The Knowledge Thief? Intellectual Property Disputes and Copying for Development in India

A Dissertation
Submitted to the Faculty of the
University of Minnesota
By

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In Partial Fulfillment of the Requirements
For the Degree of
Doctor of Philosophy

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September, 2022

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Acknowledgements

As challenging as it was to write this dissertation, acknowledging the relationships that made this possible seems even more daunting. One of the key takeaways from my research is that creative works emerge through our engagements and interactions with people. And I've had opportunities to have conversations and form friendships with some lovely humans.

I would not be here without my committee. My adviser Vinay Gidwani was unwaveringly patient and supportive as I sometimes struggled to find my feet and my voice during the PhD. My co-adviser Susan Craddock replied to a panicked email in 2017 requesting her to be on my committee, and since then, has been nothing but encouraging. The reading groups I have been a part of with Ajay Skaria have been some of the most insightful of my life. Though unrelated to my work, having Ajay guide us through texts was a masterclass in close reading. Michael Goldman's warm encouragement that it would all work out helped ease some anxious moments. Watching him teach has taught me to be a generous and engaging instructor.

A big thank you to Sara Braun and Glen Powell in the Department of Geography, Environment and Society for answering all kinds of bureaucratic questions, asked often at the list minute, with a smile. It is straight up impossible to navigate the program without them.

The Interdisciplinary Center for the Study of Global Change (ICGC) has a special place in my PhD journey. Not only was ICGC's financial support critical, it provided a space for interacting with peers from across departments. Karen Brown's research workshop was instrumental in shaping my grant proposals. A special shout out to Laura Knoppe and Shereen Sabet for their warmth. Laura has been a constant and vocal cheerleader, especially throughout the writing process. Exchanging pictures of our cats being silly and listening to Bollywood music during my research assistantship at ICGC will always be a fond memory.

Courses that I took with Bruce Braun, Cesare Casarino, Jigna Desai, and the late Qadri Ismail during graduate school have stayed with me. Jigna and Qadri were always

welcoming and generous with their time, and chats with them over food and drinks at moments when I felt low meant the world to me.

My political and intellectual growth would be incomplete without the teachers I met at Ambedkar University, Delhi (AUD). Sumangala Damodaran, Saumyajit Bhattacharya, and Asmita Kabra introduced me to critical social sciences. They started out as mentors and have become friends. I am also indebted to Shyam Menon, a conversation with whom made me want to attend AUD, one of the best decisions of my life.

A love letter to my friends

Doing a PhD is a strange experience. While there are many moments of learning, self-discovery, and joy, there are many more moments of self-doubt, isolation and vulnerability. My friends have gone through these moments with me. But it feels weird to thank them. As a famous Bollywood dialogue goes, "Friendship *mein* no sorry, no thank you." More importantly, it is not entirely clear what I am thanking them for. My friends are a part of me. I have learnt from their actions and experiences consciously and unconsciously, I have copied them, and I have "borrowed" their clothes, their jokes, their mannerisms, and their wisdom.

Poorvi Chitalkar and I met as undergraduate back benchers who thought we were cooler than most others. Since then, thankfully, we have learnt about humility, privilege, critical thinking, love, and relationships together. The notes we made together for our law exams laid the basis of how I break down texts and make notes today. Together, we are Chit-Chat (Chitalkar-Chatterjee). Yamini Roy is the younger sister I never had. We grew up in the same building, went to the same college, have the same ridiculous dance moves, and have seen each other through highs and lows. Together, we are "YamJu, the pohaaaaaaa sisters." I cannot think of myself today without immediately thinking of Poorvi and Yamini. They are my soul mates, my "doods," and we will always giggle at "Balwant Rai, why are you vomiting???"

Renu Gupta is the older sister I never had. Calm and dependable, she is one of the first calls I make when dealing with "real world problems." She would always take me out on delicious food dates in Delhi, and ask, "Dude, when are you finishing and coming

back?" ("Dude, I finished!"). Neha "Naturally Beautiful" Simlai is a friend for life, no matter how rarely we catch up. Our conversations make zero sense, since we love going off on tangents, but her standing offer to live with her if things did not as planned during or after the PhD made me feel safe. Kaushiki Sanyal also gave older sister vibes, reminding me in moments of dread or cynicism, that academia was not the only option post-PhD. Mili Seoni, one of my oldest friends, provided familiarity and advice when I was acclimatizing to the US.

Lalit Batra was my first point of contact in the Department of Geography at University of Minnesota. When I asked him about Minnesota winters, he replied with a deceptively casual, "Just wear a good jacket." I will never forgive him for this. But, he *almost* made up for it by being a shifting combination of friend, big brother, younger brother, interlocutor, mentor, and trouble maker, always generous with his time, ideas, and energy. Equally significant was my second point of contact in the department, Julia Corwin. Graduate life would be no fun without long sessions with her on our research, grumbling about Minnesotan winters, the soul shriveling moments of graduate school, and the pretentiousness of parts of academia, and chatting about cats, *pakoras*, men, and all things Delhi.

Ketaki Jaywant was my first and longest roommate in Minneapolis. We made our way to friendship cautiously, but firmly. We started graduate school together and I learnt a lot from watching Ketaki work, especially how to be a careful reader. I also hope I absorbed some of her diplomacy and patience through osmosis. We managed to make each other laugh, and take care of each other during some seriously difficult semesters.

Devika Narayan was a lifeline in graduate school. Not only did I learn from listening to her articulate arguments with clarity and precision, she also taught me that the camera is not Satan. We were in India at the same time during fieldwork, both going through a rough patch. Having each other to talk to made it easier to get over some of the bumps. There are very few people who are as deeply caring and giving of themselves in their friendships as Kriti Budhiraja. It is good to be in close proximity with Kriti's ability to cut through all kinds of bull****, including mine. Devika and Kriti have also been much needed and strict caller-outs of my self-deprecating tendencies.

Snigdha Kumar, aka “Sirrr,” is a friend for life because of our non-negotiable definitions of what good and correct *chai* tastes like. She is one of my favorite people to be on the dance floor with, and her funnies never fail to lift my spirits. Sayan Bhattacharya is my only competition when it comes to Bollywood gossip, and our serious contemplation of Instagram posts by celebrities have tided me over many a moment of frustration. I can only aspire to Sayan’s lyricism in writing and his resilience in the face of personal upheaval.

Koel Banerjee, who I lived with for one year, got me through my preliminary exams with cakes, cocktails, and pork ribs. We share an unbreakable bond through our unwavering love for Shahrukh Khan. My bestie Sonal Sharma and I share a love for fabulous fashion, and Sephora, and Instagram forwards are our love language. The nonchalant way in which he wears his brilliance is always a source of amazement. I could always count on Vishal Jamkar and Varnica Arora to remind me of home in the best possible way. I do not remember becoming friends with them. I only recall the immediate sense of comfort. Arif Nairang was my last roommate in Minneapolis. Making fun of him and with him made this crucial last year a little less torturous. Harsha Anantharaman, Sangeeta Banerji, Harshit Rathi, and Maria Gutierrez were part of many raucous, fun filled dinners.

Jacqui Daigneault and Laura Matson took care of me, regularly checking in, and asking me how I was, knowing full well that I would proceed to give a long-winded answer, filled with unnecessary details. Jacqui’s baked treats filled my soul and my waistline. Elizabeth Schneider, Spencer Cox, Kwame Tsikudo, and Melinda Kernik made the department feel cool and welcoming.

There are some friends I made towards the end of my graduate school career, but I feel like I have known them forever. Nithya Rajan’s cooking made many wintry Minnesotan nights feel warm. We also share a love for Malayalam cinema and Fawad Khan, and a dubious business plan based on us settling down in Kerala. Niharika Yadav’s ability to spout filmy dialogues with as much ease as she cites scholarship made for an immediate sense of sisterhood.

And finally, my family

If it is difficult to thank friends, it is almost impossible to thank family. My father, Shoumitra Chatterjee, was always my first call when I felt overwhelmed by work. His calm voice telling me to not stress and take things one step at a time got me through many panic-filled moments. My mother, Nanda Chatterjee's faith in me, when I had little faith in myself to finish this, was unwavering, and her pride during my public presentation made my heart warm. My brother, Abhishek Chatterjee became an increasingly responsible adult during my PhD, which meant that I could be in the US, and not worry every second about my parents, especially during Covid. Last but not the least, a massive thank you to my cat Chintu, without whom the last three years would have been unbearable. I would be a lot less sane without this one-sided love affair, and Chintu's resigned acceptance of my aggressive cuddles.

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Prologue: Finding Common Ground

Does Glivec, a leukemia medication, have anything in common with *course packs*, i.e. compilations of photocopied excerpts from books, used in higher education?[1]

As things, both are available to the senses. Yet, the two look and feel different. Visually and tactilely, they are distinct. Glivec is available as 100 mg and 400 mg tablets or capsules colored a burnt orange. Course packs are photocopied bundles of paper, sometimes slim, sometimes obese, rarely aesthetically pleasing, but usually competently held together by spiral binding.

Images from Google

The two also differ in what they do and the social function they serve. On the one hand, Swiss pharmaceutical giant Novartis' drug Glivec is a chemical compound able to treat a relatively rare but particularly vicious type of cancer called Chronic Myeloid Leukemia (CML). Glivec overturns what is otherwise almost certainly a death sentence, preventing the human body from aggressively devouring itself. On the other hand, course packs are

[1] In this dissertation, higher education refers to both undergraduate and graduate education.

used widely in higher education in India, their ubiquity in colleges pointing to their economic significance as affordable alternatives to expensive books.

Certainly, both are commodities. Medicines and books (as the basis of course packs), generally speaking, are capitalist commodities in contemporary society. They are produced for sale and profit, subject to "the logic of accumulation for accumulation's sake within a market framework" (Castree, 2001, p.1521). Thus, it is possible to discuss the characteristics they share as capitalist commodities (*ibid*). Yet, the social lives of Glivec and course packs have little in common, each moving through the commodity-verse in substantially different ways.

As a medicine, Glivec is a highly regulated commodity. Its production and circulation entail a complex "global institutional ecology" (Petryna and Kleinman, 2006, p.5) which includes national governments, pharmaceutical companies, international entities like the World Trade Organization, regulatory authorities, specialized medical professionals, venture capital, universities, contract research organizations, human and animal bodies, scientific journals, and laws and policies at multiple scales. Access to Glivec—its approval, its price, its distribution, and its availability—is shaped by the interplay of these forces. Standing as it does in the gap between life and death, Glivec is also arguably a more urgent commodity, one whose ethical charge is very much on the surface, apparent and explicit.

Moreover, if things have "biographies" (Kopytoff, 1986), Glivec's is flashy and chequered. The drug has been the subject of a film, a magazine cover, numerous books and articles, as well as legal and regulatory action. After showing remarkable results in clinical trials, Glivec earned the distinction of receiving US Food and Drug Administration (FDA) approval in a record time of two and a half months. As the first successful instantiation of targeted cancer therapy, whereby it was able to arrest cancerous growth while leaving healthy cells unharmed, Glivec appeared on the cover of TIME magazine in May 2001 as "new ammunition in the war against cancer." Its career as a commodity has been notorious, or illustrious, depending on your point of view. While launched at the wholesale list price of approximately $30,000 per patient per year ($2500 per month; Keating and Cambrosio, 2012) in the US, this figure has steadily increased, reaching $120,000 per year in 2016 ($10,000 per month; Johnson, 2016). This

price trajectory, coupled with the fact that Glivec is a recurring, usually life-long expense, made it a blockbuster drug that earned multiple billions annually for its owner Novartis. Conversely, it also made Glivec the subject of pricing scandals. For instance, in 2013, over hundred CML experts wrote an article criticizing its exorbitant price despite Novartis having recouped more than its research and development costs within the first two years of its launch (Experts in Chronic Myeloid Leukemia, 2013).[2] Glivec was even the subject of a hit Chinese film, in which the protagonist after being diagnosed with CML, finds himself unable to afford Glivec, and becomes a hero by importing cheaper generic versions from India.[3]

In contrast, course packs are a humble commodity. Their production requires little infrastructure—a copy machine, electricity, paper, and of course, books to be copied—and they circulate with greater ease—they can be bought from colleges or copy shops, or are shared between students. Course packs also occupy a very different position on the price spectrum: photocopying costs one cent per page in India, and between two and four cents per page in the US. Thus, photocopying all 268 pages of Ranajit Guha's seminal work, "Dominance without Hegemony," published by Harvard University Press and sold at $42, would cost $2 in India and between $5-11 in the US.

Yet, the stories of these distinct things, these disparate commodities intersect in my dissertation by way of disputes over *intellectual property rights*.

What does it mean to think of a leukemia medicine and books as intellectual property? What are the histories, politics, and stakes of such (re)cognition? What kinds of conflicts arise in the process? These are the questions that I ask in my dissertation, "The Knowledge Thief? Intellectual Property Disputes and Copying for Development in India."

[2] See also *Red Carpet Courts* (2019) for an account of the Columbian government's ill-fated fight against Novartis over breaking its monopoly and lowering the price of Glivec.
[3] The film, *Dying to Survive*, was based on the true story of a textiles trader, Lu Yong. Although arrested for illegally distributing the unapproved drug, Yong was acquitted after a massive outpouring of public support. The film's success was reported to have prompted the Chinese state to expedite price cuts for cancer drugs (Kuo, 2018).

Introduction

1. **Intellectual Property Rights: An Overview**

Intellectual property rights created the conditions of possibility for the two legal disputes I analyze in my dissertation—(1) the Glivec case, and (2) the Delhi University photocopy case.

Intellectual property rights (IPRs) are rights in or to what are called "creations of the mind" (WIPO, n.d., p.2), a phrase that refers to intangibles like information, knowledge, feelings, and creativity, and includes inventions, literary and artistic works, symbols, names, and images used in commerce, etcetera. The World Intellectual Property Organization (WIPO) defines IPRs as "any other property right. They allow creators, or owners [of the rights] to benefit from their own work or investment in a creation" (WIPO, n.d., p.3).[4]

But what does it mean to say that IPRs are like any other property right? While property must not be equated with private property, it would be more precise to say that IP law creates and protects *private* property rights in knowledge and creative works for a limited period of time.[5] And private property rights are essentially constituted by rights to exclude. In other words, having intellectual property rights in knowledge means having the rights, and the power, to exclude others from using it, selling it, charging rent for it, and most consequentially, from copying it. Thus, Kapczynski characterizes IPRs as "alchemy that turns immaterial expressions and ideas into tradeable commodities, [effectively giving] creators the ability to market information while also preventing it from being imitated and reproduced by others" (2010, p.23). Or, as May and Sell write, when knowledge becomes subject to ownership, IPRs express the following legal benefits that accrue to the rights holder for a limited duration: (1) the ability to charge rent for use, (2) the right to receive compensation for loss, and (3) the right to demand payment for transfer to another party through the market (May and Sell, 2006, p.6). IPRs are also codified as human rights in Article 27(2) of the Universal Declaration of Human Rights: "Everyone has the right to protection of the moral and material interests resulting from

[4] WIPO is a United Nations agency that aims to lead the development of a balanced and effective international IP system

[5] I return to the question of property in the Conclusion.

any scientific, literary or artistic production of which he is the author." [6] Despite this declaration, however, IPRs are held/owned most commonly by corporations. In fact, as I show in this dissertation, it is the concentration and monetization of IPRs in the hands of transnational corporations, headquartered largely in the Global North, that gives rise to pressing questions of power, human freedoms, and justice.[7]

I also note here that while intellectual property is discussed in terms of intangibles, IP law requires such intangibles to be materially fixed.[8] Thus, things as varied as medicines, books, seeds, films, design, fertilizers and slogans are understood as material expressions of ideas, knowledge, feelings, and creativity, causing their use and circulation to be regulated by IP law, thereby artificially creating regimes of scarcity (Chapman and Coombe, 2020).

While IPRs are of many kinds, my dissertation focuses on patents and copyrights. Patents are IPRs attached to technological inventions, a category that has come to include medicines, while copyright protects literary works. In the disputes I analyze in this dissertation, a leukemia medicine and books are contested objects of IPRs, i.e. patents and copyright respectively.[9] It is their reproduction and circulation, regulated and restricted by law, that is the subject of these disputes.

Thus, it is in their reincarnation, albeit disputed, as private property that we begin to see, or rather, are forced to see common ground between a leukemia medicine and course packs. This, in turn, is premised on the re-cognition of medicines and books not as

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[6] These characterizations of IPRs draw from (i) Locke's discussion of property as labor's 'just dessert,' with intellectual property rights being deemed reward for intellectual labor; and (ii) the Hegelian idea that property is necessary to the development of personality ("the personality theory of property"). The latter has been repurposed by IPR advocates to argue that intellectual property rights necessitate protection not just because (or even irrespective) of their economic efficiency, but because creative works are modes of self-expression, and embody the creator's distinct essence, will, or personality.

[7] The invocation of Lockean and Hegelian justifications for IPRs obfuscate this very fact of corporate ownership. I am thankful to Vinay Gidwani for pointing out that a theory of corporate personhood is necessary to understand the global sway of the IP regime. While this is beyond the scope of my dissertation, I plan to return to it in further writings.

[8] In fact, this mandated tangible form is often used as a justification to treat knowledge as analogous to things to which legal protections under property are granted (Munzer, 1990).

[9] In the Delhi University photocopy case, books are the objects of intellectual property rights, while course packs are alleged to be the infringing objects. I elaborate on this in Chapter 3.

things-in-themselves but as knowledge-fixed-in-things. This juxtaposition—between a blockbuster drug and modest course packs, between the Glivec case and the Delhi University photocopy case—forms the basis of my dissertation.

2. **The Cases**

2.1 *The Glivec Case (2006): Deflecting the magic bullet*

In 1993, Novartis applied for an American patent on a chemical compound called imatinib (Zimmermann, 1996). Patents are intellectual property rights granted for technological inventions. In order to be granted a patent, a technology must be shown to be an "invention," defined broadly as (i) new; (ii) useful; and (iii) non-obvious.[10] If the technology meets these criteria, a patent is issued which grants the patent holder the exclusive right, *for a minimum period of twenty years*, to decide how the technology will be disseminated (WIPO, n.d.).

Imatinib had shown therapeutic promise in the laboratory: it was able to latch onto the rogue chromosome that creates havoc in the bone marrow by ordering the frenzied proliferation of cancer cells, thereby causing chronic myeloid leukemia (CML); it was then able to switch it off. The American patent office found imatinib to be an invention and in 1996 granted Novartis a patent on it (Zimmermann, 1996).[11] Thus, Novartis had the right to exclude others from using, selling, and copying imatinib for atleast twenty years, as well as the attendant power to fix its price during this time. In 2001, Novartis requested the approval of the US FDA for imatinib's market launch under the brand name Glivec. In documents submitted to the FDA, as well as in the package insert accompanying the medicine, it named imatinib mesylate (IM), a salt form of imatinib, as the active ingredient, i.e. the therapeutic agent in Glivec.

Glivec made its market debut in North America and Europe in 2001. By 2003, it had become Novartis' number two drug. Since its launch, this "magic cancer bullet" (Vasella, 2003) has been a blockbuster drug, consistently netting multiple billions

[10] See, for instance, Article 27.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, and clauses (j), (ac), and (ja) of Section 2(1) of the Indian Patents Act, 2005.

[11] Imatinib was also granted patents in Canada, the European Union, and many other countries.

annually for the pharmaceutical giant (Johnson, 2016).[12] For instance, in 2015 alone, Glivec revenues worldwide were a towering $4.7 billion (Reuters, 2016).[13] This despite CML's small patient pool—there are about 3000 new CML patients per year in the US, and about 1.3 per 100,000 worldwide (Keating and Cambrosio, 2012, p.319).[14] To offset the smaller consumer base, Novartis established a single universal price of around $2500 per month for Glivec, instead of setting different prices for high-income and low- to middle-income countries (*ibid*). Glivec's earnings were the result of Novartis' pricing strategy, which in turn was scaffolded by the market exclusivity that a patent entails. Novartis' patent cordoned off the US and European markets for Glivec from competition with generics. Thus, Novartis could command whatever price it wished, since CML patients in these markets had little recourse besides Glivec. When Glivec's patent was set to expire in July 2015, Novartis' CEO Joe Jimenez called it one of the biggest patent expirations in the companies' history (Staton, 2016).

However, Novartis had not been able to patent imatinib in India. Patents are territorial rights, i.e. a patent has to be applied for in each national jurisdiction, and is granted on the basis of national patent laws. India at the time of imatinib's invention, did not allow patents on medicines. Further, Indian pharmaceutical companies, with their sharply honed skills in manufacturing generics, had reverse engineered Glivec and by 2001, began selling generics of the drug in India. The price difference between these generic versions and Novartis' branded drug was substantial—while Glivec cost $2500 per month at the time, generics cost between $100-$300 per month.

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[12] In the pharmaceutical industry, a blockbuster drug is one that earns more than a billion dollars in revenue per year. Daniel Vasella was Novartis' Chairman at the time of Glivec's approval and production. In telling Glivec's story, his book, *Magic Cancer Bullet: How a Tiny Orange Pill is Rewriting Medical History*, provides a linear and romanticized account of scientific innovation and corporate risk-taking.

[13] A lawsuit filed by workers' unions in 2015 accused Novartis of having unlawfully extended its market exclusivity by seven months (United Food and Commercial Workers Unions & others *v*. Novartis, 2015).

[14] Oncologist Brian Druker, who played a key role in the development of Glivec, has noted that despite imatinib's success in the lab, Novartis was reluctant to move it to animal and clinical trials. The company saw Glivec as a loss-making proposition due to CML's small patient/consumer pool (Druker, 2007).

Yet, India was set to change its patent law and allow patents on medicines in 2005. As the change came into effect, Novartis' application for an Indian patent on a chemical compound it called "beta crystalline form of imatinib mesylate" (IM-ß) was opened by the Indian Patent Office. IM-ß is a polymorph, a structural cousin as it were, of imatinib mesylate. Herein lay the rub. Although India began permitting pharmaceutical patents in 2005, the revised law doesn't allow patents on "a new form of a known substance" unless it exhibits significantly enhanced efficacy (Section 3d of the 2005 Patents Act; hereinafter 3d). This novel provision was aimed at curbing "evergreening"—a widespread practice in the transnational pharmaceutical industry, whereby companies attempt to extend the patent life of medicines by making cosmetic/minor modifications to them. Novartis' patent application, therefore, raised the following questions: was IM-ß a novel compound? Or, was IM-ß merely imatinib dressed in monocles and a top hat? In other words, was IM-ß a new form of an already known substance? If yes, was IM-ß more efficacious than its predecessors? Novartis claimed that not only was IM-ß different from, and much better and more effective than both imatinib and imatinib mesylate, but that there was no Glivec without IM-ß. IM-ß, claimed Novartis, was Glivec.

In 2005, the Indian Patent Office ruled that IM-ß was not an invention. This triggered a seven-years-long legal battle that wound its way through the hierarchy of courts in India. In 2013, the Supreme Court, India's apex judicial forum, also ruled against Novartis, holding that IM-ß failed the 3d test and did not warrant protection as an invention under India's revised law, since it was merely a new form of a known substance.

2.2 *The Delhi University Photocopy Case (2012): Of course packs and copy machines*

In 2012, three international academic presses—Oxford University Press, Cambridge University Press, and Taylor & Francis Group (the publishers)—filed a lawsuit in the Delhi High Court against Rameshwari Photocopy Services (RPS), a non-descript photocopy shop located in the premises of the University of Delhi (DU), and the

University itself. Their accusation: RPS and DU were complicit in egregious copyright violation.[15]

Copyright is an intellectual property right that attaches to original literary and artistic works, which takes the form of rights-to-exclude specified uses (Elkin-Koren, 2017, p.158), for a period of over a hundred years.[16] In other words, such uses—for instance, in the case of literary works, publishing, reproducing, adapting, translating, and publicly performing it—are the exclusive preserve of "the author," and doing them without the author's permission is designated as wrongful use, i.e. copyright infringement. Thus, an author can prevent third parties from making copies of their work. However, while copyright is often discussed in terms of authors' rights, it is assignable and transferable. In the instance of books and journal articles, copyright is often assigned to, and, therefore, owned by the publisher.

Graduate courses at DU, much like graduate education across the world, are taught using chapters and essays drawn from multiple books. In DU, RPS photocopies the recommended texts from disparate sources, compiles them into course packs, and sells them to students. However, since it does all this without authorization from, and payment to them, it was, the publishers argued, guilty of copyright violation. They also accused DU of "institutionalized copyright infringement" for allowing and enabling such violations to occur.[17]

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[15] The case was heard by a Single Judge (Justice Endlaw) of the Court: The Chancellor, Masters & Scholars of the University of Oxford & Others v. Rameshwari Photocopy Services & Others (accessed from http://164.100.69.66/jupload/dhc/RSE/judgement/16-09-2016/RSE16092016S24392012.pdf; hereafter HC, 2016). The publishers appealed against Justice Endlaw's ruling before a Division Bench of the High Court: The Chancellor, Masters & Scholars of the University of Oxford & Others v. Rameshwari Photocopy Services & Others (accessed from http://164.100.69.66/jupload/dhc/PNJ/judgement/09-12-2016/PNJ09122016RFAOS812016.pdf; hereafter DB, 2016).

[16] International intellectual property law requires copyright terms to last a minimum of fifty years plus the life of the author (Article 7(1) of the Berne Convention). Beyond this, the term varies by country. For instance, the term of copyright in India is sixty years plus life of the author (Section 22, Indian Copyright Act), while in the US it is seventy years plus life of the author (for works created on or after January 1, 1978; Section 302, Title 17 of the United States Code).

[17] The publishers contended that DU was culpable on the grounds of (i) setting the syllabus that forms the basis of the course packs; (ii) granting an operating license to RPS; (iii) its library issuing books to RPS for photocopying; and (iv) its faculty recommending that students buy course packs instead of "legitimate copies" of the books. (HS, 2016, paras 1, 2, 14.)

Yet, national copyright laws subject the rights of authors or copyright owners to some limitations and exceptions in order to balance them with the rights of users (Liang, 2017). Thus, copyright may be switched off for legally defined purposes, users, and/or types of work. In this vein, Indian copyright law permits copying literary works for the purpose of education (Section 52(1)(i), Indian Copyright Act). The case, therefore, involved questions about the relationship between copyright law and education, the specific importance of education, as well as how education happens.

Following an interim order issued by the Court, RPS was raided by the police—its employees roughed up, "infringing and pirated copies" of the publishers' books seized and catalogued—and was directed not to sell course packs while the case was being heard (HC, paras 3, 8; Oberoi, 2016). This produced a ripple effect, with dozens of photocopy shops in and around DU temporarily freezing the sale of course packs (Bhatia, 2014).

As word of the publishers' action spread, University students and teachers responded on multiple fronts. A protest meeting organized in the University discussed the political economy of publishing, arguing that it is skewed in favor of publishers, and against authors and users. DU students assembled outside the publishers' stalls at the New Delhi World Book Fair, and distributed to visitors a statement "condemning the attack of corporate publishers on students" (Tankha, 2013). Students and noted scholars in India and beyond also signed a petition urging publishers to withdraw the lawsuit.[18] When the decision in the original case went against them, the publishers appealed against the ruling of the Delhi High Court. But after unfavorable rulings in the appeal as well, they discontinued their legal action.

3. **Methods**

I left for fieldwork in Fall 2016. At the time, my project foregrounded patents and was located squarely within the pharmaceutical industry. I sought to interview persons with current or previous experience in the pharmaceutical industry, patent law specialists, and researchers with expertise in public health, to ask the following questions:

[18] DU photocopy case: Who's afraid of copyright?; Appeal to publishers to withdraw suit filed against Delhi University. See also, Tankha (2013).

1) How has the introduction of product patents impacted the production of generics manufacturing by Indian pharmaceutical companies, and what strategies have such companies adopted to navigate the post-TRIPs terrain?

2) How has law defined and understood patentable innovation under Section 3 of the Indian Patents Act?

3) What is the geography of drug innovation and production globally, and where are Indian companies located in this landscape?

However, fieldwork posed two significant challenges. The first was professional. Industry insiders proved highly reticent, particularly on the question of patents. My reading of this reluctance was that it was attributable to patents having become increasingly important in the generation of value in the pharmaceutical industry. With a stagnant pipeline of new drugs, and the demands of finance capital, patenting new chemical entities, biological drugs, processes to make them, as well as changes to medicines that purportedly made them better is a critical component of pharmaceutical profits. I found it increasingly difficult to get interviewees to comment on the post-TRIPs patent landscape, and discuss the kinds of patents Indian firms were looking to secure in the near future, which was my area of interest.

The second challenge was personal. I went through a severe health crisis for well over a year, which made it difficult for me engage in conversation with people I didn't know, move freely and pursue difficult respondents. It was difficult to come to terms with this failing in what was a crucial year, but it became evident that coupled with the difficulties I was facing in interviews with patent experts and pharmaceutical professionals, I would not be able to pursue the research I had originally planned.

I had been in Law School when the Glivec dispute began. It was a subject of some conversation, especially among those of us who were taking additional classes in intellectual property rights. When the Supreme Court issued its final order in 2013, the intensity and volume of relief from public health and access to medicines activists stayed with me. At the same time, it was in 2016 that the Delhi High Court issued two judgments against the publishers in the Delhi High Court. I had been a keen follower of the case, not simply because of my legal training and the stakes of it, but also because many of my friends were from Delhi University and had been involved in supporting

RPS as well as doing crucial legwork for the legal case. As the verdicts came out, I went to DU and had a brief conversation with Dharam Pal Singh, the owner of RPS. I was also introduced to two former students of the University who had been at the forefront of mobilizing against the publishers. This unplanned visit led me to read the actual verdicts the Court had issued. I began to track parallels between the DU photocopy case and the Glivec case.

By 2018, I decided to change my research project. I became interested in similarities as well as differences between these two cases. In particular, I wanted to get into the legal minutiae to understand the relationship between legal reasoning and interpretation and the politics of knowledge. I was also intrigued by how law policed boundaries between sameness and difference, between the original and the copy in IP disputes. I looked at other domains of IP as well. I waded into copyright disputes in works of fiction as well as trademark disputes over subversive appropriation of corporate brands. While I spent considerable time building a basic grasp over these domains, there was something about the public and heightened significance of the domains of health and education that I felt more compelled towards.

My dissertation relies primarily on a close reading of the case archives and allied material, including multiple judgments, opinion and advocacy pieces, industry reports and statements, and legal commentaries. I was able to access most of the judgments through the databases of the Supreme Court of India, the Delhi High Court, the Indian Patent Offices, and *Manupatra*. The online repositories of SpicyIP, MSF, A2K, and KEI were also critical to access commentaries, reports, and legal and policy actions taken by various parties across the world. I read them with and against each other and offer textually layered analyses. As previously stated, I have also conducted select expert interviews to complement and complicate what these documents allow me to speak on.

