



**ACCESS TO KNOWLEDGE IN**

**BRAZIL**



**ACCESS TO KNOWLEDGE IN**

**BRAZIL**

**NEW RESEARCH ON**  
**INTELLECTUAL PROPERTY,**  
**INNOVATION AND**  
**DEVELOPMENT**

EDITED BY LEA SHAVER



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by the generous support of*

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# FOREWORD

JACK BALKIN

*Director, Information Society Project*

Since its founding in 1997, the Information Society Project at Yale Law School has studied the implications of the Internet and new information technologies for law and society. Our mission is to promote the values of democracy, human development and social justice in a changing world. To fulfill this mission, the ISP trains law students in a wide variety of areas relating to law and technology, provides an academic base for its fellows to engage in original research, and advocates for the public interest in domestic and international policy forums. The ISP currently supports the work of over a dozen post-doctoral fellows and an even larger number of law student fellows, as well as ISP alumni and affiliated faculty located around the globe.

The present volume is the fruit of a research initiative on Access to Knowledge begun in 2004 by Yochai Benkler, Eddan Katz, and myself. Access to Knowledge is both a social movement and an approach to international and domestic policy. In the present era of globalization, intellectual property and information and

communications technology are major determinants of wealth and power. The principle of access to knowledge argues that we best serve both human rights and economic development through policies that make knowledge, knowledge-creating tools, and knowledge-embedded goods as widely available as possible for decentralized innovation and use. Open technological standards, a balanced approach to intellectual property rights, and expansion of an open telecommunications infrastructure enable ordinary people around the world to benefit from the technological advances of the information age and allow them to generate a vibrant, participatory and democratic culture. Law plays a crucial role in securing access to knowledge, determining whether knowledge and knowledge goods are shared widely for the benefit of all, or controlled and monopolized for the benefit of a few.

Aided by a generous grant from the MacArthur Foundation, the ISP has begun a multi-year research initiative to document the key issues and challenges facing access to knowledge in various countries around the world. The present volume on access to knowledge in Brazil is the first in a new series of original scholarship, produced in partnership with colleagues from across the global South. This project exemplifies the ISP's mission—our commitment to research relevant to real-world policy concerns, to the promotion of new legal perspectives, and to academic collaboration across national and disciplinary boundaries. This volume also marks an important institutional milestone for the ISP: our first venture in the role of publisher. In many ways, this new endeavor is a logical extension of our long history of exploring, promoting and diffusing new ideas about law and technology.

I would like to personally acknowledge Yale Law School's Dean Harold Koh—as well as President Jonathan Fanton, Elspeth Revere and Kathy Im of the MacArthur Foundation—without whose

support this research could not have been completed. This work is a fitting tribute to their collective commitment to human rights, the development of knowledge and the strengthening of institutions to build a more just world.







# INTRODUCTION

LEA SHAVER

Few areas of law touch so closely upon our everyday activities—yet are so poorly understood—as intellectual property law. Consider this short quiz: Is it legal to make a photocopy of this eleven-page introduction to share with a colleague? To make a copy of the whole book? One chapter? What if your colleague lives in Canada? If you answered “I don’t know” at least once, chances are you are not alone.<sup>1</sup>

If policymakers and the public find it difficult to understand how IP rules work—respecting copyright, patents and other areas of intellectual property—it is all the more challenging to evaluate whether those rules work *well*. Even agreeing on the criteria by which to make this evaluation can be difficult, because our public discourse on IP often fails to ask the fundamental question: *What is the purpose of intellectual property?* The premise of this volume, of course, is that

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<sup>1</sup> The answer to all these questions is yes—if only because the authors, editor and publisher have released this volume under a Creative Commons license. See the copyright information page for further detail.

intellectual property law exists to promote innovation and human development. First and foremost, IP policy must be judged by how well it advances—or frustrates—these goals.

### **Intellectual property, innovation and development**

If the twentieth century's primary objects of trade were oil, steel and unskilled labor; the twenty-first century deals in information, technology and knowledge. Scholars and policymakers have used various labels to describe this new global reality: the information economy (Shapiro and Varian 1999; UNCTAD 2005), the knowledge economy (Drahos and Braithwaite 2002; Mokyr 2002; World Bank 2005) or simply the New Economy (Castells 1996; OECD 2000). Regardless of terminology, however, no area of law has a more pervasive impact than intellectual property.

IP rules determine who may use and control the most important assets of this new economy, in what ways and with whose permission. Despite this fundamental importance, intellectual property law—and particularly its relationship to innovation and economic growth—remains poorly understood by most policymakers in both developed and developing countries. It is too often assumed that greater IP protection yields greater development, or that the number of patents filed can be taken as an indicator of underlying innovation. In fact, the relationship between intellectual property, innovation and development is much more complex.

The monopolies provided by intellectual property protections certainly provide incentives for innovation, but they are not the only or necessarily the best incentives (Maskus 2000; Gallin and Scotchmer 2002). Too much protection—particularly of the wrong kinds—can retard or stifle innovation. Important trade-offs also exist between IP protection and other desirable economic outcomes such as the wide and rapid diffusion of innovations and the existence of

competitive markets. Such trade-offs also extend to outcomes less amenable to price tags; such as health, education, equality and freedom of expression. Much like tax policy, economists suggest, the optimal design of intellectual property protections requires careful balancing and tailoring (Nordhaus 1969).<sup>2</sup>

This is not, unfortunately, the approach predominantly reflected in IP law and policy today. To understand why, it is necessary to examine the concept of “rent-seeking,” first identified by economists in the 1960s and 1970s (Tullock 1967; Krueger 1974). This term refers to a situation in which a group of decision-makers holds the power to transfer wealth from one individual or group to another, particularly through the creation of legal monopolies. Under such conditions, the theory predicts, market actors will invest enormous resources in lobbying those policy-makers to create, preserve and extend such monopolies. The result is for governments to gradually expand intellectual property protections well beyond the levels that would be most beneficial to society as a whole (Mueller 1989; Landes and Posner 2003). The evolution of the international IP regime reflects the influence of these rent-seeking pressures (Sell and May 2001, Drahos and Braithewaite 2002, Grandstand 2006).

Efforts to regulate intellectual property at the international level began in 1883 with the Paris Convention for the Protection of Industrial Property. Through this treaty, the eleven member countries agreed to abstain from discrimination against the others’ nationals in

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<sup>2</sup> Although the term “intellectual property rights” dominates public discourse on patents, copyrights and trademarks, I prefer the more neutral term “intellectual property protections.” The language of “rights” connotes those entitlements that are inherent in the dignity of the human person and can never be surrendered. In contrast, intellectual property claims are time-limited and alienable, they may be bought or sold, and may be registered by corporations as well as individuals. It may be preferable, in fact, to speak of “intellectual property privileges” to underscore the original understanding of these legal monopolies on knowledge as a temporary license, established for the benefit of the public.

registration of intellectual property claims. From this humble beginning, the international IP regime has expanded to include nearly every country in the world. In addition to these original principles of non-discrimination, the treaties administered by the World Intellectual Property Organization (WIPO) now strictly define the substantive terms of intellectual property policy as well. These treaties embody an IP-maximalist logic, specifying minimum protections in many areas, while making no effort to impose any limits. The World Trade Organization's 1994 Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement) further entrenched international commitment to uniformly high levels of IP protection. According to one legal scholar, these rules reflect the misguided notion that "One size fits all. And it is 'extra large'" (Boyle 2004).

### **Access to knowledge as movement and theory**

The theory of rent-seeking does not predict that special interest lobbies will always be successful in pushing for broader monopolies. Their efforts may be opposed by voices from civil society asserting the public interest over private ones and resisted by policymakers of sound judgment. Largely sidelined in the World Trade Organization's push toward the landmark treaty on Trade Related Aspects of Intellectual Property (TRIPS Agreement), these public-interest advocates are now playing catch-up.

The first salvo in this battle came in from activists fighting to expand access to anti-retroviral medicines (ARVs) in the late 1990s. With tens of millions of HIV-positive people worldwide, no situation better illustrated the cruel ironies of an innovation system that would produce life-saving discoveries, but then fail to make them available

to most of the world.<sup>3</sup> Over time, the access to medicines activists were joined by other groups with common interests in the commons (Boyle 2003). These included farmers in the developing world concerned about rights over seeds, educators concerned about access to learning materials and even software developers disturbed by the expansion of patents to computer code. Gradually, a loose movement has emerged under the banner of “access to knowledge” (Kapczynski 2008).<sup>4</sup>

The strongest expression of this growing movement is an insurrection of sorts within the World Intellectual Property Organization. In 2004, these voices succeeded in prompting a call for a new WIPO Development Agenda that would redefine the institution’s mission to consider IP regulation as a means toward the end of equitable development, rather than as an end in itself (WO/GA/31/11 2004). As approved by the WIPO General Assembly in 2007, the 45 Adopted Recommendations under the Development Agenda specifically invoke the language of “access to knowledge” as a goal to be promoted by balanced intellectual property policies (WIPO 2007, Recommendation 19).

As used by these public-interest advocates, the concept of access to knowledge communicates something much broader than access to education and opportunities for learning. Within this

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<sup>3</sup> Approximately 40 million people worldwide are HIV-positive, including nearly 2.5 million children (UNAIDS 2006, 1). Almost two-thirds of those affected live in Sub-Saharan Africa (*ibid.*, 2). Total health care expenditures in this region—both public and private—average \$13 per person annually, excluding South Africa (World Bank 2005, 136). In contrast, governments and consumers in developed countries spend an average of \$2735 per person annually on health (*ibid.*). From a market perspective, Sub-Saharan demand for these medicines is insignificant.

<sup>4</sup> For a comprehensive listing of the demands of this movement, readers should consult the movement’s proposed *Draft Treaty on Access to Knowledge*, located at [http://www.cptech.org/a2k/a2k\\_treaty\\_may9.pdf](http://www.cptech.org/a2k/a2k_treaty_may9.pdf).

framework, the term “knowledge” is understood to broadly refer to data, information, tools, inventions, literature, scholarship, art, popular media and other expressions of human inquiry and understanding. The demand for “access” is also broadly intended—pertaining not only to the right to access these products as consumers, but also the right to participate as producers in their creation, manipulation and extension.

Thus far, scholarship on access to knowledge has primarily articulated this concept within the frame of economic development (Benkler 2005, Balkin 2006, Shaver 2008). This frame emphasizes the broad economic benefits that may be achieved by promoting greater access to knowledge. This is also the frame primarily used by the access to knowledge movement, notably in the WIPO Development Agenda. There is also great potential, however, to advance access to knowledge claims within the international human rights framework. The 1948 Universal Declaration of Human Rights states: “Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits” (UDHR, Art.27). This is precisely the claim of the access to knowledge movement.

For some, support for the access to knowledge movement reflects skepticism of capitalism’s ability to innovate the solutions humanity needs most—such as low-cost health interventions and improved seeds suited to conditions in the global South. For others, access to knowledge represents a way to unlock trapped economic value, which will inevitably lead to new and expanded business opportunities. From both perspectives, the access to knowledge movement is a reaction against “intellectual enclosure,” seeking to reclaim things that were once treated as part of the common heritage of humanity, before they were converted into private property (Boyle

2003). Access to knowledge is a demand for democratic participation, for global inclusion and for economic justice.

### **The role of research for access to knowledge**

Although a growing body of groups are now advocating for the public interest in intellectual property regulation, the amplification of these voices in the marketplace of ideas is still very skewed. Rent-seeking lobbyists have invested in spreading the doctrine of IP maximalism not only among elected officials, but also among national and international bureaucrats and even in legal scholarship. This perspective remains conventional wisdom in policymaking circles, the dominant approach against which civil society advocates for the public interest must struggle to be heard.

This battle of ideas is not merely a political one, however. The optimal design perspective suggests that rigorous empirical research is a necessary foundation for the proposal of better policies. Yet research to conceptualize and investigate the economic and legal issues confronting intellectual property reform is still at an early stage. A number of scholars are already doing important work in this field (e.g. Boyle 1997, Helfer 2003, Sell 2003, Jaffe and Lerner 2004, Reichman and Maskus 2004, Drahos 2005, Lessig 2005, Benkler 2006, Chon 2006, Sunder 2006, Dinwoodie 2008, Okediji 2008). There is a need, however, for even greater efforts to be invested and for this scholarship to become more geographically diverse. The countries of the global South have a very different history of intellectual property regulation and a very different reality of intellectual property enforcement. These contexts offer a perspective from which to identify both challenges and opportunities that might be overlooked by Northern scholars.

It is with these goals in mind that the Information Society Project at Yale Law School has established a new series of research on access to knowledge in comparative perspective. Each volume in this series features original research by scholars from the global South, analyzing access to knowledge policy challenges from a national perspective. The goal is to document both success stories and challenges in information policy design that may inform global debates and offer lessons for similarly situated countries.

### **The contributions of this volume: a preview and themes**

This first volume in the series features the contributions of an exemplary team of scholars from the Fundação Getulio Vargas Law Schools in Rio de Janeiro and São Paulo. The chapters that follow examine the themes of intellectual property, innovation and development through essays on four topics: 1) open business models, 2) exceptions and limitations to copyright, 3) open innovation in biotechnology and 4) pharmaceutical patents and access to medicines.

