the identification of genes involved in these translocations, *abl* (on chromosome 9) and *Bcr* (on chromosome 22), whose fusion was found to result in the *Bcr-abl* oncogene; the engineering of a mouse containing *Bcr-abl*, which proved the relationship between this oncogene and the development of CML; and functional studies of *Bcr-abl* that identified it as a tyrosine kinase.[36]

The trajectory of research at Ciba-Geigy was on a quite different problem, a search for molecules that could inhibit the family of enzymes called kinases (which are involved in regulating cellular activity through phosphorylation, that is, adding phosphate groups to molecules to cause their activation, inactivation, stimulation, or inhibition), but selectively (since kinases are essential enzymes that are involved in the regulation of all manner of biochemical pathways, and a nonselective kinase inhibitor would be impossibly toxic). This was a team led by the chemist Nicholas Lydon, who found a molecule with potential selective kinase inhibitory properties. Jurg Zimmermann, who became the lead author on the 1993 patent claim for imatinib, created thousands of variants of this molecule, while Elisabeth Buchdunger tested these molecules on cells. In the process, Ciba-Geigy scientists were coming up with kinase inhibitors without a specific disease target, while basic research on CML had led to an understanding of disease mechanism that involved a tyrosine kinase, *Bcr-abl*.

One of the researchers studying *Bcr-abl* kinase was Brian Druker at the Dana-Farber Cancer Institute of Harvard Medical School, who heard of Lydon's collection of potential kinase inhibitors and approached him to collaborate. In spite of the enthusiasm of the individuals concerned, the collaboration could not proceed institutionally because of legal objections from Harvard's side (see Keating and Cambrosio 2012). Ironically, this was because of an exclusive agreement between Dana-Farber and Ciba-Geigy's competitor Sandoz (which would subsequently merge with Ciba-Geigy to form Novartis). It was only after Druker left Harvard to join the Oregon Health and Sciences University (OHSU) that the collaboration could proceed, as OHSU's lawyers allowed a collaboration that Dana-Farber's did not. Druker conducted a series of studies on Lydon's molecule—first, in vitro studies on CML cells in a petri dish; then experiments in mice implanted with CML cells; and finally, experiments on human bone marrow from CML patients. These were the results published in *Nature Medicine* that would subsequently come to be central to establishing the trajectory of the drug in the Supreme Court case, albeit in the specific matter of the name of the molecule disclosed in the article, which had no mention of the β-crystalline isoform of imatinib mesylate.[37]

This history suggests a trajectory of invention very different from that implied in a patent claim, which implies simply that the pharmaceutical company is the innovator of a new drug. But it also suggests a trajectory different from that claimed by opponents to Novartis, in whose eyes the real inventor of Gleevec was Druker.[38] Both of these are based in romantic imaginaries of invention, whether by the innovative company or by the genius scientist. In fact, what was critical was the collaboration between Druker and Lydon that allowed two independent research trajectories to find each other and merge. This set the stage for the clinical trials of Gleevec, which required further collaborations with physicians and clinical researchers.[39]

The Gleevec trials can be seen as revolutionary, both because of their outcome (showing significantly better results than the current standard of care, which was interferon and/or bone marrow transplantation) and their speed (the entire process from the start of Phase 1 trials to market approval took less than four years, unlike the typical ten-to-fifteen-year process that most drug trials involve). The Phase 1 results on eighty-three patients were published in the *New England Journal of Medicine* in 2001 (Druker et al. 2001), but Novartis had activated Phase 2 and 3 trials even before this publication. Keating and Cambrosio point to the unusual nature of these trials, not just in terms of their speed, but also in terms of the relatively large number of Phase 1 enrollees, since Phase 1 studies are toxicity studies that typically enroll only about ten volunteers. Most enrollees in early-stage oncology trials tend to be patients in the terminal stages of the disease: given the high toxicity of most anticancer drugs, they cannot be tested on healthy volunteers, and are often tested only on people for whom other avenues have been largely exhausted. Yet the Gleevec trials included patients in less terminal stages. This meant that the Phase 1 trial was not simply a test of the drug's toxicity, but already was an initial test of its potential curative effects. Because those effects were so substantial, many Phase 1 enrollees were still receiving the drug at the time of the *NEJM* publication, making for an unusually long experimental duration of a Phase 1 trial. Keating and Cambrosio draw upon Vasella's account of the development of Gleevec to suggest the pressures the company felt from patients who had heard of the promising early results from the Phase 1 trials, leading to their fast-tracking of Phase 2 and 3 trials even before Phase 1 was completed. This is an example of what they refer to as oncopolitics.

Ironically, Novartis was reluctant to initiate clinical trials even after Druker's promising early results, mirroring similar reluctance on Genentech's part to invest in the R&D of Herceptin. Druker and Lydon's collaboration was throughout conditional on institutional enthusiasms, and was nearly scuttled by both the academic and corporate institutions involved. Mukherjee emphasizes this in his account as he describes the Gleevec story in terms of "an inverted world in which an academic researcher had to beg a pharmaceutical company to push its own products into clinical trials" (2011, 436). Druker assembled his own team to run the trials, and managed to persuade Novartis to give him a few grams of the drug to use for the Phase 1 studies. In Mukherjee's words, "Druker would have a shot—but only one shot. To Novartis, CGP57148 [the name given to Gleevec when it was still a research molecule], the product of its most ambitious drug-discovery program to date, was already a failure" (436).[40]

The imbrication of science and technology in the political is explicit in Mukherjee's and Keating and Cambrosio's accounts of Gleevec, but they are focused on the United States and Europe. I argue that understanding politics involves a situated perspective from beyond Euro-American centers of R&D in the life sciences, and requires a comparative attentiveness to the differentiations and striations that such perspectives provide. While India is not considered a part of the scientific story of Gleevec to the extent that R&D and clinical trials for the drug did not take place there, the legal trajectory that emerged around the drug there put into question particular authoritative narratives of invention. As Gleevec's history gets situated out of India, interruptions of logics of capital and of romantic ideologies of innovation as underwritten by the decontextualized authority of a patent claim come to be at stake. This has consequences for understanding politics, but also for understanding science.

There are two elements to the oncopolitics that Keating and Cambrosio describe. One concerns the politics of institutional collaboration, especially between academe and industry, and the second concerns the politics of especially American patient advocacy in accelerating R&D into anticancer therapies. The second element of oncopolitics is most certainly present in the Indian story, since the initial pregrant opposition to the Gleevec patent in India was initiated by CPAA, a cancer patients' advocacy group. But how politics is constituted and what it means is very different in a context where patient advocacy around access is not coupled to R&D the way it usually is in western Europe and North America. I wish to add to and complicate Mukherjee's and Keating and Cambrosio's accounts with a simple observation: the fact that R&D into anticancer therapeutics is almost exclusively a Euro-American enterprise, yet people get cancer in other parts of the world as well. What kind of an oncopolitics might emerge in such situations where questions of access are dislocated from those of experiment?[41]

I have thus far emphasized the active interpretation of legislative intent by the judiciary in India. But how did legislative intent itself come to be what it was? In other words, what were the pulls toward the enactment of legislation such as Section 3(d)? Answering this involves understanding the dialogues between executive and legislative branches of the Indian state in the context of coalitional parliamentary party politics, especially the involvement of leftist political parties in intellectual property–related policy debates. It should be emphasized that there is a long political history of Left-progressive

mobilization against multilateral trade and intellectual property regimes in India, dating back to opposition to the Uruguay Round of GATT negotiations in the late 1980s and early 1990s (Sengupta 2010, 2013). Understanding what happened with Gleevec involves situating it within a longer trajectory of activism that rendered questions of intellectual property and access to medicines in India already deeply politicized.[42]

Leftist political parties became aware of intellectual property–related issues because of the concerns of their powerful trade union of pharmaceutical medical representatives, the Federation of Medical Representatives Association of India.[43] Their involvement was "part of a policy movement to have aspects of public health enshrined in our policy regime"; "the question of having a proper, people oriented drug policy, where main emphasis was to have generic drugs."[44] This involved not just taking an oppositional political position with respect to TRIPS, but also intervening in the process by which its provisions would come to be enshrined in policy. The Indian Constitution contains an omnibus provision whereby international treaties, whether bilateral or multilateral, do not have to be legislatively ratified by Parliament. According to Nilotpal Basu, CPI-M Member of Parliament, this was intended as an interim arrangement at the time of the drafting of the Constitution to allow executive flexibility, but was never changed. It was also based on the assumption that governments would be single-party majorities in Parliament, and therefore that "the ruling party, or the prime minister, who represents the majority of the ruling party . . . can be deemed to be the representative of the Parliament as a whole, or at the least the majority of the Parliament as a whole" (Basu interview). Between 1996 and 2014, India was ruled exclusively by coalition governments, which means that the ruling party did not even necessarily represent the majority will of the ruling government, let alone of Parliament as a whole.