Pursuing this project meant dusting off the cobwebs that had gathered on my legal training. I revisited the world of statutes and judgments, relearning the specificities of the legal universe. This process felt both familiar and strangely new, since I was coming back to law after working in the development sector, a Master's in development studies, and my ongoing training in geography. My undergraduate education had taught law as a form of systematic knowledge that had the status and methodological rigor of a science. Its

critical entanglements with socio-political, economic, and ethical questions were for the large part bracketed. However, my experiences after law school meant that I was now reading law differently. As I went through the cases, law was alive, fragmentary, inconsistent, and even violent.

The Glivec case posed a major challenge: that of understanding the basics of drug chemistry, pharmaceutical research and development, and pharmacological claims. I characterize this as nothing less than learning a new and intimidating language. While most of the textbooks, primers, and You Tube videos I slogged through have not made it to my in-text citations, they were critical in understanding the knowledge claims and counter claims being made in the Glivec case. I show in Chapter 1, that what makes medicines available for patent protection is their abstraction as technology, which in turn is understood as knowledge fixed in things (I have identified TRIPs as mandating such abstraction). The corollary of this is that patents contain e/valuations of scientific knowledge, and make such knowledge the primary ground for contesting patent applications and grants. Therefore, not understanding what claims were being made about drug chemistry and drug action was not an option, since it was on these very grounds that the grant of a patent in the Glivec case rested. Similarly, I had to learn how to read patents, their architecture and form, since this determined the extent of property claims. Chapters 1 and 2 demonstrate that I engage deeply and critically with patents as a legal instrument and with knowledge claims about pharmacological sameness, difference, and efficacy. On the other hand, the world of the DU photocopy case felt more familiar and more easy to grasp. At the same time, reading these two cases meant situating them in their specific contexts. As a result, my research is interdisciplinary. I draw from works on the political economy of pharmaceuticals, the history of chemistry, science and technology studies, medical anthropology and many other genres of interdisciplinary scholarship to contextualize, understand the stakes of, and analyze the Glivec case. Conversely, I draw on geographies and sociology of education, and political economy works that help to understanding the academic publishing industry.

Law, however is a common thread. I draw from social studies of law, legal geography, and legal humanities to enable a critical and politically inflected reading of legal texts. This careful attention to the law, I believe, is one of the strengths of my

dissertation. Further, my research underscores the methodological value of examining legal cases from the Global South where IP jurisprudence is not robust. This allows for the critical evaluation of assumptions, principles, and standards that have sedimented as common sense in IP law.

It was this process that highlighted the stakes of my research and enabled me to make the key interventions discussed in the following section.

4. The Stakes and the Interventions

In this section, I discuss the stakes of the specific disputes I outlined above, as well as of patents and copyright more broadly.

4.1 *The Glivec case and pharmaceutical patents*

The Glivec case highlights the controversial nature of pharmaceutical patents. If Novartis' application for an Indian patent on IM-ß was successful, its monopoly over Glivec's production in India would be activated, and the generic versions of the life-saving drug offered by Indian pharmaceutical companies would have to be withdrawn from the Indian market. As noted previously, the price difference between Novartis' branded medicine and the generic versions was exponential. Alternatively, Novartis, on being granted a patent, could ink a licensing agreement with the Indian manufacturers, which would allow these generics to continue to be available but on terms set by Novartis. Further, Novartis had challenged not just the Indian Patent Office's finding that IM-ß was not an invention, but also the validity of the legal provision under which this decision was made. In other words, Section 3d of the Indian Patents Act was on trial before the courts for the first time since its enactment, with Novartis challenging not just its meaning but its very existence.

Patents enable pharmaceutical companies to curb competition, granting them a legal form of absolute, albeit temporary, monopoly (Prindle, 1906 cited in Christophers, 2016). The monopoly in turn means that companies have the power to unilaterally fix the prices of patented medicines for a minimum of twenty years. In principle, patents contain the potential and not necessarily the inevitability of temporary monopoly creation: "A patent in itself does not determine the way… technology is disseminated. All that it allows is for the patent holder to negotiate the market terrain with a set of exclusive rights

that others do not possess." (Sunder Rajan, 2012, p.4).[19] Yet, *patents do have "unusual importance" in medicines policy* (WHO, 2004, p.109; italics mine). The monopoly power inherent in them is often used by pharmaceutical companies, as was done by Novartis in the case of Glivec, to generate profits in amounts that have little connection with recouping research and development costs (Experts in Chronic Myeloid Leukemia, 2013). And the transnational pharmaceutical industry has a proven track record in hoarding and what can only be called weaponizing patents at the cost of human lives, such as during the HIV/AIDS crisis in Africa during the nineties (Horner, 2013; I-MAK, 2017).

This explains the intense public scrutiny of the Glivec case, which was closely monitored by public health and access to medicine activists, as well as the Indian and transnational pharmaceutical companies. The Supreme Court's ruling against Novartis, which meant that the exponentially cheaper generic versions of Glivec produced by Indian pharmaceutical companies would continue to be sold in the domestic market and to be available for export to other countries, was celebrated widely as a "victory for global public health" ('t Hoen, 2013), and "a just order" (The Hindu, 2013). Médecins Sans Frontières (MSF), the renowned international medical humanitarian organisation, also argued that the ruling set a precedent for refusing patents on minor modifications to old medicines (MSF, 2013).

Thus mediating questions of who gets to live, and to heal their bodies and minds, and at what cost, pharmaceutical patents are inextricably entangled in the politics of access to medicines, of health, and of "life itself" (Rose, 2007; Kapczynski, 2010).

4.2 *The DU photocopy case and copyright in education*

On the other hand, the DU photocopy case highlights how copyright law has become an important source of conflict in higher education. As key material forms that academic knowledge takes, books, articles, and journals are foundational to higher education infrastructures. Enabling students and scholars to talk to each other, and to thinkers and

[19] Universities, for instance, have, on occasion, patented therapeutic substances (University of Toronto's patent on insulin) and technological innovations (Stanford University's patent on recombinant DNA technology) to facilitate their dissemination though the grant of non-exclusive licenses and insistence on moderate pricing (Cassier and Sinding, 2008; Sunder Rajan, 2012).

writers long dead, they are critical for participation in global conversations and circuits of research. Yet, today, access to such knowledge is difficult without running up against copyright law, which sets up unauthorized photocopying as theft of the author's or publisher's intellectual property. This, in turn, jeopardizes the circulation of photocopied texts and course packs, used especially in countries of the Global South to offset the question of affordability of books and journals, and higher education more generally. Copyright law, therefore, mediates what we are able to read, how we think and imagine, and who is able to participate in knowledge production and creative activity.

DU is one of the largest and most prominent public universities in India, comprised of 90 Colleges, 16 Faculties, 87 Departments, and 16 Centers. In 2017-18, there were around 650,000 students enrolled in the University across over 500 programmes at the undergraduate and graduate levels (University of Delhi Brochure, 2018). If the publishers were able to successfully argue that course packs are unlawful copies and moving forward, would require the payment of licensing fees, it would likely set a precedent for other universities and colleges in the country, most of which use course packs as pedagogic tools. More significantly, it would mark a decisive moment in the relationship between copyright law and education in India, eroding the exceptional status granted to the latter by the Indian Copyright Act in the matter of copying works.

Together, the Glivec and DU photocopy cases demonstrate the hegemony of intellectual property in the contemporary production and circulation of knowledge. This dominance is justified primarily on economic-moral grounds. By being difficult to produce, but cheap and easy to reproduce, information, we are told, creates the economically dreaded, and the morally dreadful, "free-rider" problem. In other words, minus IPRs, it is argued that free-riders would pay merely the much lower costs of copying these goods, without paying the substantially higher costs of their production (Kapczynski, 2010). Unable to recoup their investments, rational actors, therefore, would be wary of producing and circulating knowledge and creative works in the first place. Thus, for instance, after losing its case in the Supreme Court, Novartis pronounced the verdict a death blow to pharmaceutical invention, and made thinly veiled threats to not introduce new medicines in the Indian market:

> Paul Herrling, who is leading Novartis's handling of the affair, said that a refusal by India's Supreme Court to grant patent protection for [Glivec] would have repercussions for transnational drug companies' activities in the country…."If the situation stays as now, all improvements on an original compound are not protectable and such drugs would probably not be rolled out in India," he told the Financial Times. "Why would we?" (Financial Times, March 31, 2013).

Similarly, the publishers in the DU photocopy case argued that allowing course packs to be made without the payment of licensing fees would be tantamount to sanctioning the demise of the academic publishing industry: "[T]he publishers invest in publishing books and if the copyright of the publishers is not protected, it will sound a death knell for the publication business… and that even if the academicians continue to write for themselves, the publishers would not be willing to publish" (HC, 2016, paras 14, 20).

The ever present threat of arresting scientific, technological, and artistic endeavors, therefore, acts as a powerful justification for intellectual property.

4.3 *TRIPs and the global institutionalization of IPRs*

The hegemony of IPRs in regulating the exchange of knowledge and innovation has also been institutionalized globally by way of the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

Enacted in 1994 and administered by the WTO, TRIPs defines the "minimum" standards of IP protection that countries have to comply with and sutured them into world trade. Thus, WTO members *had* to implement TRIPs, i.e. they could not opt out, and non-compliance could be punishable with trade sanctions (Kapczynski, 2010). The minimum standards of IP protection advocated by TRIPs is much higher and more stringent than what most countries in the Global South had at the time (Correa, 2008; Kapczynski, 2009). What is significant in the Indian context is that TRIPs required all signatories to revise their national patent laws to provide patents on medicines. Thus, in order to be a WTO member, India, which till then had exempted medicines from patents, would have to amend its law and make it TRIPs compliant by allowing patents on medicines. This India did in 2005.[20]

[20] Developing countries like India were given ten years to transition to the new "TRIPs compliant" patent regime. See Chapter 1.

Given that the overwhelming majority of countries in the world are WTO members, and WTO membership in turn requires implementing TRIPs, scholars have called TRIPs an "exceptionally audacious attempt" (Kapczynski, 2010, p.26) in the contemporary governance of knowledge, seeking as it does to materialize on a global scale, a "second enclosure" of information and knowledge that had previously been in the public domain (Boyle, 2003; May, 2000). I also emphasize here that TRIPs lays down *minimum* standards of IP protection for countries to adopt. Many countries individually, or by virtue of bi- and multi-lateral treaties, have enacted "TRIPs plus" provisions, i.e. higher and more stringent protections for IP.

It would seem, therefore, that the legal-political construct of intellectual property has a chokehold, both material and discursive, on thinking about and acting on knowledge and knowledge-embedded goods today, with little room to maneuver and resist. My dissertation, however, shows otherwise, demonstrating both the potential as well as the limitations of challenging IP legally. *I argue that while neither the Glivec case nor the DU photocopy case can be easily read as resistance to the IP project per se, i.e. the creation and protection of private property rights in knowledge more broadly, stakeholders are able to contest entrenched narratives, categories, norms, and histories of intellectual property during the course of legal arguments. In this process, they offer ways to blunt the sharp edges of intellectual property law through a combination of the politics of knowledge, of sovereignty, and of development. Limited though this might be since the choice in each case was between a market characterized by monopoly versus one characterized by competition, interpretations and arguments in both produce materially significant outcomes of preserving a relatively broader access to medicines and books respectively.*

4.4 *Key Interventions*

The Glivec case and, to a lesser extent, the DU photocopy case have been the subject of public and academic scrutiny. The chapters of my dissertation analyze the specificities of these cases, and discuss the ways in which I deepen, extend, and complicate existing

scholarship on each of them. In this Introduction, however, I focus on the arguments that *bringing these cases together* allows me to make.

Scholarship on intellectual property is often grouped according to types of intellectual property, i.e. patents, copyright, trademark etcetera, or according to domains of knowledge and creativity, i.e. health and medicines, software, music etcetera. But juxtaposing cases that involve different types of IP (patents and copyright) in two different domains (health and education) and industries (pharmaceutical and academic publishing) allows me to make key interventions on: (i) the politics of sovereignty; (ii) infrastructures of copying; and (iii) the notion of the copy.

4.5 *Intellectual property law and the politics of sovereignty*

The Glivec and DU photocopy cases and verdicts are amenable to a reading of the Global North versus the Global South, the core versus the periphery, and victories of David over Goliath. Certainly, most of the key actors in the cases can be placed in neat geographical boxes. Those who filed the cases, and argued for broader and more stringent protection of IP were lucrative transnational companies in pharmaceuticals (Novartis), and academic publishing (Oxford University Press, Cambridge University Press, and Taylor & Francis Group) headquartered in countries of the Global North. These actors came to be associated with "the international." They invoked India's obligations under international law. This was particularly forceful in the Glivec case, with Novartis alleging that Section 3d of the Indian Patents Act, 2005 was in gross noncompliance with TRIPs. There was a strong suggestion in these arguments that "the international" sits over and above "the national" in a hierarchical relationship with it.

Conversely, those who challenged the privileging of IP protection over other concerns were situated in the Global South, primarily India. The Glivec patent was opposed by Cancer Patients Aid Association (CPAA), a non-profit organization registered in India that supports the prevention and treatment of cancer among patients in need in the country (and to a lesser extent, in Nepal, Bangladesh, Bhutan, and Pakistan). It was joined in this opposition by pharmaceutical companies—Cipla, Ranbaxy, Natco, and Hetero—all headquartered in India, and all reputed makers of generic medicines. Similarly, a small copy shop and a public university in Delhi were the defendants in the

lawsuit filed by the publishers, while students and faculty in the university played a crucial role in articulating arguments against an overzealous copyright regime in education. These actors challenged the purported hierarchy between international and national, and emphasized India's legislative sovereignty in both enabling *and circumscribing* intellectual property rights.

The rise of international law has often been read as evidence of a decline in national sovereignty and national law. Hardt and Negri's *Empire* (2001) is a prominent work arguing that national/domestic law is powerfully overdetermined by international/supranational law (p.17). In the context of the formal end of colonialism, they contend that postmodern sovereignty has exceeded the modern form that inhered in territorial nation states, with "government and politics [being] completely integrated into the system of transnational command" (p.307). Nation-states find their sovereignty declining, their inability to regulate economic and cultural exchanges increasing, and their borders continuously transgressed and effaced (p.xii).

My analysis of TRIPs and the Glivec and DU photocopy cases, however, complicates this argument. For one, national sovereignty is foundational to international law, in that sovereignty can only be limited through its very exercise (albeit such exercise may be under pressure; Buchanan and Pahuja, 2004). As Aoki reminds us that "to dichotomize the supranational and the national creates an illusory separation between the two that obscures the constitutive role of nation-states in constructing and participating in the supranational arena" (1996, p. 1293). Moreover, such a formulation, it seems to me, obscures inequalities among nation-states, as if all were experiencing comparable decline in their sovereignty. I also show that national sovereignty and national law continue to be critical components of the global political-economic order, and have not been subsumed by the international. Equally, the international and the national are neither distinct, nor oppositional spaces or scales. Rather, they are better understood in terms of mutual constitution, asymmetrical interpenetration, and successful and failed transplants.

As noted earlier, TRIPs provides the global script for intellectual property protection, and in doing so, is considered a watershed moment in the contemporary global governance of knowledge. TRIPs is an "international agreement," a nomenclature that conveys a global "consensus on legal norms and institutional arrangements that will

best ensure continuing economic development" (Campbell, 2010, p.10). Yet, if we ask who wrote this script, the above characterization immediately crumbles. It is well-documented that TRIPs was drafted primarily by the US and Western European countries (Drahos, 1995; Horner, 2013; Jaszi, 1996). Further, the minimum standards of IP protection that TRIPs mandates for WTO members are all drawn from practices and norms of developed countries, and are quite high compared to what developing countries and least-developed countries (LDCs) had in place previously.[21] For instance, TRIPs sets the minimum term of patent protection at twenty years (Article 33, TRIPs); contrast this with India which offered five to seven years of protection for process patents on food and medicines at the time (Section 53(1)(a), Patents Act, 1970). Even more significantly, TRIPs takes aim at the categorical exception made by many countries (atleast 50, according to Correa, 2008) for medicines in matters of patentability. While these countries had shielded medicines from patents, TRIPs requires that medicines be made available for patent protection. Thus, Kapczynski terms TRIPs an attempt at "upward harmonization" of intellectual property rights, i.e. requiring developing countries and LDCs to bring their IP laws at par with developed-country standards and norms (2009, pp.1571-72).

This discussion certainly highlights that yes, TRIPs has penetrated and reconfigured *some* national IP laws. It was because of the TRIPs mandate (linked to WTO membership) that India changed its patent law in 2005, ending the exemption that medicines had from patents. The Indian Patents Act, 2005 made pharmaceutical patents legal. At the same time, I argue that the very fact of TRIPs as well as its content instantiate the extension of the sovereignty of the US and select European nation-states beyond their borders (Buchanan and Pahuja, 2004). This, as the authors note, is politically and conceptually different from "the distinct national colors of the imperialist map of the world merg[ing] and blend[ing] in the imperial global rainbow" (Hardt and Negri, 2001, p.xiii). In other words, not all national laws are overdetermined by international law; some national laws become international law. I find here a key insight of postcolonial theory: that some national laws and forms of socio-political organization

[21] I replicate here the classification of developing and least-developed countries that TRIPs uses.

become naturalized, their particularity comes to be elevated as an "exemplar of the universal" (Fitzpatrick, 2001, p.20; Buchanan and Pahuja, 2004).[22]

Thus, TRIPs is not the deterritorialization of IP law, but the *re-territorialization* and *universalization* of American and European histories, philosophies, and norms of property and personhood. Ironically though, if we were to refer to the history of IP in the West, international IP law would look different, given that US and European countries had protectionist IP regimes when their industries were nascent. For instance, the US' refused to recognize foreign copyrights till publishing them legally became an economically sound proposition for American publishers (Reddy and Chandrashekharan, 2017, pp.117-18). Similarly, pharmaceuticals had often been treated as a special category in matters of patentability (GoI, 1959), and product patents for therapeutics did not become the norm in most European countries until after the Second World War (Gaudillière, 2008). There is, therefore, an "organized forgetting" (Blomley, 2003, p. 25) of inconvenient histories; "western" IP histories are selectively sampled. The regulatory baseline represented by TRIPs is drawn from a more recent history of US and Western Europe, a period in which knowledge industries based in these countries have become multiply advantaged through colonialism and long periods of protectionist IP law.

Of course, all norms, concepts, principles, and procedures come from *somewhere and some time*. Their geographical-historical origins *per se* may not make them inadequate to specific political and economic objectives. Rather, it is the obfuscation of these origins and provincialism, and the projection of these norms etcetera as universal that are problematic. This gives the law of intellectual property the appearance of an abstraction or a conceptual structure, based not on particular histories and politics of

[22] However also note here that equating the international plane solely with the interests and norms of a handful of countries in the Global North renders invisible something like the Declaration on the TRIPs Agreement and Public Health (2001), popularly known as the Doha Declaration. The result of campaigning by developing countries and civil society organizations, it calls for TRIPs to 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." (WT/MIN(01)/DEC/2, para 4 cited in Sun, 2003, p.104). It would be misleading to read TRIPs and the Doha Declaration as equally powerfully texts. The former is enforceable in the WTO courts, and is also buoyed by extra-legal disciplinary mechanisms as well as bi-lateral and multi-lateral negotiations. The latter, on the other hand, lacks teeth. Nevertheless, it is invoked by parties, as was done in the Glivec case, to argue for greater "flexibility" in what it means for national laws to be TRIPs compliant.

substantive normative choices (of say duration of patent protection, of things that can be patented etcetera), but on principles true across space and time (Mitchell, 2002).

Yet, my dissertation also shows that it is not easy or a given that categories of law, development, and science will escape their place of provenance, into "the universal space of transcendental truth" (repurposing Gieryn, 2002). Through a detailed examination of contestations over meanings and practices such as "invention," "efficacy," "education," "course packs," "copying", and others, I argue that purportedly neutral and placeless norms, standards, and principles come apart, are charged and hybridized as they travel across geographies and confront actors who propose alternative meanings, narratives, and priorities.

It is not my argument that international law, especially international economic law like TRIPs, as well as international financial institutions such as the WTO, the World Bank, and the International Monetary Fund have not made deep excursions into the sovereignty of nation states, especially in Asia, Africa, and Latin America. At the same time, countries push back against such laws and policies through the exercise and assertion of sovereignty, which while fragile and perpetually at risk under neoliberal global capitalism, nevertheless provides an anchor for difference articulated in terms of national development. The Glivec and DU photocopy cases also underline the importance of the national Constitution in providing heft and more importantly, a normative basis to guide legal interpretation and developmental priorities. Parties in both cases invoked the fundamental rights to health and education that the higher judiciary in India has read into the "right to life" under the Constitution, arguing that patent and copyright laws must be interpreted in light of these duties of the state. The postcolonial judicialization of health and education in India, therefore, is strategically used by stakeholders to tame the excesses of IP law jurisprudence based in the Global North.[23] Together, these arguments were able to wrench IP law from IP Law. In other words, they insisted on law and knowledge both being crafts of place, working by the light of "local" imperatives and histories.

[23] See Biehl (2013) and Biehl *et al*. (2016) for how low- and middle-income patients are judicializing health to access pharmaceuticals.

4.6 *Infrastructures of copying and shifts in political economy*

A discussion on the politics of sovereignty is incomplete without considering the nature of, and shifts in global capitalism, and more specifically in my dissertation, of the global political economies of pharmaceuticals and academic publishing. Knowledge, we know, can be copied, and once produced, it is relatively mobile and transmissible, especially in light of contemporary technological innovations. Yet, my juxtaposition of the Glivec and DU photocopy cases shows that different kinds of knowledge involve vastly different infrastructures of copying. I argue that these infrastructures of copying matter to whether and how they can be cop-opted into dominant modes of value production, becoming subservient rather than subversive in the IPR regime.

In Chapter 1, I lay out the relationship between India's patent law history and the development of India's pharmaceutical industry. India's decision to prohibit the patenting of medicines and food, while allowing patents for processes to make them, meant that medicines, even if patented elsewhere, could be broken open in India, and then reverse engineered. Indian pharmaceutical companies used this provision to power their growth in the seventies and eighties, developing a critical knowledge and technological base in the skill and art of manufacturing generics. By the next decade, India had many pharmaceutical companies that came to be renowned for making affordable and quality generics. Structurally, this put Indian pharmaceutical companies in a position to challenge the transnational pharmaceutical industry which thrived on patent monopolies. This became powerfully evident during HIV/AIDs crisis in the late nineties/early 2000s. In open defiance of the latter, Indian companies like Cipla offered to supply generic ARVs to African countries at a fraction of the prices of brand name drugs. Soon, generic competition by Cipla and others radically drove down prices of ARVs. With this, Indian companies emerged as the "economic backbone" of the HIV/AIDs campaign (Roemer-Mahler, 2013, p.132).

However, following a number of shifts in the global economy since the 1990s, including the liberalization of India's economy in 1991, the line between "domestic" and "foreign" companies in the pharmaceutical sector has increasingly blurred. The pharmaceutical complex today is increasingly characterized by mergers, acquisitions, and collaborations in global research, development, and production networks (Zeller, 2007).

Indian generics manufacturers, some of which had been in an opposition position vis-à-vis "Big Pharma," are now in relationships with them, or have been acquired by them.

Further, as discussed previously, India, and many other countries, were compelled to allow pharmaceutical patents by TRIPs. This meant that Indian generic companies could no longer make legal copies of patented medicines till the patent expired. Section 3d of the 2005 Patents Act, which aims to curb patents on minor modifications to existing medicines, was a legal innovation to loosen the strait-jacket imposed by the TRIPs patent-scape. In principle, this is a provision that stands with generic companies, giving them room to challenge applications that seek to extend the patent life of known/already patented medicines. The Supreme Court's verdict in the Glivec case upholding the validity of 3d and a higher standard of patentability of medicines has also lent some (albeit a shaky) predictability to how 3d will be interpreted by Indian Patent Offices. The Glivec verdict was celebrated as a "human rights win" (Germanos, 2013), and an affirmation of "people over profits" (*ibid*).

Below, I juxtapose this Glivec moment with an interview I conducted with Mr. Feroz Ali, a leading pharmaceutical patent law specialist in India. My question to him was about the post-TRIPs trends in the relationships between generic manufacturers and "innovator" companies, and the incentives for the former to challenge patents under provisions like 3d. I produce an extended excerpt from the interview:

> [See] pharmaceutical companies are getting smarter by the day. Over the last few years we have not seen much of litigation happening because it is so easy to block these people with a nice juicy licensing deal…because why would you question or why would you enforce your rights on somebody else, your patent, and expose yourself to a challenge where validity can get questioned. So the move now is to identify all the potential people who can challenge your patent, give them nice licensing deals, saying that- Ok you operate in the Middle East, you take China and the other parts, you take Eastern Europe (and we will retain) the high value markets. At the same time these guys are getting it without an upfront litigation cost…and litigation is, the logic of litigation is if Ranbaxy challenges a patent and busts it, it is open for everyone. Whereas carve a nice licensing deal, which is given by the patentee [and] is only for you. So if you bring in some kind of game theory into it, it makes much more sense for you not to challenge a patent, get a field of operation where others will not enter. Generics always have this fear- if a patent gets busted, everyone enters the field, and this is not rocket science, everybody can do it. So it will be better for them to get one portion of the pie and be content with it, rather than challenging the pie itself and letting everyone else get into the…because we saw that in the imatinib case, there were some 10-20

> players and rock bottom price which Cipla or others will never go to…there are prices which you will never even believe, rock bottom prices. To prevent this you need to have your pie, your slice of the pie, but what if the pie is offered to you by the patentee….
>
> [To] a generic you can ask this question-will it be better for you to challenge a patent or to take a licensing deal…you can ask what is the broad cost of challenging a patent, they'll say XYZ, then you say that if you challenge a patent and it gets busted, you can actually make them walk through the process. They might just tell you that licensing is better, we did it because it is revenue generating…it's not a cost, it's an income, it's not an expenditure, you'll immediately start getting revenue for yourself…the thing about, if you challenge a patent, others [start] freeriding on it because like US there's no Orange book, there's no ANDA exclusivity where you get a 6 month…there is no such thing in India.[24] So in India you would rather sit, watch, or better get an exclusive licensing deal…if you could do this, there [is] quite a lot of geography to it because all Indian companies are global players. So you could actually pick a geographic region and say that I will give the license to you for this region. Obviously you are not going to challenge my patent because you are eating out of my hand, why will you bite it…we could bring all those things but we will need to do some more in-depth analysis of the geography and how it operates…and identify all these candidates. One of the candidates in this licensing deal is my client and I know that over the last 3 years they haven't challenged anyone. We know that they haven't been challenging, because had they been challenging the cases would be reported (Interview with Feroz Ali, February 7, 2017).

This interview suggests that despite creative provisions by 3d to restrict patent proliferation, patent challenges by generics manufacturers may decline due to their increasing collaborations and partnerships with transnational innovator companies. I offer two recent examples in the context of this interview.

In 2014, the American biopharmaceutical company Gilead entered into licensing agreements with seven Indian companies for its anti-Hepatitis C drug, sofobuvir (brand name 'Sovaldi'). Sovaldi had caught up in worldwide controversies for its exorbitant pricing. At its most expensive in the United States, the drug was selling at $1000 per tablet.[25] With the required course of treatment ranging between 12 to 24 weeks, patients

[24] In the US, an abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. The first applicant that successfully submits and maintains an ANDA gets a 180-day generic drug exclusivity. For more, see https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

[25] Gilead didn't innovate the drug themselves, but bought the whole innovator company Pharmasset for $11 billion dollars in the end of 2011. After launching at the very end of 2013, Gilead sold $10.3 billion of Sovaldi in 2014 alone. It's estimated that in total, Gilead has now

were looking at a minimum of $84,000 on drug costs alone (Samuel, 2014). The license allows Indian generic manufacturers—Cipla, Cadila Healthcare, Hetero, Strides Arcolab, Ranbaxy, Sequent Scientific and Mylan—to manufacture and sell the drug in any of the 91 voluntary licence (VL) countries at their own price but at a 7% royalty rate on any sales. The pool of 91 countries included in the deal comprise of 54 middle income countries and 37 low-middle income countries. This license includes the 'next generation' version of the drug which combines it with experimental therapy ledipasvir. It also includes complete technology transfer of Gilead's manufacturing process. A further term is that the active pharmaceutical ingredients (APIs) must manufactured be in India (*ibid*). The inclusion of strong generic competitors in the licensing arrangements is likely to ensure that the price stays low and dramatically increase access to the drug for over half of HCV patients. Yet access to medicine advocates such as MSF and Knowledge Ecology International have also pointed out that such voluntary licensing is a strategic move by Gilead to regulate generics manufacturing given that Sovaldi is facing strong patent challenges in multiple countries.[26] They also note that the license restricts export to only the 91 listed countries. This excludes many important middle income countries, including China and Brazil. MSF stresses that this is a serious concern as over 70% of HCV patients are in middle income countries (*ibid*).

Another example is the AstraZeneca Covid vaccine. In 2020, Oxford University's Jenner Institute, frontrunners in the race to develop a coronavirus vaccine, stated their intention to allow any manufacturer, anywhere, the rights to their jab. One of the early licenses they signed was with the Serum Institute, based in India, the world's largest vaccine manufacturer. One month later, acting on advice from the Gates Foundation and others, Oxford signed over exclusive rights to AstraZeneca, a UK-based multinational pharmaceutical group. AstraZeneca and Serum signed a new deal. AstraZeneca and Serum signed a new deal. Serum would produce vaccines for all poor countries eligible

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sold over $16 billion worth of Sovaldi. Meanwhile, the World Health Organization has included the Hepatitis C drug in its list of essential medicines, meaning the WHO believes its necessary for these drugs to be made available at an affordable price (Basheer, 2016; Samuel, 2014).