The volume begins with an examination of the emergence of open business models—entrepreneurial strategies that take advantage of the ease of digital reproduction to distribute free content, while earning money from the sale of related products and services. Locating the origins of open business in the open source software phenomenon, the authors suggest that the business strategies innovated there have broader economic relevance. Through a case study of the *tecnobrega* music scene in Belém, the authors illustrate how open business models can be applied to the production of cultural materials more generally. As will be seen, such models not only enable wider access to cultural materials but may also promote broader participation in creativity, a more vibrant cultural scene and expanded opportunities for small entrepreneurs. Significantly, the *tecnobrega* example demonstrates that open business models can

emerge not only around a cultural commons created through legislation and licensing, but also around a commons created by social norms alone. Greater legislative and licensing efforts are still desirable, the authors argue, to legalize these social commons and create greater room for open business to flourish.

The second chapter examines exceptions and limitations to copyright. Under the terms of the Berne Convention and TRIPS Agreement, member countries are required to enforce copyright on all works for the author's lifetime plus at least fifty years. These treaties leave room, however, for national legislatures to create exceptions and limitations to these general rules—defining specific circumstances in which users may copy, share or modify a work without obtaining the rights holder's specific consent. The first chapter examines these user rights in the Brazilian legal context. Through a review of the statutory law and two case studies, the authors illustrate how copyright can make it difficult to access scholarship and cultural materials, particularly in developing countries. Statutory exceptions and limitations can play a vital role in alleviating some of these harms and restoring balance to copyright law. The authors conclude, however, that Brazil's exceptions and limitations are currently too limited to fulfill this important role. To achieve reform, they suggest, policymakers and legal scholars must begin to approach copyright regulation as part of broader information and cultural policy, promoting the interests of the public alongside those of authors and publishers.

A third chapter analyzes Brazil's efforts to stimulate development in an emerging biotechnology sector. The immense genetic diversity of Brazil's rainforests may hold the raw materials for countless technological innovations in medicine, agriculture and beyond. The country must still determine, however, what property arrangements should govern this vast natural inheritance. Through a

case study of the ONSA Network's Genoma Program, the author demonstrates that collaborative, open approaches can be particularly beneficial to advancing innovation in developing country contexts. Drawing on the literature of the tragedy of the anticommons, the author suggests that Brazil would do well to reject calls for greater IP protection in the field of biotechnology, particularly proposals for patents on genetic sequences. Rather, an encouragement of open innovation is more likely to accelerate development in this field.

Intellectual property policy not only influences the pace of scientific innovation, but also the affordability of the products ultimately derived from that innovation. The final chapter in this volume illustrates this lesson by examining the impact of pharmaceutical patents on access to medicines in Brazil. Prior to 1996, Brazilian law did not recognize patents on pharmaceuticals. The manufacture of inexpensive generic medicines facilitated the creation of a national health system in which every Brazilian was promised a modern standard of care. Since reforming its intellectual property law to comply with TRIPS, however, Brazil has seen its public spending on medicines dramatically increase. This acute financial pressure is now pushing the nation's courts to redefine the constitutional right to health more narrowly than before. Through a careful policy analysis, the authors reveal both what mistakes were made as Brazil implemented the TRIPS Agreement, and what opportunities exist to correct them.

Taken together, these four chapters ably illustrate the importance of access to knowledge for both innovation and development. Intellectual property regulation is shown to play a crucial role in research and innovation—a role much more complex than conventional wisdom may suggest. IP law can dramatically affect the government's ability to provide public goods—ranging from health care to education. Intellectual property law also has

important implications for market competition; more open approaches may favor small entrepreneurs offering new products and services. And in the area of copyright, IP regulation has strong implications for democratic and cultural freedom, education and freedom of expression. These studies thus offer important reading for policy makers, legal scholars and the public, in Brazil and beyond.

### **Acknowledgments**

Before concluding, I would like to recognize just a few of the many people whose contributions made this book possible. As editor, it has been a true privilege to collaborate with the thoughtful and dedicated scholars of the Fundação Getulio Vargas in São Paulo and Rio de Janeiro. Particular thanks are due to Mônica Guise and Pedro Mizukami, who in addition to their roles as authors also served as my primary contacts at their respective institutions and never failed to respond enthusiastically to the call for “one more round” of edits. I am also deeply indebted to an outstanding team of colleagues who volunteered their time and talents to contribute to this project including Anupam Chander, Bruno Magrani, David Tannenbaum, Dror Ladin, Eliot Pence, Elizabeth Stark, Erin Miller, Grace Armstrong, Heloisa Griggs, Madhavi Sunder, Margot Kaminski, Maren Klawiter, Nabiha Syed, Sisule Musungu, Susan Crawford and Ted Byfield. I am particularly grateful to Jack Balkin, Eddan Katz, Laura DeNardis and Yochai Benkler for their exceptional mentorship and collegiality during my time at the Information Society Project. Special recognition is also due to my undergraduate assistant Lauren Henry, who demonstrated not only a keen eye for technical detail but also academic judgment well beyond her years in her skilled review of all four chapters. Finally, thanks is due to the artist Hilal Sami Hilal and photographer Elmo Alves, whose work graces the cover.

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# FROM FREE SOFTWARE TO FREE CULTURE: THE EMERGENCE OF OPEN BUSINESS

PEDRO NICOLETTI MIZUKAMI  
RONALDO LEMOS\*

**T**his chapter examines the emergence of open business models—systems for the production of knowledge-based goods and services that do not rely on information enclosure, but are compatible with information openness. When considering the success of the free software movement, the proliferation of new open licensing models and the

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explosion of user-generated content on the Internet—all in a landscape that continues to evolve at breakneck speed—it is hard not to be inclined toward optimism. The openness versus enclosure metaphor, probably the most important structural component of current debates on intellectual property law, can sometimes be applied in such a way that openness ends up “enclosing enclosure.”

As the Internet has become a dominant mode of accessing knowledge, potential and actual changes in the processes of cultural production, transmission and archiving have come to the foreground—along with political, social and economic consequences (Benkler 2006). It was a natural progression for the legal and economic strategies employed within the free software movement to be replicated for other knowledge-based goods. Creative Commons and Wikipedia are two notable examples of the translation of free software licensing strategies to a broader repertoire of cultural production. Reflecting this shift, we now encounter terms like *free culture*, *open content*, *open business*, *open standards*, *open licensing* and *open education resources*, that build upon the earlier concepts of *free and open source software*.

The jump from the specificity of software to the generality of information goods has been made, but the situation is still somewhat chaotic—in a good sense—with regards to terminology, the definition of political programs, academic analysis and media evaluation of these new phenomena. This chapter seeks to advance analytical understanding of this new world of open business, drawing on a case study of the Brazilian *tecnobrega* music scene, which offers a mature example of a culture industry organized around an open business model. The chapter proceeds in four parts:

**Part one** situates the concepts of “free culture” and “open business” with reference to their origins in the open-source software movement. In this presentation, the business models developed for

free software are understood as early manifestations of a different strategy of doing business based upon the distribution of free content and the sale of ancillary goods and services. This strategy, we argue, is not necessarily limited to the software industry.

**Part two** presents a case study of an open business model in the culture industry, through an examination of the *tecnobrega* music scene in the Brazilian city of Belém. The study will show how *tecnobrega* artists, producers, and distributors create and distribute their cultural works, turning substantial profits in the absence of any meaningful intellectual property enforcement.

**Part three** develops a more theoretical perspective on open business models, using the *tecnobrega* case study as a touchstone. Of particular interest is the existence—in Brazil as in many developing countries—of a “social commons” existing outside the formal legal framework, in parallel to the “legal commons” that may be established by licensing.

**Part four** analyzes the lessons learned from this case study to highlight four critical issues facing the further development of open business models in Brazil and elsewhere. These are: converting social commons into legal commons, reconciling legal diversity across multiple jurisdictions, organizing effective communities for commons management, and fostering public debates on copyright within a broader information policy framework.

## From free software to free culture

Open licensing and business models do not exist in a vacuum. They are part of a complex institutional environment that is under constant evolution, driven by regulatory, technological and economic change. It is not easy to track every development taking place in this global network of law, technology, norms, organizations,

markets and jurisdictions. A high-level framework is thus needed to provide some structure, so that we do not get lost in the complexity of the landscape. To draw a proper framework for the analysis of free software and open business in Brazil, however, we have to navigate through a sea of terms that run the risk of becoming empty buzzwords if we do not stop and critically examine them. Consequently, a closer look at these key terms—both what they mean and how they came to be—offers a useful introduction.

### **From “free software” to “open source”<sup>1</sup>**

The concept of free software, initially developed and promoted by Richard Stallman and the Free Software Foundation, grew through voluntary participation in free software projects by users and developers (Williams 2002, Moody 2001). As these free software projects accumulated, the ideological and discursive basis of the free software movement took definitive shape, achieving international status and a strong following. Around the late 1990s, the movement branched into two somewhat opposing camps with the establishment of a spin-off group, the Open Source Initiative (O’Reilly 2001). According to O’Reilly, the open source strategy was developed in response to potential misconceptions provoked by ambiguity between “free as in *gratis*” versus “free as in freedom,” as well as the perception that “free software” is strictly made by and for hackers and thus difficult for the average user to handle. A marketing campaign built around the new term “open source” sought to

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<sup>1</sup> The following discussion assumes that readers are at least somewhat familiar with free software history and the literature that has been produced so far regarding that phenomenon and the debates surrounding copyright law reform (Lessig 1998 and 1999, Benkler 2006, Boyle 1996, Lemos 2006).

position free software as a more attractive idea from a business standpoint (O'Reilly 2001, Stallman 2007b).

The open source marketing strategy was accompanied by a strong shift in emphasis from “licensing models” to “*business* models.” The Open Source Definition—indirectly based on the Free Software Definition—still emphasizes licensing characteristics to define what is and is not open source software (Open Source Definition 2006). The discourse of open source advocates, however, emphasizes this licensing structure as a platform for innovative business models, based on selling software as a service rather than as a commodity (Raymond 2000b, O'Reilly 2005, Krishnamurthy 2005). As was correctly intuited by early open source advocates, services are the best way of profiting from a product that is easily available at no or negligible cost. Instead of simply selling a package containing a GNU/Linux distribution, companies such as Red Hat provide a wide range of services including customization, technical assistance and capacity-building. Open source discourse also claimed technological superiority, based on the fact that source code in large-scale open source projects is subject to the examination of hundreds of people, all presumably on the lookout for technical flaws (Raymond 2000b).

On the following page, **Table 1** highlights the key differences between the free software and open source doctrines, based on literature that is representative of each side (Stallman 2007a, Raymond 2000a and 2000b, O'Reilly 2001).

The semantic battle between “free software” and “open source” has less resonance in Brazil than in the English-speaking world. Although the concept of freedom is as hard to define in Portuguese as it is in English, there is no ambiguity in the word *livre*—it always means “free as in freedom,” and never “free as in *gratis*.” Since the term *código aberto* (open code) is not as straightforward, Brazilians use the label *software livre* almost exclusively

**Table 1: The free software and open source doctrines**

<b>The free software doctrine</b>	<b>The open source doctrine</b>
<b>Values</b>	
Freedom	Efficiency
Solidarity	Technological superiority
<b>Goals</b>	
To guarantee the dominance of free over proprietary software, with the elimination of proprietary software as a widely adopted model.	To promote production and adoption of free software (re-named “open source software”) through recognition of its technological superiority, and of the opportunities it provides for new business models.
<b>Main Arguments</b>	
<p>Software users deserve to be granted four freedoms as a matter of moral necessity, namely: a) the freedom to run the program for any purpose; b) the freedom to study and adapt the program to personal needs; c) the freedom to redistribute copies of the program; and d) the freedom to improve the program and release the improvements to the public.</p> <p>Since proprietary software deprives users of these four liberties, it is morally questionable and thus should be avoided. Free software is a moral, not technological issue.</p> <p>Free software licenses that are built around a <i>copyleft</i> strategy—especially the GNU GPL—are preferable. <i>Copyleft</i> licensing ensures that free software remains free and is never taken away from the community of people responsible for its creation, use and distribution.</p>	<p>The open source phenomenon represents a paradigm shift from the proprietary model, forcing software providers to focus on selling services instead of products.</p> <p>Open source software is technologically superior to proprietary software because wide access to source code allows for bugs to be quickly detected and fixed.</p> <p>The open source development model provides opportunities for optimal allocation of resources as programmers self-assign to specific tasks. The elimination of formal hierarchies accelerates the process of innovation and production.</p> <p>Open source software ensures competition by eliminating monopolies and barriers to market entry, and frees consumers from vendor lock-in.</p> <p>Open source licenses should be judged by a variety of criteria. The GNU GPL is not necessarily the best choice for every project. Licenses such as the BSD and MIT licenses are legitimate alternatives.</p>

(Souza 2006). The idea of open source software, however—a technically superior product built by a community of developers selling software as a service—is alive and well in Brazil.

### **From “free culture” to “open business”**

After the derivation of *open source* from *free software* during the late 1990s, the arguments framing each of these concepts came to be so clearly defined, and acquired such strong rhetorical force, that they still provide the fundamental building blocks for discussions concerning not only software production, but also other types of cultural content. With the birth of the Creative Commons project in 2001, and the scholarly work of Larry Lessig, the concepts of “free culture” and “open business” emerged from efforts of conceptual translation.