Because of this provision, TRIPS was passed without any of the underlying issues being debated in Parliament. This is important to emphasize, because the parliamentary debates before the passage of the 2005 Patent Act in March 2005, which proved so crucial to the Supreme Court verdict against Novartis, were the only time the institutionalization of TRIPS into pharmaceutical patent policy was extensively debated legislatively. This was a function of the fact that while TRIPS itself was ratified through purely executive means, its implementation required legislative changes—such as in the Patent Act—that could not be ratified through the omnibus provision covering international agreements. This led to a series of legislative events prior to the parliamentary debates that Basu describes as follows:[45]

> The NDA [National Democratic Alliance, the BJP-led ruling coalition from 1998–2004] initiated moves to legislate the Third Amendment, and we had forced the government to have a, what you call a Select Committee. . . . On very very serious issues of public concern, where there was a major public debate and discourse, we have what you call Select Committees, [which] . . . can come up with its own version of a draft legislation, which is quite distinct and different from the initial draft legislation that the executive is obliged to move in the House. So there was a Select Committee, where of course we in the Left were in a minority. But we fought gamely. I mean, while there was [a] campaign outside—we had run a very good campaign on this GATT process, Dunkel Draft, so on and so forth. And we had at that time evolved also very well defined amendments. On that Select Committee, there was a great degree of convergence between the Congress and the BJP. . . . The entire set of amendments that we had was ultimately registered by the Left members in the committee was [a] note of dissent. And it is very interesting that subsequently when the UPA [United Progressive Alliance, the Congress-led coalition] government came [in May 2004], since they were depending on our critical support—at that time, there was a lot of political speculation as to how the absolutely conflicting approaches of the Left and the Congress could be reconciled in terms of legislation-making process. And it was specifically mentioned that what happens to the patent amendment? [This was a] pending thing, the legacy that the new government had to bear. So we made it clear that the Third Amendment that was moved by the NDA regime led by BJP, that is not acceptable to us. So no way that the government can push *that* legislation. But at the same time, these people also had a problem, because you see there was continuous pressure that while India has signed this WTO agreement, but they are not changing their patent regime. (Basu interview)

It was in this context that the Left decided that the pragmatic mode of dealing with this issue could not involve an outright rejection of TRIPS, but required critical engagement. This involved drawing upon the principles of the 2001 Doha Declaration, which would allow for the enactment of public health flexibilities in any TRIPS-compliant patent legislation. The Left pushed for various such flexibilities to be introduced in the draft legislation, one of which was the amendment to Section 3(d). According to Basu, the Congress was open to incorporating flexibilities, but was resistant to the specific changes

sought to 3(d). While the extent of distance between the positions of the two parties was not made public at the time, the Left made clear in closed-door negotiations that their continued support for the government would depend upon 3(d) being incorporated into the legislation along with other proposed flexibilities.[46] Hence, the letter and spirit of 3(d) was upheld by the state, through a judicial act that read legislative intent. But this was in spite of executive ambivalence that continued to be on display years after the passage of the amendments in the 2005 Act.[47]

I have described the intricacies of Gleevec's legal trajectory in India in part because it is so central to the interpretation of TRIPS-mandated product patent regimes in India. But it is also important in showing how the logics of capital interact with, and can potentially be tempered by, the dialogic ways in which the state is constituted, which is itself in part a function of civil society organization. The clinical trials situation was driven in contrast by logics of capital that were unfettered for a significantly longer period of time, until the trials became the subject of scandal (see chapter 2). At stake here are questions of relationships between technoscience and representative politics. The state functions as a critical transacting agent that both serves the interests of capital and can potentially be held accountable to public interest.

This is perhaps more generally true of the southern world.[48] For instance, access to Gleevec was a contentious issue in South Korea even before it had become politicized in India.[49] A Korean professor of mechanical engineering contracted CML in 2000, and found out about the clinical trials being conducted on Gleevec in the United States. He was able to organize other leukemia patients in Korea to petition the government to allow Novartis to expand its experimental access program for the drug in Korea. Thus, Korean patients became enrolled as trial subjects even as they started to politically organize to ensure broader access to Gleevec in Korea after its market approval. This was particularly important because, as in India, Novartis priced Gleevec in Korea at the same price point as in the United States and Europe.

The first salvo in the postmarket politics around Gleevec was an attempt by leukemia patient groups to get the Korean government to issue a compulsory license on the drug in 2002. This failed, leading to two other fronts being opened. The first involved approaching generics companies in India for the drug. This was facilitated by meetings with activists for Indian patients and access to medicines at the World Social Forum in Bombay in 2004, who connected Korean activists with companies that were manufacturing generic versions such as Cipla and Natco. The second involved a longer-term

engagement with both Novartis and the Korean government regarding the pricing of the drug in Korea.

In contrast to India, drug prices in Korea are regulated through price control mechanisms rather than intellectual property laws. Korea had harmonized its patent regime to a product patent regime in 1986, but has a monopsonistic system of national health insurance, with the state as the major buyer for drugs it deems essential to public health.[50] The locus of contestation therefore concerned whether the Korean government could impose price controls on the drug. The government attempted to set a ceiling price on the drug of U.S. $15 per 100 mg capsule, but Novartis refused to accept the price and demanded a 34 percent increase. The basis for Novartis's price point was that this was set in seven advanced industrial nations (the so-called A-7 group of countries)—the United States, United Kingdom, Canada, France, Germany, Switzerland, and Italy. Bilateral trade agreements between the United States and Korea stipulated that Korea would adhere to A-7 pricing of pharmaceutical products, even though it was not formally part of the group of A-7 countries. Eventually, a negotiated settlement was reached between Novartis and the Korean government, whereby the government agreed not to restrict the price of Gleevec, while Novartis donated toward the cost of the drug. In this way, the amount that patients themselves had to pay was only 10 percent of the price of the drug (the rest being paid for by national health insurance and Novartis together), but the price of the drug remained the same as it was in the United States.

The pricing of Gleevec was a contentious issue in other developing country contexts as well. For instance, the Brazilian government was able to negotiate with Novartis and brought the price down from U.S. $19 to $13 per 100 mg capsule. Hence, the politics surrounding Gleevec in India reflect a much broader constellation of southern politics around access to medicines that call into question the assumptions and paradigms of innovation in relation to drug development as they operate in Euro-America. These are histories that play out through law and advocacy that are differently coupled (or not coupled at all) to R&D than is the case in Europe and the United States. They are also histories with their own comparative intricacies, for instance around different structures of health care access (nationalized health insurance in Korea as opposed to free market competition in generics in India); different loci around which drug prices come to be internationally contentious (the patent in India, price controls in Korea); different global relationships around which this contention materializes (bilateral trade agreements with the United States in Korea's case; conformity with TRIPS in India's); different

industrial and market capacities (India as largely a Third World market but with globally competitive generic manufacturing capacity; Korea as a more developed market that nonetheless depended upon Indian generic capacity to make the drug accessible until price negotiations with Novartis could be concluded); and different configurations and articulations of patient advocacy with other forms of civil society and political advocacy (in India's case, a Left-progressive civil society that came to be highly politicized around intellectual property matters in the late 1980s and early 1990s as concerted opposition to the GATT negotiations was mounted; in Korea's case, a civil society that traced its politicization to the prodemocracy student movements of 1986).[51] Finally, there are South-South articulations to be attentive to, such as those between Korean patient groups and Indian generics companies. A more striated, differentiated, and multiply located notion of the political than the Euro-American "oncopolitics" that Keating and Cambrosio (2012) describe is necessary to understand the global manifestations of the politics of access to medicines.