[26] In India, Gilead faced about 7-8 oppositions filed by different parties. In 2016, the Deputy Controller of Patents and Designs, India gave a clear victory to Gilead. However, prominent IP scholar Shamnad Basheer has heavily criticized the ruling, calling it both legally and scientifically compromised (Basheer, May 10 and May 24, 2016).

for assistance by Gavi, the Vaccines Alliance, an organisation backed by rich countries' governments and the Gates Foundation. These 92 nations together counted for half the world – or nearly four billion people. India's fair share of these vaccines, by population, should have been 35%. However there was an unwritten arrangement that Serum would earmark 50% of its supply for domestic use and 50% for export (Prabhala and Menghaney, 2021). The deal also did not include restrictions on what price Serum could charge, despite AstraZeneca's pledge to sell its vaccine for no profit "during the pandemic", which led to Uganda, which is among the poorest countries on Earth, paying three times more than Europe for the same vaccine. Similarly, the prices charged by SII for the Oxford-AstraZeneca vaccine from state governments in India far exceeds that being paid by the European Union to AstraZeneca (Birla and Sinha, 2021).

Knowledge, we know, can be copied, and once produced, is relatively mobile and transmissible. Copying pharmaceutical knowledge, i.e. the production of generic versions of medicines, however, requires considerable investment and techno-scientific expertise; and such companies are no less motivated by the logic of profit. In fact, motivated partly by TRIPs, top Indian companies have shifted their market focus. Many Indian companies are increasingly looking to garner windfalls in the US pharma market through ANDA. Dr Reddy's was the first Indian company to market a generic (fluoxetine 40 mg) under the 180-day exclusivity provision, saw its generic sales increasing from Rs 304 million in 2000-01 to Rs 4066 million in 2001-02, with the sale of fluoxetine contributing 81% of its total generics sales and about half of the company's operating profit that year (Joseph, 2014). ANDAs filed by Indian companies have increased from 161 field by 4 companies in the last quarter of 2003 to 701 filed by 17 companies by the second quarter of 2007. Indian generics launched in the US market have also increased from 93 in 2003 to nearly 250 in 2008 (*ibid*). What implications this has for lower-income markets is unclear.

The interview, coupled with the discussion above, suggest that we may be witnessing a decisive shift in the global political economy of pharmaceuticals whereby licensing deals between companies act as a disincentive to challenge patents, and lock generics manufacturers into closer relations with innovator pharmaceutical companies, producing a more integrated global research and manufacture network. The terms of

contracts and deals within this network, however, continues to be decisively framed by the latter.

Contrast this with the copy machine. As I discuss in Chapter 3, the copy machine began its career as cost-effective and time-saving office technology (Eichhorn, 2016). Its relative affordability coupled with the fact that it did not involve messy and toxic chemical solutions nor a master copy like previous copying technologies led to its adoption beyond the gates of offices rather quickly (*ibid*). Breaking the bond between print and profit, it came to disrupt the existing print economy, enabling the production and reproduction of a "diverse spectrum of marginal, esoteric, quirky, and renegade texts," and allowing authors to bypass "moral censure, nationalist and capitalist mandates, and copyright laws," see Eichhorn (2016, pp.34-37). As Eichhorn (2016) documents, it played a crucial role in social movements in the eighties and nineties such as the AIDs crisis, and queer rights, allowing people to mobilize and protest, and counter misinformation and narratives of hate and discrimination. I argue that in the context of higher education today, it continues this legacy of being a disruptive force, by enabling the dissemination of expensive and copyrighted works which would otherwise be beyond the reach of many students, teachers and educational institutions. In fact, as I show, it is precisely because the copy machine is more decentralized and less amenable to incorporation into the dynamics of the for-profit academic publishing industry, that copy shops and those who run them have been targeted by publishers. Certain infrastructures of copying, therefore, have a much greater potential for democratizing knowledge, and subverting dominant regimes of value. The copy machine, as Eichhorn (2016) argues, has a deeper affinity to the people on the margins, both geographically and symbolically.

4.7 *Questions of the copy*

The notion of the copy is central to the narratives and practices of intellectual property. After all, intellectual property is legitimized on the basis of protecting and rewarding originality, inventiveness, and distinctiveness of ideas and things, thereby simultaneously othering copies, fakes, derivatives, counterfeits, and knockoffs. Denigrated as parasitic, misleading, of poor quality, and possibly even fatal in the case of medicines, copies—of ideas, things, and processes—are heavily surveilled and controlled by intellectual

property law (Chandna, 2019; Loughlan, 2006). Viewed as theft of knowledge, creative labor, and financial investments, copying is seen in law, policy, industry as well as parts of popular culture, as a hostile and transgressive act, and those who do it are condemned morally, provocatively, and powerfully as thieves, pirates, parasites, and copycats (Loughlan, 2006, 2008; Murphy, 2019; Weissman, 1996).[27] This centrality of the copy to intellectual property is the result of the ontology of knowledge as well as technological innovations in the production, transfer, and processing of information.

Knowledge is what economists call a non-rival good. Unlike material things, where physical control/possession is a deterrent to simultaneous use, knowledge can be used/enjoyed by multiple people at the same time. My reading *BJP and the Compulsions of Politics in India*, an Oxford University Press title that was included in one of the DU course packs, does not by itself present a barrier to anyone else wanting to read the same title. Contrast this with someone else wanting to use at the same time, the *physical* copy I am reading. Theoretically, once a work is written, it can be read eventually by everyone if that copy is shared, without the author having to write it again. This is the difference between having rights in the book versus having rights in the work. It is the latter that allows for a residual right, once the physical embodiment of the work, i.e. the book is sold and becomes the private property of the buyer. While a near impossibility in practice, this example does illustrate that knowledge, unlike material things therefore, is not rendered unavailable to others, or exhausted by its use/possession. It is inherently not consumable. Thus, scholars have argued that knowledge can be copied, is "infinitely shareable" (Kapczynski. 2010, p.28) once produced, and is relatively mobile and transmissible (Parry, 2004). Medicines and machines can be taken apart in order to retrace how they are made; in other words, they can be reverse engineered. Books, music, movies can be shared or downloaded. These characteristics of knowledge have only been heightened by technological innovations—*inter alia* the computer, the web, peer-to-peer

[27] Elsevier's Director of Universal Access had this to say when asked about the proliferation of "pirate"/file sharing websites for scholarly articles: "It's as if somehow stealing content is justifiable if it's seen as expensive, and I find that surprising… It's not as if you'd walk into a grocery store and feel vindicated about stealing an organic chocolate bar as long as you left the Kit Kat bar on the shelf…. I'm all for universal access, but not theft!" (Murphy, 2016).

file sharing—that have reconfigured the geographical lives of knowledge and cultural works.

Copy is therefore a ghost that haunts the IPR regime. As Boon writes, intellectual property rights are "restrictions placed around our access to and use of objects, processes, and ideas produced by the act of copying" (2013, p. 4). IP law polices the boundary between original and copy, as well as the line between proper and improper, good and bad, legal and illegal copies. As Coombe (1998) puts it, "intellectual property laws constitute a political economy of mimesis in capitalist societies… all in the service of maintaining the exchange value of texts" (p. 169). Yet, my dissertation argues that this is no easy task. I show that while law is called upon to resolve questions of identities of objects, sameness and difference between them is not self-evident, but a tenuous consequence of arguments by various stakeholders.

4.6.1 *The DU Photocopy Case*

In the DU photocopy case, there was no contestation over whether the publishers held copyright in the books they claimed. In this sense, there was no question of property. It was accepted that they held intellectual property rights in the books they published. One of the questions that the case hinged on was how to understand course packs? Were they copies of the books, "the same" as them? Further, were course packs legal copies of the books or illegal copies?

The publishers contended that the course packs did not contain any original material. They were *mere* copies that involved no transformation of, or value added to the copyrighted content. This is a common argument in conversations about intellectual property. As Liang points out, within the dominant public discourse, an act of copying can only be socially redeemed by way of transformative authorship (2010). However, the arguments by students and teachers in the case allow us to think differently about copies.

In the first instance, they highlighted the economics of the copy, arguing that the prices of academic books placed them beyond the financial capabilities of a majority of college-going students in India. Further, since university libraries constrained by budgetary allocations usually had no more than one copy of a book (and sometimes not even that), course packs and copies were rendered necessary. This of course, speaks to

the nature of knowledge as well as its relationship with technologies that I have already discussed. There is a massive gap between the prices of books and those of their photocopies.

More interestingly, students and teachers argued against dissolving the pedagogical specificity of course packs, refusing to lift them from their pedagogical context. They offered to the courts a conceptualization of course packs as educational bricolage—an assemblage of ideas, concepts, arguments, and information curated by faculty from a range of books and journals—which was constitutive of the teaching-learning process at the postgraduate level. Course packs, they argued, were not textbooks because they were not self-contained, internally coherent educational artifacts. They could only be legible to students if situated within the broader pedagogy of classroom discussions and analysis. This then is a refusal to "rip the text from context" (Coombe, 1996, p. 241), both economic and socio-cultural. I reproduce below the contents of one of the course packs assigned for graduate courses in Delhi University:

Course Pack I

(i) Transforming India: Social and Political Dynamics of Democracy

(ii) The BJP and Compulsions of Politics in India

(iii) Parties and Party Politics in India

(iv) Ethno-nationalism in India: A Reader

(v) Nehru and the Language Politics of India

(vi) The Political Economy of Federalism in India

(vii) Politics in India

(viii) The Production of Hindu-Muslim Violence in Contemporary India

ix) The New Cambridge History of India

x) The Politics of India since Independence

Simply because a photocopy machine is used that literally reproduces the contents of the document being copied, can we argue that the title "Ethno-nationalism in India" is *the same* as an excerpt from it that is part of a course pack with many other book portions? Seeing a portion of the title as a copy of the title is premised on the notion that "every appearance of any part of a work anywhere is a copy of it" (Litman, 2017, p. 107), and

that “an authorial work is always and everywhere the same embodiment of the author’s inner being” (Coombe, 1996, p. 1360). However, I argue that the practice of juxtaposing texts with other texts in course packs is a literal exercise in intertextuality. It creates new possibilities of meaning-making and knowledge production, thereby creating non-identity with “the original.”

Moreover, deeming course packs as mere compilations of copies, silences, denies, represses the creative work of the other, i.e. students and teachers, and abstracts “acts of reading, writing, creating, sharing, and borrowing [from] the relational, networked world they occupy” (Liang, 2010, p. 284; Coombe, 1996). This is particularly jarring in academic texts. The where, the space of copying in this instance serves to highlight the contradictions in protection of copyright in education. Boon has argued that “there is no university without copying” since the foundational mandate of the university is “disseminative mimesis” (2010, p. 242). An integral part of academic training is to think relationally, i.e. to think with or against other thinkers and writers. Cultural debts—ways of thinking, arguing, taking and interpreting interviews, collecting data, conceptualizing and writing—flowing in are expected to be explicitly acknowledged. While historicizing this particular mode of academic production is beyond the scope of this Introduction, suffice it to say that contemporary knowledge production in institutes of higher education works only through citations and quotation marks. This also distinguishes the academic project from other domains of creative and knowledge productions. Fiction, films, music, art do not, are not required to identify their sources of inspiration. It is only in their consumption that critics, readers, connoisseurs point to theft, contamination, influence, and/or tribute or ode.

Transformative use of a work of authorship being protected as the only kind of fair use of a copyrighted work is a trend that characterizes American copyright jurisprudence. Courts are increasingly granting protection only when that which is being copied is sufficiently distanced from the copy (Tushnet, 2004). Between the sacralizing of the invention and the valorization of remixing/transformation, a proper copy then is not a copy at all, atleast not in the sense of being simply an affirmation or reiteration or repetition (Hayden, 2010). Strangely enough though, a translation, adaptation, making a film or sound recording in respect of a literary work are all deemed to be derivatives of

the "original," rather than creative processes that yield works related to but not secondary to and subsumed by the original.

At the same time, what is lost in arguing that the course pack is not a *mere* copy of different books? If one of the main reasons that copies of books are made is that the latter are often unaffordable for both students and institutions, then what happens to the act of photocopying entire books. Do they become illegal because they are *mere* copies?

4.6.2 *The Glivec case*

The question of property and copy played out very differently in the Glivec case. Indian pharmaceuticals companies have come to play a significant role in the global political economy of pharmaceuticals through the act of copying medicines. Bogged down by high prices of imported medicines and a nascent domestic industry, the Indian state post-independence enacted the Patents Act, 1970, which allowed patents for drug manufacturing processes, but not for drug molecules themselves. This meant that medicines could be reverse engineered in India. In most Indian pharmaceutical firms, scientists developed skills in reverse engineering research and development through trial-and-error experimentation. It also requires the skills of purposive searching of relevant information, effective interactions among technical members within a project team and with marketing and production departments within the firm, and effective interactions with suppliers and customers. In the case of reverse engineering pharmaceutical R&D, the publicly available knowledge in the patent is not always sufficient on its own to produce a reverse engineered product (Kale and Little, 2007). This has to be supplemented with tacit knowledge to complement and interpret disclosed knowledge. One of the indicators of Indian firms' superior imitative capabilities was the shortening of the time lag between the introduction of a drug in the global market by the inventor and the marketing of the same drug in the Indian market. Further, after the liberalization of the pharmaceutical market in the nineties, Indian firms increasingly began to reverse engineer drugs, but with performance enhanced features (Joseph, 2016).

However, following Hayden, this mode of characterizing the skills and growth of Indian pharmaceutical companies does not take into account that in the absence of patents for medicines, there is no category of copy or generic: "no patents, no generics" (2010, p.

287). Reverse engineering pharmaceuticals during the term of the patent is a subversive act, and even though it does not reject the intellectual property regime, it does undermine it.

As discussed previously, Novartis applied for an Indian patent on a chemical it called IM-ß. It had previously patented imatinib, and the package insert accompanying Glivec named imatinib mesylate as the active ingredient in the medicine. Patent law requires any claimed invention to be new, useful and non-obvious. IM-ß would have to do the same, and in order to do the same it would also have to articulate a relationship and comparison with imatinib and imatinib mesylate. Thus, one of the questions was whether IM-ß was too similar to these compounds to be considered as distinct. But how was this sameness or difference to be ascertained?

I show in Chapter 2 that the arguments made by competing parties raise fundamental questions about the philosophy of chemistry and the very nature of pharmaceutical research and development, where seemingly small differences in geometries, molecular weights, pathways can come to matter in significant ways (Hayden, 2012; Hoffman, 1996). Chemical compounds act differently depending on the material spaces they inhabit (i.e. the lab, animal bodies, human bodies), molecules they are partnered with, and under what conditions of temperature, pressure etc.

Similarly, there are many examples of synthesized compounds that can fool the body into thinking that they are the body's own substances ("biomimicry") which further complicate questions of identity and non-identity. Hayden (2012) in her discussion of the politics of the similar in Mexico, outlines how the interchangeability of innovator compounds and generics proves materially and politically elusive. Mexican pharmaceutical companies and multinational pharmaceutical companies lock horns over how to define sameness. The former argues that sameness of the active pharmaceutical ingredient is the only identity that matters between the original and the generic. The latter on the other hand, argues that pharmaceutical identity cannot be reduced to the active ingredient, i.e. to chemical equivalence. In international drug regulation policy, chemical equivalence has now been substituted by the notion of bioequivalence (the amount of time taken by active ingredient to be available at the action site) in the determination of sameness between an innovator molecule and a generic (Carpenter and Tobbell, 2011).

Section 3d introduced another layer of complications into the question of the copy. I discuss at length in Chapter 1 how the provision was aimed at preventing the abuse of patents by the pharmaceutical industry, which is infamous for making minor changes to medicines to increase the duration of patent exclusivity. Under the title "Inventions not patentable," 3d provides:

> [The following are not inventions within the meaning of this Act]
> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The compounds listed in the Explanation are substances that are products of pharmaceutical and research. This process involves developing different forms of the same substance. Borrowing from copyright law, I argue that 3d designates some compounds, i.e. salts, esters, polymorphs etc as mere copies/derivatives of a "known substance," while protecting the transformative use of a known substance. However, such transformation is defined: a transformation of a known substance that significantly enhances its efficacy may be considered an invention. The difference between a compound and a derivative is expressed in terms of differences in their efficacies. As discussed in the previous section, under copyright law, copyright subsists in the publication, reproduction, performance, translation and adaptation of a literary work. In other words, copying consists in doing any of these activities, and all these objects, i.e. translations, publications, adaptations etcetera become copies or derivatives of the original. This definition broadens the scope of intellectual property rights. Conversely, by designating salts, esters, polymorphs, etc effectively as mere copies of known substances, 3d reduces the scope of intellectual property rights, and helps to undermine the multinational pharmaceutical industry's widespread practice of evergreening, whereby small changes to patented compounds are used to extend the term of patent protection.

I also argue that not all copies are held in disdain. The current system of global governance of knowledge to prevent copying clearly relies on the copying of a specific set of intellectual property norms, principles, and standards. International agreements like TRIPs and the Berne Convention for the Protection of Literary and Artistic Works ("the Berne") rely on the mimicking of legal provisions and interpretations. Such copying of law is aimed at leapfrogging over long standing socio-political, economic, and cultural differences and asymmetries between countries. Thus, certain copies, like those of legal regimes are actively sought and perpetuated for the production and circulation of value.

5. **Dissertation Outline**

This dissertation proceeds in the following manner. Chapter 1, *TRIP(ping) on medicines: Patents and Struggles over the chemico-legal universe in the Glivec case*, shows that while medicines are largely accepted as objects of property, the Glivec case serves to underline the rather short history of patents for medicines, as well as signals the unequal power relations that have made pharmaceutical patents a compulsory feature of national patent laws. The reason the Glivec case made so much noise in India and beyond has also to do with the importance of India in the global political economy of pharmaceuticals, as well as the role that patent law played in the rise of Indian pharmaceutical companies that came to be highly skilled in reverse engineering medicines and producing high quality generics. The chapter also highlights that pharmaceutical patents were made possible only by way of subsuming medicines into technology, and a willful bracketing of what medicines do. Finally, I argue that a patent is not simply a linear function of chemical excellence or innovation. Rather it is a decision that is constituted by many smaller, less glamorous decisions.

Chapter 2, *Chemical Troubles: Law and the Task of Making Sense of Medicines*, shows the complex negotiations between legal and chemical knowledges in a patent dispute. I argue that patent law is an important yet understudied arbiter of pharmaceutical identity. I ask: What claims do stakeholders make about what a medicine is, what a medicine does, and what makes a medicine "a medicine"? How is sameness and difference of chemicals assessed? How does patent law come to decide what aspects of a medicine count towards protection as intellectual property? What suppositions underlie

law's attempt to establish "a reliable epistemology of (therapeutic) efficacy" (Wilson, 2015, p. 136) to operationalize Indian patent law? I highlight the tensions, ambiguities, and incompleteness with which these moments are fraught.

Chapter 3, *Of course packs and copy machines: Copyright law and unequal geographies of education*, wrapped up in seemingly mundane artifacts, i.e. course packs, and the technology that produces them, i.e. copy machines, are unequal and unjust geographies of education. I discuss the prices of academic texts, the significance of copyright law in shaping geographies of education, and the role of the academic publishing industry in disabling participation in global communities of knowledge production. In this context, I argue that in the absence of technologies like copy machines and course packs, educational quality would suffer greatly. These things therefore, are central to the democratization of education and knowledge.

A brief note on the title of my dissertation: *The Knowledge Thief* is the title of a chapter by Lawrence Liang in the book *Shadow Libraries: Access to Knowledge in Global Higher Education*, edited by Joe Karaganis (2018). Liang's scholarship (2010a, 2010b, 2017, 2018) has been significant to shaping my understanding and critique of intellectual property. I am unable to definitively rebuff any charge of the "crime of being influenced" (Letham, 2007) by Liang's 2018 chapter title. The discourse of IPR is rife with pejoratives like thief, pirate, parasite, and copycat. This was equally true for the public conversation about the cases in my research project. For instance, the publishers in the Delhi University photocopy case labelled students who were protesting the lawsuit as thieves and called the police on them. Similarly, India's pharmaceutical industry is often called a copycat industry, able only to make "me too," i.e. generic drugs (Chandna, 2019; Singh, 2009). There is therefore, ample material in my work to conceive of this title independently. But I cannot recall whether I came up with it before or after reading Liang's chapter. I have toyed with changing my dissertation title to "Copycat Country? Intellectual Property Disputes and Copying for Development in India." However, I have decided against this. While acknowledging the importance of Lawrence Liang's work to my own, I am now consciously retaining the title as a playful nod to the messy, non-linear, not-always-conscious, and not-fully-knowable nature of knowledge production

and the creative endeavor. To quote from the *Velveteen Rabbit*, cited in Letham (2007): "Active reading is an impertinent raid on the literary preserve. Readers are like nomads, poaching their way across fields they don't own."

The Glivec case: Standing in a crowded field

In this prologue to Chapters 1 and 2 of my dissertation, I situate my analysis of the Glivec case within existing scholarship. The Glivec case has been the subject of considerable academic scrutiny, which address different facets of the dispute. The works of Ecks (2008) and Sunder Rajan (2011) show that Novartis' Glivec International Patient Assistance Program (GIPAP), which provides free Glivec to patients unable to afford it, including in India, is best understood as an instantiation of philanthro-capitalism. Through it Novartis was able to argue that it does more for the challenge of access to Glivec than generics, since the program covers many more patients. However, as Ecks and Sunder Rajan argue, this "gift giving" enables the company to maintain high prices of the drug in lucrative markets, while simultaneously allowing it to shore up moral capital as a "good global citizen" that puts patients over profits. The notion of citizenship, therefore, is simultaneously mobilized by health activists hold capital accountable as well as by capital to protect and enhance profits through what Ecks calls "pro-corporate patient activism" (2008, p.178).

Correa (2013) engages with a key complaint of Novartis, i.e. that Section 3d of the Indian Patents Act, 2005 is not TRIPs compliant. He argues that 3d fits perfectly well within the flexibilities that TRIPs itself provides to countries to determine what subject matter may be eligible for patents as well as the specifics of patentability standards. Basheer and Reddy (2008) and Basheer (2018) offer a detailed analysis of Section 3d. Evident in their writings is a faith in the patent regime to efficiently incentivize pharmaceutical research and development. Thus, their primary concern is "ironing out the creases" (Basheer and Reddy, 2008) in 3d that would address their argument that a narrow definition of therapeutic efficacy does not protect "incremental innovation" or aspects of drug development like lowering toxicity that are critical to how bodies react to medicines. They also note that denying protection to the former would disadvantage Indian pharmaceutical companies that have developed strong skills in this domain.

The Supreme Court's pronouncements in the Glivec case have come to be frozen as "The Novartis Standard" (Ali et al., 2018)—a directive/guide to assess subsequent pharmaceutical patent applications. They have also been codified in the Indian Manual of

Patent Office Practice and Procedure (2019, p.90). Recent studies have undertaken the important task of examining shifts and patterns in patents granted and denied by the Indian Patent Offices, as well as the application of 3d, pre- and post-Novartis (Ali et al., 2017, 2018; Sampat and Shadlen, 2018). Sampat and Shadlen (2018) find a steep rise in the use of 3d following the Glivec case, though it continues to be used in conjunction with other types of objections to patentability. They also note its use against new chemical entities, raising concerns about mis- or over-utilization. Ali et al. (2018) find a highly uneven application of the Novartis standard, and argue that Patent Offices have been granting an overwhelming majority of secondary patents (patents for new forms or properties of known substances, different combinations of known substances, etc; practices that are referred to as evergreening) coming their way—the kinds of patents that provisions of Section 3 including 3d were meant to prevent. This confirms Gopakumar's predictions in his 2013 article, where he had questioned the training of patent examiners to effectively implement the SC's directive.

My dissertation deepens and broaden these works on the Glivec case. As I have already laid out in my Introduction, the key interventions I make are possible only by way of juxtaposing the Glivec case with the DU photocopy case. This allows me to compare and contrast key aspects of intellectual property disputes which do not find much attention in the literature. Thus, for instance, this juxtaposition enables me to show that while the general statement that knowledge can be copied is accurate, it obscures the fact that different kinds knowledge involve vastly different infrastructures of copying. I argue that these differences in infrastructures of copying matter to their co-option into dominant regimes of value. The investments and techno-scientific know-how involved in copying pharmaceutical knowledge tames the subversive potential of the copy.

Further, situating the Glivec case—a moment that has been lauded as offering a creative way to challenge the TRIPs regime—alongside an interview with a pharmaceutical patent lawyer (2017), I show that the motivation and ability of Indian pharmaceutical companies to challenge this regime may have been decisively altered by shifts in the global political economy of pharmaceuticals. The convergence of the ethical, the economic, and post-colonial nationalism that made the Indian pharmaceutical industry, led by Cipla, the "economic backbone" (Roemer-Mahler 2013) of the

HIV/AIDS campaign in the early 2000s appears to be over. Instead, there is some evidence that transnational pharmaceutical companies may be taking the edge off patent challenges by way of licensing deals with Indian generics manufacturers (among others) that split markets. This greater degree of integration offers benefits to both: on the one hand generics manufacturers sidestep the time, cost, and uncertainty associated with patent litigation, and are guaranteed a source of profits; on the other hand, transnational innovator companies overcome the risks of patent challenges, while determining the terms of the licensing deal and retaining access to lucrative markets.

Chapter 1 complements the scholarship on Glivec but focuses on TRIPs as a key moment in which medicines are abstracted as technology. Many scholars have discussed TRIPs (Drahos with Braithwaite, 2002; Horner, 2013; Sell, 2003), but I find it useful to linger on this moment of abstraction, and its consequences. First, it highlights the point at which pharmaceuticals went from being a commodity like any other, to as I write, something else, something more, something that is worthy of being rewarded with a monopoly. This, in turn, marked a change in the nature of the pharmaceutical market in India which went from being a market characterized by competition to one in which pharmaceutical monopolies became possible. Second, it shows how the use value of medicines is bracketed. This, I argue, is a highly consequential bracketing that makes ethical, political, and economic opposition to patents extremely difficult, making medicines technical and technological things best left to pharmaceutical and legal experts. At the same time, the use value of medicines perpetually risk overwhelming the bracket, as we see in disputes over grants of compulsory licenses for patented medicines, or as in the case of Covid, the demand by many developing countries and LDCs before the WTO to endorse a global waiver of pharmaceutical monopolies (Prabhala and Clinton, 2021). It must also be said that there are flexibilities that these countries managed to insert into TRIPs, which would make room for public health considerations. However, few countries have made use of these flexibilities, which are also subject to intense legal (like in the case of Novartis which challenged the TRIPs compliance of 3d) and extra-legal pressures, particularly from pharmaceutical lobbies and the US.

In Chapter 2, I focus on law's attempts to make sense of pharmaceutical knowledge claims. As noted previously, the current IP regime casts medicines primarily

as the object of knowledge. Pharmaceutical patents are legal e/valuations of knowledge, on which rest the promise of windfall profits. And it is only through what Barry (2012) calls "knowledge controversies" that patents are disputed. It is towards the knowledge controversies in the Glivec case that my chapter turns. Sunder Rajan treads similar ground in his 2017 book chapter. Through an analysis of the various orders issued in the Glivec case, he unpacks "the relationship between chemical ontology and legal reasoning" (p.137), and the importance of the latter to charting alternative pharmaceutical politics. Following in his footsteps, I cast a closer eye on how law grapples with competing knowledge claims. I show that while law is ill-equipped to understand and make decisions on the accuracy of these claims, it nevertheless must perform these tasks. Yet, I demonstrate everything is contested: the legal universe within which to situate the dispute; the articulation of chemical entities, processes, and properties in legal terms; the assessment of pharmaceutical sameness and difference; and the meaning of efficacy. Drawing extensively on Science and Technology Studies (STS), I argue that the chemical and the technical, cannot and do not provide a final ground to determine questions of patentability, that have such high economic, ethical, and political stakes. In fact, I show the wide gap between legal knowledge and STS, and argue that if the discipline of law were to take the insights of STS (and medical anthropology) seriously, the grounds for relying on techno-science as the arbiter of disputes would crumble.

Together these chapters demonstrate how the political, i.e. questions of access to medicines, health, education, knowledge, has naturalized and depoliticized itself through the technical (Mitchell, 2002). The technical, constituted in the Glivec case by law and pharmaceutical science, attempts to be freely floating, transcendental, a triumph over place and culture. Its power lies in its denial of the normative content of its subject, and its claims of being divorced from, and impervious to the messiness and exigencies of power and politics. The political, therefore, is subsumed by the technical. At the same time, I also argue that that this subsumption is never complete. Outside the courtrooms, as Menghaney (2013) showed, campaigns like "Drop the Case" by MSF, Oxfam, and Delhi Network of Positive People, helped shift the syntax of the case from a technical issue of patentable pharmaceutical innovation into a "global outcry against the greedy practices of pharmaceutical companies" (p.53). Similarly, in the courtrooms, Novartis'

opponents opened various black boxes—efficacy, therapeutic efficacy, bioavailability—and showed that these were not neutral, self-evident terms. The technical, they argued, was always already shot through with political and ethical decisions.

Chapter 1 | TRIP(ping) on Medicines: Patents and Struggles over the Chemico-Legal Universe in the Glivec case

India ranks third worldwide in terms of production by volume and fourteenth in terms of production by value. Between 2014 and 2022, pharmaceutical exports jumped 103 percent by almost $10 billion (FE Online, 2022). In 2018–19, India exported nearly $19 billion worth of pharmaceuticals to more than 200 countries, from the highly regulated markets of North America and Europe, to countries with limited pharmaceutical industry capacity such as most of sub-Saharan Africa (Guerin *et al*., 2020). Indian pharmaceutical firms are especially significant when it comes to providing affordable and quality medicines for LMICs, vulnerable populations, and neglected diseases—markets that are largely ignored by brand name pharmaceutical companies (MSF, 2001; Sell, 2010, p.392). They supply over ninety percent of the antiretroviral (ARV) procurement in LMICs funded through donor procurement; two-thirds of the medicines used by MSF to treat HIV, tuberculosis and malaria; treatments for some neglected tropical diseases (MSF, 2016); seventy percent of pentavalent vaccines to United Nations Children's Fund for protection against diphtheria, whooping cough, tetanus, hepatitis B and haemophilus influenzae type b (Guerin *et al*., 2020); and measles vaccine for the Gavi program (*ibid*). While these figures unequivocally mean that India occupies a critical node in the global pharmaceutical complex today (and it has done since the nineties), I want to emphasize that India's significance lies in its historical role in examining and articulating the relationship between patent law, drug prices, and access to medicines. In fact, scholars have argued that India's contemporary significance in the global political economy of pharmaceuticals as the "pharmacy of the developing world" (MSF, 2016) is largely attributable to a carefully calibrated patent regime that squarely refused pharmaceutical patents (Abrol and Jayaraj, 1988; Horner, 2013; Joseph, 2016). It is only in the context of the history of Indian patent law and its centrality to the development of the Indian pharmaceutical industry, that the stakes of the Glivec case are illuminated.