*Free culture* refers to a loosely organized movement that seeks to apply free software strategies to the broader realm of cultural production. The free culture perspective critically examines the role of intellectual property law in providing incentives for the creation of content, as well as its impact on access to knowledge, education, freedom of speech and participation in cultural life (Lessig 2005a). Free culture establishes a normative desire for a culture that is free—as in freedom—very much the same way that free software expresses a normative desire for software that is free. Both free software and free culture carry moral and political undertones, and clearly point towards reformation of intellectual property law, while at the same time trying to offer alternatives to the current regime by means of licensing strategies that take advantage of the established system.

*Open business*, so far, can be broadly considered as a research effort to isolate and analyze business models based on more flexible approaches to intellectual property, particularly the distribution of

free or open content.<sup>2</sup> When one goes from free culture to open business, there is a shift from affirmations that software/culture *should be* free—for one reason or another, and in one way or another—to an altogether different type of discourse. The reasoning goes as follows: If we consider that there is a significant amount of content that *is already* free—either because it is licensed for open use or because intellectual property law is not enforced—how can we make money on it?

Just as early literature detected a change from the sale of packaged goods to the sale of services when jumping from proprietary to free software, the same is true when moving from proprietary to free culture. Instead of relying on the sale of what Jeff Tweedy calls “pieces of plastic” (Lessig 2005b), open business models emphasize sale of ancillary services and/or strategies that leverage the publicity generated by wide access to content to sell other goods. In both cases, the value of the market increases as collaboration in reproduction, distribution and adaptation of the freely shared goods multiplies. An example should make the notion clearer.

The English band Radiohead and the American musician Saul Williams recently devised open business models, taking for granted the fact that music nowadays is freely available online for download, and almost always before the official release date (Wired 2007, New York Magazine 2007, Pareles 2008). Instead of investing in digital rights management systems (DRM), digital fingerprinting and

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<sup>2</sup> Our focus is on business models built around giving free content to consumers, not simply the “open” business strategy of promoting collaboration between the research and development (R&D) departments of different companies (compare Anderson 2008 with Chesbrough 2006). For a fuller definition, visit the Open Business project’s site at <http://openbusiness.cc>, or by reading The Open Business Guide at [http://wiki.iccommons.org/index.php/The\\_OpenBusiness\\_Guide](http://wiki.iccommons.org/index.php/The_OpenBusiness_Guide).

litigation to enforce their copyrights, these artists decided to make digital copies of their latest albums available for free on their websites. Radiohead allowed users to choose what amount to pay for the download, including the option to pay nothing at all. Through producer Trent Reznor, Saul Williams offered a free version of his album for download, as well as a choice of three different file formats for the fixed price of five dollars. In both cases, CDs were also made available in stores— Radiohead gave the consumer the additional option of purchasing a deluxe disc box at the premium price of £40.

These musicians incorporated the predictable flow of online music on the Internet into a realistic business model. Like many business ventures, the success of these endeavors is subject to mixed reviews. Trent Reznor expressed disappointment that only 18.3% percent of downloaders in the first few months chose to pay for Saul Williams's album (Reznor 2008).<sup>3</sup> Reznor's initial disappointment, however, did not dissuade him from repeating the experiment with two future albums from the Nine Inch Nails: *Ghosts I-IV* and *The Slip*, both also released under a Creative Commons license. Indeed, he later took back his initial disappointment about the Saul Williams release, noting “[Williams] made infinitely more money from that record than he did from his other one. It increased his name value probably tenfold” (Pareles 2008, 2).<sup>4</sup>

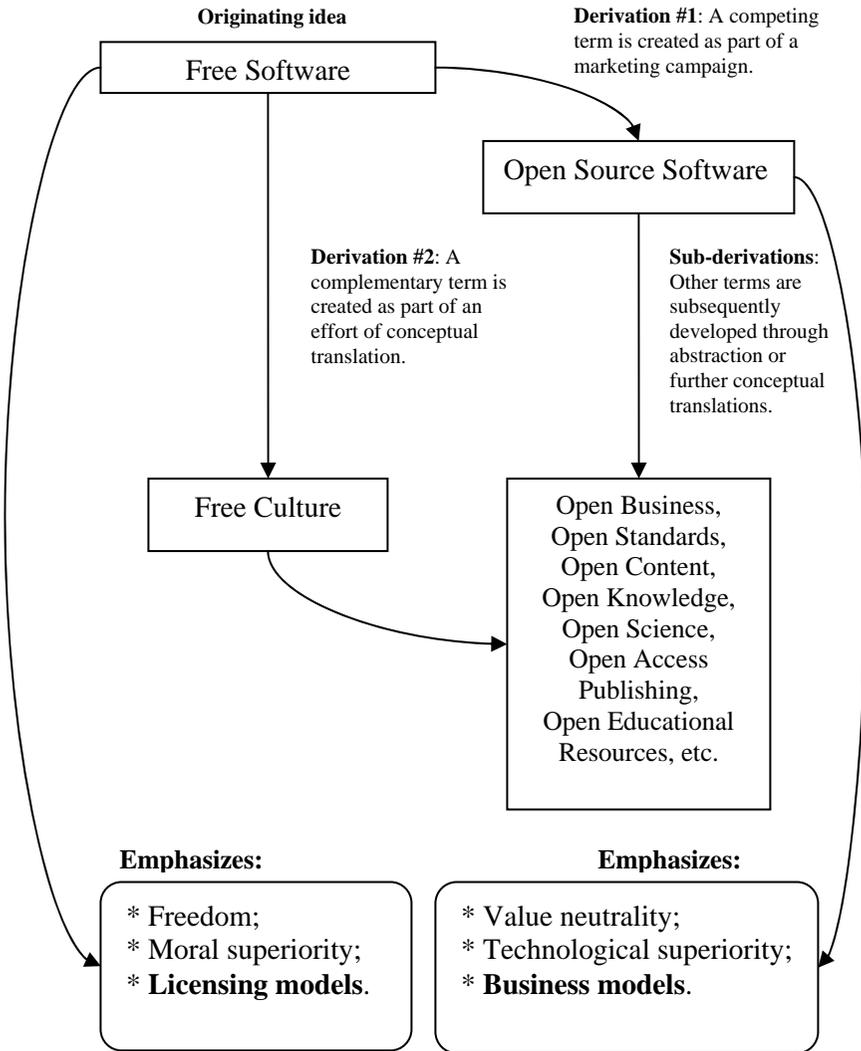
The parallel between free/open source software and free culture/open business is not a perfect one. A core tenet of open

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<sup>3</sup> In our opinion, this perspective fails to consider how many of the downloaders were only sampling the album and either decided to buy a physical CD when it came out or decided not to purchase a copy because it did not meet their expectations.

<sup>4</sup> Radiohead has not disclosed any data on the downloads and sales of their album, *In Rainbows*, but has described the project publicly as “the most positive thing we’ve done” (Radiohead.com 2008).

**Figure 1: An historical-generative map of key terms and ideas**



source discourse is the assertion that open software is of superior quality to proprietary software, thanks to the collaborative processes of production. This is not part of open business's repertoire of arguments. Unlike open source software, open business was never designed as a competitive marketing campaign and does not present claims of technological advantage linked to its production model. There is thus no sense of opposition between free culture and open business, as exists between free software and open source.

Summarizing the relationships between the key concepts introduced in this part, **Figure 1** shows an historical-generative map of key terms and ideas, beginning with free software and moving through its evolution into other words and concepts.

## Case study: the *tecnobrega* scene of Belém

Having positioned the concept of open business, we turn now to a case study of the *tecnobrega* music scene in the Brazilian city of Belém, for a fuller examination of an open business model outside the software context. The account presented here is based on in-depth, on-site, qualitative and quantitative research carried out by the Center for Technology and Society (CTS), FGV Opinião, Instituto Overmundo and the Institute for Economics Research Foundation—*Fundação Instituto de Pesquisas Econômicas* (FIPE). This research was conducted as part of the Open Business project, with support the of the International Development Research Center (IDRC).<sup>5</sup> All of the numbers mentioned below were taken from the project's final report (CTS-FGV and Overmundo 2007).

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<sup>5</sup> An English version of this study will be published at <http://openbusiness.cc>. The Portuguese version can be downloaded at <http://www.overmundo.com.br/banco/pesquisa-o-tecnobrega-de-belem-do-para-e-os-modelos-de-negocio-aberto/>.

The *tecnobrega* case study confirms that there are, in fact, multiple economic strategies for the production of information, and that the nonexclusion/market production models (Benkler 2006) can be quite lucrative. *Tecnobrega* is an extremely important force in the local economy, employing thousands of people and moving millions of dollars every month. The fact that *tecnobrega* music even exists contradicts the usual narratives of content industry actors, which insist that a strong copyright regime is necessary to incentivize the creation and distribution of knowledge goods.

The *tecnobrega* industry is a complex ecosystem involving a variety of business practices. In order to understand how all of these elements come together in a coherent business model, we first need to examine how *tecnobrega* developed from the clash of new technologies with previous popular music traditions, subverting established business practices in the process.

### **Origins of the *tecnobrega* music scene**

*Tecnobrega* is a fairly recent and extremely popular music genre, created in Belém, a city of 1.4 million people and the capital of the state of Pará, in northern Brazil. As is true of many other music genres, the *tecnobrega* sound is tremendously difficult to describe in words, much more so if the description is directed towards people unfamiliar with the parent genre of *brega music*.<sup>6</sup> *Brega*—roughly translated as *kitsch* or *tacky*—is not a precisely defined genre, but includes a variety of music styles of popular appeal, often containing romantic lyrics and themes. *Brega* music is not exclusive to the state

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<sup>6</sup> To gain a better sense of what *tecnobrega* sounds like, readers are encouraged to watch the documentary *Good Copy, Bad Copy*, available for free download at <http://www.goodcopybadcopy.net/download>.

of Pará, although *tecnobrega* is certainly a local creation, a spin-off of traditional *brega* with the addition of electronic elements.

Traditional *brega* music was a very popular genre in Belém from the 1980s up to the beginning of 2000, although it has since been eclipsed by the newer *tecnobrega* style. Up through the 1990s, the *brega* scene in Belém reflected conventional practices of the recording industry—including the usual interactions between performers, composers, producers, recording labels, publishers, and audiences. The output of production was publicized primarily through centralized channels such as radio and television.

Everything changed around 2001-2003, when a new musical style was born out of the fusion of traditional *brega* with electronic music, later dubbed *tecnobrega*. The *brega* scene of Pará then experienced a series of structural transformations, diluting the power of the intermediaries working in the production and distribution of *brega* music and turning the local processes of music production, distribution and consumption upside down. New digital technologies allowed for in-home studios and lower production costs—48% of bands now opt for self-production—while also facilitating the inclusion of electronic music elements. These transformations provoked the explosion of a new music scene in the peripheries of Belém. Within this scene an open business model was widely adopted, as musicians realized that unauthorized reproduction and informal commerce were useful promotion channels.

### **The *tecnobrega* business model**

To understand the underlying business model, it is first necessary to introduce the reader to the actors involved in *tecnobrega* production and distribution. These include artists, DJs, *aparelhagens*, party planners, mass reproducers and street vendors. The absence of

traditional music industry institutions such as recording labels, music publishers, collecting societies and record stores should be noted. They play no part in the production and distribution of *tecnobrega* music.

To see *tecnobrega* as based on a linear production chain, starting with artists and ending with consumers, is to mischaracterize the industry. These actors produce and distribute songs, performances, compilations and spectacles in a highly networked environment. Roles frequently overlap; a DJ may also work as an artist, and the line between producers and distributors is sometimes blurred. Figure 2 provides a basic map of the key relationships between the actors of the *tecnobrega* industry, though it does not attempt to fully illustrate the complexity of the scene. Solid lines indicate primary, frequent relationships. Traced lines represent secondary, less-frequent relationships. A “\$” symbol marks the flow of money from one party to another. The symbol “♪” indicates the flow of music.

### **Actors involved in *tecnobrega* production**

*Tecnobrega* production is the result of the cumulative efforts of artists, *aparelhagens* DJs and party planners.

The **artists** of the *tecnobrega* scene include both solo performers and bands. Most performers (84%) are also composers, but there are almost no individuals working exclusively as composers. Because royalties are not a feature of the *tecnobrega* business model, live performance is a necessary activity for all musicians. The absence of economic incentives for the role of full-time composer does not mean that less music gets written. Rather, the inexistence of royalties has the effect of driving musicians to perform what they compose, establishing a more immediate relationship with their audience.



In *tecnobrega*, artists are compensated primarily through payment for live performances—on average, a band receives around R\$ 2200 per concert. This income is supplemented by sales of the band's recordings at these venues—an average of 77 CDs and 53 DVDs are sold per show. To ensure a steady stream of work, artists need to work on their popularity and build a reputation. The strategy is as follows: instead of writing songs to be aggregated in packages of new material, musicians first try to make individual songs “explode” in the informal market. Only then will they build albums, assembling the proven hits alongside a few new compositions.<sup>7</sup> This means that all *tecnobrega* music must first pass through a distributed network of gatekeepers—DJs and audiences—and achieve a certain degree of success before an album is even considered.