In this chapter, I have focused on the importance of legal reasoning and its alternative paths to global pharmaceutical politics. This is not just about ideological positions around innovation and access to essential medicines (of which there are plenty, on the sides both of the multinational pharmaceutical industry and of activists who oppose it), but about the technical virtuosity of the lawyers and judges involved. Indeed, I suspect that one of the reasons Novartis kept losing its cases in India was that it employed some of the most famous lawyers in the country, who were big names but did not necessarily have that virtuosity when it came to the strategic interpretation of patent law and its relationship to scientific development, something that lawyers for Novartis's opposition seemed to possess in ample measure.[52] Therefore, the courts and legal reasoning itself are important sites for ethnographic attention to the articulations of value, politics, and knowledge.

Judicial Ethics and the Spirit of Constitutionalism

This chapter has explored judicialization as an emergent form of and space for politics, in the context of an economy that sees the expansion of multinational corporate monopoly, underwritten by ideologies of innovation and presumptions of romantic invention, and inscribed in a patent claim. The Gleevec case as it has played out in the Indian courts potentially interrupts these monopolistic logics in at least two ways. First, by providing other interpretive modalities for trajectories of invention, the verdict holds the

authority of patent claims accountable to existing national-state laws. And second, it thereby denaturalizes the ideologies of innovation that allow patents to function in the cause of increasingly unfettered corporate monopoly. I wish in this concluding section to think about the value systems that animate the kinds of judicial impulses that have been seen in the legal trajectory of Gleevec, which has continued in subsequent curtailments of intellectual property rights in India in the cause of public interest (see note 2).

The stakes of the Gleevec verdict are obviously high in terms of allowing access to a potentially life-saving anticancer drug for larger segments of people who need it. Activists fighting against the Gleevec patent have pointed to the stark (up to thirty-fold) differentials in price between Novartis's patented drug and generic versions on the Indian market. The multinational pharmaceutical lobby has meanwhile itself argued that verdicts such as those seen in India will have adverse consequences for drug access in the long term by removing incentives for innovator companies to market their drugs in countries that do not provide stable monopoly protections. One sees here a structure of polarization similar to that described in chapter 2, between Euro-American biomedical interests demanding a harmonious playing field that facilitates global movements (whether of patented medications or of clinical experimentation) underwritten by norms of spreading the health (and logics that demand growing it as surplus value), and opponents railing against multinational corporate hegemony.

Without trivializing the stakes of accessing essential medication, I wish to thicken them. The question of access in practice is more complicated than just establishing the price of the drug. Mechanisms of enabling and constraining access within particular pricing environments are a function of other kinds of infrastructural development (for drug manufacture and distribution, for instance) and themselves come to be a site of strategic maneuver and politics.[53] Similarly, indeed, the question of health goes beyond one of access to biomedical artifacts such as drugs or vaccines. The story of the HPV vaccine scandal discussed in chapter 2 is, after all, one that saw provision of a vaccine through a national immunization program, but led to concerns about pharmaceuticalization in the absence of adequate epidemiology or screening in order to expand multinational corporate markets. While Gleevec is a historic anticancer drug and the moral imperative to ensure that it is as widely available as possible to those who need it is obvious, I believe the true stakes of the long battle around its patentability in India lie elsewhere. After all, the Gleevec patent itself expired in July 2015. Even if Novartis had won the Supreme Court case, it would have enjoyed patent protection on its drug

for just a couple of years. Such a lengthy judicial battle could surely not have been undertaken for such trivial gain.

I suggest that the stakes of the Gleevec case include but go beyond access to an anticancer drug. For the multinational pharmaceutical industry, there are the stakes of establishing monopoly regimes globally (including at the expense of prevalent free market systems such as those seen in India, for which see chapters 4 and 5). It is also about the establishment of a narrow idea of invention that furthers romantic ideologies of corporate-driven innovation and which provides a normative justification for monopolistic regimes. But there are also stakes here for conceptualizing the ways in which judicialization operates as a strategy of politics. There has clearly been a Global Southern turn to judicialization over the past two decades. This has specific inflections in different situations; can both interrupt and instantiate global capital flows; and operates in complex relationships to informal and illicit economies depending on prevalent structures of representative and regulatory government.

Understanding judicialization as a form of and space for politics involves being attentive to its own spatialities and to the subjectivities it engenders. Jean and John Comaroff have posed an important series of provocations about judicialization as a condition of contemporary postcolonial politics (Comaroff and Comaroff 2006). Following their lead, I suggest that cases such as Gleevec's pose a number of conceptual and immediately political questions concerning the citizen as legal subject. How does this articulate with biomedical subject constitutions, such as those of patient-consumer-experimental subject? In what ways does the law imagine biomedical subjectivity in particular contexts of governance and representative politics? What kinds of accountability do these legal subject constitutions demand, and of whom? How is responsibility configured for those in positions of institutional power? These are some of the pharmocratic issues that emerge from intellectual property and access politics in India.

I argue that answering some of these questions requires attention to the ways in which the judicialization of pharmaceutical politics in India activates and is animated by constitutionalism (see introduction). This has often taken recourse to a discourse of rights, especially Article 21, which guarantees the right to life and suggests a liberal normative template that derives from Western legal frameworks.[54] But when I interviewed Justice Prabha Sridevan, who wrote the Madras High Court verdict on Gleevec, I heard something more. She insisted that as a judge, what was at stake for her in such cases was "the upholding of the spirit of the Constitution."[55] This is not a strict foundationalist constitutionalism, but rather an interpretive, hermeneutic, dynamic one.

It also goes beyond what Comaroff and Comaroff have called the "fetishism of constitutionality" (2006, 24), in that it is not a theological reification of the authority of a foundational national text. It is rather a strategic political deployment of both constitutional authority and rights-based norms in ways that serve to realize the "promise of justice."[56]

But where does this spirit of the Constitution come from? One of the most powerful functions of national-state constitutions is their ability to perform their own mythos, to call into being a people and their values (Ackerman 1991). Constitutions represent value-laden origin stories. Postcolonial constitutions such as India's have an obviously Euro-American, liberal inheritance, but their origin stories render them political in very particular ways.[57] The question of constitutional authority therefore is at least in part a comparative question, whose answer involves attention to the foundational myths that nations tell themselves; to the judicial cultures of constitutional interpretation that emerge in particular places and times; and to the conjuncture of their actual origination.[58] Therefore, constitutions are themselves conjunctural documents that reflect the ethos of a time and a place, even as they provide occasions for what Spivak (1990), following Jean-François Lyotard (1984), calls "paralogical legitimation"—a legitimation that operates through movement against an established way of reasoning, and thereby opens up the possibility of its own innovation and thus also of justice.[59] Constitutions must be situated if some sense of their spirit is to be understood.

First, they must be historically situated. Upendra Baxi has argued that the Indian Constitution is not simply an abstract normative document, but an "inaugural postcolonial form" (Baxi 2010; see also Austin 1967). Baxi (2010) describes how the Indian Constitution performs a creative modification of the ideas of constitutionalism by combining the (sometimes contradictory) concerns of governance, social development, rights, and justice. The contradictions of the Indian Constitution, however, are not just a function of different normative impulses that might not easily coexist. (For instance, concerns with governance often justify egregious human rights violence by Indian police and security forces fighting insurgent or terrorist movements.) They are also a function of the multiplicity of constitutionalisms that Baxi argues come to inhabit the Indian Constitution over time. Baxi suggests that, since the drafting and adoption of the Indian Constitution, there have in fact been seven kinds of constitution, replacing or coexisting with one another.[60] Critically, Baxi suggests that the seventh incarnation, which defines India entirely in terms of global market interests, is "fully at odds" with previous ones. What one sees in the Gleevec case is not just a dialogue between different

arms of the state, but also between different generational impulses and constitutional moments.