1. **Subversive acts: Refusing pharmaceutical patents and reverse engineering medicines**

In 1947, the post-colonial Indian state found itself confronted with the twin challenges of (i) nascent or stunted domestic industrial capacity; and (ii) a people with low purchasing power. This was equally true of medicines. When India won freedom from the British, eighty to ninety percent of the domestic pharmaceutical market was controlled by transnational companies, primarily through imports, and even basic medicines such as antibiotics were unaffordable for a majority of the population (Abrol *et al*., 2016; Chaudhuri, 2012; Joseph, 2016). As part of a broader effort to formulate economic policy that would enable India to become economically self-sufficient, the Ayyangar Committee was tasked with looking into the relationship between industrialization, innovation, and patent law.[28] While its report recommended the retention of patents as a policy instrument to stimulate scientific and industrial progress, it also cautioned against the misuse of patent monopolies (GoI, 1959, p.20). The Committee made a strong case for the specifics of the patent system—things that can be patented, and those that cannot, term of patent protection, grounds for revoking patents—to be crafted to suit India's developmental level (*ibid*). In this vein, one of its recommendations was to prohibit the patenting of medicines and food, while allowing patents for processes to make them (*ibid*):

> […] the denial of product claims is necessary in order that such important articles of daily use as medicine or food which are vital to the health of the community should be made available to everyone at reasonable prices and that no monopoly should be granted in respect of such articles. It is considered that the refusal of product patents would enlarge the area of competition and thus result in the production of these articles in sufficient quantity and at the lowest possible cost to the public (GoI, 1959, p.39)

This recommendation was not novel. Having researched patent law histories of multiple countries, the Committee knew that historically, pharmaceuticals had often been treated as a special category in matters of patentability (GoI, 1959). Product patents for therapeutics did not become the norm in most European countries until after the Second World War (Gaudillière, 2008).

[28] The Committee on the Revision of Patents Law was constituted in 1957 under the chairmanship of Justice N. Rajagopala Ayyangar. Its report, submitted in 1959, is popularly called the Ayyangar Committee Report.

Thus, the Patents Act, 1970, drafted on the basis of the Ayyangar Committee Report, allowed patents for drug manufacturing processes, but not for drug compounds themselves. Section 5 of the Act, under the marginal heading "Inventions where only methods or processes of manufacture [are] patentable," excluded patents on "substances intended for use, or capable of being used, as food or medicine or drug." (SC, 2013, p.24). In fact, the Act gave an expansive definition of "medicine or drug" to include chemical substances used as intermediates in the manufacture of medicines (Section 2l). This separation between pharmaceutical compounds and the ways of making them, i.e. between product and process, and the denial of granting private property rights in the former, meant that medicines, even if patented elsewhere, could be nudged open in India, and their innards examined in detail to identify and quantify major ingredients, and to analyze their interdependent functions and reactions (Friesinger and Schneider, 2014).

In other words, *medicines could be legally reverse engineered in India during their term of patent protection in other markets*. Indian pharmaceutical companies used this provision to power their growth post-1970, developing a critical knowledge and technological base in the skill and art of manufacturing generics (Abrol and Jayaraj, 1988; Chaudhari, 2005).[29] This was no easy task in the beginning. Reverse engineering research and development calls for "reading" patents, i.e. interpreting the knowledge disclosed in them, and supplementing this with experimentation and tacit knowledge (Kale and Little, 2007). Soon, however, propelled by the "no patents on medicines" law, Indian pharmaceutical firms began developing strong capabilities in organic and synthetic chemistry, highly efficient pharmaceutical production processes, high quality manufacturing facilities, as well as strong marketing and distribution networks domestically (Kim and Nelson, 2000). These capabilities in turn started showing dividends. Indian pharmaceutical companies began changing the temporality of drug availability in India: the lag between the global launch by an inventor company and its introduction in the Indian market dropped from six years for ibuprofen in 1973, to one

[29] The Indian state's investments in research laboratories like CDRI (Central Drug Research Institute), public sector pharmaceutical firms like HAL (Hindustan Antibiotics Limited) and IDPL (Indian Drugs and Pharmaceuticals Limited), as well as institutions of higher education, especially in science and technology, produced a rich firmament from which emerged pharmaceutical entrepreneurs and a scientifically skilled workforce (Kale and Little, 2007).

year for lorazepam in 1978 (Keayla, 1996 cited in Kale and Little, 2007, p.598). The patent system coupled with free market competition enabled these (and other) medicines to be available at a fraction of the cost charged by transnational innovator companies (Abrol and Jayaraj, 1988). By the mid-nineties, many became superlative not only at deconstructing drugs and devising non-infringing processes to produce them, but also at creatively adapting drugs with new/enhanced performance features (Abrol and Jayaraj, 1988; Chaudhuri, 2005; Joseph, 2016; Kale and Little, 2007).[30]

It is not my argument that India's strategy of excluding medicines from product patents was based on any peculiar or heightened understanding of the ethical and political charge they carry, or even on a strong commitment to public health. Emerging as it was from colonialism, the Indian State was primarily concerned with reducing economic dependence on foreign powers, and the Patents Act, 1970 was part of a broader policy of import substitution to develop India's domestic industries. Nevertheless, it is evident in government reports that medicines and food were thought of as critical to "national development," and hence could not be treated as simply any other techno-scientific object in matters of patentability (GoI, 1959). Thus, a post-colonial national developmentalism prompted the product patent-process patent differentiation, which was put in service of the elevated significance of medicines.

My intention with this discussion of the history of Indian patent law is two-fold. *First*, I highlight that the refusal of pharmaceutical patents and the attendant enabling of reverse engineering undermined the intellectual property regime dominant in the Global North, without rejecting it altogether, since process patents were allowed, and a link between patents and innovation was affirmed (GoI, 1959). Traditional scholarship has tended to separate law and geography as words and worlds, as immaterial and material respectively (Blomley, 1994). While we have moved away from such binaries, it is

[30] For example: Eli Lilly had patented more than seventy processes for making cefaclor, a drug used to treat bacterial infections like pneumonia. Yet the Indian firm Ranbaxy was able to develop a superior and non-infringing process, forcing Eli Lilly to enter into a joint venture with Ranbaxy for the production of cefaclor (Athreye and Kale 2006 cited in Joseph, 2016). Other government policies such as price controls on select medicines, strict regulation of the production of bulk drugs, limiting ownership of equity shares by foreign firms etc. also played a supportive role in strengthening the abilities of the Indian pharmaceutical industry (Chaudhuri, 2005; Joseph, 2016).

nevertheless instructive to note the material effects of the fifty odd words in Section 5a of the Indian Patents Act, 1970—the provision that protected medicines from product patents. Section 5a was a powerfully subversive law. It enabled India to develop knowledge and technologies necessary to make medicines at relatively affordable prices for populations in India and beyond, thereby disrupting and reshaping the existing economic geography of pharmaceutical production and access, the force of which became evident during the HIV/AIDs crisis in Africa in the early 2000s (Horner, 2013).

Second, I ask what the legal category of medicines produced by Indian companies after the 1970 Act was (and prior to the 2005 amendments). Patent law, and intellectual property law more broadly, produces a hierarchy of commodities and value based on what comes first (Nakassis, 2012). This temporal classification puts the original/innovator compound on top, followed by copies. And while copies are semiotically always less than, they are further distinguished as legal and illegal. Of course, the latter copy is theft. With regard to pharmaceutical copies, generics are predominantly understood as *legal copies*, i.e. "pharmaceutical equivalents" of the original that start circulating only *after* its patent expires, or that are produced after obtaining permission, i.e. a license from the innovator company (Hayden, 2011). On the other hand, copies made during the life of a patented drug and without a license are denounced as illicit, piracy. Hayden (2011), however, has unsettled the category of the generic. She notes that in the absence of a patent regime like in Argentina which effectively does not grant pharmaceutical patents, the distinctions between originator, generic, and pirated compound collapse (Hayden, 2011; Lakoff, 2004).[31] "No patent, no generic" is the provocation Hayden offers (2011, p.287): "without patents—the horizon against which the generic is defined—there is simply no such thing as a generic." (*ibid*, p.295). Following Hayden, I argue that the refusal of product patents contained in the Indian Patents Act, 1970 meant that there was no legal category of original compound.

[31] Argentinian pharmaceutical firms took advantage of the value structure of the transnational pharmaceutical industry, which depends not just on patents but also on brand names, rejecting the former but relying on the latter. The domestic market is dominated by Argentinian firms that have copied drugs developed elsewhere and marketed them under their own brand names. Brands and trademarks, rather than patents are valued forms of intellectual property rights in Argentina's pharmaceutical market (Hayden, 2011; Lakoff, 2004). As is evident, The Indian pharmaceutical industry has had a similar history.

Consequently, the "copies" of drugs patented elsewhere made by Indian pharmaceutical companies could not be differentiated into legal (generics) and illegal. Put differently, under India's patent law, copies meant one of many (including the innovator compound), and all copies were legal. Thus, while the importance of India's pharmaceutical industry today is discussed largely in terms of quality and affordable generics, i.e. legal copies, its historical development was premised on the negation of a hierarchy between original and copy.[32] It was this very negation that led to India having an industry that now has the capacity to make generics.

2. **The audacity(ies) of TRIPs: Abstracting medicines**

Sunder Rajan (2011) reminds us that the ability of the Indian pharmaceutical industry to produce medicines at low prices is situated squarely within a market framework. The denial of patents on medicines meant that *pharmaceuticals were a commodity like any other*, and their price was regulated largely by way of free market competition between firms. This is why I pause on the moment in which medicines go from being a mere commodity to being something else, something more.

Even as the success of India's 1970 patent law and the expanding abilities of its pharmaceutical companies materialized, international law on intellectual property was set to change. In fact, the Indian patent system "was the most direct motivation" (PhRMA, February 1999) for US efforts to enact stricter and higher global patent standards (Horner, 2013; Roemer-Mahler, 2013).[33] Getting developing countries to adopt the style and standards of intellectual property protection in place in developed countries had been a key component of international trade negotiations since the 1980s.[34] India (through its

[32] This is not unique to India. Historically, countries have promoted copying in the early stages of industrial development (see Reddy and Chandrashekharan, 2017).

[33] The Pharmaceutical Research and Manufacturers of America (PhRMA) is a highly influential lobby, and its submission for the Uruguay round of negotiations on international patent law is contained in the Special 301 Report, February 1999. More generally, CEOs from multinational companies like Merck, Pfizer, General Motors, IBM, Monsanto, etc in information industries, i.e. pharmaceutical, agrochemical, software, entertainment, etc lobbied the governments of US, Europe, and Japan that strong intellectual property laws were in their national interest (Drahos with Braithwaite, 2002; Sell, 2003).

[34] While I am critical of the use of hierarchical terms such as developed, developing, and least developed countries, I use them here because a linear and hierarchical notion of development is used to justify the universalization of intellectual property norms developed in the Global North,

industry and civil society groups) was one of the few vocal opponents of TRIPs, articulating the adverse implications of a global patent law agreement for health and development at a time when international public health activists did not (Drahos with Braithwaite, 2002; Horner, 2013).

The Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 to be administered by the World Trade Organization (WTO) solidified these efforts.[35] TRIPs sutured specific intellectual property standards into world trade (Kapczynski, 2010). In other words, WTO members *had* to implement TRIPs , i.e. they could not opt out, and non-compliance could be punishable with trade sanctions (*ibid*). Significantly, the minimum standards of intellectual property protection put forth by TRIPs was relatively high compared to what developing countries had in place at the time.[36] For instance, TRIPs set the minimum term of patent protection at twenty years (Article 33, TRIPs); contrast this with India which offered five to seven years of protection for process patents on food and medicines at the time (Section 53(1)(a), Patents Act 1970). Even more significantly, TRIPs took aim at the categorical exception made by many developing countries (atleast 50 according to Correa, 2008) for medicines in matters of patentability. Medicines could no longer be exempted from product patents. Article 27.1 of TRIPs under the heading "Patentable Subject Matter" reads:

> "…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…. *patents shall be available and patent rights enjoyable without discrimination as to* the place of invention, *the field of technology* and whether products are imported or locally produced." (Emphasis mine.)

Kapczynski has called TRIPs "an exceptionally audacious" (Kapczynski, 2010, p.6) moment in the global governance of knowledge, since it "attempt[s] to extract value from and exert control over informational domains in virtually all of the countries of the

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particularly the US and UK. The logic here is that with the adoption of such norms, less developed economies will develop automatically and fairly.

[35] Prior to this, international treaties on intellectual property were generally overseen by the World Intellectual Property Organization (WIPO). WIPO had no enforcement mechanism, and countries could join treaties in "à la carte" fashion (Kapczynski, 2012, p.25).

[36] Kapczynski terms TRIPs an attempt at "upward harmonization" of intellectual property rights, i.e. requiring developing countries to bring their intellectual property laws at par with developed-country standards and norms (2009, pp.1571-72).

world" (2010, p. 6). While some audacities of TRIPs have been scrutinized aplenty (Boyle, 1996; Drahos and Braithwaite, 2002; Gana, 1995; Jaszi, 1996; Sell, 2003), I want to focus on one particularly audacious move that TRIPs makes: the abstraction of medicines as technology.

Scholars of commodification have argued that one of the processes it turns on is abstraction, whereby "systemic representations dissolve the specificity of things in favor of their aggregation into classes of things" (Prudham, 2009, p.129). For instance, in his study of wetland commodification in the US, Robertson (2000, 2011) shows how individual wetlands are labelled as instantiations of the generic category 'wetlands,' in order to catalogue generic 'wetland services' that each individual wetland supposedly provides. In this abstraction led by ecologists, the specific and entangled ecological context of each individual wetland disappears, so that wetland services may be rendered commensurable and exchangeable, and monetized (*ibid*).

Of course, the status of medicines as commodities is considerably cemented in contemporary society. In fact, as I noted earlier, Indian patent law ensured that pharmaceuticals *were* treated as commodities in a free market, and consequently, market competition enabled their low prices. However, Article 27.1 of TRIPs enacts a further abstraction, whereby the qualitative specificity of a thing, i.e. medicines, is subsumed into the qualitative homogeneity of a broader type, i.e. technology (Castree, 2003). And within the discourse of intellectual property, technology is immaterial scientific and technical ideas/knowledge fixed in things, i.e. material expressions of (immaterial) intellectual activity. Following Leach and Davis (2012), I ask what does the abstraction of medicine as technology/knowledge by law do? What kinds of transformations and consequences does it set off?

I contend that this abstraction is highly consequential, as it enables TRIPs to bracket what medicines do. Operating quite literally in a "field of pain and death" (Cover, 1998 quoted in Sarat *et al.*, 2010, p. 4), medicines cure illnesses, prolong life, help the body fight infections, provide quick relief from aches, fevers, and a range of bodily discomfort, boost immunity, alleviate anxiety and depression, stabilize mood, etc. In doing so, they help us be active, work, pursue ambitions and passions, enjoy the company

of loved ones, and so on. As Scheper-Hughes and Lock (1991) put it, medicines help to restore the body as a site of autonomy and creative experience.

However, TRIPs makes it so that a chemical compound with therapeutic effect/potential is nothing but an instantiation of the generic category technology, which stands over and above it (Castree, 2003; Robertson, 2000). My claim is not that medicines are not, or should not be seen as technology/knowledge. But categorizing them as such entails consequences. Medicines are folded into technology/knowledge, and in such folding, there is a shift in register. They are made available for valorization not merely as commodity, but as something more. Immediately and magically, they become things that can be the object of intellectual property rights. The nature of questions being asked of medicines change: there is a concern with origins and attributions; there is a concern with protecting and rewarding those who produce such technology (Leach and Davis, 2012). Contrast this valorization of those who produce technology, i.e. ideas and knowledge made material and productive, with those who produce things that are not thought of as knowledge fixed materially: "We do not think it necessary to give car workers residual property rights in the cars they produce—wage labor is thought to work perfectly well" (Boyle, 1992, p.1463). Moreover, by re-cognizing medicines as primarily technological and technical things, they are consigned to the domain of expertise, best understood and acted on by experts in pharmaceutical chemistry and in law.[37] Moral, ethical, and economic opposition to patents are rendered almost impossible. Rather, the only way to contest patents becomes through competing knowledge claims (as I show in Chapter 2).

[37] Conversely, the Declaration on the TRIPs Agreement and Public Health (2001), popularly known as the Doha Declaration, re-inscribes on international trade law the specificity of medicines. The result of campaigning by developing countries and civil society organizations, the Doha Declaration asserts that medicines cannot be dissolved into the category of technology in matters of intellectual property rights. Instead it calls for the TRIPs Agreement to 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." (WT/MIN(01)/DEC/2, para 4 cited in Sun, 2003, p.104). Parties opposing Novartis in the Glivec case mobilized the Doha Declaration to argue that Section 3d of the Indian Patents Act 2005 had been drafted with the objective of supporting public health, and recognized the singular importance of medicines by prescribing higher patentability standards for them.

Equally important is the mandate to ensure patents "without discrimination as to the field of technology" (Article 27.1, TRIPs). Discrimination is the recognition and understanding of the difference between one thing and another (Oxford English Dictionary; Cambridge Dictionary; Merriam-Webster Dictionary). A prohibition against discrimination then, may be understood not as a denial of difference between things, but a mandate to not let such difference have any consequence or value. Unlike the Indian Patents Act, 1970, which was made to act differently when it "saw" medicines, TRIPs forbids patent laws from seeing medicines, from recognizing their use value. TRIPs therefore, incarcerates medicines within the semantic category of technology, and renders the latter a flat category: technologies however different and whatever their use, are made equal. Differentiating between a medicine, bubble wrap, and barbed wire in matters of patentability constitutes "technological discrimination," an unfair and unjust disadvantage imposed on the field of pharmaceutical research and development, and by extension, on corporations that work in the field. In what can only be termed a perverse sleight of hand, recognizing what it is that medicines do and treating them differently becomes a violation of the equality of technological fields, casting a damaging light on countries that do so:

> Glivec™ is another important anticancer therapy for which intellectual property rights have been denied. The patent was denied under section 3(d) of the Indian Patents Act, which contains a discriminatory provision concerning the inventions of the biopharmaceutical industry.[38] The provision requires certain types of inventions to show "enhanced efficacy", which limits substantially the ability to obtain a patent…. By discriminating against a particular field of technology, section 3(d) may be inconsistent with provisions of TRIPS, which sets one standard for all patents and does not allow different patent requirements for different industries. Using this prohibition, India has refused a patent to Glivec™ despite patent protection for this product that exists in nearly every other country of the world (Waldron, 2013, p.6).

In fact, a medicine is often protected by multiple patents, because patents protect "inventions," and not medicines *per se*. And, an invention is any "product or process that provides a new way of doing something" (WIPO 450E), or "a solution to a specific problem in the field of technology" (WIPO, 2004). As Boulet *et al*. (2003, p.6) warn, "In the pharmaceutical sector, an invention may relate to a product (a specific molecule), a

[38] I discuss 3d at length in the next section.

process (a method to manufacture it), a medical indication (a molecule's effect on the human body), or a combination of products (a fixed dose combination of two molecules)." A medicine is no longer a thing in itself. Instead, it is disaggregated or individuated (Castree, 2003) into discrete parts, processes, and effects, each of which become eligible for patent protection.

Having joined the World Trade Organization on January 1, 1995, India could no longer shield pharmaceuticals from product patents. Chemical compounds, irrespective of their use, *had* to be eligible for product patents. And so, India passed a new, "TRIPs compliant" Patent Act in 2005, according to which drugs developed *prior to 1995* would be subject to the *older process patent* regime (the 1970 Act), while those developed *post-1995* would be subject to the *new product patent* regime (the 2005 Act).[39] Imatinib, developed in the early nineties, and being a substance "intended or capable of being used as a drug" could not be patented in India.[40] IM-β however, developed post-1995, was a claimed technological invention that would be assessed under the new patent regime. Thus, the Glivec case was the first instance of a pharmaceutical compound being evaluated as an invention since 1972, which is when the 1970 Act came into effect. The interpretation of the new 2005 Act would determine how IM-β, a post-1995 pharmaceutical, would move in the Indian market. Thus, it is only after 1995 that the distinction between original compound, generic, and unlicensed copy comes into force in India. If IM-β was granted a patent, the copies of Glivec offered by Indian pharmaceutical companies would become illegal copies, and would either have to be withdraw from the market or require licensing agreements with Novartis.

Yet, this case not just about whether IM-ß was an invention. It was equally about the legal universe in which decisions about IM-ß would be made. As the first dispute under India's revised law, the meaning of TRIPs compliance, the legal definition of invention, the existence and interpretation of 3d were all at stake. The case was likely to set a precedent on many of these questions for future patent applications and disputes.

[39] Countries designated as "developing" and "least developed" were given transition periods to fully implement the TRIPs regime. The former were granted 10 years (from 1995) to bring their laws in compliance with TRIPs.
[40] Section 5 of the older Patents Act.

3. **Chemicals in a legal universe**

> To attain [the vantage point claimed by law as its way of looking at the world, or life] requires the transformation of the data of ordinary life into those of a special drama with its own personages, costumes, and conventions, not to mention the invention of new personages and relationships not found in the state of nature (Honoré, 1977 quoted in Zartaloudis, 2012, p.113).

3.1 *Legal universe and sovereignty*

I have argued above that TRIPs abstracts medicines as technology, which is what makes them eligible for patent protection. Further, patents are legal instruments that protect technological "inventions." When Novartis wanted, and claimed that it deserved, an Indian patent for IM-β, it was a *legal* claim.[41] By this I mean the following. First, Novartis' claim was addressed to the law, its patent application making IM-β and other chemical objects and knowledges legal things, things in respect of which the law can and must decide. Second, such things were required to be expressed in a specific idiom and convention, and situated in a "legally governed totality, a legal universe" (Zartaloudis, 2012, p.113). In order to determine whether IM-β was an invention, it had to be made legible to the law through the idiom of novelty, utility, and non-obviousness, an idiom that was standardized by TRIPs. Novartis contended that this meant that invention had the same meaning for all TRIPs signatories. Thus, Indian law should follow the lead of over thirty- five countries that had recognized IM-β as an invention and granted it a patent (IPAB, 2009, p.156).

The Indian Patent Office, the Intellectual Property Appellate Board (IPAB) and the Supreme Court all disagreed. The IPAB ruled that while TRIPs had standardized the tests of invention, countries had the flexibility to frame their national patent laws as per their own needs. Whether other countries had issued patents on IM-β was irrelevant (IPAB, 2009, p.156-57). Further, while novelty, utility, and non-obviousness could be thought of as category envelopes that all TRIPs signatories must have, their precise

[41] Claim 1 of Novartis' patent application 1602/MAS/1998 reads, "a form of the methanesulfonic acid addition salt of a compound of formula 1, comprising crystals of the β-modification" (IPAB, 2009, p.7).

contents were to be determined by national patent rules and decisions. Similarly, the Supreme Court ruled that the legal universe in which IM-β had to be situated was the Indian Patents Act, 2005 (hereafter, the 2005 Act). The 2005 Act, requires any claimed invention to satisfy the following conditions:

- It must be *new*;
- It must be capable of industrial application (i.e. of being made or used in an industry); and
- It must have come into being as a result of an *inventive step* that:
  (i) entails *technical advance* over *existing knowledge*; or
  (ii) has an economic significance; and
  (iii) makes the invention *not obvious* to a *person skilled in the art*..[42]

It also contains Section 3d. 3d of the 2005 Act does *not* recognize as an invention "a new form of a known substance" unless it enhances the "known efficacy" of that substance. To receive a patent, Novartis had to prove IM-β an invention in *this* universe of the 2005 Act. In other words, the legal designation of IM-β as a patentable invention would be the *outcome and aggregate* of findings in each of these categories, and *only* these categories. Thus, for instance, Novartis' emphasis on IM-β being the result of expensive and extensive research, and hence deserving of a patent, was deemed irrelevant by its opponents who noted that "painstaking research or expenditure of time and money were not patentability criteria under the Indian law" (IPAB, 2009, p.57). Similarly, for the Supreme Court, Novartis' claim that IM-β was a "breakthrough, life-saving in cancer medicine" (Novartis, n.d.) meant little in determining its legal status as an invention, thereby underlining the distinction between "ordinary" meaning and legal meaning.[43]

At the same time, what this legal universe consists of was also being contested. In its ruling that started the dispute, the Indian Patent Office ruled that IM-β, as a polymorph of the already known compound imatinib mesylate, was subject to 3d and needed to demonstrate significantly enhanced efficacy. Novartis, however, did not meet this requirement. Consequently, IM-β was not an invention under 3d. In its appeal against the Patent Office's decision, Novartis challenged not just the Office's specific rulings on

[42] The Supreme Court pooled clauses (j), (ac) and (ja) of section 2(1) of the Act to summarize the tests for invention.
[43] This distinction while contentious and open-ended is nevertheless assumed and enacted in drafting and adjudicating law.

IM-β, but also the very validity of 3d, arguing that it violated India's TRIPs obligations by taking away Novartis' right to patent an invention guaranteed by Article 27.1 (Mad HC, 2007, p.1266). Implicit in Novartis' argument was that 3d discriminated against chemicals and pharmaceuticals in the matter of patentability by setting additional requirements of proving significantly enhanced efficacy. Novartis also challenged the constitutional validity of 3d before the Madras High Court on the ground that absent any definition/standard of "significantly enhanced efficacy," 3d vested unfettered discretionary powers in the Patent Examiner, its vague wording enabling him to determine enhanced efficacy "based on his whims and fancies." (Mad HC, 2007, para 3). Such arbitrariness, Novartis argued, violated the Indian Constitution's guarantee of Novartis being treated equally before the law. These arguments sought to remake the legal universe within which IM-β would be assessed by expelling 3d from it.

The Madras High Court, however, rejected Novartis' arguments, and upheld the constitutionality of 3d. It also ruled that it did not have jurisdiction to determine whether 3d violated TRIPs, and that the correct form to address this question would be the WTO's dispute resolution system. What I highlight here is that what precisely constitutes "the legally governed totality, the legal universe" within which things, events, processes, and people are governed is itself a subject of legal contestation between parties—the universe contracts and expands depending on contestations over, and decisions about jurisdiction, provisions, precedents, techniques of interpretation, etc.

3d is a unique provision in the international patent law landscape. As the 2005 deadline to make its patent law TRIPs-compliant drew near, multiple people and organizations expressed anxiety about India's transition to a product patent regime. Many Asian and African countries impressed upon India that the effects of its revised patent law would reverberate beyond its borders, with likely impacts on access to future generic antiretrovirals (ARVs) and other life-saving medicines. High ranking officials of the World Health Organization and UNAIDS wrote to the Indian Government urging it to avail itself of flexibilities afforded by TRIPs, and to not adopt "TRIPs plus" provisions.[44] Members of the Indian Parliament also expressed concerns about the monopolistic

[44] Many developing countries have adopted intellectual property laws that are more restrictive than what TRIPs requires (Kapczynski, 2009, p. 1573).

tendency of patents, as well as the widespread practice of evergreening—legal and business strategies aimed at extending the patent life of a drug, by patenting minor improvements in chemical delivery system, dosage, packaging, pharmaceutical mixtures, etc.—in the pharmaceutical industry (SC, 2013, pp.43-49). These concerns were not hyperbole. The 2005 Act was coming close on the heels of the global AIDS crisis that had peaked in the late nineties. In 2001, Cipla, a Mumbai-based company, developed Triomune—a single, three-in-one fixed-dose combination of ARV, made via the creative recombination of existing drugs. This "remix" dramatically simplified treatment regimens and improved patient adherence, thereby playing a critical role in accelerating the global scale up of HIV/AIDS treatment (Park and Menghaney, 2012). Cipla also offered to supply generic versions of patented first generation ARVs, then costing between $10,000-15,000 per year, for $350 per year (Horner, 2013). This proved to be a turning point in the fight against AIDS, particularly in African countries:

> [Cipla's move] rendered an intractable problem suddenly tractable because the solution was plausibly affordable. Furthermore, it effectively isolated the impact of intellectual property protection on the affordability of these drugs. The connection between intellectual property and high prices was stark. The high prices looked more like monopoly rents than anything else (Sell, 2010, p. 396).

Soon, generic competition by Cipla and others radically drove down prices of ARVs. With this, Indian companies emerged as the "economic backbone" of the HIV/AIDs campaign, helping to articulate and demonstrate the ethico-politically charged relationship between patents, drug pricing, and access to medicines (Roemer-Mahler, 2013, p.132). Of course, patents do not exhaust the question of access to medicines, nor that of pharmaceutical pricing.[45] In fact, the very status of medicines as capitalist commodities—"objects produced for sale on the market" (Polanyi, 1944 cited in Prudham, 2009, p.125)—that allows the logic of profit to penetrate research into and production of medicines in and of itself leads to various crises of access.[46] Yet, *patents do have "unusual importance" in medicines policy* (WHO, 2004, p.109).

[45] The World Health Organization (WHO) writes that access to medicines is shaped by multiple factors like rational medicines selection process, sustainable financing, and reliable health and supply systems (WHO, 2004, p.64).

[46] Many price-gouging scandals in recent years have not involved patented medicines. For instance, the exponential increases in the price of old drugs like Daraprim (used to treat parasitic

I have previously noted that the refusal of product patents on medicines by the Indian Patents Act, 1970 meant that pharmaceuticals were treated like any other commodity, subject to free market competition. It was this competition that fueled the growth of the Indian pharmaceutical industry, enabling it to produce medicines at some of the lowest prices globally. However, a patent enchants a commodity, bestowing upon it the proverbial Midas touch through the grant of a set of exclusive rights for a limited duration. The patent holder alone has the right to use, sell, and prevent others from copying the knowledge covered. With these rights, come the possibility of a temporary absolute monopoly—a patent cordons off a commodity from competing with copies/similars. As discussed earlier, TRIPs requires that a pharmaceutical patent grant its holder exclusive rights over a medicine for a minimum of twenty years. What flows from this is the power to prevent/regulate the market entry of generics during this period, and to fix the price of the medicine. *Entangled thus in calculations over who gets to live, who gets to heal their bodies and minds, and at what cost, the question of access to medicines is constitutive of pharmaceutical patents.*

Admittedly, patents contain the potential and not necessarily the inevitability of (temporary) monopoly creation: "A patent in itself does not determine the way… technology is disseminated" (Sunder Rajan, 2012, p. 4).[47] While an important qualification, the transnational pharmaceutical industry has a proven track record in hoarding and weaponizing patents (I-MAK, 2017). For instance, a recent study found that the twelve best-selling drugs in the US are protected, on average, by seventy-one patents per drug, providing an average of thirty-eight years without generic competition (*ibid*).[48]

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infections), the tuberculosis drug Seromycin, and Epipen (used to treat anaphylaxis) have been attributed to market monopoly (lack of generic competition), and even more worryingly, to the increasing financialization of the pharmaceutical industry.