The *aparelhagens* (*aparelhagem*, singular) are the second crucial element of the *tecnobrega* scene. Similar to Jamaican sound systems, these can best be described as large structures of electronics, combining computer hardware, sound, video and lighting technology. These machines provide all the equipment necessary for large parties in which recordings of *tecnobrega* music are played, accompanied by visual effects and live performances put out by the commanding DJs and the musicians. *Aparelhagens* interact in a highly competitive circuit, and the degree of investment in technological apparatus is an important factor when measuring prestige. Yearly launch parties exhibit each *aparelhagem's* latest hardware acquisitions and new aesthetic configuration in huge celebrations. Running an *aparelhagem* is an entrepreneurial activity, and they are typically managed by family businesses. Depending on their relative size and popularity,

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<sup>7</sup> This is not to be confused with the singles model adopted by major record labels. In that model, the single is a track selected from a pre-recorded album and popularized on the radio as a marketing tool to motivate purchase of the entire album on compact disc.

*aparelhagens* can charge from R\$ 300 to R\$ 10,000 for a single performance. The *aparelhagem* market in Belém is dominated by four major players, followed by a handful of mid-range *aparelhagens* and approximately seven hundred smaller ones. Only ten percent of *aparelhagem* owners currently manage to earn a living exclusively from this work; most have a day job as well.

A third crucial set of actors are the **party planners**; these individuals have the money and managerial know-how necessary to stage the *aparelhagem* parties. Party planners organize all logistical aspects of the events, hire the *aparelhagens*, secure venues, oversee ticket sales, pay municipal fees, sell beverages and take care of security. Party planners profit from ticket sales—usually priced in the range of R\$ 10 to R\$ 20—as well as beverages. Throwing a *tecnobrega* party can be lucrative, but also involves considerable risk. Planners spend an average of R\$ 22,000 for each large-scale event. While profits can reach around 100% of initial investment, events may not turn a profit at all due to the aggressive competition found in the party market. *Aparelhagem* parties occur at least four days a week, especially in Belém’s peripheries, but also in the countryside. The Open Business study estimates that over 4000 *tecnobrega* parties take place in the state of Pará each month. The average number of people attending the largest *aparelhagem* parties in Belém ranges from 3000 to 5000. On special occasions—such as the launch of a new DVD—party attendance can reach up to 8000. The most successful party planners often sponsor *aparelhagens*, investing money in the acquisition of new technological equipment in exchange for performances at future events.

The stars of the *aparelhagem* parties are the *aparelhagem* DJs. If bands have their lead vocalists as the main focus of audience attention, *aparelhagem* parties are led by the DJs, who often achieve celebrity status. *Aparelhagens*, much more than bands, are the central

players in the Belém *tecnobrega* scene. Only a few *tecnobrega* parties involve live performances by artists. Most are run exclusively by DJs playing recorded content against a backdrop of technological pyrotechnics.

### Actors involved in *tecnobrega* distribution

The main agents of the **distribution** circuit of recorded *tecnobrega* music are studio DJs, unauthorized reproducers and street vendors. Compilations produced by studio DJs are replicated by unauthorized reproducers and then exclusively distributed through the informal market by street vendors. *Tecnobrega* CDs are not, in other words, sold at stores.

The **studio DJs** run home recording studios and edit compilations of *tecnobrega* songs, which are one of the most important vehicles for the distribution of *tecnobrega* music. Studios serve both as production facilities and as meeting points for the key actors of the entire *tecnobrega* scene. Studio DJs thus play a role not unlike that of the master printers of early print culture—establishing networks between actors in an emerging system of cultural production.<sup>8</sup> The longest-running studio in Belém charges artists around R\$ 300 for the recording of a single song. Fees can be as low as R\$ 30, however, depending on the sophistication of the studio. An additional fee—up

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<sup>8</sup> “As the key figure around whom all arrangements revolved, the master printer himself bridged many worlds. He was responsible for obtaining money, supplies and labor, while developing complex production schedules, coping with strikes, trying to estimate book markets and lining up learned assistants. He had to keep on good terms with officials who provided protection and lucrative jobs, while cultivating and promoting talented authors and artists who might bring his firm profits or prestige. In those places where his enterprise prospered and he achieved a position of influence with fellow townsmen, his workshop became a veritable cultural center attracting local litterati and celebrated foreigners; providing both a meeting place and a message center for an expanding cosmopolitan Commonwealth of Learning” (Eisenstein 1997, 55-56).

to R\$ 50—may be charged by the most popular DJs to include a band's song in their compilations. As a general rule, however, DJs simply select what they feel are the best or most relevant songs at the time. The most famous studio DJs may also sell custom-made jingles or songs to *aparelhagens*. Less famous studio DJs will typically perform this service for free, in exchange for the publicity gained through the use of their content. Since almost half of artists self-produce their songs, the studio DJ's primary role is that of a tastemaker.

**Unauthorized reproducers** run mass reproduction facilities and distribute their goods through street vendors. These are elusive, secretive individuals, since they also deal with the unauthorized reproduction of traditional music genres. Due to this fact, personally knowing the largest mass reproducers is a sign of prestige in the *tecnobrega* scene. Studio DJs typically act as the agents to establish bridges between artists and the mass reproducers, though artists can also make their songs reach the hands of unauthorized reproducers simply by leaving a CD with a street vendor. Nevertheless, the most popular CDs sold by street vendors are compilations authored by studio DJs. These reproducers should not be considered “pirates” as far as *tecnobrega* is concerned, however, since the unauthorized reproduction and sale of songs in the *tecnobrega* scene is based on a tacit agreement and backed by social norms. Although there is no explicit, formally granted authorization to reproduce these works, the entire production and distribution network of the *tecnobrega* industry depends on this reproduction and immediate distribution, which is taken by almost every actor to be both natural and desirable.

The **street vendors** are the final step in the distribution chain, retailing *tecnobrega* music at an average price of R\$ 3.54 per CD and R\$4.17 per DVD. Bands also sell their own CDs and DVDs in venues after live performances, typically at higher prices—on average, R\$ 7.46 and R\$ 10.00, respectively. Street vendors, however,

are the source for the vast majority of *tecnobrega* purchases, selling an average of 286,208 CDs and 178,708 DVDs each month in Belém alone. In theory, street vendors could reproduce discs themselves. In practice, however, only 16% do so, while 80% rely on supplies from mass reproducers. A handful of production facilities manufacture most of the CDs and DVDs sold on the streets of Belém. Street vendors often sell discs without correct documentation; thus *tecnobrega* artists frequently work personal references into their music to ensure attribution of their works.

Emerging artists understand street vendors as allies in their promotion efforts. According to our research, 66% of the interviewed artists encouraged—to a greater or lesser degree—the sale of their works through street vendors, while only 34% actively discouraged it. Similarly, 59% of the artists said they considered street vendors to be beneficial to their careers and 32% considered them detrimental, with the remaining interviewees taking a neutral stance. When musicians achieve greater popularity and start to press their own CDs and DVDs, they begin to look at unauthorized reproducers and street vendors in a more ambiguous light. Bands sometimes adopt an anti-piracy discourse with respect to albums, but continue to make use of unauthorized reproducers and street vendors in order to push individual songs forward. This is the way the *tecnobrega* scene operates—for beginning *and* established acts.

## Learning from the social commons

One of the most striking features of the *tecnobrega* business model is how informal it is. This is apparent both in the illegal—but tacitly approved—sale of mass reproduced copies by street vendors, as well as in the informal nature of business relations and general absence of written contracts. *Tecnobrega* is an example of a business

model based upon *norms* rather than *law*. Intellectual property rights play absolutely no role in providing incentives for content creation. Instead, the *absence* of players seeking effective enforcement of intellectual property rights and the *absence* of a strong copyright culture are the dominant factors of an environment in which a new, different cultural industry has been able to evolve.

### **Institutional ecology: legal and social commons**

We assume, following Yochai Benkler, that the current transformations caused by the Internet and digital technology—with the emergence of a networked information economy and the explosion of commons-based peer production—offer opportunities for positive economic and social change. These opportunities, however, may be undermined if the wrong choices are made (Benkler 2006). Benkler’s framework puts heavy emphasis on the role of social practices in the shaping of the institutional ecology, particularly as a source of openness (*ibid.* at 394-95). We also make use of the complementary notions of the legal commons and social commons developed by Ronaldo Lemos (2006) to handle a set of problematic issues that are particularly present in developing countries.

“Legal commons,” are commons established by law, or with support in the legal system. An example is the case of open content licensing. By voluntary action, and aware of the legal implications, content producers license their works under terms that will allow for the building and management of a commons. “Social commons,” on the other hand, are created when historical and social circumstances “generate a situation *in which the very idea of intellectual property becomes inapplicable, irrelevant, unfamiliar or unenforceable*” (Lemos 2006, 34).

A social commons, by definition, is not generated by intellectual property regimes, such as copyright law. Social commons

depend, instead, on tensions between “legality” and “illegality” when intellectual property enforcement efforts are overwhelmed by deeper structural problems. A good example is the incompatibility between the conventional business models of the music industry and economic realities in Brazil—where legal albums are marketed at a price well above what most of the population of the country can afford (Lemos 2006, 34). In situations where intellectual property enforcement is either impossible or counterproductive, people frequently *behave* towards protected content *as if it were part of a commons*, and *as if intellectual property regimes did not exist, or simply did not matter*. The concept of a social commons incorporates the actual relations people establish with content and information—both as producers and consumers—into a theoretical model that does not turn a blind eye to the production of content in zones outside the effective domain of intellectual property regimes.

### **Lessons of the social commons**

What, then, can we learn from the social commons? The most obvious lesson is that adaptation to adverse conditions can lead to innovation. The collapse of intellectual property enforcement in the music industry of Pará did not lead to a decline in music production, nor even to the end of music as a for-profit endeavor. Rather, entrepreneurial initiatives emerged with new business models that take advantage of the social commons.

Conventional intellectual property thought assumes that legal protection is necessary for content production and for the existence of a healthy cultural market. According to this argument, the law must provide incentives for money to be invested in the production, distribution and upkeep of content and society is better off suffering some restrictions on access in order for a thriving culture to exist.

Production models based on both legal and social commons challenge this traditional justification for intellectual property.

Legal commons approaches—such as open content licensing—prove that content can be produced outside the realm of all-rights-reserved copyright and that creators are willing to work in a system of that operates on freedom of access, non-exclusion and unfettered creativity. Social commons-based approaches, in turn—such as the *tecnobrega* business model—prove that cultural production, and even a mature industry, can emerge in spaces where intellectual property protection is either *non-existent*, *irrelevant* or *unenforceable*.

These legal vacuums are a problem that is most visible in developing countries, but they can and do exist in developed countries as well. An example of a social commons born in developed countries is that of the mix tape markets in New York and London. Thus, social commons should not be considered as a phenomenon observed only in global *peripheries*; it is also applicable to the *center*. Indeed, the center/periphery distinction can also be applied within the center itself; the center has its own peripheries.

This also applies to the peripheries of the global Internet community. Away from the centers of industrial distribution, where intellectual property is simply not a force to be reckoned with, communities of file sharers behave towards the material they share as though it were part of a commons. This does not mean that there is no wealth to be captured from file sharing; both legal and social commons strategies could be pursued to facilitate new business models. A legal commons approach would be to establish a system based on compulsory or voluntary licenses, as has already been proposed (Netanel 2003; Shih Ray Ku 2003; von Lohmann 2004; Fisher 2004, 199-258). A social commons approach would be to simply face reality and offer consumers the option to pay *something*, as Radiohead, Saul Williams and Trent Reznor did, taking advantage of

the value created by openness in terms of concert attendance, sale of merchandise, and increased popularity.

## Four challenges facing open business

The free software phenomenon is now well-studied, but researchers have only begun to turn attention to how law and policy can encourage open cultural production more generally. As Yochai Benkler writes, the correct question to be asked is “*Are we leaving enough institutional space for the social-economic practices of the networked information economy to emerge?*” (2006, 393). Looking more narrowly at licensing for open business models, we could ask:

*How can free/open licensing models for intellectual property be translated into public policy, legal doctrine, activism, and research in a variety of disciplines, so as to construct institutional spaces within which creators, consumers and entrepreneurs may find safe room for social action?*

“Room for social action,” in this understanding, refers to room for collaboration in the production of information—which can be valuable in and of itself or as a building block to other activities, including entrepreneurial ones. This question can be used to focus research efforts and convert them into public and community policy, legal doctrine and further research agendas. It can also be used as a starting point for thinking about free software and open business in a more strategic and focused way, emphasizing the creation and defense of a healthy institutional environment.

A preliminary sketch of prominent challenges for the establishment of a receptive institutional environment for open

business models in Brazil can be made around four main issues.<sup>9</sup> The four interrelated challenges identified below are intended to provide a starting point for policy analysis and research. They relate to: **1)** bridging the legal and social commons, **2)** organizing communities of users/producers of information **3)** reconciling diversity in legal regimes and multiple jurisdictions and **4)** educating public opinion for the purposes of reforming information policy.

### **Solving the social commons conundrum**

While functional business models can and do emerge from social commons, this should not be taken as an excuse for a “divided kingdom” approach to intellectual property law. Rather, opportunities for convergence between the social and legal commons should be actively pursued. Legalization of social commons can provide greater certainty to producers and users, and a better business climate for entrepreneurs.