And second, constitutions must also be spatially situated. The very idea of the spirit of the Constitution demands a spatial attentiveness. When Justice Sridevan speaks of the Constitution whose spirit she wishes to uphold, she is speaking of a specific thing, of this Constitution, one which operates in this nation of India in order to provide a governing rationale and a set of directive obligations to the state. This is reflected in the critical line that she wrote in the Madras High Court verdict quoted earlier, which I reiterate here with a different set of emphases than before: "We have borne in mind the object which the Amending Act wanted to achieve, namely . . . to provide easy access to the citizens of *this country* to life saving drugs and to discharge their Constitutional obligation of providing good health care to *its citizens*."[61]

Just as a particular set of obligations is emphasized, and a particular idea and ideal of health assumed (one that is about healthiness, and not about generating surplus value for capital), so too is the nation-state as a jurisdictional and representative body of governance invoked;[62] and further, a specific nation-state, with its values and normative commitments, which in the case of the Indian Constitution have been enshrined most explicitly in its directive principles. Granville Austin (1967) has described the importance of these principles. He has argued that while "negative obligations," providing domains of protection for citizens from the power of the state and usually articulated in terms of rights, are inherent to most liberal democratic constitutions, the uniqueness of the Indian Constitution lies in its further attention to the state's "positive obligations" toward its citizens. These were written into the constitution as directive principles, which are not legally enforceable, but nonetheless provide an idealistic roadmap for the state to follow.

In discussing judicialization as a form of and space for politics in this chapter, I have described the ways in which the Gleevec case initially resolved, in an apparent purification, into technical and constitutional components; how the technical components remained unsettled and in some sense could not be settled without taking recourse to the constitutional; and how the constitutional components open up questions regarding what Sheila Jasanoff (2011) has called bioconstitutionalism, moments of resolution and adjudication that put both law and health/life at stake. While I have focused on judicial problematizations and resolutions of the technical and the constitutional—and in the process, upon the coproduction of the patent as something that is legally and scientifically determined—broader trajectories are at stake in this story.

First, there is the question of the movements of a product patent to India through the dictates of multilateral forums such as the WTO. This speaks to the nature of relationships between different scales and forms of governance, and more specifically the question of how global governance dictates or impacts national-state governance, or fails to do so. It might seem like the export of patent regimes is a purely technical matter, but in the Indian context it came to be rendered a constitutional one: not just in the narrow textual sense of homogenizing global agreements with the letter of the Indian law, but in the broader sense of forging and defining the contours and the terrain of the technical and the political in relation to which the product patent can operate in a given national-state context.[63] Second, this rendering of the apparently technical as constitutional has to do in part with the specific judicial and political cultures in India, and the ways in which these render and animate constitutional histories. But it also has to do with historical contexts of pharmaceutical development in India, the building of generic manufacturing capacity under an earlier process patent regime, and the particular ways in which that has more recently come to be inscribed within a global politics of access to essential medicines (see chapter 5). And third, there is a broader ideology that provides political traction and sanction to monopolistic product patent regimes through a valorization of innovation (but that also defines innovation in the rather narrow terms of making new drugs).[64] The trajectory of Indian judicialization interrupts these arguments, even as it opens up possibilities of interpretive legal innovation.

One way to ground a conceptualization of constitutionalism and judicialization is to specify it in terms of national histories and locations. Another way to do so is by asking how science comes to be lodged in the court (Jasanoff 1997). This question is not merely an institutional one, but is a broader conceptual question concerning epistemic authority. When the spirit of a constitution that emphasizes a right to health and distributive justice is deemed to have more authority than a patent claim, one is seeing the consolidation of certain modes of public reason over others.[65] Who has the institutional authority to make such determinations is a deeply political question, one that has fundamental stakes for democracy.

Within the structure of pharmaceutical crisis described in chapter 1, bioconstitutional moments play out in ways that constitute the state as a site for political struggle. Financialized, multinational pharmaceutical capital attempts to capture the state, but is opposed by (national and global) civil society, which itself forms strategic alliances with certain (in this case, Indian generic) corporate interests to keep the state accountable. The constitution of the political

in relation to the Gleevec case is thus coproduced with the situating of cancer in India (or Korea, or Brazil) in different ways than those seen in Euro-America. Chapters 4 and 5 elaborate upon such politics by situating it in terms of the materialization of logics of capital in/as different capitalisms, resulting in a competition between the monopoly capitalism of the Euro-American R&D-driven pharmaceutical industry and the postcolonial nationalist free market capitalism of the Indian generic industry that itself comes to be less and less viable in post-TRIPS global market environments.

POSTSCRIPT: PHARMACO(LAW)GIC

The Indian Supreme Court verdict on Gleevec has provided a significant precedent for limiting the practice of pharmaceutical evergreening, one that certainly establishes interpretive room for maneuver within India's product patent regime, which could also have implications that extend beyond India.[66] *But there is more at stake in this verdict than simply policy precedent. It is worth thinking about the court itself as an institutional site of democratic articulation. The particular mechanisms of such articulation—the very texture of legal argumentation that was employed, and the modes of interpretation of the patent (literal versus hermeneutic) that brought the different assumptions underlying invention to the fore—are worth paying attention to. And institutions such as the Supreme Court have their own aura, lending a certain kind of authority to verdicts, a gravitas borne of a self-conscious sense of justice being dispensed. It was clear for instance that the judges hearing the Gleevec case were aware of the precedential power that was vested within them. The length, detail, and explanatory reasoning of the verdict, and the insistence on wiping the slate clean and adjudicating all aspects of the issue (concerning both Sections 2(1)(j) and 3(d)) suggest that the justices knew that they were hearing a landmark case whose consequences would be felt over the long term and well beyond access to a single drug.*

Is this form of judicialization, one that orients pharmaceutical politics toward socially just possibilities, in principle democratic? It is easy to be swept away by romanticism while considering a judicial intervention such as this. The emergence of the Indian Supreme Court as a bulwark against corporate capital is in stark contrast to recent decisions of the American Supreme Court such as Citizens United, which provide corporations with First Amendment rights to free speech as if they were people.[67] *More generally, the Indian Supreme Court has taken on an activist role on a host of social justice issues, ranging from corruption to food distribution to women's rights, demanding that the state act to fulfill its representative obligations to its citizens. It is important to acknowledge the radical potential of such judicial intervention.*

But it is equally important to think through its limits. At one level, these are the conceptual limits of the law itself, as the question of justice always exceeds formal legal adjudication and can never be entirely contained within it (Derrida 1992). But at another level, there are pragmatic, institutional, and political limits. Scholars have recognized that judicialization constitutes a complex terrain and site for politics and does not necessarily result in socially progressive outcomes. João Biehl and Adriana Petryna (2011) have shown, for instance, how the judicialization of pharmaceutical politics in Brazil serves as an instrument of pharmaceuticalization, whereby individual citizens make demands upon the state (in the context of nationalized health care) for drugs as a matter of entitlement. This puts burdens on the health system even as it often bypasses the authority of evidence-based medicine; the right to health operates as consumer demand upon the state, which then becomes the broker in procuring drugs for an ever more demanding citizenry that also emerges as a market for pharmaceutical companies. Jean and John Comaroff have pointed to the hyperlegal sphere of postcolonial politics that comes to operate in the judicialized context of South Africa, with consequences not just for promises of justice but also for state conceptions of crime and policing (Comaroff and Comaroff 2006). And Gautam Bhan (2009) has shown how the public interest litigation has served as an instrument to enforce evictions in Delhi, thereby serving simultaneously to uphold tenancy as a right even as it has acted in certain situations to displace people from their homes.[68]

Hence if the emancipatory potential of judicialized pharmaceutical politics comes to be obvious in situations such as the Gleevec case, then its democratic potential is more tenuous. At an empirical historical level, the story of the Indian judiciary is marked by failures as much as by stunning successes. The structure of judicial politics in India today sees the operation of activist higher courts that intervene substantially in the making of policy alongside virtually nonfunctional middle and lower courts that are often mired in corruption and inefficiency. In terms of political horizons, it is possible to imagine a judiciary that is not invested in the ideals of social justice, as witnessed in rulings such as the criminalization of homosexuality through the upholding of Section 377 of the Indian Penal Code, an article of the law that traces back to a colonial British statute enacted in 1860 that defines homosexuality as an "unnatural offense."[69]

The judiciary as an instrument of social justice is also a historically and generationally specific institution, reflective of a turn in this direction that occurred after the lifting of Indira Gandhi's state-imposed Emergency in the late 1970s

(Baxi 2010). There is no guarantee that it will always remain thus. Indeed, in the domain of access to essential medicines, one has seen moves to sensitize the Indian judiciary through programs that have involved teaching Indian judges the principles of intellectual property law. This has included programs facilitated by the U.S. embassy in Delhi in concert with industry lobby groups in India and the United States.[70] Judicial common sense is not static, and one could envision the pedagogical indoctrination of a new generation of Indian judges who are far more sympathetic to multinational corporate ideas and ideals of intellectual property than the current generation has been.[71]

The law itself, the courts themselves, cannot therefore be deemed just or unjust, democratic or not, in any absolute sense. What is significant is the particular way in which the Constitution came to be activated in the Gleevec case. An image that endures in my mind from the Supreme Court hearings is that of Anand Grover, representing the CPAA, arguing in court and walking around its halls during recess with a copy of the Indian Constitution tucked under his arm, his inseparable companion, resource, and recourse. A spirit of constitutionalism that depends upon an interpretive, nontechnocratic hermeneutics has emerged as a democratic counterweight to logics of multinational pharmaceutical capital.