[47] Universities, for instance, have, on occasion, patented therapeutic substances (University of Toronto's patent on insulin) and technological innovations (Stanford University's patent on recombinant DNA technology) to facilitate their dissemination though the grant of non-exclusive licenses and insistence on moderate pricing (Cassier and Sinding, 2008; Sunder Rajan, 2012).

[48] The average number of patent applications attempted per drug in the study was 125. AbbVie's Humira was the worst offender in terms of patent applications filed (247), Pfizer's Lyrica in terms of price hike in 6 years (163%), and Roche/Genentech's Herceptin in terms of years blocking generic competition (48 years) (I-MAK, 2017). Another study of three high-cost drugs for cancer and hepatitis C revealed that "anti-competitive strategies by branded pharmaceutical companies are driving excess costs to American payers and patients. Product lifecycle management, whereby branded companies obtain unmerited patents to delay competition, is the primary strategy

Further, the market exclusivity that follows patents is directly linked to exorbitant price increases in most cases—the same study found an average price increase of 68% per drug since 2012 (*ibid*).

It was precisely these anxieties that were reflected in legislative and civil society debates in the run-up to the 2005 Act. 3d, therefore, was intended by the Indian Parliament to act as a shield against stockpiling patents. The Supreme Court noted as much in its judgment:

> To anyone going through the debate on the Bill, Parliament would appear keenly alive to national interests, human rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices. Cutting across party lines, member after member from the Opposition benches highlighted the grave risk in creating private monopolies in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high…. *an amendment (by way of addition) in clause (d) of section 3 was proposed by the Government in order to allay the fears of the members from the Opposition concerning the introduction of product patents for pharmaceuticals and agricultural chemicals, and it was on the Government's assurance that the proposed amendment in section 3(d) (besides some other changes in the Act) would take care of the apprehensions about the abuse of product patent in medicines and agricultural chemical substances that the Bill was passed by Parliament…. A perusal of the Parliamentary debate would further reveal that the whole debate centered on medicines and drugs.* It would not be an exaggeration to say that eighty percent of the debate was focused on medicines and drugs and the remaining twenty percent on agricultural chemicals. In the entire debate, no substance of any other kind came under discussion [Supreme Court (SC, 2013, paras 79, 94, 97; emphasis mine)].

In other words, 3d was, first and foremost, a legal response to the question of access to medicines in the strait-jacketed post-TRIPs patent-scape. In terms of the argument I advanced in the previous section, 3d pushes back against medicines being subsumed into the category of technology by TRIPs. 3d draws inspiration from the Declaration on the

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identified and evaluated by this study. A related strategy is "pay-for-delay": branded companies pay generics to stay off the market, a symptom of underlying unmerited patents and misaligned incentives in the patent and regulatory systems." (I-MAK, 2017, p.1). Another way in which patents shape the question of access to medicines is by skewing incentives for pharmaceutical R&D. A patent-based innovation system links innovation with high prices; therefore, companies are less interested in developing medicines for illnesses prominent in countries and among populations with low purchasing power (Krikorian and Kapczynski, 2010, p.38).

TRIPs Agreement and Public Health (2001), popularly known as the Doha Declaration, which re-inscribes the specificity of medicines on international trade law. The result of campaigning by developing countries and civil society organizations, the Doha Declaration asserts that medicines cannot be dissolved into the category of technology in matters of intellectual property rights. Instead it calls for the TRIPs Agreement to 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" (WT/MIN(01)/DEC/2, para 4 cited in Sun, 2003, p.104). Novartis' opponents in the Glivec case mobilized the Doha Declaration to argue that 3d had been drafted with the objective of supporting public health, and recognized the singular importance of medicines by prescribing higher patentability standards for them.

The Supreme Court agreed. Using legislative debates to rule on the scope and meaning of 3d, the Supreme Court held that the 2005 Act "sets different standards for qualifying as "inventions" things belonging to different classes," with 3d setting a higher threshold for chemical substances, particularly pharmaceutical products (SC, 2013, pp. 56-57): "Something may be an "invention" as the term is generally understood and yet it may not qualify as an "invention" for the purposes of the Act. Further, something may even qualify as an "invention" as defined under the Act and yet may be denied patent for other larger considerations as may be stipulated in the Act" (SC, 2013, p.52).

This discussion on struggles over the legal universe in which IM-β had to be situated enables a consideration of the question of sovereignty. "[The] conceptual map of the archetypical jurist is organized strictly along national lines…. Implicit in this map of jurisdictional inquiry is a view of the state as a sovereign body not only representing a demarcated territory and a fixed population, but also able to aggregate collective wishes and translate them into acts" (HLR, 1990, p. 1285). While the geographical limits of intellectual property rights have traditionally mapped onto the territorial boundaries of nation-states (Aoki, 1996; Biagioli, 2006), international, bilateral, and multilateral trade and intellectual property agreements that enable specific and parochial conceptions, norms, and standards of property and personhood to jump over borders, have exerted tremendous pressure on this understanding and assertion of sovereignty, particularly of nation-states in the Global South. Institutions like WTO and agreements like TRIPs

represent and materialize a deep incursion into their national sovereignty. Of course, nation-states play a constitutive role in constructing and materializing the supranational plane (Aoki, 1996). This formulation, however, must be qualified take into account the fundamental inequalities in the global political economy, which simultaneously constrain the power of some nation-states, while multiplying the power of a select few to exercise their sovereignty. If "it is only through an exercise of sovereignty that sovereignty can be limited" (Buchanan and Pahuja, 2004, p.85), it is also the case that limits on sovereignty may be lessened through the assertion of sovereignty. This is what we see in the Glivec case. Refusing any universal legal understanding of invention, the Supreme Court highlighted that invention and patentability were simultaneously enabled, defined, and circumscribed by the 2005 Act, and that the Indian legislature had the power to frame these concepts to reflect and implement its national priorities and concerns. Thus, 3d's refusal to treat all technologies equally was seen by the Court as an exercise of India's legal sovereignty. This rendered irrelevant Novartis' repeated invocation of Glivec having been awarded a patent in over thirty-five jurisdictions: just because Glivec had been deemed an invention in other countries did not mean that it fit the definitions and standards encoded in Indian law.

What I suggest here is not that TRIPs and the 2005 Act be seen as distinct laws. Certainly, the former forced and shaped the latter. Yet, the Indian Patent Office, the IPAB, and the Courts were able to assert the relative autonomy of the 2005 Act from the requirements of TRIPs, as well as precedents and principles from elsewheres. National sovereignty was also implicitly or explicitly invoked by parties when they argue against the adoption of "western" standards of patentability (SC, 2013, p.37), and when Courts choose specific interpretive techniques such as referencing legislative history and (SC, 2013, p.56), and India's constitutional obligation to provide for the good health of its citizens (Mad HC, 2007, p. 30), to read legal provisions. The practice of legislative and judicial borrowings and transplants from other jurisdictions does make it difficult to sustain a distinction between the "national" and the "foreign" in law. Nevertheless, sovereignty provides an important anchor to shape legal arguments and decisions, creating crucial space for the consideration of difference—difference in developmental

priorities, purchasing power, legal histories, interpretive techniques—and consequently for particularizing putatively universal categories such as invention.

3.2 *Which chemical?*

I have examined contestations over definitions of the legal universe in which IM-β had to be placed in order to determine its patentability. Yet, IM-β's place in this universe depended on placing two other compounds: (i) imatinib, and (ii) imatinib mesylate. I provide below a quick recap of what these three compounds were.

In 1996, Novartis was granted a patent for derivatives of N-phenyl-2-pyrimidine-amine ("pyrimidine derivatives") in North America and Europe.[49] Pyrimidine derivatives were structurally related molecules that were able to distinguish between deceptively similar looking proteins in the body, and bind with specific ones, without interfering with the others. One such derivative was imatinib in free base form, which was able to latch onto a rogue chromosome that unleashes a cascade of signals, commanding cancer cells to proliferate, and causing CML; it then was able to turn off this chromosome (Jack Li, 2006; Mukherjee, 2011). This patent, popularly called the "Zimmermann patent" after its named inventor marked the legal/patent origins of imatinib.[50] In 1998, Novartis requested the US FDA's approval to launch Glivec in the market. In documents submitted to the FDA, imatinib mesylate, a salt form of imatinib, was named as the active ingredient in Glivec. Novartis' patent application in India, however, was for IM-β—a specific crystal configuration, i.e. polymorph, of imatinib mesylate.[51] It claimed that IM-β was easier to

[49] Ciba-Geigy (which subsequently became Novartis, had funded some of the early discovery research into the drug, and was also involved in developing a chemical library whose screening would lead to the initial identification of imatinib as a potential therapeutic molecule) filed for a patent application for imatinib and its "pharmaceutically acceptable salts," including imatinib mesylate, in the United States in 1993.

[50] The patent was granted in 1996.

[51] Polymorphism refers to the ability of a solid chemical compound to exist in two or more crystalline forms where molecules are packed/arranged differently. Novartis filed a patent application for IM-β in the US in 2000. Though rejected by the Patent Examiner, Novartis won its appeal in the Board of Patent Appeals in 2003, and a patent was granted for IM-β in 2005.

store and process, and hence new, superior, and deserving of a patent (SC, 2013, p. 7).[52] Thus, the Glivec case involved parsing three chemical compounds:

Imatinib	• Pyrimidine derivative • Able to switch off the Philadelphia chromosome that causes CML	• Patents granted in the North America and Europe in 1996.
Imatinib Mesylate	• Salt form of imatinib prepared by adding methanesulfonic acid to imatinib	• Named in multiple documents as Glivec's active ingredient .
IM-β	• Polymorph, i.e. a structural cousin of imatinib mesylate	• Indian patent application claimed that IM-β was easier to process and store.

Table 1: The chemicals in the Glivec case

The patentability of IM-β depended on articulating its relationship and comparison with imatinib and imatinib mesylate. But this was easier said than done. Questions piled up: Was imatinib mesylate "known" from the Zimmermann patent, making IM-β a "new form of a *known* substance," and therefore subject to the 3d test? Which compounds needed comparing—did IM-β have to demonstrate enhanced efficacy over imatinib mesylate or imatinib?[53] Which properties of a chemical compound counted towards assessing patentability? How was pharmaceutical advantage to be defined? What made two compounds "the same?" What properties were "inherent" to a compound and could not be said to be "surprising?" For instance, in response to Novartis' contention about the higher solubility of IM-β over imatinib, the Supreme Court noted, "… for all one knows the higher solubility that is attributed to the beta crystalline form of imatinib mesylate may actually be a property of imatinib mesylate itself. One does not have to be an expert

[52] The Supreme Court noted: "The appellant filed the application (Application No.1602/MAS/1998) for grant of patent for imatinib mesylate in beta crystalline form at the Chennai Patent Office on July 17, 1998. In the application it claimed that the invented product, the beta crystal form of imatinib mesylate, has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of imatinib mesylate. It further claimed that the aforesaid properties makes the invented product "new" (and superior!) as it "stores better and is easier to process," has "better processability of the methanesulfonic acid addition salt of a compound of formula I," and has a "further advantage for processing and storing" (SC, 2013, p.7).

[53] The Supreme Court held that Novartis' application was required to show IM-β's enhanced efficacy over imatinib mesylate and not imatinib (SC, 2013, p.88).

in chemistry to know that salts normally have much better solubility than compounds in free base form" (SC, 2013, p.88). Similarly, the Court held that while IM-β may be "superior" to imatinib mesylate in terms of "physico-chemical" properties, these had no bearing on its "efficacy," and hence on its patentability (SC, 2013, p.94).

Thus, IM-β could not be discerned chemically or legally without reference to imatinib and imatinib mesylate. My point here is that chemical compounds are battlegrounds, not obvious data. They are not already known, discreet entities that easily map onto legal categories of new, non-obvious etc. Rather, the chemical that matters to law—its properties, its effects, its relationship to other chemicals—is itself a subject of contestation between parties.

But in methodological terms, *how* were these compounds appraised and compared to each other? In the final section of this chapter, I discuss the various roles that documents play in the patent law universe, and their heightened significance when it comes to chemical inventions as in the Glivec case.

3.3 *Paperwork*

In the Glivec case, the lives of, and relationship between imatinib, imatinib mesylate, and IM-β, had to be stitched together and deduced from knowledge claims and assertions made in various documents. And with these documents came contestations about their permissibility, reliability, form, content, and techniques of interpretation. Documents matter in the chemical patents universe in three ways. *First*, chemicals do not, and cannot, enter patent offices and courts (neither, of course, do medicines and patients). What enters these forums is documents. Chemicals "speak" only through documents (Hendy, 2005)—documents that attest to what they are made of, what they look like, how they act under specific conditions, what they may be used for, and so on.[54]

Second, patent law does not encounter an invention *per se*. Rather, an invention must be made legible to law by way of the patent specification, a document that contains (i) claims, whose function is to define the invention; and (ii) description/disclosure, which must contextualize the invention and teach how to reproduce it. The knowledge

[54] Hendy (2005, p. 26) has argued that chemical structures speak through testing/experimentation and corresponding documentation. It is only the latter that patent offices examine.

claimed or disclosed in a granted patent, no matter its geography, falls in the public domain and is deemed known once the patent is issued (although the invention cannot be copied till the patent expires). This constitutes "the patent bargain" (Biagioli, 2006, p.1131): exclusive rights for the term of patent in exchange for making useful and valuable knowledge public. This bargain is what makes the patent politically defensible (*ibid*). It is the patent specification that is examined in patent offices to determine what precisely a patent will protect.

Third, the identity of an invention is established in juxtaposition with what already exists or is known. The legal requirements of novelty and non-obviousness position the claimed invention in relation to the public, and ask whether it was already in the public domain, with documents playing a key role in answering this question.[55] A claimed invention is (i) not new if it is substantially similar to an existing product, or if any prior document describes something similar; and (ii) non-obvious if it is *not* simply a re-ordering of what is already known in the field, or a trivial, insubstantial, or inevitable advance in the field (Holbrook, 2016).[56] In the Glivec case, patent examiners and Courts were directed by competing parties towards various documents to determine what knowledge and knowledge-objects were new, and conversely, what was already in the public domain explicitly, or would be "common sense" in the relevant field, and hence could not be claimed as inventions.

The chemico-legal status of IM-β depended on the scope of the already issued Zimmermann patent.[57] The Zimmermann patent details pyrimidine derivatives including

[55] Holbrook (2016) has argued that the tests of novelty and non-obviousness in patent law are variations of the concept of possession in property law. They essentially ask if the public was already in possession of the invention prior to the inventor, rejecting the patent if the answer is in the affirmative.

[56] The invention needs to be non-obvious to a person having ordinary skill in the relevant field. Patent law is required to judge whether such a (fictitious) person would have been able to make the invention by piecing together from multiple sources common/available knowledge in the field. The non-obviousness criterion is rife with problems and contradictions (see Holbrook, 2016).

[57] As the Supreme Court noted, "The subject product [IM-β] admittedly emerges from the Zimmermann patent. Hence, in order to test the correctness of the claim made on behalf of the appellant, that the subject product is brought into being through inventive research, we need to examine in some detail the Zimmermann patent and certain developments that took place on that basis." (SC, 2013, p.59).

Imatinib—its molecular formula, structure, chemical and pharmacological properties, and various possible salts are contained in the patent.[58] While imatinib was explicitly claimed and disclosed in the Zimmermann patent, what was being contested in the Glivec case was whether imatinib mesylate was also known from the patent. Novartis argued that IM-β was brought into being by "not one, but two inventions" (SC, 2013, p.57):

1. Although the Zimmermann patent discussed imatinib, it did not specifically mention imatinib mesylate, did not suggest that the mesylate salt of imatinib be chosen over numerous other possible salt forms, and did not teach how to make imatinib mesylate. Novartis' first invention, it therefore claimed, lay in selecting imatinib from among the derivatives listed in the Zimmermann patent, and then choosing to produce the Mesylate salt by the addition of methanesulfonic acid.[59]
2. Its second invention lay in developing imatinib mesylate to ensure that it can be administered in solid oral dosage form. This, claimed Novartis, led it to discover its polymorphism, and thereafter to synthesize the beta crystalline form of the salt (SC, 2013, pp.57-59).

Thus, Novartis' argument was that in the absence of clear instructions in the Zimmermann patent on how to make it, or even the prompt that it be made, imatinib mesylate must be held to be not known, i.e. legally new (IPAB, 2009, pp.99, 14). The stakes of this particular argument were considerable in that if imatinib mesylate was held by the Courts to be known from the Zimmermann patent, Novartis would lose the first tier of its claim, rendering IM-β (as a "new form of a known substance") subject to scrutiny under the higher standards set by Section 3d of the 2005 Act.

Its opponents, however, argued that the Zimmermann patent disclosed methanesulfonic acid as one of the salt-forming groups, and instructed that acid addition salts be obtained in the "customary manner," both of which were sufficient for a person

[58] The Zimmermann patent is formally titled "Pyrimidine derivatives and processes for the preparation thereof."

[59] Novartis contended: "What [the 1993 Zimmermann] patent disclosed was the possibility of making various salt forms of the imatinib free base which could run into hundreds…. But no reference was there for any specific choice of salt as the cancer curing drug…. There was no example disclosing the preparation of imatinib mesylate…. No procedure was described how to prepare the salt, what conditions to apply and what physical properties the obtained salt might have" (IPAB, 2009, pp.24, 31, 15).

skilled in the field to make imatinib mesylate. They also listed the a series of documents—paperwork submitted by Novartis to the US FDA and the Patent Office, the package insert accompanying Glivec™ capsules when it was launched in the market, and an injunction notice sent by Novartis to a company selling generic versions of Glivec—all of which named imatinib mesylate as Glivec's active pharmaceutical ingredient; their point being imatinib mesylate was a known compound, and not an invention. They further contended that it was common knowledge/practice in the pharmaceutical field to convert drug candidates into salt forms that are then able to work better in the human body; they also referenced studies that claimed a good success rate for mesylate salts of lead pharmaceutical compounds. This enabled them to argue that even if the Zimmermann patent was read as not suggesting the making of the mesylate salt of imatinib, a researcher of ordinary skill in pharmaceutical chemistry would have made it based on common outcomes in the field (IPAB, 2009, pp.57-58, 49). Together, these arguments framed imatinib mesylate as both *not new* and *obvious*.

Thus, documents—patent specifications, technical reports, institutional paperwork, journal articles, and expert testimonies—are how claims of chemical innovation are assessed. In the words of Biagioli (2006, p. 1146), documents, coupled with customary practices and general knowledge in pharmaceutical chemistry, constituted "the other" against which the identity of imatinib mesylate and IM-β as inventions, as new and non-obvious, were being constructed and contested.

4. **Conclusion**

In this chapter, I have shown that the Glivec case provided an opportunity to historicize pharmaceutical product patents. That medicines can be the object of intellectual property protection is now almost universally accepted. This is not to suggest a lack of friction in this normalization. High prices of medicines in general, and high prices of patented medicines specifically, spark outrage from time to time. However, as the first patent dispute over a pharmaceutical compound in post-colonial India, the Glivec case generated much conversation inside and outside patent offices and Courts, as well as within and beyond India. This conversation brought into focus how *short* the history of product patents for pharmaceuticals is, and also signaled to unequal power relations in the world

economy that have resulted in making product patents for medicines a compulsory feature of national patent laws.

I have also argued that the question of patentability of medicines is made possible only by subsuming medicines into the category of technology, a feat achieved by TRIPs. This abstraction is powerful. It enables the bracketing of what medicines do and their significance in leading functional and healthy lives, and instead posits medicines as the mere sum of discreet substances, processes, and effects, each of which is viewed as technology. The TRIPs mandate of "not discriminating against a field of technology" is therefore, predicated on "medicine blindness." However, this flattening of the category of technology has not gone unchallenged. Situating the Glivec case in the history of Indian patent law, I have shown how concerns over the relationship between patents, drug pricing, and access to medicines animated the drafting of the new TRIPs-compliant Indian Patents Act. Civil society pressure within and outside India, and anxieties expressed by members of Parliament over patent abuse by the multinational pharmaceutical industry led to the formulation of Section 3d (and other provisions). 3d sets higher standards for pharmaceutical patents, and I have argued that this be read as re-inscribing on India's patent law the specificity of medicines, and their singular importance in human well-being. Refusing a universal definition of invention, 3d makes some room for the consideration of India's developmental priorities and the low purchasing power of a majority of its citizens. In fact, the possibility of 3d travelling to other countries and disrupting existing standards of patentability drew the ire of the multinational pharmaceutical industry. The industry saw 3d as confusing evergreening with "incremental innovation" and suffocating the latter, a critical component in pharmaceutical research and development. A report published by the US Chamber of Commerce denounced the deterioration of India's national IP environment:

> In the biopharmaceutical space, Indian policy continued to breach international standards of the protection of innovation and patent rights, revoking patents generally accepted around the world….Most notable was the April decision by the Supreme Court of India on the patentability of the anti-cancer drug Glivec; the court held that the drug did not meet patentability standards as imposed by the Indian Patent Act's Section 3(d) regarding "incremental innovation" and limiting patent protection to what is specifically disclosed, again in contradiction to global norms. This is despite Glivec being recognized as a breakthrough drug and given protection in 40 jurisdictions around the world. Given the prominence and size of

> India's generic pharmaceutical industry, other countries have taken notice and begun to introduce similar provisions into their own laws and regulations…. For instance, in Brazil the government introduced a patent reform initiative in Bill No. H.R. 5402/2013 in 2013; among other things, the bill purports to narrow patentability criteria, even further disallowing patents on new uses or new forms of known substances unless a significant improvement to the known efficacy is present, in many ways matching India's infamous Section 3(d) (Pugatch *et al*., 2014, p.27).

Finally, I have discussed the legal universe within which IM-β was required to be situated. This was no straightforward task. Chemical knowledge and practices had to be made legible to the law and fitted into legal categories, a process rife with competing claims and interpretations. Further, the chemicals themselves—imatinib, imatinib mesylate, and IM-β—proved slippery. They were not self-evident material things that could readily and reliably ground the legal question of patentability. Rather, parties argued over their properties, their functions, and their relationship to each other. I have also shown that documents occupy a particularly significant place in pharmaceutical patents, since chemicals speak only through documents. In one instance, the opponents pointed out that Novartis knowingly suppressed a journal article which disclosed the existence of imatinib mesylate and its cancer-inhibiting properties, in order to construct a *false identity of imatinib mesylate as new* (IPAB, 2009, p.148). Novartis' response to this allegation was to argue that Indian patent law did not require such documents to be included in the patent application. The Intellectual Property Appellate Board, however, ruled even though not required by the 2005 Act, Novartis had an obligation to submit to the Patent Office all documents that would help evaluate whether its product was an invention. *My point here is that a patent is not simply a linear function of the quality or the merit of* a claimed invention. There is no pure question of chemical excellence or innovation. Rather, a final decision on a patent is constituted by many smaller decisions, including for instance decisions on which documents and expert testimonies are admissible as evidence, compliance with procedural requirements etc.

Yet, despite the ingenuity of 3d and the celebration of the Glivec ruling, I underline the many limits of routing the ethico-political question of access to medicines via the legal and chemical domains. *First,* patents are dense and nearly impenetrable documents. Challenging them requires specialized knowledge in pharmacology and law.

While cases like Glivec and the access to knowledge and medicines movement more broadly have worked to politicize a highly technocratic discourse (Kapczynski and Krikorian, 2010, p.14), unentangling the web of patents within which a medicine is imprisoned (I-MAK, 2017) and challenging specific patent applications or grants can only be undertaken by vigilant and competent patent lawyers and select civil society groups. Generics manufacturers also have the incentive to challenge patent applications. However, the time and costs associated with litigation, coupled with practices such as licensing agreements that split markets between the innovator company and generic producers, and paid settlements to delay market launch of generics, skew these incentives. Moreover, patent decisions are open to "extra-legal" pressures such as trade negotiations between countries. *Second*, the primacy of documents—how they are written, how they are read, what they reveal, and what they suppress, what they center, and what they put on the margins, whether they are permitted in a court—are critical to determining whether or not a patent is granted, often at the cost of displacing the invention itself. In fact, since the patent system relies heavily on the voluntary disclosure of knowledge by the applicant, the costs of discovering deceitful conduct are high (Thambisetty, 2007). As a result, questions of access are buried under hide and seek of documents, artful drafting of patent claims involving strategic silences and semantic gymnastics, and a thicket of legal rules and chemical complexity.

Chapter 2 | Chemical Troubles: Law and the Task of Making Sense of Medicines

In this chapter, I descend into the chemical realm and examine the legal gaze, as various actors make (non)sense of chemical/pharmacological knowledge claims. As shown in the previous chapter, patents are "legal forms of e/valuation" (Kang, 2015, p.36) of scientific knowledge, on which rest financial promises. The re-cognition of medicines as technology, i.e. knowledge fixed in things and processes, which makes them available for patent protection, also makes competing knowledge claims the primary form of contesting patents. It is in the confrontation and reworking of legal categories and chemical knowledges that sameness and difference between pharmaceutical entities are produced.

In the pages that follow, I discuss the deliberations over Section 3d of the Indian Patents Act, 2005. I reproduce the text of 3d below for the sake of convenience.

> Under the title "Inventions not patentable," 3d provides:
> [The following are not inventions within the meaning of this Act]
> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation.—For the purposes of this clause, salts, esters, ethers, *polymorphs*, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Slowing down these deliberations, I show that pharmaceutical patents contain politicized representations of drug chemistry. I also highlight that conceptually, the patent regime makes law an important arbiter of pharmaceutical identity as stakeholders clash over a series of questions. What a medicine is, what a medicine does, and what makes a medicine "a medicine?" How does patent law come to decide what aspects of a medicine count towards protection as intellectual property? What suppositions underlie law's attempt to establish "a reliable epistemology of efficacy" (Wilson, 2015, p.136) to operationalize 3d? I highlight the tensions, ambiguities, and incompleteness with which these moments are fraught. I also discuss how law soothes these disturbances, arriving at

a judgment premised on choices/decisions of meaning and reasoning whether explicitly rationalized or not.

But before delving into these deliberations, I offer a brief note on how the politics of the copy is configured in 3d. The process of pharmaceutical and research involves developing different forms of the same substance, such as the compounds listed in the Explanation. In the Introduction, I argued that 3d designates some compounds, i.e. salts, esters, polymorphs etc as mere copies/derivatives of a "known substance," while protecting the "transformative use" of a known substance. Such transformation is defined in terms of efficacy. Not all transformations of a known substance count towards patentability. Rather, such transformation must be expressed in terms of significantly enhanced efficacy of the known substance. Thus, by designating salts, esters, polymorphs, etc effectively as mere copies of known substances, 3d attempts to reduce the scope of intellectual property rights, and helps to undermine the multinational pharmaceutical industry's widespread practice of evergreening, whereby small changes to patented compounds are used to extend the term of patent protection.

1. **Making sense of pharmacological sameness and difference**

> […] The patent application submitted by the appellant contains a clear and unambiguous averment that all the therapeutic qualities of beta crystalline form of Imatinib Mesylate are also possessed by Imatinib in free base. The relevant extract from the patent application is once again reproduced here:
> "It goes without saying that all the indicated inhibitory and pharmacological effects are also found with the free base, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl) pyrimidin-2-ylamino)phenyl] benzamide, or other cells thereof."
> Now, 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? [Supreme Court (SC, 2013, paras 162, 163)].[60]

> […] Imatinib free base is actually the active therapeutic ingredient, but in free base form Imatinib has very little or no solubility. It is, therefore, not capable of being administered as a drug to human beings….if given in solid dosage form, Imatinib free base would sit in the stomach like a brick and would pass out with

[60] This position was also taken by the Indian Patent Office and the Intellectual Property Appellate Board.

> no therapeutic effect. The invention of methanesulfonic acid addition salt of Imatinib makes the therapeutic ingredient (that continues to be the same) highly soluble, and therefore very suitable for being administered as a drug to humans. The further invention of the beta crystalline form of Imatinib Mesylate adds to its properties and makes it an even better drug than Imatinib Mesylate. The subject product, that is, the beta crystalline form of Imatinib Mesylate, thus demonstrates a definite and tangible enhancement of efficacy over Imatinib in free base form. [Novartis' contention (SC, 2013, para 175)].

3d, as discussed in the last chapter, is an anomaly in the patent law landscape. It asks new questions of pharmaceutical compounds for the grant of a patent: what is "a new form" or "derivative" of a "known substance?" What constitutes "significant [difference] in properties with regard to efficacy?" In other words, it compels the articulation of sameness and difference between compounds in these terms.

The Supreme Court's confusion in the quotations above is evident. How could Novartis claim pharmacological sameness/equality of imatinib and its salts in the patent application, and simultaneously argue that IM-β had enhanced efficacy over imatinib and imatinib mesylate, thereby meeting the 3d test? Was Novartis' contention that imatinib mesylate and IM-β were progressively better and more effective versions of the active ingredient imatinib, a mere ploy, lacking any pharmacological basis, to obtain a patent?[61] Yet, what law finds baffling can be accommodated within interventions by Science & Technology Studies and Philosophy of Chemistry.

Research and theorization in these fields have made a decisive turn towards thinking of molecules/chemical compounds as relational entities, whose identity and properties "vary considerably depending on the form and circumstances of their associations with others" (Barry, 2005, p.56). And relatedly, thinking of chemistry as "a science of associations and relations" (*ibid*). The material spaces that chemicals inhabit, what they are partnered with, and under what conditions, all shape how chemicals

[61] The Supreme Court did note that the Gleevec package insert stated that each film coated tablet contains 100 mg Imatinib (as Mesylate), and contained no reference to IM-β. On this basis, the Court concluded that what was sold as Glivec was Imatinib Mesylate and not IM-β. This, felt the Court, showed Novartis in "poor light" because it indicated the possibility that IM-β was a sleight of hand, a naming maneuver to patent Imatinib Mesylate which had already been claimed and disclosed in the Zimmermann patent (SC, 2013, p.96). I find this persuasive. However, at this point I bracket the possibility of IM-β as a misrepresentation, and take Novartis' claims at face value, which is also what the Courts did.

behave, what they are able to do, and what they are not able to do (Barry, 2005; Hardon and Sanabria, 2017; Hayden, 2012). Thus, the intrigue for the chemist lies in how chemical protagonists act differently depending on who their fellow actors are, the "bonds" between them, the mise-en-scène and so on (Barry, 2005; Hoffman, 1995).[62] Barry writes, "For chemists, the fact that molecules have changing properties depending on their associations is an everyday reality. The molecule that is isolated and purified in the laboratory will not have the same properties as it has in the field, the city street or the body." (2005, p.57). *What is evident in such conceptualization is the capriciousness of chemical identity.* Further, Barry offers the notion of "invention of informed materials" to describe what pharmaceutical research and development entails:

> Pharmaceutical companies do not produce bare molecules – structures of carbon, hydrogen, oxygen and other elements – isolated from their environments. Rather, they produce a multitude of informed molecules, including multiple informational and material forms of the same molecule. Pharmaceutical companies do not just sell information, nor do they just sell material objects (drug molecules). The molecules produced by pharmaceutical companies are more or less purified, but they are also enhanced and enriched through laboratory practice. The molecules produced by a pharmaceutical company are already part of a rich informational material environment, even before they are consumed. This environment includes, for example, data about potency, metabolism and toxicity and information regarding the intellectual property rights associated with different molecules (Barry, 2005, p.59).