The *tecnobrega* business model is, above all, a viable business model; yet its informality comes with a price. Some *tecnobrega* actors are held back by the same informality that gave birth to their success. Such is the case of the *aparelhagens*, which are financially dependent on party planners. Only a handful of *aparelhagem* enterprises are formally constituted as a corporation, and thus able to pursue a wider range of financing options. In addition, any situation involving lack of certainty in legal status is a potential source of financial and

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<sup>9</sup> These issues do not cover the entire range of problems. Two basic structural problems of Brazilian society are not covered here: unequal access to information processing tools and online connectivity (the digital divide problem), and especially, insufficient access to education. These related problems are deeply connected to the issues examined in this report, but are also part of a much broader context, which cannot be examined with proper depth here. Suffice it to say that there is more to be done in the area of information policy than can be accomplished through intellectual property reform alone.

personal risk. Are these businesses operating legally or illegally, after all? Tacit permission to reproduce and distribute *tecnobrega* music might not be a sufficient defense, given that Brazilian copyright law states that these acts demand “previous and express authorization” from rightsholders (Lei 9.610/98, Article 29). It may be possible to find legal arguments outside the copyright statute to support the legality of these activities. If a *tecnobrega* artist decided to sue, however, the outcome would be very difficult to predict. The fact that Brazilian law also designates every act of copyright infringement as a criminal offense further raises the risks for actors in the *tecnobrega* industry.

The social commons of the *tecnobrega* scene does not need to be a social commons—there is no reason not to pursue legalization. The problem, however, is exactly how to translate such opportunities for convergence into public policy? Creative Commons licensing could be a good instrument to move some of the actors of the *tecnobrega* production and distribution networks into the security of legality. This is, of course, easier said than done. The *tecnobrega* culture is now an established one, and intellectual property law is certainly not a popular topic. To expect judges and legislators to become aware of the *tecnobrega* phenomenon, and translate experiences such as this into legal rules is probably also wishful thinking at the present moment. Nonetheless, it is not an unreachable goal.

### **Reconciling legal diversity and multiple jurisdictions**

Licensing provides a way to give legal structure to a social commons, without requiring wholesale shifts in intellectual property law. Since open content licenses are intended to create platforms for collective international collaboration, however, licenses must be written with a global community in mind. This entails challenges of both textual and legal translation. Open content licensing is very

jurisdiction-sensitive, and diversity of legal interpretations and implementations is to be expected.

Take for example, the legal status of the GNU General Public License (GPL). The Free Software Foundation maintains that the GPL is not a contract.<sup>10</sup> Under American law, that may be a valid statement (Rosen 2005). According to the laws of continental European or Latin American states, however—where contracts do not always require consideration—the situation may be different. Under Brazilian law, the GPL is unquestionably a contract (Lemos and Senna 2007). A similar interpretation prevails under German Law (Metzger and Jaeger 2001).

Both the Free Software Foundation and Creative Commons have done a great deal to ensure that their licenses are appropriate for an international community of users (Stallman and Moglen 2005, Garlick 2008). Even after conscientious internationalization efforts, however, the possibility remains for conflicts due to legal diversity. Problems of “legal interlinking” need particular consideration. Most discussions on the legal aspects of free and open licensing concentrate on intellectual property law. A wealth of possible interactions, however, exists between these licenses and other fields of law, again with great room for diversity from country to country. The connections that can be drawn between copyright law, and contract law, consumer law, administrative law, and constitutional law in Brazil are good examples.

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<sup>10</sup> “Licenses are not contracts: the work’s user is obliged to remain within the bounds of the license not because she voluntarily promised, but because she doesn’t have any right to act at all except as the license permits” (Moglen 2001). While some licenses could be contract-based, the official position of the Free Software Foundation is that it is strategically sounder to base licenses on copyright law because this is more uniform globally than contract law (Stallman 2006).

This challenge is not exclusive to communities of users and creators of content. It also affects individuals holding positions in all branches and at all levels of government. Correct interpretation of licenses requires not only knowledge of a given jurisdiction's law and international law, but also a considerable amount of background information that is not necessarily the domain of judges, legislators, and administrators. There are consequently many opportunities for error in establishing the proper meaning of licenses, and relating them correctly to the facts at hand. This might happen even when licenses are considered to be clear by the communities and actors that are most directly involved in their use.

Legal scholarship can play an important role in preparing legislators, judges, administrators, and communities to adapt previous legal doctrine to new licensing models, and in mapping the territory of possible interactions between copyright law and other fields of the law, to provide solutions for potential controversies. This is a challenge not yet taken up by the legal community in Brazil, albeit with occasional exception (Falcão et al 2007). Key problems remain to be unpacked by legal scholars: How do these new licensing models fit in with the existing legal categories? How can legal instruments created for a certain legal reality be translated into doctrine that is understandable in terms of the law of other countries?

### **Community organization for commons management**

Open licensing gives birth to project-oriented communities, which can be managed in varying ways. Each free software/open content project has the potential to attract groups of developers, users and other supporting individuals whose interpersonal relationships surround the creation, use and management of a commons. The potential to form communities, however, is not always met. Many free software projects, for example, are run by one

or two developers, with user bases that are negligible in size or structure. This means that not every open and collaborative project will result in a commons-based peer production model. When projects succeed in attracting an active community, however, new challenges of community policy and commons management arise. What specific license terms best reflect the community's intentions towards the content to be produced? How should a project be organized in order for it to be sustainable and achieve its goals?

Licenses are, in many ways, the most important political documents of communities built around the production of information over the Internet, "used as glue to bind groups of people together in common" (St. Laurent 2004, ix). Licenses function like social contracts, or even constitutions (Moody 2001, 27), establishing the ground rules for efforts of collaborative creation. Because of this importance, licenses can also be a key source of controversy and dissent. Some people may believe that the GNU GPL is the best license for a specific project, while others consider it too restrictive when compared to the BSD or MIT licenses. When use of material produced by other communities is necessary, moreover, licensing turns out to be more than an ideological problem; the range of choices is actually constrained by the licensing terms attached to existing material.

As an example, consider the issue of interaction between Wikipedia's GNU Free Documentation License (GFDL) and the Creative Commons' popular attribution-share alike (CC-BY-SA) license. In their current forms, these licenses are incompatible, meaning that a world of valuable Creative Commons content cannot legally be integrated into Wikipedia. This situation may eventually be fixed through a change in the GFDL terms, "retro-fitting" them for compatibility with Creative Commons content (Wikimedia Foundation 2007). In order for this to occur, however, extensive

discussion and negotiation efforts were necessary between leaders of the two communities, all subject to community approval. There is thus a significant cost to solving problems of incompatibility retroactively, in terms of community time and energy spent.

Deciding on proper licensing arrangements, then, becomes one of the key problems when building a community based on information production and sharing. But how to achieve consensus in an organized fashion? Content-licensing communities can exist on a spectrum of formality. Some communities work perfectly well with *ad hoc* leaderships and a total lack of internal organization. Others end up adopting political structures and procedures modeled after corporate or governmental organization for the sake of decision-making efficiency.

Hacker ethos—or one conception of what qualifies as a hacker ethos—may resist such efforts at centralization (O'Mahony 2005). Centralization and the acquisition of legal personhood, however, can be crucial for some communities to defend the environment that allows them to thrive, and to establish relations with other actors, such as corporate entities. This can be seen as both a defensive and an offensive strategy that should be considered by communities, depending on how hostile the institutional environment is to informal collective action, or how active the community feels it should be within environments that work on different terms, such as that of traditional businesses.

That does not mean—borrowing terms from software development (Raymond 2000a)—leaving the bazaar entirely to take refuge inside the cathedral. Two different issues are at stake here. The decentralized production of information is to be maintained in the way community members relate to each other. The institutional centralization provided by the status of being a legal person, however, enables the community to relate to those outside. The

acquisition of legal personhood is not something that should be done by every community involved with open content projects, but for some, it may be a necessity.

### **Information policy and public opinion**

The relationship between intellectual property law and public opinion is one of the greatest challenges for both free software and open business in Brazil. As discussed in the preceding chapter on copyright exceptions and limitations, there is no tradition in Brazil of considering intellectual property regulation as a matter of information policy. This is, however, beginning to change.

The Brazilian federal government, through its Ministry of Culture, has recently started a year-long cycle of debates dedicated to the revision of Brazil's copyright law. This multi-stakeholder forum approaches copyright as a matter of public policy and balancing conflicting interests, instead of merely as a natural right, or as the only possible incentive for information production (Fórum Nacional de Direito Autoral 2008). The results of this process are still impossible to predict, but the fact that it is happening at all is a positive sign. An increase in public awareness of copyright law also occurs every time the entertainment industry publicizes a new piracy-related arrest, or a blogger gets sent a take-down notice. Copyright acceptance does not necessarily follow suit; instead such actions often breed dissent and outrage towards the law—dissent and outrage of the positive, democratically necessary kind.

Regardless of the desire and potential for legal reform, there is also much catching up to do. Intellectual property policy has been, for a long time, a game played by only a handful of corporate actors, mostly behind closed doors. The interests at stake are still unequally represented, and because *experience* in dealing with decision-makers is

a factor of the utmost importance, the scales are heavily tipped. This is not, in other words, a level playing field. Greater mobilization and coordination of the groups that find common interests in access to knowledge is urgently needed.

Since many of the issues involved are extremely complex and require high levels of legal and technical knowledge, public opinion is very easy to manipulate. Content industry actors have already begun to conduct campaigns that play upon the fears of Brazilian consumers. (e.g. Teixeira 2006). More recently, the Creative Commons project has suffered misinformation attacks from the Brazilian royalty collecting societies. These groups characterize the CC licenses as harmful to the interests of authors, culture and legislative victories dating back to the Enlightenment; and beneficial to only a small number of large content providers, such as Google and Microsoft. According to these recent attacks, CC licenses are ultimately conducive to “barbarism.”<sup>11</sup>

When these mischaracterizations reach a population that is not well informed about copyright law, and has no experience in dealing with these issues in terms of information policy, the results may be disastrous. These campaigns have an effect not only on the average citizen, but also on legislative and judicial decision-makers. A state procurement preference for free software in Brazil is currently under legal attack from proprietary software interests, aided and abetted by judges’ confusion about the nature of free software. This reinforces the conclusion that a greater degree of mobilization and organization of the affected communities is needed. Communities that rely on cultural commons must account for the costs of

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<sup>11</sup> The attacks have been mostly penned by Fernando Brant, a composer who is also the president of the Brazilian Union of Composers—*União Brasileira de Compositores*—but also by others (e.g. Brant 2006 and 2007; Lichote 2007).

inactivity in a political context that is not necessarily friendly to the activities of building, fostering, and managing a commons—no matter how legally entrenched the licensing practices that enable them appear to be.

## Conclusion

Although this chapter began with an invocation of optimism, it concludes on a note of caution; an evaluation of free software culture and open business trends could easily fall into two traps of excessive optimism.

To fall into the first trap is to look at how knowledge and culture continue to be produced and shared despite unfair and arguably irrational intellectual property legislation and to be satisfied. The free software movement has accomplished a great deal so far, and maximalist reforms to copyright law and new enforcement technologies have been extraordinarily unsuccessful in stopping the free flow of information. It would be a mistake, however, to conclude that we are hearing the last gasps of transforming industries and trust that the situation will eventually resolve itself in favor of access to knowledge. An open future is not inevitable.

The second trap is that of thinking that clever license drafting is sufficient to provide breathing room within legal and technological constraints over the production, flow and consumption of information and knowledge.<sup>12</sup> Free software licensing is an elegant

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<sup>12</sup> This is a trap that both the Free Software Foundations and Creative Commons, to name only two key organizations, are well aware of, and do a great deal not to fall into. But from the point-of-view of content creators and users—the communities that use these licenses—it may seem that all that could be done has been done, and that it is up for government, media, NGOs, and corporations to fight for new legislation, or adapt to the current trends.

reaction against improper or unfair use of copyright law, by means of copyright law itself. The same can be said of every licensing model inspired by the free software movement, such as the Creative Commons licenses. These licenses provide major relief, and they are powerful instruments for change. As intelligent and essential as these licensing models may be, however, they exist in institutional environments that are extremely hostile to their ultimate viability.

Both traps may lead to political inaction. This would be a grave mistake. As tempting as these optimistic scenarios may be, they give the impression of closure where in fact none has been reached. Recent developments are encouraging, but could be reversed. The complexity of these topics needs to be streamlined to facilitate informed public discourse and policymaking. This implies building a semantic repertoire that is not simply composed of buzzwords and slogans—“DRM is evil,” “Information wants to be free,” etc.—and backing this new analytical framework with serious research.

Areas in which a social commons produces viable open business models provide a privileged point of view for the analysis of copyright regimes. With tensions between legal and social norms increasing rather than diminishing, it may be more productive to find a solution that welcomes the social commons and tries to achieve convergence through cleverly drafted legal reform, rather than pursuing the enforcement of an ever-more-unreasonable copyright regime. This is an option that will remain open only if information policy discussions are themselves characterized by openness.

Finally, open-content communities must also play a more active role. The *tecnobrega* case study highlights the disadvantages of informality and the need for greater coordination and mobilization. Instead of acting solely in the realm of content production and sharing, these communities must also organize to stand in defense of

a legal environment that welcomes social production of information in a cultural commons.