CHAPTER FOUR

Philanthropic Values

Corporate Social Responsibility & Monopoly in the Pharmocracy

Monopoly and GIPAP

This chapter describes Novartis's philanthropic drug donation program for Gleevec, the Gleevec International Patient Assistance Program (GIPAP). Established in 2002, GIPAP is a mechanism to make Gleevec accessible to patients who cannot afford the drug. Since its inception, it has come to be operational in over eighty countries, and Novartis claims that it has helped over 60,000 patients through the program. I show how this ethical program is imbricated with Novartis's insistence on monopolistic protection for its drugs, which drove its extensive legal battles around Gleevec in India. I further argue that corporate philanthropy provides the justification for monopoly even as monopoly provides the conditions of possibility for philanthropy. This is a case of the multinational pharmaceutical industry projecting itself as an agent of humanitarian redemption while emphasizing the necessity of monopoly protections in order to do so. This articulates not just to politics of access to medicines but also to that of clinical trials and therapeutic care.

At the very start of the Supreme Court hearings on the Gleevec case, and periodically throughout, Justice Aftab Alam asked Novartis counsel a simple question that was never answered: why not just price the drug on the free

One sees similar divisions in feminist debates around prostitution and sex work, as Rajeswari Sunder Rajan (2003, 117–146) has explored.

87. See especially appendix 12 of 2013 Schedule Y revisions.

88. "Formula to Determine the Quantum of Compensation in the Cases of Clinical Trial Related Serious Adverse Events (SAEs) or Deaths Occurring during Clinical Trials," report prepared by expert committee constituted by the Drug Controller General of India, March 14, 2013 (henceforth "Compensation formula").

89. The ways in which particular kinds of experimental subjectivity, rendered ethical by way of "voluntary" contract, come to be retroactively figured at the moment of pain or death has parallels to the ways in which the subject of widow immolation (sati) has been figured, as Rajeswari Sunder Rajan (1993, 15–39) has shown. Tanika Sarkar (2012) had argued that the widow who had to immolate herself in colonial Bengal in the early to mid-nineteenth century was the bearer of "something like rights," as the regulation of sati by the British colonial state saw a gradual transmutation of the idea of consent. Far from framing it as a "traditional" practice that was antithetical to the modern liberal law that the colonial state was instituting, Sarkar shows how in fact the British regime allowed for a continuation of the practice, as long as it could be rendered lawful, which itself was based (in the early colonial state in Bengal) in the formal institutionalization of the widow's consent to be immolated: what was deemed proper consent. In the process, Sarkar argues that the colonial state gave consent an importance that did not exist earlier. Just as it is worth dislocating experimental subjectivity as voluntary activity in a gift economy by attending to the actually prevalent, deeply capitalized political economies in which it increasingly operates today, so too is it worth recognizing that the normative ideals of consent that give sanction to these fictions of voluntarism have roots not just in twentieth-century liberal ethics as instituted in Euro-American contexts, but in much longer colonial legal histories of regulating traditional patriarchal practices which themselves have postcolonial echoes and continuities. See also Pedersen (1991), whose arguments about the early twentieth-century British colonial regulation of clitoridectomy in Kenya show considerable parallels with Sarkar's account of the nineteenth-century regulation of sati in Bengal.

90. A similar discursive structure is also reflected in portrayals of the organ trade, such as Manjula Padmanabhan's (2003) dystopic play *Harvest*.

91. For instance, the HPV vaccine studies could legitimately be seen as Western exploitation of Indian bodies; given that a number of the experimental subjects were tribal girls, it could equally be seen as yet another extractive biomedical enterprise performed upon indigenous populations, layered onto the enormous amount of resource extraction of land populated by indigenous people ongoing in areas such as Chattisgarh. For indigenous and First Nations critiques of biocolonialism, see especially Maori author Patricia Grace's (1998) stunning novel *Baby No-Eyes*. It is also important here to note the complex racialized histories of biomedical research in the United States, for which see note 17.

92. In this regard, see especially Sarah Franklin's (2006) exploration of what she calls "the spaces of transbiology" in her account of embryo transfer.

93. For biosociality, see Rabinow (1992, 2007); for biological citizenship, see Petryna (2002), Novas and Rose (2005), Rose (2006).

94. See Sheila Jasanoff's (2011) development of the idea of constitutional moment in relation to the life sciences in terms of what she calls bioconstitutionalism. I expand upon this term in greater detail in chapter 3. See introduction for the salience of constitutionalism to understanding pharmocracy.

95. In chapter 3, I elaborate upon this argument for the importance of situating cancer in contexts that are distinct and dispersed from Euro-American centers of research and development. As with Gleevec, India was a site where safety and efficacy trials for HPV vaccines had not been conducted; but this did not prevent India from becoming a critical site of public health intervention and capital accumulation from these vaccines. It is worth reading Lochlann Jain's (2013) *Malignant*, which theorizes cancer largely out of American contexts, alongside Julie Livingston's (2012) *Improvising Medicine*, an ethnographic account of Botswana's solitary oncology ward. Both are extraordinary narratives, and their juxtaposition suggests that situating cancer involves something more than just imagining Euro-America as a site of plenty and the Third World as one of lack. Rather, the very configurations of both biomedicine and disease come to be at stake.

96. Again, one can see an identical structure of ethical publicity in feminist debates around the regulation of prostitution, between abolitionists who see prostitution as fundamentally exploitative, and liberals who see it as potentially a volitional and contractual act that needs only to be regulated so that its violent and violating aspects are curtailed (R. Sunder Rajan 2003, 117–146). As Rajeswari Sunder Rajan points out, these positions tend to elide the structural political economies of poverty and debt that operate in the lives of most (especially Third World) prostitutes, which in fact render exploitation a more complicated sociological phenomenon than the agential transaction of money for sex, and that render claims to volition hollow. This is not to say that an acknowledgment of these political economies is entirely absent in feminist debate; just that the framing of the problem in terms of ethics alone has no space for it. Neither ethical solution in itself would actually intervene in the structuring of the conditions that render these normative binaries as solutions in the first place. Similarly, Cohen points to the political economy of indebtedness that almost without exception led the kidney sellers he interviewed (who were invariably women) to sell their kidneys. These sellers would again fall back into debt, but now they would only have one kidney left to sell.

97. See Bateson et al. (1956) and Bateson (1972, 271–278), for elaborations of the notion of the double bind, and Fortun (2001) for its use in studying the political economy of global technoscience.

CHAPTER THREE. Constitutional Values

1. Paragraphs 4–6 of the Doha Declaration are especially pertinent here:

> 4. 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.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

See World Trade Organization, Ministerial Declaration of November 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002).

2. Examples include the 2010 revocation of Roche's patent on its antiviral drug Valcyte, which is used as part of HIV-AIDS treatment regimens; the dismissal, early in 2012, by the Delhi High Court of a patent infringement suit filed by Hoffmann-La Roche against Cipla, relating to its anticancer drug Tarceva; the issuance of India's first compulsory license in March 2012 on Bayer's anticancer drug Nexavar, which allowed the Hyderabad-based Natco Pharmaceuticals to manufacture generic versions of the drug; the revocation of Pfizer's patent for its anticancer drug Sutent in October 2012, which was a reversal by the Patent Controller of India of a 2007 patent that had been granted on this drug, following adjudication of an opposition filed by the Indian company Cipla to the granting of the patent; and the revocation of Hoffman-La Roche's 2006 patent for its anti–hepatitis C drug Pegasys in November 2012 by India's IPAB, following an appeal by the Indian company Wockhardt and the civil society group Sankalp Rehabilitation Trust.