How do we understand Novartis' claims about imatinib and its salts in light of such an understanding of therapeutic compounds and the pharmaceutical enterprise?

Pyrimidine derivatives, a group of molecules with a shared scaffolding, came into being in the laboratory of Ciba-Geigy (which later became Novartis) following a long process of coaxing, tweaking, calibrating, and recalibrating (Mukherjee, 2011, p.432). These derivatives, Imatinib among them, were able to bind with and block deviant activities of specific kinases.[63] Imatinib's therapeutic abilities, however, at the time were

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[62] "Bonds" here is a literal reference to atomic bonds—chemical properties depend greatly on how atoms are connected to each other. I reproduce Barry's examples: "The properties of a hydrogen atom bound within a water molecule are different from the properties of a hydrogen atom bound within a hydrogen molecule. The properties of a water molecule are quite different at temperatures above and below 0°C. The properties of a metal vary considerably depending on whether it contains trace impurities of other elements" (Barry, 2005, p.57).

[63] A kinase is a protein enzyme that attaches phosphate groups to other proteins, thereby playing a critical role in cellular processes such as cell cycle, signaling, growth, death etc.

a potentiality, a promising hypothesis. Because no matter how proficient a compound is in the "aseptic space of a laboratory" (Bensaude-Vincent and Stengers, 1996, p.263), in order to be a pharmaceutical, a therapeutic compound, a medicine, it must "work" in the human body.[64] After all, "humanity delegates active chemical substances to act not in the aseptic space of a laboratory but in a living labyrinth whose topology varies in time, where partial and circumstantial causalities are so intertwined that they escape any a priori intelligibility" (*ibid*). This is precisely what Novartis' position was:

> The misconception regarding the innovation of Glivec is based on a patent that was granted in 1993 (not in India) for the synthesis of the molecule imatinib. This molecule, without further development, could not safely be administered to patients and represented only the first step in the process to develop Glivec as a viable treatment for cancer. We selected the mesylate salt of imatinib and then developed the beta crystal form of imatinib mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine. The research and development process (R&D), which took years, created more than just an incremental improvement, it was a breakthrough, life-saving cancer medicine (Novartis' FAQ on the India Glivec Patent Case, n.d.).

Yet, it is "impossible to establish an identity between the molecule in the laboratory and a molecule elsewhere," although what "may be possible is to establish a relation of translation" (Barry, 2005, p.57). The human body presents a particularly complex site for translation of a therapeutic molecule—considered the "valley of death" in pharmaceutical development, where "a new drug moves smoothly along in its early phase of clinical development, seemingly achieving all its scientific milestones, yet it inevitably falters and dies during an actual clinical trial" (involving human subjects; Mukherjee, 2015, p.46). Thus, pharmaceutical research and development between different sites, different forms of experiments, and different forms of existence of molecules (Barry, 2005).

Imatinib was made to move from Ciba-Geigy's freezer in Basel to be tested in vitro—in petri dishes containing CML cells and bone marrow samples from CML patients in oncologist Brian Druker's laboratory at the Oregon Health and Science University (Mukherjee, 2011, p. 35). Yet, despite Imatinib's triumphs over CML cells in

[64] I say "works," because what counts as working in the human body is itself a subject of contestation. For instance, a drug might work in the sense of being able to switch off cancer causing cells, but might also be highly toxic, adversely affecting other parts and processes in the body.

Druker's laboratory, what could be said with certainty was only that leukemia had been "cured in the dish" (*ibid*). Its status as a medicine would be actualized only if Novartis was able to successfully translate it into a form that works "in the field," i.e. in human bodies afflicted with CML—a journey riddled with false promises and uncertainties, because the space and difference between the laboratory and the human body has been conceptualized as not just ontological (Bensaude-Vincent and Stengers, 1996), but "equally economic, regulatory, and legal"[65] (Barry, 2005, p.57). This is the framework that Novartis implicitly uses when it claims that imatinib, despite being the active ingredient, could not be administered as a drug to humans. If made to enter the body, imatinib would sit in the stomach, doing nothing, therapeutically impotent, before being unceremoniously ejected. On the other hand, it argued that as compounds that could dissolve in, and be absorbed by the human body, imatinib mesylate and IM-β actually have therapeutic efficacy, and thereby demonstrate enhanced efficacy over imatinib (SC, 2013, para 175).[66] Seen thus, imatinib, imatinib mesylate, and IM-β are informational and material forms of the same molecule, "produced and recontextualized as simultaneously the same, and not the same" (Hayden, 2012, p.271). Yet, understanding the pharmaceutical enterprise in this manner present a nearly impossible dilemma for patent law: how different is different enough for a molecule's alter ego to be considered worthy of patent protection?

2. **Making (non)sense of efficacy**

> […] the enhanced efficacy… of a drug or advantageous properties in a drug stood for the same thing. [Novartis' counsel] also referred to the [IM-β] specification where enhanced efficacy was actually meant for the advantageous properties of beta form of imatinib mesylate with its more thermodynamic stability at room

[65] To illustrate, pharmaceutical companies take into account prior patents on products and process while formulating research strategies. They might, for instance, try to develop compounds just outside the legal-chemical space defined by a patent (Barry, 2005, p. 64). The size of pharmaceutical markets also impacts which therapeutic chemical entities move from the lab to clinical trials. This, in fact, was the story of Glivec. Novartis was highly reluctant to clinically develop it because it afflicts a relatively small patient population (Mukherjee, 2011; Vasella, 2003).

[66] This also explains Novartis' contention before the IPAB—that imatinib in free base form had no "known efficacy" as it was never employed as an active ingredient in a drug, and that IM-β was not an improved version of an earlier product, but a breakthrough medicine (IPAB, 2009, p. 94).

> temperature, lesser hygroscopicity, better storability and easier processability [Novartis' contention (IPAB, 2009, pp.114, 90)].
>
> […] properties such as thermodynamic stability, flow properties and hygroscopicity were important to formulate the active ingredients in capsule or the desired product form. However, these properties did not affect the actual therapeutic effectiveness of the compound [Opponents' contention (IPAB, 2009, pp.125-26)].

What questions does *efficacy* ask of a drug? And what enables a drug to be efficacious, or effective? The extracts quoted above offer a window into the conceptual sparring between Novartis and its opponents over what properties mattered for Glivec's efficacy, or to be more precise, for IM-β's enhanced efficacy over imatinib and imatinib mesylate.

I noted in the previous section that 3d introduces efficacy as a criterion to assess sameness and difference between compounds. The concept of efficacy therefore, is critical to the structural integrity of 3d. 3d makes a patent for a "new form of a known substance" contingent on changes in efficacy. Relatedly, "properties with regard to efficacy" are the only kind of difference between a "known substance" and its "derivatives" that is made to matter to patent law (Explanation to 3d). Legislation, as we know, creates meaning, with most statutes having a separate section on definitions. However, despite efficacy being its lynchpin, 3d does not define it (neither is it defined elsewhere in the Act), the task implicitly delegated to Patent Offices and Courts. And the Glivec case marked the first occasion that these forums found themselves in the role of arbiters of pharmaceutical efficacy: the question of a patent for IM-β depended on how efficacy was made legible to law, and how law made sense of efficacy. Below, I examine how Novartis and its opponents confronted each other over efficacy, each offering to the Courts and Patent Offices different ways to define efficacy, locate it, quantify and qualify it, and prove it.

2.1 *Efficacy in Pharmacology*

As the branch of biomedical sciences that studies uses, effects, and modes of action of drugs, it is hardly surprising that pharmacology was repeatedly invoked during the arguments. Key pharmacological texts such as Goodman and Gilman's "The Pharmacological Basis of Therapeutics," and the International Union of Pure and Applied

Chemistry's Glossary of Terms were used by Novartis' opponents to define efficacy in precise molecular/chemical terms (SC, 2013, para 183). What was emphasized was its difference from other properties of drugs such affinity, specificity, selectivity, and potency, thereby narrowing efficacy's field of meaning.[67]

One of the key pillars of Novartis' argument was that the increased bioavailability of IM-β was a surrogate marker of enhanced efficacy. Bioavailability refers to the rate at, and extent to which a drug enters systemic circulation unchanged, and therefore becomes available at the target site; in simpler terms, it is the fraction of a dose that reaches the target as unchanged drug, and is a subcategory of absorption. And the field of pharmacology—"common" knowledge and practice, textbooks, and published papers—was activated by all parties to both support and undermine the relationship between bioavailability and efficacy. Thus, for instance, Novartis' opponents argued that while bioavailability was "loosely related" to dosage/potency, efficacy was independent of the latter (IPAB, 2009, p.50). Or, consider the following explanation of drug action presented by them:

> […] the drug action process [can] broadly be divided into three categories – absorption, binding and response. The absorption related to the amount of active ingredient that had been absorbed by the body. However, this absorption did not automatically translate into therapeutic response. After the active ingredient was absorbed by the body, for it to act, it must bind with the relevant reception of the target cell. This binding was the crucial step that determined effect, where there were less number of receptor sites, increased availability of the active ingredient did not produce any therapeutic response. Therefore, binding and not absorption was the key to healing the disease. Subsequently, after the receptor-drug binding occurs, the subsequent response could be measured. The response was typically in the form of increase or decrease of some parameter (in this case the white blood cell count). Bioavailability was related to the absorption and not the binding stage of the drug action and therefore was not a measure of the efficacy of drug [Opponents' contention (IPAB, 2009, p.51)].

[67] Affinity refers to how tightly a drug latches onto a receptor. Affinity is a property that permits a drug to interact with a receptor, but the result of this interaction is determined by the property of intrinsic efficacy (sometimes also called intrinsic activity). Specificity and selectivity refer to the ability of a drug to distinguish between receptors and receptor sites. *Potency refers to the dose of a drug need to produce a given effect, and is usually the property of a drug most explicitly distinguished from efficacy in pharmacological literature.* See, for instance, the definition given in Dorland's Medical Dictionary quoted by the Madras High Court (I reproduce the High Court's ruling at the end of this section).

On the other hand, Novartis used pharmacology to argue the opposite: "In the field of pharmacology, any substance which had a variance of 20-25% bioavailability (either more or less) was not considered bioequivalent with the other compound under comparison and therefore could not be termed 'same substance'" (IPAB, 2009, p.14). Consequently, IM-β being 30% more bioavailable than Imatinib counted as a significant pharmacological difference between a known substance and its derivative, and ought to be considered an improvement in efficacy (*ibid*).

2.2 *Mere-ing the chemical*

> If a drug company was able to discover a substance which was metastable, i.e. not stable in ordinary condition, it was clear that it could not be developed into drugs. Therefore, its pharmaceutical efficacy would be very low since that drug would require to be manufactured in very difficult condition, stored in special conditions and even a patient would require special condition to keep the same. Thus, the pharmaceutical efficacy of a drug required it to be in a form which was stable at the room temperature [Novartis' contention (IPAB, 2009, p.114)].

> […] properties such as thermodynamic stability, flow properties and hygroscopicity were important to formulate the active ingredients in capsule or the desired product form. However, these properties did not affect the actual therapeutic effectiveness of the compound… the [IM-β] application remained silent on properties relating to efficacy. Therefore, it was safe to conclude that [Novartis'] efforts were not directed to improving the efficacy of the ingredients but merely to improve its delivery and formulation. Under the section 3(d) the efforts directed to the improvement of efficacy were recognized as patentable but not those encompassing improvement to other properties… [Opponents' contention (IPAB, 2009, pp.125-26)].

I juxtapose the above quotes to highlight different notions of "pharmacological agency" (Wilson, 2015, p.99) put forth by parties. Glivec's efficacy, argued Novartis, was not reducible to the active ingredient, the "bare molecule" imatinib (Barry, 2005, p.59). In order to for imatinib to do its job, pack its therapeutic punch, it required to be materially and informationally enriched (*ibid*). Even more significant was the thirty percent increase in IM-β's bioavailability over imatinib. Bioavailability, argued Novartis, mattered for efficacy, particularly the efficacy of anti-cancer drugs, by way of lower doses and fewer adverse effects:

> […] the study conducted on rats highlighted 30% lower bio-availability for free base of imatinib than its mesylate salt meaning thereby that 400 mg dose, the recommended startup dose, would deliver only 70% of the total 400 mg dose

> strength (280 mg). This would certainly have significant clinical implication. It was well known that in a cancer drug, bioavailability was a very important feature of the drug because if in a particular form the bioavailability of the drug could be enhanced, it was possible to give lower doses of the drug… and the lower doses would reduce the adverse effects of that drug to a very significant extent. Thus, reducing the adverse effect by reducing the dose should be taken as enhanced efficacy. [Referring to an article published in Blood (2002)] … an increase in the dose of the drug, though imatinib was generally well tolerated, induced an increase in the number of adverse events which could ultimately result in the discontinuation of the treatment [Novartis' contention (IPAB, 2009, p.30)].

Novartis therefore, was advocating an expansive notion of pharmacological agency. Such an "'anti-reductionist' or, in Stengers' terms, 'irreductionist'" notion (Hayden, 2012, p.274) of what a pharmaceutical is and how it works is also present in the debates over generic substitution of name-brand drugs. Previously, this substitution was premised on the notion that being chemically identical meant either same or largely similar therapeutic results (Carpenter and Tobbell, 2011; Hayden, 2012). Chemical identity of the active compound was what mattered, it was the essence of therapeutic efficacy: "Two hundred milligrams of ibuprofen equals two hundred milligrams of ibuprofen, whether the tablet sports a fancy brand name or a generic label; whether it is made in Mexico or Switzerland; India or the United States" (Hayden, 2012, p.276). *The same chemical identity of the active compound meant that pharmacologically, the drugs were copies of each other.*

This understanding began shifting in the 1960s, when a wedge was driven between chemical equivalence and therapeutic equivalence (Carpenter and Tobbell, 2011). At the "interstices" of regulatory, medico-scientific, and industry debates, new understandings were articulated—the "inactive" ingredients in a drug were less inactive, and more consequential than previously believed, manufacturing processes and equipment mattered, and most significantly, the bioavailability of a drug was critical to its therapeutic efficacy (Carpenter and Tobbell, 2011; Hayden, 2012). In the words of Hayden, the multinational pharmaceutical industry (among others) was saying "The chemical is not enough!" (2012, p.277). Therapeutic equivalence and clinical effectiveness now became a function of bioequivalence. A generic had to prove not just that it is chemically identical to the "pioneer" molecule, but that it took the same time to be equally available at the action site, and consequently had identical effects in the body

(Carpenter and Tobbell, 2011; Hayden, 2012).[68] *The definition of a pharmaceutical copy changed.*

Novartis' argument in the Glivec case was similar: imatinib is not enough! As is evident in the extracts quoted above, Novartis was resisting the "mere-ing" (Hayden, 2012, p. 277) by its opponents, of the superior physio-chemical properties of IM-β:

> […] *the enhanced efficacy… of a drug or advantageous properties in a drug stood for the same thing.* [Novartis' counsel] also referred to the [IM-β] specification where enhanced efficacy was actually meant for the advantageous properties of beta form of imatinib mesylate with its more thermodynamic stability at room temperature, lesser hygroscopicity, better storability and easier processability (IPAB, p.90; emphasis mine).

Being stable at room temperature, absorbing less moisture from the air, having fewer flow problems, i.e. thermodynamic stability, hygroscopicity, and flow properties respectively, made IM-β easier to store and process. And these advantageous properties, Novartis argued, were not peripheral or "ancillary to pharmaceutical action" (Wilson, 2015, p.11). Rather, making Glivec easier to manufacture, ensuring its stability as it sat on pharmacy shelves or bedside tables, etcetera were the conditions of possibility for Glivec's efficacy and its enhancement. And so was the case with bioavailability. For Novartis, not considering bioavailability's relationship to dosage and side effects lost sight of a highly important aspect of a drug's work, and of an important determinant of whether a patient would stick to the treatment. And the absence of this consideration made for an emaciated understanding of efficacy and its enhancement.

2.3 *Pinning efficacy down*

How did the Patent Offices and Courts take cognizance of these arguments? The Madras High Court combined dictionaries to arrive at a definition of efficacy:

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[68] "Drug products are considered to be pharmaceutical equivalents if they contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration. Two pharmaceutically equivalent drug products are considered to be bioequivalent when the rates and extents of bioavailability of the active ingredient in the two products are not significantly different under suitable test conditions." (Brunton *et al*., 2006, p. 7). Bioequivalence too is not an uncontested measure of therapeutic equivalence, but nevertheless is now widely accepted as the standard (Carpenter and Tobbell, 2011; Greene, 2011). It is a statistically oriented measure of sameness which compares the absorption rates of drugs in a small number of human subjects (*ibid*).

> Dorland's Medical Dictionary defines the expression "efficacy" in the field of Pharmacology as "the ability of a drug to produce the desired therapeutic effect" and "efficacy" is independent of potency of the drug. Dictionary meaning of "Therapeutic" is "healing of disease - having a good effect on the body." Going by the meaning for the word "efficacy" and "therapeutic" extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore, it is a simple exercise of, though preceded by research - we state - for any Patent applicant to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy [Madras High Court (2007, para 13)].[69]

This notion of efficacy as the ability to heal was subsequently used by the IPAB to undercut Novartis' argument that bioavailability and efficacy were synonymous, and that an increase in the former meant an increase in the latter. Understanding bioavailability in terms of dosage, the IPAB asked, "If a dose of a drug is increased to double with respect to the recommended dose, would the healing process be enhanced to double[?] We don't believe so. Thus, we are convinced that bioavailability and efficacy are generally not one and the same" (2009, p.156). The Supreme Court also came to a similar understanding of efficacy as therapeutic efficacy:

> It may be seen that the word "efficacy" is used both in the text added to the substantive provision as also in the explanation added to the provision. What is "efficacy"? Efficacy means "the ability to produce a desired or intended result" [New Oxford Dictionary of English (1998)]…. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy."… With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly…. What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy [Supreme Court (SC, 2013, para 180)].

[69] The judgment does not mention which edition of Dorland's Medical Dictionary was invoked. Neither does it cite the specific dictionary from which the meaning of therapeutic was drawn. The latter seems to have been drawn from a "general" dictionary. I also note here that since the Madras High Court did not have to rule on the patentability of IM-β, it, unlike the Supreme Court, was not required to go into greater precision about therapeutic efficacy (for instance, ascertaining its "determinants").

Since efficacy was not defined in the 2005 Act, law looked to spaces and sources outside it.[70] What we see in the extracts cited above is the Courts taking recourse to excursions into legislative history, dictionary definitions (both "specialized" and "general"), and "common sense" to pin down efficacy.[71] In this pinning down, law chose/decided to invoke legislative history and intention to read a statutory provision, and narrow a potentially vast field of meaning of efficacy to fewer "worthy" contenders ("Not all advantageous or beneficial properties are relevant."). My point here is that this interpretive technique cannot be taken for granted. Courts in India often give considerable weight to legislative intention and history, but in the US, for instance, many judges and legal commentators strongly oppose any reference to legislative intent in legal interpretation, saying that there is no such coherent intent to begin with (Solan, 2005). Further, legislative intent is no guarantor of "progressive" interpretations. Similarly, recourse to dictionary meaning is also an interpretive choice made, and is not without problems.

In these determinations, a pharmaceutical "is what it does" (Hendy, 2005, p.12), its identity wrapped up largely, if not wholly, in the things it is able to achieve, its results: as the IPAB asked, will doubling the dose double the healing? Efficacy is therapeutic efficacy, and verb/action and identity are fused. Thus, Acetaminophen relieves pain and reduces fever, Loratadine relieves allergic reactions, Imatinib blocks an oncogene, and so on (Hendy, 2005). Van der Geest *et al.* sum up the Courts' understanding when they write that a pharmaceutical's efficacy is "its ultimate and decisive life stage…. The fulfillment of [its] life['s] purpose lies in [its] effect on the well-being of the person who took [it]" (1996, p. 156).

This was merely the beginning of pinning down efficacy. Questions arose: What enables a drug to "heal a disease" or "have a good effect" on the body? What are the properties that "directly relate to" therapeutic efficacy? Thus, for instance, having ruled

[70] I am not suggesting that the boundaries between "legal meaning" and other kinds of meaning are anything but porous. My point here is simply that when something is not defined within the four corners of a legislation, stakeholders look to a range of sources, some legal (defined in other statutes or judicial precedents), and some non-legal, to establish meaning.

[71] The IPAB invoked "common sense" to rule that efficacy pertains to the curing effect of a drug, whereas properties like better shelf life, flow properties etc have no bearing on the drug's effect (2009, p. 158).

that "the test of enhanced therapeutic efficacy must be applied strictly," the Supreme Court observed that "the question needs to be considered with greater precision" (SC, 2013, para 182). However, when it was offered greater precision by the Cancer Patients Aid Association (CPAA; the party that had initiated the opposition to Novartis' application) in terms of the difference between pharmacodynamics and pharmacokinetics, it qualified it as a "rigid position," without explaining why (SC, 2013, paras 183-84).

What the Court did with all these possibilities of meaning was not define efficacy positively (i.e. with content), but rule out what did not count towards efficacy: physico-chemical properties of beta crystalline form of imatinib mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy (*ibid*, para 187).

Bioavailability's relationship to efficacy fared better in the Supreme Court's assessment, in that it was not ruled out completely as having no effect on efficacy. Even in this regard, the CPAA's invocation of pharmacodynamics and pharmacokinetics was viewed by the Court with hesitation; it appeared unwilling to rule on bioavailability on *this* ground (*ibid*, paras 188-89). Instead, based on a journal article referenced by an *amicus curae*, the Court held that a causal relationship between the two was not a general pharmaceutical principle, and that whether increased bioavailability in a given case enhanced a drug's efficacy had to be "specifically claimed and established by research data" (which Novartis had failed to do in the Glivec case) (*ibid*, para 189).[72] Thus, for the Court, physio-chemical properties having no impact on therapeutic efficacy was a general principle, true for *any* pharmaceutical, while bioavailability having impact on therapeutic efficacy was a question of fact, to be determined on the basis of evidence for

[72] The excerpt from the journal article that the Court relied on read, "It is not the intent of a bio-availability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective. *However, a determination that a drug product is bio-available is not in itself a determination of effectiveness.*" [SC, 2013, para 188; emphasis by the Court]. The article, published in 1977, is unnamed in the record of the Court's judgment.

the pharmaceutical being considered. These determinations have come to be reified as the Novartis Standard.

Novartis and its opponents "broke open the pharmaceutical object" (Hardon and Sanabria, 2017, p. 118), trying to locate Glivec's efficacy, and clashing over what properties mattered for IM-β's enhanced efficacy over Imatinib and Imatinib Mesylate. The arguments in the Glivec case both demonstrated, and gave occasion to consider, efficacy's history of notoriety as a slippery concept in pharmacology and regulatory standards. Recent work in the social sciences has further muddied the waters by arguing for a relational and diffused understanding of therapeutic efficacy. I position Novartis' and its opponents' claims within this work.

I have argued that Novartis advocated an expansive notion of efficacy, in that the active ingredient was in and of itself, necessary but far from sufficient, in ensuring that Glivec worked in CML patients. Rather, better physio-chemical properties, increased solubility, and increased bioavailability were synonyms of enhanced efficacy. In their absence, Imatinib could not work, could not effect, or at the very least, its effects would be inferior. However, in Novartis' arguments, efficacy is a function of the interiority of chemicals. Efficacy is located within the chemical, although, as discussed, where in the chemical—its structure, its form, its properties, the relationships between them—is difficult to pinpoint.

On the other hand, scholarship at the intersection of Science & Technology Studies and Anthropology has troubled the attribution of "all the pharmacological agency to the pill" (Wilson, 2015, p.99). Rather, chemical and therapeutic effects are mediated and potentialized by, *inter alia*, trial dispositifs (Gomart, 2002); experimental structures and observational methods that ask specific questions of chemicals, generate and measure effects, and link them to substances (Hendy, 2005); changes in pharmaceutical markets and regulation (Peterson, 2014); the "placebo texts and imageries" circulated by way of marketing and advertising (Degrandpre, 2006, Martin, 2006); variable rates of disease as well as the geopolitical urgency articulated by national and global health agencies (Craddock, 2017); care givers and care settings (Langlitz, 2016; Whitmarsh, 2008); and how they are "trafficked, circulated, transformed, and broken down" in and by the body (Wilson, 2015, p.102).

Pharmaceutical action and therapeutic efficacy then, are "not reducible to the chemical properties of pharmaceuticals but is articulated, elicited, and informed within a meshwork of […] spaces, relationships, expectations, and ritual practices" (Hardon and Sanabria, 2017, pp.126, 120). Therapeutic efficacy, in this rendering, hovers between different registers, from the molecular to the systemic—the body, the economy, the social, and the cultural. And this rendering would make efficacy-based pharmaceutical patents conceptually impossible.

The Glivec case, therefore, illuminates the following. Where patentability turns on efficacy, the proliferation of "sites" within the chemical where efficacy resides (or perhaps, the fuzziness of such sites) certainly favors the multinational pharmaceutical industry (proprietary companies). Efficacy is everywhere in the chemical, and small changes within it could be argued to warrant patent protection. However, the proliferation of sites outside the chemical through which efficacy is realized undermines the logic of pharmaceutical patents. Thinking of efficacy as an effect of complex networks, calls into question the logic of locating it inside a compound and giving its "inventor" the power to draw monopoly rents from it.

Chapter 3 | Of Course Packs and Copy Machines: Copyright and Unequal Geographies of Education

A day in the life of …

There is no sign board outside Rameshwari Photocopy Services (RPS)—a two-roomed, nondescript photocopy shop in the premises of the Delhi School of Economics, popularly called "D School." Inside: intermittent beeping, rhythmic whirring, and flashes of light beams emanating from copy machines as they spit out paper hot to the touch; stacks of unopened reams of copy paper; and surfaces crowded with photocopied bundles, from the slim to the intimidatingly obese, most efficiently held together by white, plastic snakes coiling their way through a series of punched holes. A photocopy shop is a curious equalizer of texts. Thinkers who disliked each other in real life rub shoulders in aesthetically bland course packs; those dead for over a hundred years lie bound with upcoming scholars making a nervous debut; and chapters from canonical texts find themselves unceremoniously bundled with notes scribbled by students who were fastidious about attending lectures.

With exams around the corner, there is a hint of panic in the shop. A photocopy *bhaiyya* can be overheard lightly scolding a student, "Ghurye *ko kyun nai xerox kiya? Woh important hai. Pass nahi hoga uske bina.*"[73] (Referring to the pioneering work of Indian sociologist G.S Ghurye, "Why haven't you photocopied him? It's important. You won't pass without it.") The other students chuckle hearing this. Dharam Pal Singh, the owner of RPS, and his employees, interact with students with camaraderie and warmth. RPS has been a part of D School since the 90s. A few steps in either direction of the shop: a tea stall, a canteen, and the Ratan Tata Library of D School. Student traffic is high in this part of the campus. They hang out here: chatting while downing steaming glasses of *Deepu bhaiyya's* chai; taking breaks from working in the library; playing carrom, with photocopy *bhaiyyas* joining them occasionally; and waiting while getting difficult, confusing, thought-provoking, boring, and almost always costly books photocopied from RPS.[74]

1. **Case overview: David versus Goliath**

In 2012, three academic presses—Oxford University Press, Cambridge University Press, and Taylor & Francis Group (hereafter, "the publishers")—filed a lawsuit in the Delhi

[73] Bhaiyya is a colloquial term for brother, which can be used to refer to older siblings, as well as unrelated young men.

[74] This vignette draws on my visit to RPS and the D School campus; my experiences, and those of my friends and peers who attended college in India; journalistic accounts of the case (Mittal and Singh, 2016; Oberoi, 2016); and a delightful essay on the 'note' economy in Indian higher education by Sumana Roy (Roy, 2020).

High Court against RPS, accusing it of egregious copyright violation.[75] Copyright is an intellectual property right that covers original literary works. Copyright vests in the author of such work, a bundle of entitlements including the exclusive right, for a period of over hundred years, to authorize the reproduction of the work.[76] In other words, an author can prevent third parties from copying their work. However, they can also assign or transfer their copyright to a third party, such as their publisher.

Graduate courses at D School, much like graduate education across the world, are taught using chapters and essays drawn from multiple books. RPS photocopies the recommended texts from disparate sources, compiles them into "course packs," and sells them to students. However, since it does all this without authorization from, and payment to them, it was, the publishers argued, guilty of copyright violation. They also accused the University of Delhi (DU) of "institutionalized copyright infringement" for allowing and enabling such violations to occur.[77]

Yet, national copyright laws subject the rights of authors or copyright owners to some limitations and exceptions in order to balance them with the rights of users (Liang, 2017). Thus, copyright may be switched off for legally defined purposes, users, and/or

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[75] The case was heard by a Single Judge (Justice Endlaw) of the Court: The Chancellor, Masters & Scholars of the University of Oxford & Others v. Rameshwari Photocopy Services & Others (accessed from http://164.100.69.66/jupload/dhc/RSE/judgement/16-09-2016/RSE16092016S24392012.pdf; hereafter "HC 2016"). The publishers appealed against Justice Endlaw's ruling before a Division Bench of the High Court: The Chancellor, Masters & Scholars of the University of Oxford & Others v. Rameshwari Photocopy Services & Others (accessed from http://164.100.69.66/jupload/dhc/PNJ/judgement/09-12-2016/PNJ09122016RFAOS812016.pdf; hereafter "DB 2016").

[76] International intellectual property law requires copyright terms to last a minimum of fifty years plus the life of the author (Article 7(1) of the Berne Convention). Beyond this, the term varies by country. For instance, the term of copyright in India is sixty years plus life of the author (Section 22, Indian Copyright Act), while in the US it is seventy years plus life of the author (for works created on or after January 1, 1978; Section 302, Title 17 of the United States Code).