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# EXCEPTIONS AND LIMITATIONS TO COPYRIGHT IN BRAZIL: A CALL FOR REFORM

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**T**his chapter offers a critical analysis of Brazilian copyright law and legal scholarship, through the particular lens of exceptions and limitations. Copyright exceptions and limitations are those positive rights granted to users of cultural materials, to be exercised without prior

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authorization of copyright holders.<sup>1</sup> Exceptions and limitations are widely recognized as an essential part of the balance between public and private interests inherent in copyright law, deeply linked to the underlying rationales for copyright itself. This is an essential starting point; however, two additional perspectives also merit emphasis.

First, copyright exceptions and limitations are a particularly important strategy for addressing the challenges and opportunities posed by new information and communication technologies. These include the challenges that the Internet and digital reproduction technologies pose to traditional copyright-based business models, as well as the opportunities these technologies offer to move from a society of information consumers to a society of information users—a transition that is already under way (Benkler 2000, 2006; Lessig 2005). Exceptions and limitations are a critical means for dealing with these ongoing technological upheavals of copyright law, while at the same time allowing the development of the creative potential of these new technologies.

Second, copyright exceptions and limitations are an issue of particular importance to developing countries (Drahos and Braithwaite 2003, Chang 2002, Kanniah 2006, Paranaguá Moniz 2006). In Brazil, access to knowledge remains a privilege of the most affluent citizens, with negative effects on the quality of life and fundamental rights of the less-affluent majority. This is also the case in many other parts of the world where a majority of the population does not have the resources to purchase knowledge goods priced to sell in higher-income markets. Seen in this light, exceptions and

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<sup>1</sup> We make no distinction between exceptions and limitations, but use the two terms interchangeably. A distinction can certainly be made, however, with limitations referring to works falling entirely outside the scope of copyright protection, and exceptions referring to permitted uses of works that are protected by copyright (Ricketson 2003).

limitations to copyright must also be understood as a matter of national development policy—the challenges of international harmonization notwithstanding. With these perspectives in mind, this chapter follows a four-part structure:

**Part one** takes a historical view of the Brazilian system of exceptions and limitations to copyright, identifying particular challenges posed by this legal tradition. It is an effort to unearth problems that have remained buried for a long time in Brazilian copyright history, and are consequently avoided or glossed over by Brazilian legal scholars, judges, legislators and citizens. These include the unhealthy reliance of Brazilian copyright regulation on criminal law and the failure of both constitutional and statutory regulation to articulate the purposes of copyright protection and exceptions in a manner that could better guide legal interpretation and legislative reform.

**Part two** offers an account of the current state of Brazilian copyright exceptions and limitations. It is an effort to make sense of rules which, when individually considered, may have little meaning. A complete listing of the existing exceptions and limitations is provided, as well as a discussion and analysis of some of the more obvious gaps. As will be seen, the scope of exceptions and limitations in Brazil is extremely narrow, leaving little room for many traditional and emerging uses of cultural materials.

**Part three** offers an account of the widening gap between copyright legislation and prevailing social practices of mass copyright infringement. Two cases are analyzed: the recent crackdown on the traditional practice of photocopying academic texts, and the efforts of Brazilian law to come to terms with the emerging practice of online file sharing. These accounts suggest that the stakes of exceptions and limitations policy in Brazil are rising, with a growing

conflict between the demands of content-industry actors for greater protection and the demands of the Brazilian public for greater access.

**Part four** takes issue with Brazilian legal literature and its interpretation of copyright law, which has neglected the necessity of balancing the interests of authors with those of the public. Offering a critique of the dominant approach to this subject, it concludes with a call for greater attention to the interplay between exceptions and limitations and constitutional values.

## **The historical development of Brazilian copyright law**

Before presenting the current system of copyright exceptions and limitations in Brazil, some historical context is helpful. The particular way in which copyright law developed in Brazil has greatly shaped the challenges faced today.

Looking back, three especially troublesome problems are rooted in the historical tradition of copyright law in Brazil. First, whereas the criminalization of non-commercial copyright infringement is a recent phenomenon in Europe and the United States, Brazilian copyright was born out of criminal law and is still relies on it heavily. Second, while mention of copyright found its way into the Brazilian constitution as early as 1891, the constitution did not then and still does not articulate the values or purposes of copyright. Third, the exceptions and limitations to copyright found in Brazilian civil law—beginning with the 1898 Medeiros e Albuquerque Law—also omit a rationale.

All three of these factors complicate the attempts of legal scholars today to focus on the values and counter-values implicated by copyright law, and to suggest appropriate ways of balancing them.

## **Criminal beginnings**

If the increasing reach of criminal law over copyright issues is cause for controversy in North America and Europe (Harvard Law Review 1999, Moohr 2003, Alexander 2007), Brazilian lawyers and citizens take it naturally. Article 261 of the Imperial Criminal Code of 1830 was the first Brazilian law to establish a proper reproduction right, imposing criminal sanctions when writings or drawings made by Brazilian citizens were reproduced without prior authorization.<sup>2</sup> Once caught with illegal copies, offenders would lose all of the copies to the author or his or her heirs and pay a fine. The criminal offense was extant as long as the work was unlawfully reproduced during the author's life or within ten years after her or his death if heirs survived. Translators were given equal standing as authors of original works. If the works were corporately owned, protection would last for a term of ten years. Hence, both the reproduction right itself, as well as its term, were originally defined through the criminal law.

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<sup>2</sup> Texts on the history of copyright law in Brazil usually begin with an Imperial statute, Lei de 11 de Agosto de 1827, placing the origins of Brazilian copyright legislation almost sixty years before the Berne Convention of 1886 (see e.g. Costa Netto 1998, Bittar 2003, Ascensão 2007). It is questionable, however, if this is a proper starting point for the history of Brazilian copyright law. While the 1827 statute did create a privilege over literary property—analogueous to the privileges that were granted in Europe before the first proper copyright laws emerged—its scope was very narrow. The primary purpose of the statute was to found Brazil's first two universities. Incidentally, it also granted a ten-year privilege covering professors' lecture notes. This privilege was only applicable after a bureaucratic process involving approval of the work's content by universities and the government, which would afterwards provide for printing and distribution of the material for internal use within each university. It was solely the final product of this process that was subject to the ten-year privilege. The 1827 statute is thus hardly comparable to either the printing privileges that were commonly granted across Europe since the fifteenth century, or the stationer's copyright developed in England in the sixteenth century, which would later serve as a model to the 1710 Statute of Anne (Patterson 1968).

Articles 342-350 of the Penal Code of 1890 continued the Brazilian tradition of legislating copyright through criminal law. Compared to the Imperial Criminal Code, the 1890 Code enhanced copyright protection and introduced in Brazilian legal parlance the concepts of “literary,” “artistic,” “industrial” and “commercial” properties. Whereas the Imperial Criminal Code classified unlawful reproduction as a “crime against property,” the 1890 Code explicitly considered it a violation of “intellectual” property rights. The 1890 Code also granted a copyright on statutes, decrees, resolutions, reports and official documents of the Legislative and Executive branches to the state, coupled with a limitation that allowed reprinting on newspapers, compendia, treatises or any other scientific or literary works. The reselling of these works was explicitly permitted, along the lines of the first sale doctrine. A limitation was also established by Article 347, allowing partial citation of any written work with the aim of “criticism, polemics or teaching.” Thus, in the Brazilian legal tradition, copyright emerged from criminal law, as did exceptions and limitations.

Criminal law still plays a prominent role in copyright today. According to Article 184 of the Brazilian Penal Code, any act of copyright infringement—no matter how minor and regardless of commercial intent—is also automatically a criminal offense.<sup>3</sup> Criminal

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<sup>3</sup> Article 184, as amended by Lei 10.695/03, has a main provision covering acts of infringement in a general manner, and three other provisions establishing increased penalties for more specific offenses. The main provision simply states that it is a crime to “violate author’s rights and neighboring rights,” with a penalty of three months to one year of imprisonment, or a fine to be judicially determined. Article 184, §§ 1 through 3 deal with copyright infringement in the context of commercial activity, requiring either direct or indirect profit. These offenses are punished with two to four years of imprisonment and a judicially determined fine. Software-related infringement is separately regulated by Lei 9609/98 and, curiously, punished with different penalties: six months to two years of imprisonment or a fine for

law ends up not as a last-resort measure for dealing with severe copyright infringement, but as a natural, organic part of copyright law. Since the Brazilian exceptions and limitations are so limited, mass copyright infringement inevitably follows—along with mass criminal infringement. While other countries debate whether it is appropriate for every single act of copyright infringement to be treated as a criminal offense—as some in the content industries advocate—in Brazil such debate does not occur, because this has been usual practice since 1830.

### **Constitutional copyright**

While copyright was originally treated as a matter for criminal law, it became a constitutional issue with the adoption of Brazil's second constitution in 1891. The 1891 constitution was heavily influenced by American constitutional thought (da Silva 1999, Bonavides 2006), and the consideration of copyright as subject of constitutional relevance was probably derived from the U.S. Constitution.

Unlike the U.S. Constitution's intellectual property clause, however, the Brazilian 1891 constitutional provision on copyright lacks a stated purpose for copyright. The U.S. Constitution gives Congress the power—but not the obligation—to establish patents and copyrights, for a specific stated purpose: “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” (Article I, § 8(8)).

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general infringement (Article 12), and one to four years of imprisonment and a fine for commercial reproduction (Article 12, § 1) or the general commercial use of unlawfully reproduced material (Article 12, § 2).

Brazil's 1891 constitution mandated a life-plus term for copyright, but did not provide a reasoning for the right. Article 72, paragraph 26 reads: "Authors are granted an exclusive right on the reproduction of their artistic and literary works through the printing press or other mechanical processes. The authors' heirs will be allowed the same right for a period of time established by law." Authors' reproduction rights are stated, and the public domain is asserted through reference to a copyright term established by law, but with no explanation of copyright's function in society. Since the textual formula of Brazilian constitutional copyright has remained fundamentally unchanged throughout Brazil's many constitutions, we are still left today without an explicit reference to copyright's goals.<sup>4</sup>

### **Civil copyright**

The 1891 Constitution did not specify what exceptions and limitations should be placed on copyright. For this purpose, Brazil's first non-criminal copyright statute was adopted in 1898. Known as the Medeiros e Albuquerque Law after the congressman who proposed it, Lei 496/1898 was approved not long after the 1886 Berne Convention.<sup>5</sup> Although there have been significant changes to Brazilian copyright law since 1898, the nineteenth century law inaugurated a strategy for the regulation of limitations and exceptions that remains to this day.

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<sup>4</sup> All of Brazil's constitutions, with the exception of the 1937 Constitution, which had no copyright provisions, kept the same structure of the 1891 copyright clause. Brazil's current constitution (1988) included new provisions on co-authorship, publishing rights and authors' right to supervise the revenues related to their works (Article 5, XXVIII, a and b), but preserved the original copyright provision under Article 5, XVII.

<sup>5</sup> Brazil did not become a member of the Berne Convention until 1922.

Seven limitations were established under article 22 of the Medeiros e Albuquerque Law. *Limitation 1* allowed partial or total reproduction of smaller works within the body of a larger work, as long as the latter had scientific purposes or was to be used for public learning. *Limitation 2* allowed newspapers the reproduction of news articles from other periodicals as long as credit was given, as well as the reproduction of any speeches given in public reunions. *Limitation 3* granted permission for the reproduction of official documents from all levels of the Brazilian Federation. *Limitation 4* allowed the reproduction of excerpts from any work in books or newspapers, for the purpose of criticism. *Limitation 5* authorized the reproduction of works of figurative art within written works, as long their main element was the text itself, and as long as credit was given. *Limitation 6* permitted the reproduction of any works of art kept in public spaces. *Limitation 7* allowed the reproduction of privately commissioned portraits or sculpted busts, when made by the owner of the physical objects. Although the statute did not specify the reasons backing the limitations, it appears that the unifying concerns were to facilitate free speech and education.

Ever since the Medeiros e Albuquerque Law, every Brazilian copyright statute begins by establishing the scope and term of copyright protection, along with a few definitions, and then presents a list of limitations without specifying the principles that justify their existence. This was true of the Brazilian Civil Code of 1916 as well as the more recent copyright statutes of 1973 and 1998. Both kept the basic framework of the Medeiros e Albuquerque Law with some changes, particularly to the private copy exception.<sup>6</sup> None of these

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<sup>6</sup> The Civil Code of 1916 extended the copyright term to life plus 60 years, and increased the scope of protection. Article 666 came with a list of ten limitations,

versions, however, attempted to articulate a logic behind the shifting set of exceptions and limitations. Nor did they provide general principles that could be used to infer other appropriate, unforeseen uses of copyrighted material. This is a system that is considerably distant from American fair use; it is closer to the more rigid fair dealing systems observed in Latin America and continental Europe. The consequence is that not only legislation, but also legal literature and public opinion fail to adapt to the current technological challenges to copyright tradition.

### **Lessons from copyright history**

Looking back, the Brazilian legal tradition creates three especially troublesome barriers to copyright reform and balanced legal interpretation.

First, there is the constitutional tradition of never stating a clear goal for copyright protection. This accounts for why Brazilian scholarship has neglected the question of copyright's purpose. Natural rights discourses dominate discussions concerning the rationales for copyright; other public or private interests are ignored.