3. A significant interlude that set the stage for the Supreme Court hearing was a ruling by a newly constituted tribunal, the IPAB, which upheld the Madras High Court verdict. The Supreme Court however largely disregarded the IPAB verdict and considered the case more or less afresh. Hence, while I allude to the IPAB verdict in this chapter, I do not enter a detailed account or discussion of it.

4. *Novartis AG v. Cipla Ltd.*, http://saffron.pharmabiz.com/red.asp?fn=/services/docs/PatAct1970-06.asp, accessed July 10, 2016, emphasis added.

5. The parallels between Indian and Brazilian state strategies in such pushing back in the arena of pharmaceuticals are essential to think through in comparative perspective. In addition to Biehl and Petryna (2011), see Biehl (2013) for accounts of judicialization of pharmaceutical politics in Brazil; see also Cassier (2012) for important accounts of contemporary pharmaceutical politics in Brazil that are more centrally concerned with capitalist logics.

6. *Novartis AG and Another v. Union of India and Others*, 4 MLJ 1153 (2007), emphasis added.

7. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

8. Of course, the sacrality of property in the United States, especially as it pertains to intellectual property rights, has always been contested. The U.S. Constitution says that patents and copyrights are intended to make knowledge and invention available for public good and not for monopoly ownership rights. It is just that the pendulum has swung far from this. This is why a constitutional analysis can never be concerned just with what is stated in an authoritative constitutional text but has to see constitution as a process, which resolves differently in the context of different judicial and political cultures. See for instance Jasanoff (2012), who shows how the patent application for the transgenic Oncomouse followed different trajectories in the United States (where it was granted) and in Canada (where it was subsequently denied). Even today, there is friction over the unquestioned sanctity of intellectual property rights in biotechnology in the United States. The seminal verdict denying a patent on the *brca* genes to Myriad Genetics, *Association for Molecular Pathology v. Myriad Genetics, Inc.* (U.S. 12-398, 2013), which held that isolated human genes cannot be patented, is an important example of such friction. However, it is the case that while the United States has seen contention around gene patents, it has not done so in any significant manner around the question of drug patents as instruments of corporate monopoly, a value system that has become progressively naturalized.

9. For an elaboration of the notion of technoscientic imaginaries, see Marcus (1995) and Jasanoff and Kim (2015) (who refer to "socio-technical imaginaries").

10. Special Leave Petition (Civil) of 2009, between Novartis AG and (1) Union of India (2) the Controller General of Patents and Designs (3) Assistant Controller of Patents and Designs (4) M/S Cancer Patients Aid Association (5) Natco Pharma Ltd (6) Cipla Ltd (7) Ranbaxy Laboratories Ltd (8) Hetero Drugs Ltd (henceforth "Novartis Supreme Court SLP"). In between the High Court verdict and the Supreme Court appeal, the matter of the technical adjudication of the patentability of Gleevec had passed through a newly constituted tribunal, the IPAB. Hence, this was, strictly speaking, an appeal against the IPAB verdict, which itself had a number of interesting

and significant aspects. Briefly, while the Patent Office had initially denied the Gleevec patent on three grounds—utility, nonobviousness (the criteria by which the molecule would have been deemed inventive), and Section 3(d)—the IPAB upheld the denial only on the grounds of Section 3(d), stating that in fact the drug was useful and nonobvious. Therefore, the CPAA and Natco Pharmaceuticals filed their own petitions to the Supreme Court, challenging those aspects of the IPAB verdict that supported Novartis's claims of invention and nonobviousness. All these petitions were heard together, and a single verdict given by the court. In the process, the court chose to largely disregard the IPAB verdict and considered all aspects of the case afresh. Because the IPAB verdict did not impact the Supreme Court judgment, I do not discuss it in detail here. However, the IPAB would subsequently become an important appellate tribunal in its own right, deciding further cases that would have an impact on the interpretative landscape of intellectual property law. See for instance the IPAB's upholding of a compulsory license that had been issued on Bayer's anticancer drug Nexavar in September 2012, and its revocation of Hoffman-La Roche's 2006 patent for its anti–hepatitis C drug Pegasys in November 2012 following an appeal by the Indian company Wockhardt and the civil society group Sankalp Rehabilitation Trust. For the former, see Intellectual Property Appellate Board, 2012, *Bayer Corporation v. Union of India and Others*, Chennai, 14 September, M.P. Nos. 74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM, Order number 223 of 2012. For the latter, see Intellectual Property Appellate Board, 2012, *Sankalp Rehabilitation Trust v. F. Hoffmann La Roche AG and Another*, 2 November, OA/8/2009/PT/CH and M.P. Nos. 85 & 111 of 2012 In OA/8/2009/PT/CH, Order number 250 of 2012.

11. Recall that one saw this in the initial High Court verdict regarding Section 3(d)'s constitutionality as well, which saw the court insisting upon the objective that the amended section sought to achieve, the ensurance of good health for Indian citizens.

12. Supreme Court of India, Civil Appellate Jurisdiction, Civil Appeal Nos. 2706–2716 of 2013 (arising out of SLP (C) Nos. 20539–20549 of 2009), *Novartis AG v. Union or India and Others*, with Civil Appeal No. 2728 of 2013 (arising out of SLP (C) No. 32706 of 2009), *Natco Pharma Ltd. v. Union of India and Others*, and Civil Appeal Nos. 2717–2727 of 2013 (arising out of SLP (C) Nos. 12984–12994 of 2013), SLP (C). . . . /2011 CC Nos. 6667–6677, *M/s Cancer Patients Aid Association v. Union of India and Others*. The two-member bench was constituted by Justice Aftab Alam and Justice Ranjana Prakash Desai. Justice Alam wrote the verdict for the court, which was delivered on April 1, 2013. (Henceforth referred to as "Supreme Court verdict.")

13. 3 SCC 279 (1987), cited in Supreme Court verdict, 15.

14. 1 SCC 424 (1987), cited in Supreme Court verdict, 15. Both of the verdicts read as methodological precedent for judicial interpretation were delivered by Justice Chinnappa Reddy, who was a bold supporter of democratic freedoms during the state of Emergency imposed by Indira Gandhi from 1975–77. Justice Reddy died on April 20, 2013, less than three weeks after the verdict on Gleevec was delivered using his teachings on legislative interpretation. It is important to be attentive to the generational dynamics of judicial cultures in India.

15. This is not to say that legal history does not matter in American judicial cultures. It is one of the fundamental things that has to be outlined in the briefing of a case and is important in the writing of decisions in the United States as well. What I wish to emphasize here is the naturalized purification of the authority of the patent claim in the United States in a manner that the Indian courts have refused, a refusal that is exemplified in the mode of reasoning employed by the Indian Supreme Court, as I describe here.

16. The schematic outline provided below is based on that found in the Supreme Court verdict. For a more detailed analysis of the history of Indian patent law and its impact on the Indian pharmaceutical industry, see Chaudhuri (2005).

17. See especially Section 83(b): "that [patents] are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article"; (c) "that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare"; (d) "that patents granted do not impede protection of public health and nutrition and should act as an instrument to promote public interest"; and (g) "that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

18. Letter from Jim Yong Kim, HIV/AIDS director of the World Health Organization, to A. Ramadoss, minister for health and family welfare, Government of India, December 17, 2004, http://www.cptech.org/ip/health/c/india/who12172004.html; letter from Achmat Dangor, director of advocacy, communication and leadership, UNAIDS, to Kamal Nath, minister for commerce and industry, Government of India, February 23, 2005, http://www.cptech.org/ip/health/c/india/unaids02232005.html.

19. Section 2(1)(j) defined invention in the following terms: "a new product or process involving an inventive step and capable of industrial application." *Inventive step* was further defined in Section 2(1)(j(a)) as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."

20. Recall that the question of whether Gleevec was an invention was a matter for adjudication for the court in spite of the IPAB's decision that it was, because of CPAA's and Natco's petitions before the court that challenged those elements of the IPAB verdict that were in Novartis's favor. Hence, the court reconsidered the questions of whether the conversion of imatinib to β-imatinib mesylate constituted a nonobvious invention, alongside a consideration of whether the latter showed enhanced efficacy in order to meet the requirements of 3(d). During the hearing of the case, Justice Alam declared that "the IPAB order, with due respect, is a strange mishmash. We will come to our own findings, [and] are not at all satisfied with the findings of the IPAB" (author's field notes taken at Supreme Court hearings, October 31, 2012).