[77] D School is part of the University of Delhi—one of the largest and most prominent public universities in India. DU is a network of 90 Colleges, 16 Faculties, 87 Departments, and 16 Centers. In 2017-18, there were around 650,000 students enrolled in the University across over 500 programmes at the undergraduate and graduate levels (University of Delhi Brochure 2018). The publishers contended that DU was culpable on grounds of (i) setting the syllabus that forms the basis of the course packs; (ii) granting an operating license to RPS; (iii) its library issuing books to RPS for photocopying; and (iv) its faculty recommending that students buy course packs instead of "legitimate copies" of the books. (DEL HC: paras 1, 2, 14.)

types of work. In this vein, Indian copyright law permits copying literary works for the purpose of education (Section 52(1)(i), Indian Copyright Act). The case therefore, involved questions about the specific importance of education, as well as how education happens. Further, since course packs are extensively used as a pedagogic tool in Indian universities, the DU photocopy case became a litmus test for the determination of their legal status, which likely would have repercussions for higher education in India more broadly.

Following an interim order issued by the Court, RPS was raided by the police—its employees roughed up, "infringing and pirated copies" of the publishers' books seized and catalogued—and was directed not to sell course packs while the case was being heard (HC, paras 3, 8; Oberoi, 2016). This produced a ripple effect, with dozens of photocopy shops in and around DU temporarily freezing the sale of course packs (Bhatia, 2014). As word of the publishers' action spread, University students and teachers responded on multiple fronts. A protest meeting organized at D School discussed the political economy of publishing, arguing that it is skewed in favor of publishers, and against authors and users. DU students assembled outside the publishers' stalls at the New Delhi World Book Fair, and distributed to visitors a statement "condemning the attack of corporate publishers on students" (Tankha, 2013). Students and noted scholars in India and beyond also signed a petition urging publishers to withdraw the lawsuit.[78] The publishers appealed against the ruling of the Delhi High Court in the original suit, which went against them. But after losing the appeal as well, they discontinued their legal action.

2. **Contrasting representations**

The preceding paragraphs offer two contrasting representations of educational space. In the opening vignette, RPS is very much a part of the assemblage of higher education in DU. Its machines, and the people working them, are critical allies of student life, providing services and guidance that complement classroom teaching-learning. The *bhaiyyas* of RPS embody a different kind of knowledge. Drawing on years of experience, they know which thinkers are part of canons, which materials are likely to appear in

[78] DU photocopy case: Who's afraid of copyright?; Appeal to publishers to withdraw suit filed against Delhi University. See also, Tankha (2013).

different examinations, and which notes are the most valuable. RPS therefore, helps constitute an assemblage of people, ideas, and resources that *together* materialize and shape educational experience and social life in D School. In stark contrast, the publishers' action frames RPS and DU in the idiom of law and delinquency: they become a space in which regular transgressions of copyright law occur, with RPS' owner and employees, and University students and teachers repeatedly trespassing on private property in written words.

The juxtaposition teased above forms the basis of this chapter, in which I examine the braiding of copyright law, social space, and education that animate the "DU photocopy case." Proceedings in the case went on for four years, generating a rich archive that includes case reports and allied materials like opinion pieces, industry statements, newspaper reports, and petitions. Reading this archive closely, I provide textually layered analyses and argue that wrapped up in seemingly mundane artifacts, i.e. course packs, and the technology that produces them, i.e. copy machines, are unequal and unjust geographies of education. Similar to the Glivec case, I also show that space/place and rights can only be understood in terms of each other. Students and educators in the DU photocopy case succeeded by siting copyright law (i) within the university as a distinctive place of higher education; and (ii) in India as a nation-state with distinct developmental priorities, as well as a history of judicialization of the politics of education.

3. **The stuff of education: Course packs and copy machines**

Research on education as a "deeply geographic [and] urgently political" (Nguyen *et al.*, 2017, p. 3) question has multiplied in the last decade. [79] Scholars have studied how different students navigate and experience the university as a distinctive, bounded place

[79] A significant portion of this literature focuses on schools: the centrality of school reforms to the production of racialized urban geographies (Buras, 2013), gentrification (Hankins, 2007), and to broader processes of neoliberal urban restructuring like the destruction of public housing (Pedroni, 2011; Yoon, 2011); travel to school (Wilson et al., 2010); schools as the final frontier of gentrification (Akers, 2012); mobilities of families for schooling (Waters, 2017); and student experiences in specific parts of schools like the dining hall and the playground (Holt, 2007; Pike and Colquhoun, 2012). For overviews of the literature, see Holloway and Jöns, 2012; Nguyen et al., 2017; Waters, 2016.

(Andersson *et al.*, 2012; Ploner, 2015; Turner and Manderson, 2007), and have also shown that universities are constituted by flows—of talent, knowledge, capital, and resources (Holloway and Jöns, 2012; Abelmann, 2009; Collins *et al.*, 2014). Within this growing literature, scholarship has called for attention to the materialities of education, arguing that education practice, opportunity, and experience is made possible, and shaped by the conjunction (or lack thereof) of different kinds of tangible things and spatial arrangements (Brooks and Waters, 2018; Lawn and Grosvenor, 2005). This includes the more elaborate and conspicuous "moorings" (Brooks and Waters, 2018, p.1) like transport systems and architecture of school buildings, as well as things like classroom layout and blackboards (Kalthoff and Roehl, 2011; Mulcahy, 2016). At the same time, geographers have highlighted the need for critical geographies of education that "maps inequalities and disadvantages in the education landscape" (Pini *et al.*, 2017, p.16; Nguyen *et al.*, 2017). It is my contention that the DU photocopy case brings these concerns together.

As key material forms that academic knowledge takes, books, articles, and journals are foundational to higher education infrastructures.[80] Enabling students and scholars to talk to each other, and to thinkers and writers long dead, they are a *sine qua non* for participation in global conversations and circuits of research. They are both input and output, both process and product in higher education. However, as higher education has become increasingly subsumed by market logic, various costs associated with it, including that of academic texts. have increased. Broadly classified into textbooks, monographs, and journals (Karagnis, 2018, p. 4), academic texts are costly commodities. Studies have shown, for instance, that prices of college textbooks in the US have risen seventy three percent between 2006 and 2016, at over four times the rate of inflation (Senack and Donoghue, 2016).[81] The last decade has seen an intensification of conflicts over subscription prices between major journal publishers and prestigious and relatively well-funded universities and libraries in the US, Netherlands, and Germany (this includes Harvard, the world's richest university; Schiermeier, 2017; SPARC). In February 2019,

[80] For the purposes of this paper, higher education refers to undergraduate and graduate education.

[81] Four publishers—Pearson, Cengage, Wiley, and McGraw Hill—control nearly eighty percent of the textbook market in the US

the University of California (UC) ended its 11 million dollar subscription deal with Elsevier, the world biggest publisher of scientific journals—negotiations broke down over UC's demands for a reduction in prices and more significantly, for open access to articles by UC authors (Kell, 2019).

While these costs are clearly prohibitive even in North America and Western Europe, this crisis of affordability is exacerbated in low- and middle-income countries (LMIC), where per capita incomes are significantly lower, and even elite institutions have access to only a fraction of the books and journals available to their Northern counterparts (Liang, 2018; Mizukami and Reia, 2018). In fact, contrary to expectations that books are cheaper in these countries, Liang (2010) has shown that absolute prices of books are often higher in the Global South than in the Global North, and that consumers in the South have to commit higher proportions of their income to buy books.[82] It is in this context that the DU photocopy case underlines course packs and copy machines as "stuff" critical to making education happen in India (Brooks and Waters, 2018). As authors and educators argued in their appeal to the publishers to withdraw the lawsuit:

> [W]e would like to place on record our distress at this act of the publishers, as we recognize the fact that in a country like India marked by sharp economic inequalities, it is often not possible for every student to obtain a personal copy of a book. In that situation the next best thing would have been for multiple copies of the book to be available in the library so that students are able to access these books without any difficulty. But given the constraints that libraries in India work with, they may only have a single copy of a book and in many instances, none at all. The reason we make course packs is to ensure that students have access to the most relevant portions of the book without which we would be seriously compromising their education.

Similarly, the use of copy machines to make course packs in this case, and copies of books more broadly, both reflects and responds to the problem of affordability in higher education.[83] Since its inception in the 1950s as a time and money saving office technology, the copy machine was increasingly embraced across the world as an

[82] This study was invoked by RPS, DU, students, and teachers to economically contextualize the use of course packs (HC, p.27).

[83] It is worth noting two other factors here: (i) India has seen an exponential increase in university enrollment since the nineties, due in part to affirmative action policies; (ii) yet public investment in education has either declined or remained stagnant (this is true for many countries) (Karagnis, 2018).

inexpensive mode of (re)production of documents, precisely because it enabled the forging of new reading and writing publics (Eichhorn, 2016).[84] The development and diffusion of technologies such as the copy machine, and more recently, the computer and the web, have reconfigured the geographical lives of knowledge. However, the penetration of screens—computers, tablets, e-readers—through which digital and digitized content is distributed and consumed, as well as other kinds of infrastructure like wireless access and data plans, have been stunted in LMICs (Karagnis, 2018; Liang, 2018).[85] Thus, while the Global North may now be ready to write a "requiem" for the copy machine given that a lot of work is available as electronic editions or contraband pdfs (Eichhorn, 2016), this humble technology continues to be central to education assemblages in LMICs.[86] Photocopy shops dot the urban landscape in India, clustering in particular around higher education institutions, offering students affordable alternatives to expensive books. The opening vignette of this article, though set in D School, will be familiar to any college-goer in India. As students pointed out during the DU photocopy case, "Students across the country are heavily dependent on studying from photocopies. If we have a choice we would rather study from books. But most of the books in higher education are unaffordable" (Jairath cited in Tankha, 2013; Oberoi, 2016).

Moreover, since graduate courses in D School, much like graduate education across the world, move through diverse concepts, ideas, arguments, and information drawn from multiple books, buying all of them would render an "ordinary MA" prohibitively expensive for most students (Deshpande cited in Oberoi, 2016; Tankha, 2013). This undermined the publishers' assertion that every book copied is a sale lost: students and teachers forcefully argued that the former were not potential customers at all, and absent cheap copying, were more likely to go without the requisite knowledge than bear the costs of purchasing books (HC, p. 85).

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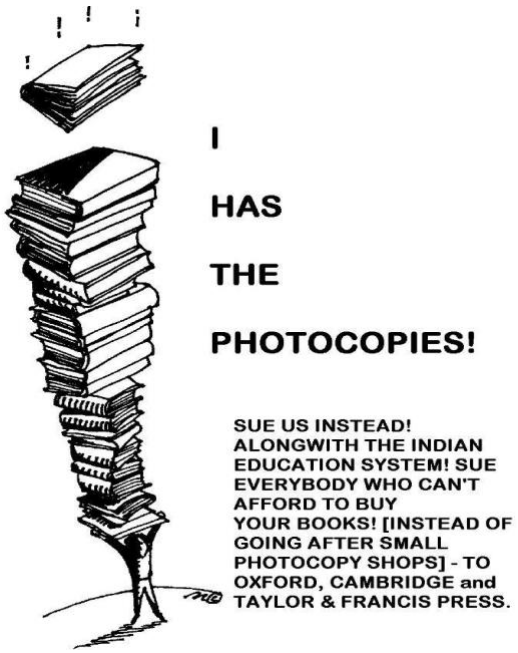
[84] For an account of how the copy machine disrupted the existing print economy, and enabled the production and reproduction of a "diverse spectrum of marginal, esoteric, quirky, and renegade texts" by allowing authors to bypass "moral censure, nationalist and capitalist mandates, and copyright laws," see Eichhorn (2016, pp. 34-37).

[85] High-income countries like US, UK, Canada etc. have better access to digital technologies at the institutional and individual levels, but such access is bound up with broader questions of economic inequality, and is not even (Karagnis, 2018).

[86] This is due in part to the uneven and relatively poor quality of access to digital technologies in these countries (Karagnis, 2018).



An image made by a student, Rashmi Singh, that was widely circulated as news of the publishers' lawsuit spread. *Source: Kriti Budhiraja*

In their edited volume, *Materialities of Schooling*, Lawn and Grosvenor caution against treating objects and technologies as frivolous and subsidiary in education. While often "overshadowed by arguments about equality or city policy or progress in education," they argue that "[t]he pencil, cheap paper, color printing […] are the tools […] which allow the grand narratives to function, for without tools and their systems they would fail" (2005, p. 7). I have shown in this section that the two are not distinct: copy machines and course packs, far from being minor or incidental to education practice in India, provide indispensable fixes to inadequacies and inequalities in disposable incomes, and institutional budgets and resources. If, as Horton and Kraftl (2014) argue, contact lenses, dental implants, and sports drinks all have the effect of extending our bodily capacities, then the copy machine, I argue, plays a vital role in extending the intellectual universe and abilities of students, institutions, and countries of more limited means. Bridging the gap between immediate capacity on the one hand, and both necessity and desire on the other, it allows spaces and people that may otherwise be either shut out of scientific and educational communities, or relegated to their margins, to participate more fully in them. In other words, arguments by students and educators in the DU photocopy case

conceptualize the copy machine and course packs as facilitating the democratization of education and knowledge.

4. **Copyright and legal geographies of knowledge**

In the previous section, I discussed the significance of academic texts to the process and quality of higher education. However, the contemporary production and circulation of such "literary works" (WIPO, 2019) is impossible without a "profound confrontation with [copyright] law" (Boon, 2013, p. 242). It is copyright law that creates the conditions of possibility for the publishers' lawsuit against RPS and DU. In this section, I show that the DU photocopy case must be situated within geographies of knowledge shaped by the interplay between law and technology. While law has locked knowledge up, technology has enabled social practices of sharing and transfer, thereby subverting the legally produced artificial scarcity of knowledge.

Copyright law says two things: first, that "[copying] is all wrong (except when it's right)" (Boon, 2010, p.5); and second, that the term copying embraces a multitude of acts including publishing, reproducing, performing, translating, and adapting a literary work (Section 14(a), Indian Copyright Act).[87] The ubiquitous and seemingly innocuous symbol © therefore, is shorthand for a bundle of legal entitlements, which is the sole preserve of the author; doing any of the specified acts without the author's permission is illegal. Authorship, writes Coombe, has the "alchemical power" (1996, p. 1358) to transform any literary work it can be made to stick to, into private property, giving the author near absolute control over it for a temporary, but long period of time (Aoki, 1996; Coombe,

[87] Meaning of Copyright.— For the purposes of this Act, "copyright" means the exclusive right subject to the provisions of this Act, to do or authorise the doing of any of the following acts in respect of a work or any substantial part thereof, namely:—
(a) in the case of a literary work—
(i) to reproduce the work in any material form including the storing of it in any medium by electronic means;
(ii) to issue copies of the work to the public not being copies already in circulation;
(iii) to perform the work in public, or communicate it to the public;
(iv) to make any cinematograph film or sound recording in respect of the work;
(v) to make any translation of the work;
(vi) to make any adaptation of the work;
(vii) to do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi). (Section 14(a), Indian Copyright Act) Thus, copyright takes the form of rights-to-exclude others from these specified uses of literary (and other) works.

1996). For instance, the term of copyright in India is sixty years plus life of the author (Section 22, Indian Copyright Act). Copyright law, therefore, sets up unauthorized photocopying as theft of an author's intellectual property. Yet, copyright in a work is usually held by its publisher, who is deemed as the "author-in-law" (Jaszi, 1994, p.34)—a fact reflected on the first page of a journal article, or the 'copyright page' of any book. Consequently, it is usually publishers as copyright owners that dictate how and at what price these works will circulate.

At the same time, the universally recognized public interest folded into education presents a dilemma for the logic of private property rights in knowledge.[88] Education's significance for individual and collective well-being has been reiterated in its theorization as a social equalizer (Mann, 1848); a means of expanding human capabilities and freedoms (Sen, 1999); critical to exercising democratic citizenship (Nussbaum, 1997); a form of human capital that increases economic growth (Becker, 1993); a public good that produces positive externalities (Levin, 1987); and a human right (Article 26, UDHR; Articles 13-14, ICESCR).[89] Consequently, education is treated in law and/or practice, as warranting the muting or turning down of copyright in most jurisdictions. It is precisely because education is considered "right" (Boon, 2010, p.5) that illegal copying in copy shops has been an "open secret" in the US (Eichhorn, 2016, p.59):

> Despite ominous signs reminding customers that copying more than 10 percent of any book is a criminal offence, there has always been a high, even unprecedented degree of tolerance for illegal activities carried out in copy shops.[90] Of course this is neither entirely surprising nor does it necessarily point to a case of negligence. After all, it hardly seems a valuable use of public resources to crack down on undergrads making photocopies of Foucault's *Discipline and Punish*….

[88] Conceptualizing knowledge as intellectual property is no less universal by virtue of international laws such as The Berne Convention for the Protection of Literary and Artistic Works (Berne) and The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). These agreements prescribe high standards of intellectual property protection, which benefit knowledge and cultural industries headquartered in the Global North (See *Introduction* and *TRIP(ping) on Medicines*).

[89] UDHR- Universal Declaration of Human Rights; ICESCR- International Covenant on Economic, Social and Cultural Rights.

[90] The designation of such copying as illegal is premised on a specific design of limits to copyright: the fair use test ("FUT"). The US is the most famous proponent of this test. Under it, copying upto ten percent of a copyrighted work for the purpose of education, weighs in favor of a finding of fair use.

> [S]uch illegal activities have also historically benefited from the tacit support of public institutions, especially colleges and universities (*ibid*, pp.59-60).

In recent decades however, the academic publishing industry has sought to do away with the older social contract of allowing texts to be copied for teaching-learning. Instead, academic presses, copyright societies, and occasionally the state, have pursued punitive action for copyright infringement against libraries, universities, and technological intermediaries in the copying ecosystem (Karagnis, 2018).[91]

Thus, while a modest photocopy shop and a public university in a developing country hardly seem like commensurate adversaries to three international publishing giants, they point to two things: 1) the attempt by the publishing industry to whittle down education's exceptionalism vis-à-vis copyright by normalizing the practice of licensing (I discuss this in the following section.); and 2) the anxious relationship between copyright ownership and technology. The latter is an anxiety rooted in the characteristics of knowledge. For knowledge is amenable to moving, being "infinitely shareable" (Kapczynski, 2010, p. 28), and being copied. It, therefore, makes for unruly private property and commodity. Moreover, the development and diffusion of technologies have heightened these characteristics, enabling knowledge and knowledge-embedded goods to overcome the friction of space-time more easily. Thus, in the absence of legal control and surveillance, the inherent characteristics of knowledge, amplified by technological innovation, pose a threat to the realization and maximization of exchange value (Prudham, 2007).

In fact, copyright law and technology are historically entangled. The Statute of Anne, 1710—the precursor to modern copyright law in common law jurisdictions—showed little concern over interests of working writers. Rather, it was the outcome of lobbying by London-based publishers and booksellers "seeking new legal weapons against down-market competition spawned by the proliferation of print technology"

[91] In 2010, software developer and access to knowledge activist Aaron Swartz entered an unlocked storage room at the Massachusetts Institute of Technology, connected his computer to the MIT network, and ran a script that enabled him to download over 4 million files from the academic database JSTOR. He was eventually arrested by MIT campus police, and even though JSTOR did not want to pursue prosecution, the US federal government charged him with multiple counts of wire fraud and computer fraud, carrying a cumulative maximum penalty of 35 years.

(Jaszi, 1994, p.). More recently, and as I have shown in the previous section, it is the copy machine that has posed a radical challenge to print economies and the restrictions on circulation of texts engendered by copyright law, particularly in higher education. Repeated police raids in Brazil and Uruguay of copy shops in and around universities for copyright infringement serve to reinforce their significance in these contexts (Karagnis, 2018, p.10).

As discussed previously, geographers have emphasized the need to identify sources of inequalities in the education landscape. They have also argued that education needs to be understood in terms of flows and mobilities: "Educational institutions are constituted by complex networks that are created and maintained by incoming and outgoing mobility of its students and staff, and by diverse flows of knowledge, information, capital and resources" (Holloway and Jöns, 2012, p.485). Scholars have discussed different kinds of mobilities—of families for education (Holdsworth, 2009); of policies to attract "talent" (Geddie, 2014); of academic institutions by way of establishing off-shore campuses (Leung and Waters, 2013); and of ideas and pedagogy (Williams, 2007)—while being cognizant that such mobilities are unevenly distributed in space. Conversely, I show that copyright law, and more specifically, its increasingly aggressive enforcement by the academic publishing industry, circumscribes the mobilities of knowledge, pinning it down in specific places. Consider, for instance, that SciHub, a massive online knowledge repository that provides free access to millions of copyrighted and paywalled scientific and academic research papers and books, was started by a graduate student in Kazakhstan, Alexandra Elbakyan, who found her research stymied because her university was unable to purchase access to relevant scientific journals (Oxenham, 2016). This is yet another illustration of technology undermining the legal imprisonment of knowledge.

Copyright law is therefore, a significant source of inequality and disadvantage in the global education landscape. Layered on other inequalities in global political economy, the dominant copyright regime increases stratification in education by ensuring that knowledge flows only to countries and institutions with deep pockets. Further, a critique of contemporary legal geographies of knowledge must be attentive to history. In international agreements like the Berne and TRIPs, as well as in the discourse of theft and

piracy that accompanies copyright law, there is an "organized forgetting" (Blomley, 2003, p.25) of inconvenient pasts including for instance, the US' refusal to recognize foreign copyrights till publishing them legally became an economically sound proposition for American publishers (Reddy and Chandrashekharan, 2017, pp.117-18); or, the siphoning from South Asia of books and materials on the subcontinent to populate libraries in US universities as part of Cold War politics (Liang, 2017, pp.53-54).

5. **Performing discursive operations: Representing education**

In this section, I examine competing representations of place and process in education in the DU photocopy case.

5.1 *Licensing, theft and "space doctors"*

As pointed out in the preceding section, recent decades have seen a decisive shift in the older social contract of allowing texts to be copied for education. Instead, the publishing industry has sought to increase rents from education by entrenching a new normal in the access to copyrighted works: the practice of licensing.

Licensing gathered momentum in the late twentieth century with the diffusion of the copy machine, which enabled copyright owners to amass profits in small payments by charging users a fee to copy a work in whole or in part (Patterson, 1992). Following lawsuits and lobbying by publishers, it is more or less the institutional norm in universities in the Global North.[92] In the DU photocopy case too, the publishers proposed licensing as the answer to balancing the "good cause" of education (DB, para 27) with the protection of reproduction as a copyright. Invoking the functioning existence of IRRO,

[92] Such normalization has not been without friction. To give a recent example, in 2008, three publishers sent a draft federal court complaint letter regarding uncontrolled digital copying to nearly a dozen institutions in the US, indicating that the complaint would be filed unless they contacted lawyers representing the AAP. While most of the institutions complied by adopting "appropriate" policies, Georgia State University refused, arguing that offering e-reserves—free downloadable course materials that include scanned pages from print textbooks—to its students constitutes fair use of copyrighted materials (*supra*, note 14). The publishers went on to sue the University for copyright infringement. The case bounced between courts, but in 2016, US District Judge Orinda Evans came up with a mathematical formula to determine that 44 out of 48 cases of alleged infringement amounted to fair use (Cambridge University Press et al v. Becker et al [2012]; McKenzie, 2018). See also, CCH Canadian Ltd. V. Law Society of Upper Canada (2004).

and noting that costs to students would increase only fractionally if DU were to obtain a license from it, they argued:

> [The] objective of this litigation is not to compel the buying of books but to compel [DU] to enter into a licensing agreement with IRRO which is now fully functional…. [A licensing regime] is the only solution to harmonize the rights of the users and those of the copyright holders….What the [publishers] are wanting is only a paltry license fee and on obtaining such license, the course packs can be made in terms of the said license…. [RPS and DU] on the one hand are infringing copyright of the [publishers] and on the other hand also depriving [them] of the IRRO license fee (DB, para 27; HC, paras 20, 14).[93]

Securing a license to copy therefore, is posited as benefitting both publishers and users. In this articulation, copyright is highly reasonable. It is, as Marcus Boon writes, "a discourse of meeting needs, providing solutions, allowing access, getting jobs done, and of course compensating all interested parties fairly" (Boon, 2013, p. 241).

Yet, this cloak of reasonableness notwithstanding, copyright transforms knowledge into private property and objects of ownership. As a corollary, the language of theft (and piracy) permeates the discourse of copyright. In the DU photocopy case, the publishers labeled students (as well as RPS) as thieves, and called the police on them when students assembled outside their stalls at the New Delhi World Book Fair to protest the lawsuit (Bhatia, 2014; Tankha, 2013).

[93] IRRO, Indian Reprographic Rights Organization, is a copyright society established under the Indian Copyright Act, and the "sole authority to issue licenses to users of copyrighted works of its members, collect royalties on behalf of rights owners and distribute them" (IRRO, 2000).

A protest meeting organized by students and teachers in D School. *Source: Devika Narayan*

Students and educators however, fought back, forcefully countering the publishers' narratives inside and outside the courtroom. Most consequentially, they formed two ad-hoc groups—Association of Students for Equitable Access to Knowledge (ASEAK) and Society for Promoting Educational Access and Knowledge (SPEAK)—which sought, and were allowed, to be represented in the hearings on the grounds that they were *de facto* significant stakeholders in the questions being raised in this case. Theirs then, was a bid to be included as "nomospheric technicians" (Delaney, 2004, p.854), or "space doctors" (Lefebvre, 1991, p.99): socio-political actors, including but not restricted to legal practitioners, who craft arguments and conjure up syllogisms and interpretive tools (such as right to education) to challenge dominant narratives and legal interpretation. In Delaney's terms, they perform vital "discursive operations" (*ibid*) that offer alternative connections and dis-connections between legal signs, material places, and embodied experiences of education (*ibid*).

5.2 *Placing instruction*

The publishers' licensing proposition was also an attempt to short circuit India's copyright law which allows reproduction for educational purposes. As the Court pointed out, the licensing solution was based on the assumption that the use of copyrighted works

in the DU photocopy case is not protected by the Copyright Act, when it was, in fact, this very question which was at issue before the law (HC, para 23).

India's educational use exception is codified in Section 52(1)(i) which provides that "reproduction of any work by a teacher or a pupil in the course of instruction" shall not constitute copyright infringement. The publishers' proposed interpretation of this provision sought to isolate RPS from the rest of D School. They argued that in order to be protected by 52(1)(i), copies had to be made *in* the classroom, and by either a student or a teacher.[94] Instruction was a discrete activity, temporally and spatially confined to classroom interactions between teachers and students: neither did it cover the use of pre-planned and prepared course packs, nor did it protect a space of reproduction that was separate from the space of instruction. The material boundaries of the classroom were sought to also signify legal boundaries: copies made within the classroom by those who rightfully belonged in education merited protection under 52(1)(i); copies made outside it by intermediaries (and interlopers) were theft of rents owed to the publishers.

The Court however, refused such uncoupling of spaces, as well as the arbitrary fragmentation of the process of education. Education, it noted, is a multi-sited process, and encompasses relationships and interactions between teachers and students, among students, and among teachers. Thus, it held that "in the course of instruction" included all activities that are "intimately and closely connected," and "incidental" to teaching (DB, para 34).

> [T]he words "in the course of instruction" within the meaning of Section 52(1)(i) would include reproduction of any work while the process of imparting instruction by the teacher and receiving instruction by the pupil continues i.e. during the entire academic session for which the pupil is under the tutelage of the teacher and that imparting and receiving of instruction is not limited to personal interface between teacher and pupil but is a process commencing from the teacher readying herself/himself for imparting instruction, setting syllabus, prescribing text books, readings and ensuring, whether by interface in classroom/tutorials or otherwise by holding tests from time to time or clarifying doubts of students, that the pupil stands instructed in what he/she has approached the teacher to learn. Similarly the words "in the course of instruction," even if the word "instruction" have to be given the same meaning as 'lecture,' have to include within their ambit the prescription of syllabus the preparation of which both the teacher and the

[94] Copies, they argued, should be said to be made in the course of instruction *only* if the need for them arose impromptu in the act of teaching, such that a request for permission from publishers would be unlikely to yield a timely response (DB, para 27).

> pupil are required to do before the lecture and the studies which the pupils are to do post lecture and so that the teachers can reproduce the work as part of the question and the pupils can answer the questions by reproducing the work, in an examination (HC, para 72).

5.3 *Academic labor*

The publishers argued that allowing course packs to be made without the payment of licensing fees would be tantamount to sanctioning the demise of the academic publishing industry: "[T]he publishers invest in publishing books and if the copyright of the publishers is not protected, it will sound a death knell for the publication business… and that even if the academicians continue to write for themselves, the publishers would not be willing to publish" (HC, paras 14, 20).

Authors and educators however, challenged the narrative that the academic publishing ecosystem is buttressed in any significant way by the publishers. Gifting signed photocopied versions of their books to the D School library, they wrote:

> We would… like to refute the claim that academic publishing is sustained by the investments made by publishers. This claim hides the fact that most academics are able to write books because they are supported by public infrastructure and money by virtue of being employed by universities or research centers. Academic writers are paid salaries and make their living from the university system, which in India is still largely government subsidized. Academic authors could not possibly make anything close to a living from the royalties that publishing houses offer them. This means in effect that the profits of academic publishing houses are under-written by tax-payers' money, and there is a huge public contribution to the profits made by academic publishing houses (Petition, 2012).

I pause here to reflect on the specificity of academic publishing. Much (though certainly not all) research and publication in higher education is by people employed within the university system. As the statement by authors and educators quoted above suggests, they draw their salaries from this system, unlike other kinds of authors who are paid commissions to write books. In the case of the latter, commissions and royalties by publishing houses are substantial sources of income. Further, publication comes at the tail end of the knowledge production process, which consists of years of formulating research questions, conducting fieldwork and experiments, and mining data, analysis, writing, as well as teaching and conversations with students and peers, none of which are funded by

publishers. Similarly, labor that ensures intellectual and ethical rigor, particularly in journals, such as substantive editing and peer review are performed by scholars, who also sit on editorial boards, all with zero/nominal payment. Academic texts are, in the words of Satish Deshpande (2016), products of the "inescapably collective" epistemological context of scholarship and higher education, which owes little to industry investment.