Second, the statutory exceptions and limitations similarly fail to make explicit the reasons motivating their existence. Making sense of these lists as a coherent body of rules that serve specific purposes

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mostly repeating the text of Medeiros e Albuquerque's Article 22, but with a few important modifications. Number VI authorized full copies of any work, as long as they were for non-commercial use and made by hand. The use of a typewriter for making a copy, for instance, would be considered copyright infringement, revealing that concerns about technologies that ease reproduction dates back to the early twentieth century. As of 1973, full private copies were allowed without any technological restrictions, with the condition that they were limited to a single copy and not-for-profit (Lei 5.988/73, Article 49, II). The private copy exception was restricted in 1998, however, and now allows for a private copy only of "small excerpts" rather than of the full work (Lei 9.610/98, art. 46ii).

is not easy, particularly as the lists have been successively altered from 1898 to 1998, resulting in a somewhat jumbled text. The lack of clearly articulated reasons for the existence of exceptions and limitations greatly frustrates attempts to discuss the coherence and purposes of lists of exceptions and limitations, and makes them vulnerable to narrowing interpretations in the name of greater protection for authors' rights.

Third, by long tradition in Brazilian law, any act of copyright infringement—no matter how minor—is automatically a criminal offense. Since the limitations lists are so strict, mass criminal infringement inevitably follows. Furthermore, the lack of stated reasons for copyright and its exceptions and limitations helps reinforce content industry pressure for even stronger criminal protection.

## **Exceptions and limitations in the law**

Brazilian copyright law is defined by the Penal Code of 1940—recently altered in its copyright-related matter by Lei 10.695/03—by the main copyright statute (Lei 9.610/98), and by Brazil's "Software Law" (Lei 9.609/98).<sup>7</sup> Together, these laws form the current body of Brazilian copyright legislation. All provide for some copyright limitations, even the Penal Code of 1940. This part attempts to approach the current system in a systematic fashion and

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<sup>7</sup> The 1998 legislation built upon the 1973 copyright statute, altering it to comply with the World Trade Organization's TRIPS Agreement. In fact, the Brazilian copyright reforms go far beyond the TRIPS requirements, offering even broader copyright protection and further restricting existing exceptions and limitations.

offer insight on a few interpretation issues that may arise when one attempts to understand the statutory text.<sup>8</sup>

The current body of Brazilian copyright exceptions and limitations may be divided into three groups, relating to: 1) partial or full reproduction 2) derivative works, and 3) performing rights. The three tables in the following sections provide an exhaustive list of the limitations present in Brazilian copyright legislation.<sup>9</sup> The dominant view in Brazilian literature is that exceptions and limitations lists are to be strictly construed, with no credence given to implied limitations. This is a primary tenet of Brazilian legal scholarship with respect to copyright; it is taken as dogma in academic writing and, as a result, often by courts as well.

### **Reproduction-related limitations**

**Table 1** on the following page shows that some of the reproduction-related limitations found in Brazilian law were directly inspired by the Berne Convention. The Berne three-step test was not itself turned into law in Brazil,<sup>10</sup> although traces of the Berne-three

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<sup>8</sup> This may clash with current dominant interpretations of Brazilian copyright law, which are usually done article by article in the most restrictive way possible, without any serious attempt to discern order behind what may appear as randomness.

<sup>9</sup> We have not offered literal translations, since the result, in many cases, would read very awkwardly. Great care has been taken, however, for the texts provided in tables 1, 2 and 3 to be a faithful representation of the law.

<sup>10</sup> Article 9(2) of the Berne Convention states: "It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author." In some Latin American countries, the Berne 9(2) criteria of normal exploitation and unreasonable prejudice are explicitly written into national legislation as mandatory guides for the interpretation of limitations and exceptions. These criteria are not always helpful, but provide at least some logical orientation with regards to limitations. No such guidance exists in Brazilian law.

step test can be seen in the Article 46 VIII provision on reproduction within the context of a larger work. Overall, however, there is a distinct lack of underlying principles and clear criteria for interpreting the precise scope of exceptions and limitations. This is very much in accordance with the historical roots of Brazilian copyright.

Consider the private copy provision. A common motivation for establishing a private copy exception is to accommodate research and education purposes. Yet, the limitation established by Article 46, II does not specify this or any other purpose. As of 1998, moreover, the exception now permits a private copy of only “small excerpts,” which often results in interpretations that do not allow for reasonable use within a research or classroom context. Other common uses for private copies have also been affected, such as time shifting of broadcast programs for later viewing. In this way, the statutory text’s failure to state the intended function of an exception may lead to later changes that completely undermine its existence.

Coherence is also sometimes lacking. At least one of the “limitations” in this list is not a limitation at all. This is the case, for example, with the language at Article 46, I, c, which requires the authorization of the person pictured in a work of visual arts, if the owner of the work should wish to reproduce it. Put under critical evaluation, Article 46, IV also acts not as a limitation regarding student’s lecture notes, but as a reinforcement of the lecturer’s copyright. That the lawmakers felt that there was a need to state what should be obvious—that students may take notes at lectures—is egregious. The real purpose of Article 46, IV is to make clear the lecturer’s right to control later uses of such notes.

In light of the technological changes introduced in the past fifteen years or so, moreover, the list of exceptions and limitations appears antiquated. The permission to write down and publish public

**Table 1.** Reproduction-related exceptions and limitations**News or information articles.** Lei 9.610/98, 46, I, a

- *Corresponding international law: Berne, 10bis (1)*
- The reproduction of news or information articles in the daily press is permitted. Credit must be given to the article's author and the original publisher.

**Public speeches.** Lei 9.610/98, 46, I, b

- *Corresponding international law: Berne, 2bis (1) and (2)*
- Public speeches may be reproduced in daily or periodical publications.

**Portraits or visual works made for hire.** Lei 9.610/98, 46, I, c

- *No corresponding international law*
- The owner of portraits or other works of visual arts representing persons may reproduce the work, as long as the pictured person or their heirs make no opposition.

**Reproduction of works for the visually impaired.** Lei 9.610/98, 46, I, d

- *Corresponding international law: Berne, 9 (2)*
- Literary, artistic and scientific works may be reproduced in the Braille system, or through any other methods devised for the use of the visually impaired, as long as the reproduction is not-for-profit.

**Private copies (I).** Lei 9.610/98, 46, II

- *Corresponding international law: Berne, 9 (2)*
- The reproduction of small excerpts of a protected work is permitted, as long as it is for the private use of the person responsible for the reproduction. The reproduction must not be done for profit, and must be limited to a single copy.

**Private copies (II).** Penal Code, 184, § 4.

- *Corresponding international law: Berne, 9 (2)*
- The reproduction of a single copy of "an intellectual work or phonogram" is allowed, for the private use of the person responsible for the reproduction, as long it is not directly or indirectly for-profit.

**Quotations.** Lei 9.610/98, 46, III

- *Corresponding international law: Berne, 10 (1)*
- Quotations of a protected work in books, magazines or other publications are allowed for the means of study, criticism or polemics. The extent of the quotation should be within the reasonable measure required for the ends sought.

**Students' lecture notes.\*** Lei 9.610/98, 46, IV

- *No corresponding international law.*
- Students may take lecture notes, but are not allowed to publish either the complete lecture or excerpts of it, without the lecturer's prior authorization.

**Judicial or administrative evidence.\*\*** Lei 9.610/98, 46, VII

- *No corresponding international law.*
- The use of protected works is permitted for the purpose of producing judicial evidence.

**Reproduction within the context of a larger work.** Lei 9.610/98, 46, VIII

- *No corresponding international law.*
- The reproduction of small excerpts of preexisting works of any nature, or of an entire work of visual art, is allowed within the context of a larger work. The reproduction itself must not be the main object of the larger work, and must not interfere with the normal exploitation of the work or cause unjustified harm to the legitimate interests of the author.

**Private copies of computer programs.** Lei 9.609/98, 6, I

- *No corresponding international law. Inspired by EU Council Directive 91/250/EEC of 14 May 1991.*
- A single full copy is allowed for backup or archival purposes, as long as an original copy was legitimately acquired.

**Partial citation of computer programs.** Lei 9.609/98, 6, II

- *No corresponding international law.*
- It is permitted to partially cite from a program's source code, for educational purposes. The program and its author must be identified.

**Similarity of computer programs.** Lei 9.609/98, 6, III

- *No corresponding international law.*
- If two computer programs are functionally alike, or if solutions to a given problem force programmers to adopt identical approaches to code writing, similarities in source code are not considered to be copyright infringement. If, likewise, the observance of technical standards forces code writers to write similar code, they are covered by the limitation.

\* Also covers derivation.

\*\* Also covers performance.

speeches (Art. 46, I, b) and to reproduce daily press articles (Art. 46, I, a) may have provided an adequate degree of freedom of information and healthy flow of ideas in the nineteenth century. The era of digital technology, however, is much more complex and demands additional exceptions and limitations. The rise of the search engines—which rely on limitations and exceptions to function—and citizen journalism provide opportunities for political discourse to be enriched and broadened. Open content licensing strategies can only go so far in providing an environment for change; copyright reform is urgently needed to realize unprecedented positive opportunities for individual and social development (Benkler 2006).

### **An unintended limitation**

When the copyright provisions of the Brazilian Penal Code were amended in 2003, an additional limitation was created. The amendment process—motivated by international pressure—established new infringement crimes with increased penalties. It was, however, so hastily drafted that it also established a new, unintended limitation to copyright. This occurred because the amendment was written with the 1973 version of copyright law in mind; proper care was not taken to verify the amendment’s language against the newer statute, resulting in the enactment of a new limitation.

Article 184, § 4 of the Penal Code establishes that there is no crime when the act under consideration is covered by an exception or limitation according to Lei 9.610/98, or yet, if it consists in a “copy of an intellectual work or phonogram, in a single copy, for the private use of the copyist, without intent of direct or indirect profit.” Thus, the 2003 amendment to the Penal Code appears to reinstate the 1973 private copy limitation, overriding the narrower private copy

provision of the 1998 statute. Since all that is constitutionally required for copyright legislation to be valid is that it be enacted at federal level (Art. 22, I), the criterion of *lex posterior derogat priori* (Decreto Lei 4.707/42, art. 2, 1) indicates that the 2003 Penal Code amendment—being latter in time—should take precedence. There is no way to argue that *lex specialis derogat generali*—a specialized law overrules a general one—in this case, since both provisions are copyright-specific.

By our reading of the law, Brazil has reinstated the earlier, broader exception allowing a single full copy of any intellectual work for private, non-commercial use. Mainstream copyright scholarship, however, behaves as if the relevant private copy limitation is still the one of article 46, II, of Lei 9.610/98, which permits private copies of only “small excerpts.” No attention is given to the Penal Code except when it comes to discussion of criminal infringement. Even then, no arguments can be seen that acknowledge and attempt to resolve the clear conflict between these two laws. It appears, rather, that scholars are reluctant to engage with this issue at all. This is unfortunate, as wider awareness and acceptance of the newer and broader private copy exception created by the 2003 reforms would go a long way toward establishing a better balance between copyright privileges and the promotion of access to knowledge.

### **Derivation-related limitations**

Limitations concerning derived works in Brazilian law—listed in **Table 2** on the following page—are particularly inadequate for the digital environment, where the creative re-use of content is a given. With all that has been written about the remix culture, Web 2.0, video, music and Web mashups and peer production in general, the

importance of derivation-related limitations is well established. Brazilian law provides little room for these new modalities of cultural production, however, even when they are entirely non-commercial.

**Table 2.** Derivation-related limitations

**Parodies and paraphrases.** Lei 9.610/98, 47

- *No corresponding international law.*
- Parodies and paraphrases are permitted, as long as they do not constitute actual reproduction of the original work or discredit it.

**Works in public spaces.** Lei 9.610/98, 48

- *No corresponding international law.*
- Works that permanently remain in public spaces may be freely represented by painting, drawings, photographs or audiovisual procedures.

**Software integration.** Lei 9.609/98, 6, IV

- *No corresponding international law. Inspired by EU Council Directive 91/250/EEC of 14 May 1991*
- To integrate any given computer program into others, be it at application or operating system level, is permitted if done for personal use and unavoidable considering the user's needs. Integration must be done for the exclusive use of the person who carries it out.

In *droit d'auteur* countries, the idea of derivation-related limitations finds an even greater barrier than elsewhere due to the doctrines of moral rights and personality rights—especially the so-called “right of integrity.” There is widespread fear—at least from traditional scholarship—that any derivation or creative use of a work might be detrimental to the author's personality and reputation. It is extremely hard to argue for creative derivation—even when the “standing on the shoulders of giants” effect of cumulative cultural creation is brought to attention—because strong natural rights-based rationales for copyright insist on the figure of an original author whose work is tantamount to—or at least a poor but worthy

imitation of—divine creation. Therefore, many forms of content production which build upon previous works are viewed with distrust, as potential attacks on the author’s integrity or reputation.

This is evident in the parodies and paraphrases limitation (Lei 9.610/98, Article 47), which severely restricts the range of legal parody. Parodies are explicitly permitted, but with a key condition: the author of a parody cannot discredit the parodied work. Since the entire point of parody is often to discredit the original work to some extent, this limitation offers protection to very tame parodies. While supposedly granting the right to parody, this limitation leaves open the door to state-enforced private censorship.

### Performing rights-related limitations

Limitations related to performing rights in Brazil are scant. What few exist are listed below in **Table 3**. As is quickly apparent, there is little room for amateur public performance.