21. See Pottage and Sherman (2012), who develop this argument with reference to the history of the figure of invention in liberal Western patent law.

22. Recall that the patent application for β-imatinib mesylate in India was filed in 1998. This was subsequent to the 1997 filing of a patent application in Switzerland, not the United States.

23. The NDA is the basis upon which all drugs are evaluated and approved for market by the FDA. As stated by the FDA, "The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged" (U.S. Food and Drug Administration 2016).

24. NDA #21-335.

25. As cited in Supreme Court verdict, 65. A package insert is the document provided along with a prescription medication when it is marketed, and provides the formal regulatory description of the drug as approved for market. In the United States, it must be approved by the FDA.

26. Author's field notes taken at Supreme Court hearings, October 31, 2012.

27. This means that the drafting of the patent claim, and the forms that it takes, is a complex strategic exercise that embodies what Pottage and Sherman (2012) call the "figure of invention." See their argument in *Figures of Invention* for a historical elaboration of these forms and their role in the history of the legal constitution of invention.

28. The focus of my analysis in chapter 4 is GIPAP. I do not discuss it further here because the court did not deem it relevant in its own judgment of the patentability of Gleevec. Indeed, counsel for Novartis tried repeatedly to bring GIPAP to the attention of the court during its hearings, until Justice Alam finally admonished them by stating that he did not want to hear mention of its charitable program any more since it did not have bearing on the case at hand. While rendered irrelevant to the legal interpretation of India's new patent laws, initiatives such as GIPAP are central to the broader political terrain of pharmaceutical monopoly, pricing, and access.

29. "A patent relating to a particular area of technology which prevents another patent from being used because the other patent relies on technology covered by the first," as defined at Wiktionary, http://en.wiktionary.org/wiki/blocking_patent, accessed February 18, 2014.

30. Written submissions on behalf of the intervenor, in the matter of *Novartis AG v. Union of India and Others*, Shamnad Basheer, intervenor (henceforth "Basheer intervention"). Basheer has been a leading voice in matters relating to intellectual property rights and their interpretation in India over the past decade. At the time of the Supreme Court case, Basheer was a professor of law at the National University of Juridical Sciences, Kolkata.

31. The ODA was passed in 1983 to facilitate the development and commercialization of drugs for diseases with small markets by providing incentives in terms of tax breaks and market monopolies to the developers of such drugs.

32. Of course, if one considers the appropriation of health by capital as described in chapter 1, one could argue that it is increasingly the case that the purpose of medicines is not to cure disease but to grow markets. Hence, the court here is insisting upon a definition of health that has not been appropriated into logics of surplus value generation.

33. The original quote is from Mofitt (1979), cited in Basheer intervention, 18, and subsequently in Supreme Court verdict, 94.

34. *Economic and Political Weekly*, 48, no. 32, August 10, 2013.

35. This politics played out in the case of Herceptin in the early 1990s, and was deeply influenced by the politics of HIV-AIDS patient groups such as ACT-UP in the United States in the late 1980s and early 1990s. See Epstein (1996) for an account of the latter.

36. For key articles that describe some of these developments, see Witte et al. (1978), Witte, Dasgupta, and Baltimore (1980), de Klein et al. (1982), Heisterkamp et al. (1982, 1985), and Fainstein et al. (1987). Also see Mukherjee (2011, 430–431), and Keating and Cambrosio (2012, 323–330); also Wapner (2014) for a longer history of research into the Philadelphia chromosome.

37. It is worth pointing out that both Mukherjee and Keating and Cambrosio only ever refer to Gleevec as imatinib.

38. See for instance Dutfield (2013).

39. My account of the trials is a summary of Keating and Cambrosio's (2012, 316–323) more detailed account.

40. For an elaboration of this initial reluctance, and the institutional politics involved in Druker's push to conduct trials, see his own account (Druker 2007b).

41. Keating and Cambrosio do mention the (political and judicial, not clinical) trials of Gleevec in India in their account, by devoting a paragraph to how Gleevec's "success story has been partly clouded" by Indian generic competition and a "series of setbacks in the Indian courts" (2012, 319–320). The fact that Gleevec has had a checkered history in India is acknowledged in their account, but almost parenthetically; it is in no way deemed central to either the history of the development of the drug, or even to the notion of oncopolitics as developed by the authors in relation to that history. My attempt here is to provide a differently situated perspective on the history of Gleevec, one that does not similarly reproduce center-periphery dichotomies where politics elsewhere is acknowledged only to be bracketed and then dismissed.

42. I am indebted to conversations with a number of key actors on the left who have been involved with these debates as activists, interlocutors, and policy makers over the past three decades. They could be placed in four broad and sometimes overlapping categories and include (1) Members of Parliament of leftist parties, especially the Communist Party of India (Marxist) (CPI-M), who have been important legislative voices in these debates; (2) members of CPI-M affiliated trade unions, especially medical representatives' unions; (3) members of the Peoples Science Movement, founded in Kerala in the late 1970s (for accounts of which, see Kannan 1976, 1978, 1990; Varma 2001; and (4) members of the National Working Group on Patent Laws (NWGPL), founded in the late 1980s. Unlike the other three, NWGPL is not formally affiliated with the Communist Parties of India, but has had a major role in providing policy-based opposition and alternatives to global intellectual property regimes throughout and since the Uruguay Round negotiations (see Sengupta 2010, 2013). I am especially grateful to Nilotpal Basu and Brinda Karat (CPI-M Members of Parliament), Amitava

Guha (CPI-M trade union activist), Amit Sengupta of the Peoples Science Movement, and Dinesh Abrol of NWGPL for insights and material on the history of the politics around intellectual property rights issues in India since the mid-1980s. I draw upon perspectives gleaned from them individually over the years in my account here, but especially from an interview with Basu, who was actively involved in interparty and parliamentary negotiations around Section 3(d).

43. In the United States, medical representatives are usually known as sales representatives. Unlike those in the United States, medical representatives in India are strongly unionized.

44. These and subsequent quotes in this section, unless otherwise specified, are from Nilotpal Basu, CPI-M Member of Parliament, interview with the author, November 30, 2011 (henceforth "Basu interview").

45. The Congress-led coalition government under Prime Minister Manmohan Singh that passed the 2005 Patent Act came to power in May 2004, with the leftist parties as coalition members. Prior to this, the Bharatiya Janata Party (BJP) headed two separate coalition governments from 1998 to 2004. The first two amendments to the 1970 Patent Act, in 1999 (initiating provisions for mailbox applications and exclusive marketing rights) and 2002 (broadening the definition of invention) had been enacted by this government. The 2005 Amendment was the third amendment. The BJP itself was in a contradictory position with relation to multinational corporate capital. On the one hand, its ideological wing, the Rashtriya Swayamsevak Sangh, has always adopted a nationalist aversion to multinational capital in the interests of protecting domestic industry; on the other hand, the BJP as a political party has always tended to be pro-business of any kind, domestic or multinational. On the whole, in spite of internal contradictions, the BJP coalition did not indicate any significant opposition to TRIPS while in power.

46. While the Congress gave in to leftist demands in the case of 2005 Patent Act flexibilities, similar negotiations between the two parties would break down in 2008 around a proposed nuclear deal between India and the United States, which the Left strongly opposed, leading to their leaving the coalition.

47. This ambivalence is reflected, for instance, in a note circulated by the Prime Minister's Office to the Ministry of Health and Family Welfare, Department of Industrial Policy and Promotion, the Department of Legal Affairs, and the Department of Pharmaceuticals on July 16, 2010. The note records discussions held by the Prime Minister's Office with the Organization of Pharmaceutical Producers of India, which is the major lobbying group for the multinational pharmaceutical industry in India. CEOs of the Indian divisions of Novartis, Pfizer, Bristol-Myers Squibb, and Sanofi-Aventis were reportedly at this meeting. A copy of this note was obtained by civil society groups fighting for access to essential medicines. The note requests feedback on the adoption of monopolistic intellectual property measures that go far beyond the requirements of the TRIPS agreement, including the dilution of Section 3(d). L. K. Latheeq, Prime Minister's Office, South Block, note to Secretary, Ministry of Health and Family Welfare; Secretary, Department of Industrial Policy and Promotion; Secretary, Department of Legal Affairs; and Secretary, Department of Pharmaceuticals, July 16, 2010.