This is not to suggest that academic publishers offer no investment or services at all. Journal publishers and university presses fund copyediting, printing, distribution, marketing, archiving of past issues, platforms to manage digital content etc. However, the political economy of academic publishing is skewed considerably in favor of publishers. Consider, for instance, that the Author's Guild in the US notes that copyright contracts offered by university presses contain "the single most draconian, unfair clause we routinely encounter, taking all the exclusive rights to an author's work as if the press itself authored the work," often limiting authors' abilities to incorporate elements into future publications or even to use their own work in teaching. "The copyright grab," writes the Guild, "is endemic among university presses," and most academic authors, increasingly weighed down by the "publish or perish" requirement of the academic job market, rarely negotiate their contract, or know how to protect against restrictions on various uses of their work.[95] Or consider that in January 2012, a blog post by a renowned British mathematician stating that he would decline to submit or review papers for any journal published by Elsevier, triggered "the academic spring": a boycott of the publisher by over 17,500 academics over escalating costs. Journal publishers charge UK universities about 200 million pounds annually to access scientific journals, which amounts to nearly a tenth of the funds distributed to them via the government for the basic costs of running university research (Jha, 2012). Despite a recession, these charges helped academic publishers operate with profit margins of thirty five percent or more, while getting their raw materials and the work of thousands of taxpayer- and charity-funded scientists free (*ibid*).

The "journal subscription problem" seems particularly acute in the hard sciences, which are article disciplines rather than book disciplines. Even the promise of open

[95] https://www.authorsguild.org/industry-advocacy/authors-keep-your-copyrights-you-earned-them/

access has proved elusive. The funding of open access publications is largely opaque, and its costs have too often been transferred from subscriptions to submissions, from readers to authors. This has exacerbated inequity in publishing, by largely excluding young academics from developing countries who lack access to research grants that might cover submission costs (De Wit *et al.*, 2018).

I do not want to make too fine a distinction between academic and "nonacademic" literary works. All authors take public goods, draw from the knowledge commons, which includes ideas, themes, language, genre, humor and so on (Boyle, 1992); all incur "cultural debts" (Lethem, 2007). What this discussion underlines, however, is that private profits in the academic publishing industry are particularly buoyed by subsidized spaces and labors—subsidies that are often rendered invisible.

These contrasting representations of the making of academic texts also highlight an enduring conflict in copyright law: even though "authorship is the functional and moral center of the copyright system" (Ginsburg, 2017, p.61), and the discourse of copyright articulates an opposition between authors' rights and users' rights, "the interests most directly at stake in disputes over the content of copyright law usually are those of firms and individuals with capital investments in the means by which the productions of creative workers are distributed to consumers" (Jaszi, 1994, p.33). So too in the DU photocopy case, publishers were less concerned with the interests of those who produced academic texts; rather, they sought to expand their capillaries by way of licensing.[96]

5.4 *Course packs*

Course packs were the material objects at the heart of the case. For the publishers, course packs were *mere* copies that involved no transformation of, or value added to copyrighted content. Students and educators however, refused this mere-ing of course packs, and instead asserted their pedagogical specificity:

> [D School], where the course packs in question were photocopied offers Post-Graduate Degrees where reading, research, analysis and discussions in the

[96] The scientific publishing industry today is characterized by concentration and relatively high profit margins (Jha, 2012; Larivière et al., 2015). This is due in no small measure to monopolies conferred by copyright law.

> classroom play a very important role. The aim is not to award a degree at the end of the course but is to ensure growth and development of knowledge. The curriculum is set by the academic council of the University of Delhi. The teachers at the institute sit down and prescribe the relevant reading material, which would obviously include publications. Eclectic selection of reading material results at the end of this exercise. This reading material is then bound. The compilation is random and does not comprise chapters akin to a textbook. As against a textbook which is capable of being comprehended by even an outsider, the course pack would make no sense to an outsider and would appear to be irrelevant. It has a limited use. It has a meaning only if used as part of a lecture or a discussion in the course of instructions as reference material. It is not to be that one can sit at home and after reading the course pack and proclaim that one has understood the subject. It is a primer and a precursor to the discussions which transpire in the class as part of the course (DB, para 28).

These are different conceptions of course packs. Equally, they signal different ideas of meaning making and education. For the publishers, "every appearance of any part of a work anywhere should be deemed a 'copy' of it, and every single copy needs a license or excuse" (Litman, 2017, p.107). On the other hand, students and educators rejected the logic of copyright law that "silences and denies the creative work of the other" (Coombe, 1996, p.1360), refusing to abstract "acts of reading, writing, creating, sharing, and borrowing [from] the relational, networked world they occupy" (Liang, 2010, p.284).

5.5 *Right to education*

Further, ASEAK and SPEAK situated course packs within a geographically specific discourse of right to education. Post-colonial India has a history of articulating education in constitutional and legal terms. While the drafters of the Constitution debated making education a fundamental right, it was ultimately cast as a directive principle of state policy: a socio-economic goal meant to guide governance, without being actionable under law. And, even though (or perhaps, precisely because) the Indian state's commitment to, and investment in education has tended towards insipid, the higher judiciary has been repeatedly called upon to address the questions of access to education. It is in this context that the Supreme Court of India recognized a fundamental right to education, holding that absent education a dignified life was an impossibility, and hence a right to education flows directly from the "right to life" guaranteed and firewalled by Article 21 of the Constitution (Mohini Jain, 1992).

Although the right to education was ultimately whittled down to the right to education till the age of fourteen, what is significant is the articulation and hence subsequent availability of a rights discourse on education in India—one in which the higher judiciary had played a critical assertive role. Claiming education as a fundamental right of citizens, particularly one which is constitutive of the right to life, as well as a constitutional duty of the state, is "to not just make a legal claim to resources, […] but it is also to insist that, without those resources…one's equal dignity, autonomy, and participatory parity are fundamentally impaired" (Alston and Bhuta, 2005)—an argument that the SC had accepted. It was this potent history and constitutional articulation of education that was invoked in the DU photocopy case when ASEAK and SPEAK argued:

> …(ii) that the question, though relating to copyright law, has to be judged in the light of the right to access to knowledge; (iii) that the right to education finds mention in the Constitution not only as a Fundamental Right but also as a Directive Principle of State Policy; (iv) that access to education is a cherished constitutional value and includes within it access for students to books in library and right to research and to use all materials available…" (HC, para 18).

The Courts agreed, holding that "knowledge modules," as a concomitant aspect of education, called for "equitable access":

> The importance of education lies in the fact that education alone is the foundation on which a progressive and prosperous society can be built. Teaching is an essential part of education, at least in the formative years, and perhaps till post graduate level. It would be difficult for a human to educate herself without somebody: a teacher, helping. It is thus necessary, by whatever nomenclature we may call them, that development of knowledge modules, having the right content, to take care of the needs of the learner is encouraged…. So fundamental is education to a society – it warrants the promotion of equitable access to knowledge to all segments of the society, irrespective of their caste, creed and financial position. Of course, the more indigent the learner, the greater the responsibility to ensure equitable access (DB, para 30).

I argue that *this* marks a significant point of departure of the DU photocopy case from similar copyright disputes in other jurisdictions (including the US). It is not that pricing of educational materials does not pose a significant barrier to affordability and accessibility of higher education in "developed" countries. a study in the US found that textbooks are the largest out-of-pocket expenses for undergraduate students, and disproportionately impact students of color and students at community colleges. A

majority of the respondent-students in the study admitted to not buying/renting assigned textbooks on the ground of costs, even though this meant accepting the consequent risk of a lower grade (Senack, 2014). This, however, does not factor into legal decision-making in copyright disputes.

In contrast, the DU photocopy case saw the coupling of the socio-economic with the constitutional in guiding the interpretation of copyright law. The Courts' rulings are premised on, and endorse, education as a critical social/national objective, reflected in its status as a constitutional right. In other words, for the Courts, copyright law in the domain of education has a singular charge and far-reaching consequences, and this specificity, rather than being bracketed, is relevant to and significant for determining how the Indian Copyright Act should be interpreted. Thus, for instance, the Court opined that increasing the consumption of copyrighted works more generally, is not compatible with an overzealous copyright law in education:

> In the context of the argument of an adverse impact or the likelihood of the same on the market of the copyrighted work in question, taking the example of a literacy programme, assuming the whole of the copyrighted material is used to spread literacy, one cannot think of any adverse impact on the market of the copyrighted work for the simple reason the recipient of the literacy programme is not a potential customer. Similar would be the situation of a student/pupil, who would not be a potential customer to buy thirty or forty reference books relevant to the subject at hand. For purposes of reference she would visit the library. It could well be argued that by producing more citizens with greater literacy skills and earning potential, in the long run, improved education expands the market for copyrighted materials (DB, para 36).

6. **Conclusion**

In this chapter, I have argued that the DU photocopy case brings together questions of the materialities of education and sources of inequality in the global landscape of education. Mundane things like course packs and copy machines, it turns out, are critical to materializing education, particularly in low- and middle income countries like India. They simultaneously reflect and respond to uneven and unequal geographies of education. I have shown that copyright law is a critical source of disadvantage in contemporary higher education and research.

The DU photocopy case also enables an examination of the contradictions specific to the copyright question in education. Education has been conceived of as

critical to individual and collective development. This is precisely why all jurisdictions acknowledge and recognize education as an exception to, or limitation on, copyright. However, this treatment of education as a special category vis-à-vis copyright has been under attack in recent decades from the academic publishing industry, and the DU photocopy case is very much an instantiation of this general attack. At the same time, it is education that marks the departure of this case from similar ones in other jurisdictions. The sociological stakes and economic context of education in India, and the articulation in constitutional terms of a right to education, are brought to bear on the interpretation of copyright law. This then is a moment when the universality claimed for knowledge-as-commodity and intellectual property rights runs up against contending national imperatives and context.

Finally, as I have discussed before, the copyright question in education has a distinctive charge because of assumed as well as proven significance of education to personal and social/national growth. In part, it is this exceptionalism attached to education that played a key role in the arguments in the DU photocopy case. While I certainly do not reject the educational use exception to copyright, what it fails to challenge and therefore leaves in place, is the epistemological basis of intellectual property, whereby "our acts of reading, writing, creating, sharing, and borrowing" are abstracted from the relational, networked world they occupy, and posited as proprietary (Liang 2010, p.284). The university, if anything, is a space where this nature of knowledge and creative production, is starkly apparent and heightened. As Boon has argued, "there is no university without copying" since the foundational mandate of the university is "disseminative mimesis" (Boon, 2010, p.242). Copyright disputes in education therefore are particularly paradoxical, since universities are, by their very nature, steeped in copying and in copies.

Conclusion

1. **Forgotten property?**

In 2005, the same year that the Indian patent office rejected Novartis' application for a patent on IM-ß under India's newly revised patent law, the geographer Nicholas Blomley published a piece titled, "Remember property?" lamenting the decline of critical scholarly engagement with questions of property. He attributed this forgetting to the conceptual dominance within liberal societies of the Blackstonian model of property (Blomley, 2005, p.125). A discussion on Blackstone's writings on property is beyond the scope of this dissertation. However, as Blomley's article suggests, commentaries on Blackstonian property have attributed to him the canonical idea of property as exclusive dominion (Burns, 1985; Madison, 1792; Vandevelde, 1980).[97] Whether an accurate reading of Blackstone on property or not, this idea, which Rose calls the "Exclusivity Axiom" (1998, p.603), has left a strong imprint on property scholarship. The American legal philosopher, Felix Cohen, summarized it as property with the following notice attached: "To the world, keep off X unless you have my permission, which I may grant or withhold. Signed: Private Citizen. Endorsed: The State" (Cohen, 1954, p.374).

Blackstonian property has also been read as thing-centered, in that the concept of property was based on a taxonomy of things, and the nature of each thing determined its treatment at law (*ibid*, p. 331). If a thing was legally categorized as property, the owner's

[97] Blackstone's commentary on Property states: "The third absolute right, inherent in every Englishman, is that of property: which consists in the free use, enjoyment, and disposal of all his acquisitions, without any control or diminution, save only by the laws of the land … Upon this principle the great charter has declared that no freeman shall be disseised, or divested, of his freehold, or of his liberties, or free customs, but by the judgment of his peers, or by the law of the land."

Certainly, Blackstone's property was largely restricted to white male ownership, and did make concessions to "laws of the land." Similarly, Rose notes that atleast one scholar has observed that Blackstone asserted that property law recognizes claims by the destitute to some minimal assistance by those more prosperous (Rose 1998, pointing to Alschuler, 1996). Burns, on the other hand, argues that for conservative legal scholars, Blackstone was an antidote to Locke, because contrary to the latter, Blackstone had demonstrated that property was an absolute right vested in the individual by the immutable law of nature, which in turn, coincided with the will of God. Discussing Blackstone's uptake by American lawyers, he notes that Blackstone liberated them "from allegiance to the notion that property rights derived from the Lockean social compact or that they were in any sense dependent on society's recognition that the owner had made something his own by mixing his labor in it" (Miller, 1965 cited in Burns, 1985, p.67).

control over it could be deduced with certainty (*ibid*, p. 329). Yet, the notion of thingness in Blackstone's taxonomy was compromised: while land, tenements, and material goods were things, rents, annuities, franchises etc were not. A holder of property in rent held a right, not a thing, albeit it was a right issuing from a thing. This conceptual thorn was resolved by reifying such rights. Their essence was deemed to be a "thinglikeness;" they were "thinglike rights" (Pollock and Maitland cited in Vandevelde, 1980, p.332). Thus, conceptually, Blackstonian property was *physicalist* and *absolutist*, even though the practice of property law saw many exceptions to the above (Vandevelde, 1980, pp.331-32). Noting that this model's dominance likely made property boringly familiar and static, Blomley urged geographers to study the effects of this model, as well as the messier and more interesting realities of property (2005, pp.125-127).

Blomley's exhortation seems to point to a disciplinary lethargy or amnesia regarding property. Because outside geography, property had not been forgotten. For one, scholars had charted the increasing dilution of Blackstonian property by English and American courts over the course of the nineteenth century (Vandevelde, 1980). During this period, not only did property become a set of *limited* rights depending on the specifics of the dispute, it was also "dephysicalized" (*ibid*). Courts began severing the link between tangible thing and property rights, and instead held property to be "the right to value rather than to [a] thing" (*ibid*, p.333). Thus, for instance, they ruled that property in business goodwill could exist without reference to a particular location, or specific equipment, or even tangible incidents of business (*ibid*, pp.335-36). Similarly, intangibles like trademarks and trade secrets came to be protected as property (*ibid*). Vandevelde argues that through these changes "property was completely positivized" (p.366). Owning property came to mean having a bundle of rights, privileges, powers, and immunities in respect of a resource, although the precise contents of this bundle were context dependent (Hohfeld, 1913, 1917 discussed Vandevelde, 1980). In other words, there was nothing natural or self-evident about property. Some valuable interests were held to be property, others weren't. Thus, property was what the law said it was (Vandevelde, 1980, p.364).

Similarly, Macpherson (1978) wrote that property is not a thing, but "rights in or to things" (p.2): "[…] to have a property is to have a right in the sense of an enforceable

claim to some use or benefit of something, whether it is a right to a share in some common resource or an individual right in some particular things" (p.3). I note here that Macpherson's definition does not equate property exclusively with private property.

2. **Intellectual property**

More significantly however, and as I have shown in this dissertation, starting from the nineties, there emerged a burgeoning literature on intellectual property rights. I have discussed IPRs, and specifically, patents and copyright, at length in preceding chapters. The long and fragmented history of the notion of property in the products of intellectual activity is beyond the scope of this dissertation (see May and Sell, 2006).[98] So too are the justifications for governing knowledge and creativity through IPRs (May, 2000; Kapczynski, 2010). I have examined, however, the TRIPs moment and its aftermath, which kicked off an avalanche of empirical and conceptual considerations of intellectual property. Thus, even as Blomley mused that property had perhaps become less exciting because "enclosure, on this account, is complete" (2005, p.125), scholars were writing about intellectual property rights as a "second enclosure" of information and knowledge that had previously been in the public domain, and one that TRIPs sought to materialize on a global scale (Boyle, 2003; May, 2000).[99]

In the concluding chapter of my dissertation, I focus on the relationship between materiality and immateriality in property. Scholarship on intellectual property discusses it as a subset of property, mapping out the differences between traditional theories of property, based primarily on land and other tangible things, and intellectual property which deals with intangibles. As I discussed in my Introduction, knowledge is what economists call a non-rival good. Unlike material things, where physical control/possession is a deterrent to simultaneous use, knowledge can be used/enjoyed by multiple people at the same time that knowledge. When I use a physical thing, like a

[98] May and Sell (2006) argue that fifteenth century Venice was the birthplace of modern intellectual property through the first formalized patent system: "For the first time, a legal and institutional form of intellectual property rights established the ownership of knowledge and was explicitly utilized to promote innovation" (p.58).

[99] My invocation of Blomley's article is not to call him out on this blind spot but to help stage this discussion.

computer or a car, my use of it prevents someone else from using it. This forms (one of) the basis of the perceived need to protect such things as property. Unlike physical things, however, knowledge is not rendered unavailable to others, or exhausted by its use/possession. It is inherently not consumable. Rather, knowledge can be copied, is "infinitely shareable" (Kapczynski. 2010, p.28) once produced, and is relatively mobile and transmissible (Parry, 2004). Therefore, scholars argue that the rationale of protecting it as property is weak. I will return to this issue later.

I first turn my attention to the two cases.

I have already signaled that thingness is a tricky notion in property law, even though property is popularly thought of as things. Rather, only rights can be property (Hohfeld 1913, 1917 discussed in Vandevelde). In the sense that rights are not things but entitlements, property itself may be thought to be incorporeal. The emphasis on rights also makes it evident that property is relational, since rights are only held against others. Property then is "fundamentally concerned with legally defined and policed relations between individuals [and/or communities and corporations]" (Blomley, 2003, p.130). At the same time, these rights are anchored to material things. If I own private property in land, it is a material space—bounded and discrete, with coordinates—what Harvey (2004) calls "absolute space." I can identify a trespasser with regards to whether he breaches the boundaries of this physical space without my permission. Similarly, buying a car, a computer, a water bottle gives me rights—to use them, share them, sell them—that are attached to concrete things. Alternatively, if a park is designated as common property by the state/society, with everyone having the right of passage, my property right means I can walk through a defined chunk of land.

This association with materiality becomes more nebulous when it comes to intellectual property rights. Intellectual property is defined as nonphysical property that stems from the use or value of an idea (Hughes, 1988). Intellectual property rights create rights in intangibles like thoughts, information, knowledge, and feeling. However, IP law also requires that immaterial labor and creativity be fixed materially (or now, digitally)—as books, as medicines, as seeds, as films, as maps, as machines, as photographs, as fertilizers etc (Chapman and Coombe, 2020; Hunter, 2012). This mandated tangible form

is used to justify the treatment of knowledge as analogous to things to which legal protections under property are granted (Munzer, 1990). I do want to draw this out.

2.1 *Materiality and immateriality in copyright law*

Scholars have argued that just because intellectual property protects intangibles, does not mean the absence of materiality. Thus, for instance, Gordon (1989) argues that fixation and demarcation requirements function as boundaries of copyright. "Federal statutory copyright gives ownership not in vague and hazy abstractions but in "works of authorship" which are "fixed" in a "tangible medium of expression" (17 USC Section 102a) The works so fixed—whether pencil-written melodies, tape-recorded symphonies, printed books, or computer programs embedded in plastic disks—have identifiable boundaries and stable identities much as physical things do" (Gordon, 1989, p.1380). Yet, copyright is concerned with rights in texts as distinct from rights in these material objects. A book—solid, available to the senses, made of ink and paper, something that you can hold, touch, flip through, something that might give you a paper cut, the thing that you earmark or put a book mark in, the thing that sits on a bookshelf or the night stand, the thing in which you underline words, write your thoughts—is not the object of copyright. Rather, it is the literary "work" that transcends its fixing that is the object of copyright (Coombe, 1993).[100] This conception of literary property is enabled by the valorization of mental labor. Originality in mental as opposed to manual labor enables the

[100] I note here that property rights granted to authors and inventors are exceptional, when compared to an average worker who alienates their labor at a fairly low hourly wage and does not gain a property right in the products of their labor. Authors and inventors, however, are granted increasingly strong property rights in what they create. This exceptionalism relies on the intersecting discourses of possessive individualism and original genius to produce the idea of the Romantic author (Rose, 1993). Copyright is equally a creature of the printing press. "Until it became possible to distinguish between composing a poem and reciting one, or writing a book and copying one; until books could be classified by something other than incipits; how could the modern game of books and authors be played? The wish to see one's work in print (fixed forever with one's name in card files and anthologies) is different from the desire to pen lines that could never get fixed in a permanent form, might be lost forever, altered by copying, or-if truly memorable-be carried by oral transmission and assigned ultimately to "anon"" (Eisenstein, 1979, p.121). Ironically enough, it was a heavy, clanking machine that enabled the notion of intangible literary property.

author to claim not merely the physical object produced but the literary/artistic expression itself.[101]

Yet, this was not always so. In fact, early copyright was not meant to confer property rights on an author at all, but to regulate the production of copies of literary works (Aoki, 1996; Rose, 1993). The monopoly granted by the Crown to the Stationers Company in the sixteenth century prohibiting unauthorized editions of texts had more to do with sovereign suppression of heterodox and critical ideas than the assertion of private property rights (Aoki, 1996). Prior to late seventeenth century, authors did not own their text but did own their manuscripts, the physical object they made with their own hands or caused to be made. The author's claim ceased with the transfer of the manuscript. But literary property began to move away from its old basis in the material manuscript during the seventeenth century. In the words of Rose (1993), the author's words began to fly free from the page on which they were written. "Not ink and paper, but pure signs, separated from any material support, have become the protected property" (*ibid*, p.65). The following example by Gordon (1989) highlights the difference in rights in tangibles from the rights in intangibles: If a museum purchases a copyrighted painting but does not also purchase the artist's copyright interest, the museum would infringe the copyright by making posters or postcards of the painting for sale in its gift shop without the artist's permission (p.1367).

2.2 *Materiality and immateriality in patent law*

A similar trajectory is discernable with the object of patents. The discourse of patents as property rights is relatively recent, becoming increasingly common from early twentieth century. Prior to this, courts and commentators usually referred to patents as monopolies (Varadarajan, 2016) or privileges (Biagioli, 2006). The Venetian patent system, critical to the history of institutionalizing intellectual property rights, was concerned with working

[101] As Vinay Gidwani pointed out, the author is able to claim rights to the physical object only because it is the material extension of the expression that is owned. In short, it is a derivative right. What I want to stress here is that in the case of the physical object, ownership passes to me upon sale. I can do what I want with it. But ownership of the "work" by the author means I can't do a list of things which are seen as uses of the work.

technological inventions, materially understood. If one applied for a patent for a water pump, they eventually wanted to see a water pump work. They granted a patent on the basis of local utility and novelty, impact of local labor, commerce, and prices, but they did require to see a working device within a few months to a couple of years from when the patent was granted. Moreover, a water pump that worked in swampy Venice was just that, a water pump. It was not conceptualized as the embodiment of an idea (*ibid*). The questions of novelty and originality were locally assessed; imports of technologies from other countries were equally eligible for patents. However, by the late 1700s, things had changed. What the patent regime now required was a detailed description of the invention such that it could be understood and replicated by any person "skilled in the art." This came to be called the specification requirement and Biagioli has argued that it is this that "created the conditions of possibility for treating the actual material invention (the entity that used to be protected by early modern privileges) as separate from its "idea" (the entity that would become protected by patent law)" (*ibid*, p.1143) As the idea became the immaterial essence of the invention, the material invention became debased as one among many possible embodiments of the idea. Thus, the material was made subservient to the immaterial. At the same time, patent law does not allow for the patenting of ideas or principles in and of themselves. It requires "inventive ideas" to be materially fixed (Biagioli, 2006; Hunter, 2012). However, this line between the idea and its embodiment is disturbingly fuzzy. I reproduce an example by Chiang (2012, p. 1213) to highlight this point.

It is often said that the Wright brothers invented the "airplane." But of course the Wright brothers did not invent the idea of airplanes. They invented only one airplane embodiment: a single barely-flying wooden glider. A strict application of the quid pro quo principle might therefore say that the Wright brothers should be confined to replicas of their wooden glider. But this would eviscerate patent incentives, because a later pirate would change a few nuts and bolts while copying the core aerodynamic concepts. Courts therefore define the invention more abstractly, as an airplane and not a wooden glider airplane. But once we reject confining patent scope to the precise embodiment that has been disclosed, there is no obvious principled limit to this abstraction process. For example, did the Wright brothers invent:

(1) A wooden flying machine with wings and rudders?

(2) A flying machine with wings and rudders?

(3) A flying machine with wings?

(4) A flying machine?

Clearly some limit is needed, since otherwise the Wright brothers would claim all flying machines, including a future anti-gravity spaceship. As a historical matter, courts limited the Wright brothers to airplanes using wings and rudders, and did not give them all flying machines. But any limit (except to the literal embodiment) is arbitrary from the perspective of disclosure theory. After all, the Wrights did not teach how to make every airplane using wings and rudders—they taught nothing except a single wooden glider. And if they could cover some undisclosed flying machines, why not all undisclosed flying machines?

My discussion above is meant to convey the confusing relationship between materiality and immateriality that continues to be conceptually and legally troubling and unresolved in intellectual property law. I also aim to show in the Glivec and DU photocopy disputes, it was the definitions and significance of material things that were at stake, albeit in different ways.

Medicines are of course the material stuff of therapy, and the fundamental technology of biomedicine as an applied science. They are as Whyte *et al.*, (p.3) writes, "the most personal of material objects, swallowed, inserted into bodies, rubbed on by anxious mothers, used to express care and intimately empower the uncertain individual." Power is attributed to this very thingness of medicines: their therapeutic effect is attributed to properties of the thing. In the Glivec case, it was the tangible, physical stuff of Glivec—the chemical compound, its forms, its structure, its properties, and its effects—that was foregrounded in the dispute. The ways in which they were understood would determine what inventive idea would be protected as intellectual property.

In the DU photocopy case, the copy machine as a technology of reproduction is at the center of the dispute. Following Eichhorn (2016), my dissertation shows that the copy machine—embodying a history of "feathers, lint, dust, and powder" (*ibid*, p.10)—has enabled the subversion of the political economy of print, and copyright mandates, and has been a particularly significant part of the higher education infrastructure in India. In fact,

repeated police raids of copy shops in and around universities in Brazil and Uruguay for copyright infringement highlight their significance. In the same year that the publishers filed their case against RPS, thousands of students marched in San Jose, Costa Rica protesting for their right to photocopy textbooks for educational purposes in the face of high prices charged by the publishers (Moody, 2012). Further, the relatively low penetration of digital screens, means that books—as physical objects—and their copies—also as physical objects—continue to be important in middle- and low-income countries. Further, the nature of copyright protection in the case was dependent on questions in the material realm, such as: what constitutes a "substantial portion" of the copyrighted work; whether the course packs competed in the market with textbooks and so on.

3. *Property for thought*

Following this discussion, I want to suggest that instead of seeing intellectual property as a subset of property, we might consider that intellectual property is paradigmatic of property, particularly in the ways in which materiality comes to be mediated by an immateriality.[102] Due to technological and financial innovations, tangible things are increasingly circulating as information and knowledge. For instance, biotechnologies have allowed a certain degree of dissociation between an organism and the information embedded in it, triggering off the commodification of "nature as information" (Castree 2003); and it is this "bioinformation" that is considered to be the source of value in the biotechnology and pharmaceutical industries (Parry 2004). Similarly, printed information, music and money can now be presented in new artefactual forms, such as digital MP3 files, electronic cash, and e-journals, creating new markets in these commodities as well (Parry 2004). Thus in industries as varied as publishing, music, film, banking, and finance, what is of most value in a work, and hence most in need of protection, is not the physical commodity, but its transmissible content. But these very technologies have also made knowledge easier to reproduce and transmit; circuits of knowledge-as-commodity have been rendered particularly leaky. This has posed, for instance, a challenge for copyright law that has conventionally concerned itself with prohibiting the physical reproduction of works of authorship (*ibid*).

[102] I am thankful to Ajay Skaria for pushing me to elaborate on this.

Thus, what is distinctive about the contemporary information age is not simply the centrality of information, nor the development of technologies that could facilitate its transmission, but by the creation of technologies able to act on or creatively reprocess information in ways that could add value to it (Parry 2004). They act upon information in order to create from it other types of processed information that are themselves a source of productivity (*ibid*). This has also posed challenges for law. In her analysis of contemporary bioprospecting, Parry argues that laws which attempt to right historical wrongs by compensating the people and places from which biological and genetic materials have been prospected, fail to grasp the ontological status of the commodity that generates value in the biotechnological and pharmaceutical industries. Such laws providing (small sums of) compensation for the materials only till they remain in corporeal form; their translation into more informational or artefactual forms, forms that underpin massive profits in these industries, is completely overlooked by law (Parry 2006).

In a similar vein, Biagioli (2012) notes a trend in the US of patenting knowledge as such, unconnected to machines or material transformations of any sort. As an example he cites a case where a patent was granted for a method to detect deficiency of cobalamin or folate in warm blooded animals. The patent was granted not for the testing technique or the apparatus to "assay a body fluid for an elevated level of homocysteine," but only the immaterial relationship between the quantity of homocysteine and vitamin B.[103] Law, he argues, is not grafting immaterial over material, but doing away with the latter altogether.

Increasing financialization of the global economy also means that physical things associated with traditional notions of property and trespass, such as land, housing, ecological areas such as wetlands, forests etcetera are increasingly thought of, and circulating as immaterial futures contracts, securities, and credits, thereby putting tremendous, perhaps unbearable pressure on the specificity or exceptionality of intellectual property. A deeper reflection in this will be the subject of my future research.

4. *On law*

[103] Laboratory Corporation of American Holdings *v.* Metabolite Lab Incorporated (2006)

I end with a brief note on law. In this dissertation, I have focused on both the promise as well as the limitations of law when it comes to challenging the IP as the dominant regime of regulating knowledge production and exchange in contemporary society. I show that both such promise and limitations arise in part from the palpable nonsingularity of law (Christophers 2016:14). It can simultaneously refer to: (i) statutes enacted by legislatures; (ii) pronouncements of adjudicating bodies like courts and tribunals; (iii) legal concepts articulated within and beyond legal institutions; and (iv) "legal consciousness" (Silbey 2005), i.e. the ways in which legal practitioners and experts as well as other individuals and groups deploy, interpret, practice and contest legal rules and concepts (Barkan 2011). Law has multiple components which do not make up a coherent or consistent whole. Law, as Koskenniemi writes, is never a single norm but the norm and the exception, the principle and the counter-principle, the justification and the critique of hegemonic interests" (2004, p.11). It is precisely this duality of law that lends itself to not just the assertion of power by dominant stakeholders, but also its resistance by those who want to think, imagine, and act differently.

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