48. I recognize that the question of what constitutes the southern world is a complex one, given emergent economies throughout the former Third World; the becoming global of many southern cities; increasing inequalities within northern countries; and demographic transformations through postcolonial migrations that constitute postcolonies within the First World (for which, see especially Balibar [2004] regarding Europe). At the same time, long shadows of colonial geopolitical histories persist, and take new and continuing imperialist forms. In the context of this discussion, I use *southern* simply to extend the Gleevec story beyond the Euro-American focus of Keating and Cambrosio's account. Global geopolitical configurations in the pharmaceutical political economies are more fully considered in chapter 5.

49. The account of Gleevec's history in Korea that I provide here is summarized from interviews I conducted there in 2009 with leukemia patient activists, pharmacists, lawyers, and doctors. I am grateful to Ahn Gi Jong, Mi-Ran Kwon, Chul Won Jung, Hee Seob Nam, and Seoc-Kyun Woo for their conversations and insights on this history; to Sang-Hyun Kim and Youngyung Paik for facilitating introductions with key actors involved with Gleevec there, and for providing me with historical context of Korean social movements around health; and to Youngyung Paik and Seo-Young Park for acting as translators as I conducted my interviews.

50. For an elaboration of the notion of monopsony and its relationship to global pharmaceutical pricing strategies, see chapter 1.

51. It is worth bearing in mind that Euro-America is not a singular entity either, and there are huge differences in both health care structures and state relationships with the pharmaceutical industry within Europe and between Europe and the United States.

52. A wonderful moment in the Supreme Court hearings came when Justice Alam was attempting to understand some complicated chemistry relating to imatinib and its crystalline salts, and counsel for Natco Pharmaceuticals (who happened to be one of the only female lawyers arguing the case of either side) explained it to him. Justice Alam paused and said, "That is remarkable. You know the law and you know chemistry. Our country needs more young women like you." Author's field notes taken at Supreme Court hearings, October 31, 2012.

53. While India has well-developed infrastructure for drug manufacture (its local pharmaceutical industry) and distribution (a thriving pharmacy market), these often raise acute problems in other national contexts where such infrastructures are weaker. See especially Kristin Peterson's (2014b) account of the political economy of drug access in Nigeria. Peterson shows that the lack of infrastructure in the country is itself a function of global economic logics that saw capital flight after the oil bust in the late 1970s and the subsequent evisceration of drug manufacture and distribution under World Bank–imposed structural adjustment programs in the 1980s. Also see chapter 4 for an account of strategic maneuvering around provision of drugs, as I discuss Novartis's drug donation program for Gleevec, GIPAP.

54. More than in the Gleevec patent case, one can see this is an earlier case brought before the Supreme Court around exclusive marketing rights that had been granted for the drug in 2002. I discuss this in chapter 4.

55. Justice Prabha Sridevan, interview with the author, October 29, 2012.

56. See Derrida (1992) for a philosophical development of the place of law in relation to what he calls "the promise of justice." The law itself, as a formal instrument of adjudication and governance, too often is inadequate to justice—too instrumental, too reductive, and appropriable by powerful interests. And yet the law provides an opening to justice, which itself is not something teleological, capable of being posited or defined in advance. Rather it is a promissory horizon, always deferred and itself a site of politics. Crucially for Derrida, the very possibility of democracy depends upon the promise of justice, just as the work of deconstruction is that of keeping this promise open (see also Derrida 1994).

57. See Chakrabarty (2000) for the absolute importance of understanding European philosophical inheritance for any adequate conceptualization of postcolonial politics.

58. In this regard, Gayatri Spivak distinguishes a mid-twentieth-century postcolonial constitution such as India's from the American Constitution. While the latter is also strictly speaking a postcolonial constitution, a particular kind of origin story—one signifying a clean slate upon which to make a fresh start—could only be secured "because the colonists encountered a sparsely populated, thoroughly pre-capitalist social formation that could be managed by pre-political maneuvers" (Spivak 1990, 136). Comaroff and Comaroff (2006) further distinguish mid-twentieth-century constitutions from the slew of constitutions (over a hundred) that have come to be drafted since 1989, ones that have emerged in a conjuncture of neoliberalism.

59. Compare this to the form of normative legitimation that biomedical ethics underlying good clinical practice operates through, as discussed in the conclusion to chapter 2. In contrast to the paralogical legitimation employed by the Indian courts, what one sees there is rather a procedural legitimation, one that narrows and closes down possibilities for normative questioning and innovation and therefore at its worst becomes nothing more than a ritual that is appropriate to capital expansion, one whose breaches are not adequately held accountable.

60. He outlines these as follows: "(i) the text adopted in 1950; (ii) the Nehruvian constitution, demanding a compelling respect by the [Supreme Court of India] for parliamentary sovereignty; (iii) the 1973 *Kesavananda Bharati* constitution, a decision that confers constitutional power on the [Supreme Court of India]; (iv) the state Finance Capitalist constitution presaged by the Indira Nehru Gandhi constitution, via the nationalization of banks and insurance industries and the abolition of the privy purses; (v) the Emergency constitution of 1975–77; (vi) the post-Emergency constitution which marks both judicial populism as well as the emergence of expansive judicial activism; and (vii) the Neo-liberal constitution which redefines India as a vast global market" (Baxi 2010).

61. *Novartis AG and Another v. Union of India and Others*, 4 MLJ 1153 (2007), emphasis added.

62. In this regard, see John Kelly and Martha Kaplan's (2001) theorization of the nation as a "represented community."

63. For an analysis of intellectual property in this broader framework of the politics of technology in the American context, see Hilgartner (2009).

64. I have discussed this ideological role of innovation discourse in the context of the Gleevec Supreme Court case in an op-ed in the *Indian Express* (see K. Sunder Rajan 2012).

65. See Jasanoff (2013) for a broader consideration of the relationship between science and public reason.

66. In 2007, the Philippines passed legislation inspired by and similar to India's Section 3(d); the Supreme Court verdict provides strength and legitimacy to such policies. This is recognized by the multinational pharmaceutical lobby and the American government, as evidenced in TRIPS-plus frameworks that are being pushed which restrict such flexibilities (see chapter 5).

67. *Citizens United v. Federal Election Commission*, No. 08-205, 558 U.S. 310 (2010).

68. Public interest litigation is a form of litigation that seeks to advance the interests of disadvantaged groups. It has been a major mechanism by which social policy issues have come to be judicialized in India since the late 1970s. See Deva (2009) for a broader critique of public interest litigation in India. It is worth remembering that while this has become a common route to judicialization, the Gleevec case was one of a corporation suing the government, and was not therefore itself public interest litigation.

69. In 2009, the Delhi High Court had deemed Section 377 unconstitutional, but the Supreme Court overturned this in December 2013, just months after the Gleevec verdict (see Supreme Court of India, Civil Appeal No. 10972 of 2013 (Arising Out of SLP (C) No. 15436 of 2009, December 11, 2013, http://judis.nic.in/supremecourt/imgs1.aspx?filename=41070). Hence, even within the same time horizon, one sees radically divergent verdicts from the perspective of social justice. See R. Sunder Rajan (2003) (especially the introduction) for an elaboration of the tenuous nature of the law in relation to questions of feminism; Sunder Rajan nonetheless insists that the law's own checkered history is not enough cause to abandon it as a site for articulating progressive political demands.

70. Latha Jishnu's reportage has been invaluable and relentless in exposing such moves to sensitize judges to intellectual property (see for instance Jishnu 2010b). See also her article regarding the role of George Washington University's India Project in such sensitization (Jishnu 2010a). I am grateful to Jishnu for conversations that have helped me understand the processes by which such sensitization occurs.

71. I use "common sense" in the sense that Gramsci does, as a set of naturalized background assumptions that provide the basis for hegemonic interpretations of situations at particular places and times. Given that the Indian judiciary has been crucial in interrupting multinational corporate hegemony, changing its common sense becomes a crucial site of politics.

CHAPTER FOUR. Philanthropic Values

1. Even though Novartis counsel did not answer this question, there are some obvious structural reasons why, for which see chapter 1.

2. See also Peterson (2014a), who discusses pharmaceutical monopoly in Nigeria, and Ecks (2008), who discusses this point in relation to Gleevec in India.