**Table 3.** Performing rights-related limitations

**Use of protected works for demonstration purposes.** Lei 9.610/98, 46, V

- *No corresponding international law.*
- The use of literary, musical or audiovisual works, as well as radio broadcasts, is permitted for the purposes of demonstrating technical equipment in stores.

**Theatrical and musical performances.** Lei 9.610/98, 46, VI

- *No corresponding international law.*
- Theatrical and musical performances may be carried out within private family environments or, for strictly educational purposes, in learning institutions. In both cases, performance must be non-profit

The Central Collection and Distribution Office—*Escritório Central de Arrecadação e Distribuição* (ECAD), the umbrella organization

for Brazilian collecting societies, is an extremely litigious organization. The 1998 law granted even further permission for ECAD to pursue strategies of litigation by eliminating the previous requirement of indirect profit.<sup>11</sup> There is still controversy regarding what exactly qualifies as a “public performance” in an online environment. Judging from ECAD’s high rates of success in courts so far, however, it remains to be seen how far the ability to collect will be extended, in the absence of clear rules.

## Exceptions and limitations in action

Thus far this chapter has offered a historical perspective on the unique challenges posed by the Brazilian legal tradition and examined the existing system of copyright exceptions and limitations. An accurate picture of the problems imposed by Brazilian copyright law on the use of protected content, however, can only be fully drawn when we observe how this system is worked into practice.

Since the exceptions and limitations lists of Brazilian copyright law are strictly construed, mass infringement inevitably follows. Consider three examples: a) the reproduction of protected content by libraries for preservation or managerial purposes; b) the

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<sup>11</sup> Article 73 of Lei 5.988/73 required that indirect profit be proved for royalties to be owed. The 1998 law imposes no such constraint, and ECAD has been achieving high rates of success in courts in charging royalties even when it comes to radios inside hospital rooms (see, for a representative judicial opinion on the matter: REsp 791630/RJ; STJ, 3<sup>a</sup> T.; Rel. Min. Nancy Andrighi, DJ 04.09.2006 p. 270). It must be mentioned that there is room for “indirect profit” to be construed as any personal advantage received by the infringer, regardless of commercial activity. Historically, however, “indirect profit” always referred to profit gained from the public performance of protected works as an incentive to the consumption of unrelated goods or services, such as the use of background music in restaurants in order to attract clientele. See, for example: REsp 58589/GO; STJ, 4<sup>a</sup> T., Rel. Min. Barros Monteiro, DJ 22.05.1995 p. 14416.

showing of a single scene of a film in a classroom; and c) time- or space-shifting of music and film legitimately acquired by consumers. None of these acts is covered by Brazil's current regime of exceptions and limitations, which is blind to education, research and the preservation and archival of content. This compromises the development of new business models in a digital environment, as well as a good number of reasonable non-commercial uses for copyrighted content.

The following two case studies will provide concrete examples of how inflexible limitations create a state of mass criminality.

The first case presents an account of the conflict between the Brazilian Association for Reproductive Rights—*Associação Brasileira de Direitos Reprográficos (ABDR)*—and university students and faculty. Not content with the already strict limitations list, the ABDR has systematically misinterpreted copyright exceptions to discourage even legally permitted uses of copyrighted materials. The effect has been to significantly complicate access to scholarly knowledge in the Brazilian higher education system.

The second case examines file sharing in Brazil. This case study demonstrates how digital technologies and worldwide computer networks are amplifying traditional practices of non-commercial information exchange into a parallel version of copyright norms that has so far proved much more reasonable than the official list of exceptions and limitations. The current status of the content industry's world campaign against file sharing will be discussed in its Brazilian ramifications, along with reaction from file sharing communities, and the emergent scenario that points to rethinking copyright law.

## **Photocopying and access to scholarship**

Higher education institutions in Brazil usually do not provide clear policy guidance on course readers and textbook copying. In practice, the unlicensed reproduction of copyrighted material is essential to academic life. Course readers, copies of book chapters and even entire books can be found in files hosted by copy shops, ready for on-demand reproduction. Professors usually keep personal files as well, in which they include all of their courses' required and complementary reading material. Students are frequently seen carrying spiral-bound photocopied textbooks to class. This is all done without prior authorization from rights holders.

This deeply-rooted practice stems not only from the convenience provided by reprographic services, but also from demand factors specific to the national context. The Brazilian book market features high prices, most academic library collections are inadequate, and out-of-print, foreign, or otherwise hard-to-find books are often required reading material.

### **The quest for knowledge in a book-scarce setting**

A recent study carried out by Brazil's largest consumer group, helps put things in perspective (IDEC 2008). The study calculated the average costs for the required reading material for law, business and economics majors in the first year of seven private and public institutions in São Paulo and Rio de Janeiro. According to the IDEC's numbers, the average costs for the required reading material for a freshman, totaled R\$ 2578.46 in public institutions and R\$ 3907.89 in private institutions. These values take into consideration only the books that could be readily found at bookstores; more than

one-third of required books in both public and private institutions were out-of-print.

Considering that minimum wage in Brazil as of March 2008 is R\$ 415.00 per month, it is simply not feasible for most students to buy all of the required reading materials. Books in Brazil may be cheaper than in many other countries in absolute terms, but when purchasing power is taken into account, they are much more expensive. Sá Earp and Kornis (2005) have developed an index for measuring the relative price of books in different countries, taking into account GDP per capita and the average price of a book. Their work suggests that the relative price of a book in Brazil is 270% higher than in Japan and 150% higher than in United States. The scarcity of bookshops throughout Brazil is symptomatic of this reality.<sup>12</sup>

Libraries, unfortunately, are not a good alternative for students in Brazil. The IDEC research also evaluated library collections from all the institutions involved. The average collection numbered no more than six books per 100 students at public institutions; no higher than eight at their private counterparts.

Paying a fee for the authorized reproduction of printed works is also not an option for Brazilian students and professors. The Brazilian Association of Reprographic Rights—*Associação Brasileira de Direitos Reprográficos* (ABDR)—is the nation's sole reprographic rights organization (RRO). It refuses to establish a licensing system for

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<sup>12</sup> “[I]f one considers the existence of bookstores as a proxy for access to books, the market in Brazil is very small. The country as a whole has approximately 2000 bookstores, or an average of just one bookstore for every 84,400 Brazilians. The absolute majority of Brazilian cities do not have any bookstores. Entire states such as Roraima, Tocantins, and Amapá have only two bookstores each. In the overall Northern region of the country, the average is one bookstore for every 215,300 inhabitants” (Lemos 2007, 13).

academic copying. Since 2004, indeed, ABDR has revoked what little licensing it had previously authorized. Instead, it has initiated an extremely aggressive legal and media campaign against “book piracy,” preaching that books should be bought or—in a worst-case scenario—borrowed from a library. ABDR has turned into a copyright enforcement association, pushing forward a business model that restricts itself to sales of hard-copy books backed by threats of criminal litigation.

### **Rewriting copyright law through misinformation and intimidation**

Threat, in fact, is a crucial element of ABDR’s business model for the publishing industry. ABDR has unleashed the police on universities and copy shop owners, then taken them to court. Reaction has been shaped by student unions of a small number of universities into the “Copiar Livro é Direito”—“To Copy a Book is a Right”—movement (Magrani 2006), unfortunately without any sizeable impact. ABDR’s strategy has managed to intimidate copy shop owners and instill in them with a paranoid approach to their daily activities. It has become somewhat difficult to make copies even of public domain and Creative Commons licensed materials. Yet copying is still a reality on Brazilian *campi*, and all it takes is to establish a few contacts or win the trust of copy shop employees to make legal or illegal reproductions.

In university copy shops around Brazil, the existing narrow exceptions and limitations are being further narrowed in practice. According to the ABDR’s publicity campaigns, even the

reproduction of small excerpts of a protected work is prohibited.<sup>13</sup> The proviso that copies should be made “*pelo próprio copista*”—that is, by the person responsible for the reproduction—is used to argue that such reproductions are legal only if the copy’s end-user is the one physically operating the reprographic machine. On top of that, there is the issue of determining what exactly amounts to a “small excerpt,” with legal scholars disagreeing on how to interpret the law or even sidestepping the question entirely (Cabral 2000, Bittar 2003, Abrão 2002). A couple of institutions, such as Universidade de São Paulo (USP) and Pontifícia Universidade Católica de São Paulo (PUC-SP), have been forced to draft policy clearly adopting a 10% standard for “small excerpts,” attracting international industry criticism in the process (IIPA 2008).

### **New legislative proposals on an educational exception**

There are three bills related to the reproduction of printed material currently under discussion at Congress. Bill 131/06, proposed by Senator Valdir Raupp, would alter article 46, II of Lei 9.610/98 to allow a single copy of up to 25% of any work, for the private use of the person responsible for the act of reproduction. The rationale for the bill is that the actions of the ABDR against students and universities have been excessively aggressive, and that the new text would better meet public expectations of “access to information and knowledge.”

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<sup>13</sup> Most copyright notices in Brazilian books state that no full *or partial* copies of the work are permitted. Rather than quoting directly from the law, these notices make reference to Lei 9.610/98 by number only; few readers actually verify if the law backs the notices’ claims. The phenomenon of misleading copyright notices is by no means exclusively Brazilian (Patterson and Lindberg 1991, 7-11).

Bill 5046/05, introduced by Representative Antonio Carlos Mendes Thame, would go considerably further than Bill 131/06, creating a new limitation to allow university students to make a full single copy of any work for noncommercial uses. Representative Thame justifies the proposal with three arguments: 1) there are hundreds of works which are out-of-print, and thus out of reach for many students; copying these books would hardly provoke any serious economic harm to the publishers, but would provide students with easier access to knowledge; 2) university libraries often do not carry the necessary number of copies to fill the needs of every student; 3) lower-income students have no means to pay for increasingly expensive books, and to require of these students any action other than photocopying these books would be unfair, and violate their constitutional right to equality; 4) considering that every act of copyright infringement is automatically criminal in Brazil, to make use of criminal law to solve a social educational problem is not good public policy.

A third bill has been appended to Bill 5046/05, for joint consideration. Representative Bilac Pinto's Bill 1197/07 follows an entirely different line of reasoning: according to Bilac Pinto, universities blatantly violate the law by providing students with the means to illegally reproduce content. Since the law must be respected at all costs, the solution for this problem is to completely prohibit universities from even having reprographic machines or any other device capable of replicating literary works.

Little progress has been reached with Bill 131/06, which has been stalled in the Senate since June 2007. Bill 5046/05 and 1197/07 were considered, however by the House of Representative's Committee of Education and Culture on June 2008. The Committee

rejected the punitive Bill 1197/07 outright, but proposed heavy amendments to Bill 5046/05.

The sponsor of these amendments, Representative Rodrigo Rocha Loures favored the creation of a new copyright exception for university students, but only as far as out-of-print works were concerned. His amendments would limit the educational exception to this circumstance. According to Representative Loures, to impose a new exception allowing the full copy of any work just because students have no means to pay for them, or because libraries do not carry enough copies of the work, is to burden the private sector with an issue that should be dealt with by the state.

Even in their original forms, both proposals to expand the educational exception are deeply flawed: Senator Raupp's for its questionable 25% limit, and Representative Thame's for its restriction to university students instead of the preferable "for educational ends" formula. Yet, they are a sign of progress, or at least a recognition that a problem exists. Reaction, predictably, has come in form of Representative Bilac Pinto's Bill 1197/07, which could still resurface in less obviously unconstitutional wording. International pressure is already mounting: the International Intellectual Property Alliance mentions in its Special 301 report that the bills "should be monitored, as any move to take them forward no doubt place Brazil in violation of international copyright mandates" (IIPA 2008).

Regardless of the outcome of these bills, exceptions attending to educational needs are sorely needed in Brazilian copyright. They should be clearly drafted, leaving little room for academic dispute regarding the extent and nature of the works to be reproduced, and respect Brazil's social context and development needs.

## **File sharing in Brazil: a new challenge to copyright**

File sharing is as rampant among Brazil's online population as elsewhere in the connected world. Estimating the population of file sharers in any country is a thorny issue, due to the technological profile of some of the systems employed for file sharing. It is safe to assume, however, that the population of file sharers is growing, despite organized industry attacks through both legal and technological means (Yu 2005). In Brazil, where the possibility of being sued over file sharing is still insignificant, file sharing is a popular and openly practiced Internet activity. A simple Google search with a few keywords—such as “emule,” “torrents,” “brasil,” “br,” “p2p” and “comunidade” (community)—will point the way to the many websites, forums and blogs that form the infrastructure used by Brazilians for file sharing, gateways to vast global repositories of content spread throughout millions of computers.

### **Technology and community**

Infrastructures for file sharing are easier to understand if we think of them as being composed by two types of layers: data transfer layers and community layers.<sup>14</sup> Different systems are used for data transfer, for example, p2p networks. These are technical means of getting data from a given computer to another across the networks

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<sup>14</sup> One cannot underestimate the importance of IRC-related protocols such as DCCP, newsgroups, and file storage sites such as [www.megaupload.com](http://www.megaupload.com) for file sharing. A simple combination of a forum and storage sites can be used for file sharing, and in some cases be even more efficient than a p2p network. Users simply request or post what they have available in forum posts, and then provide links for the content, which point towards storage sites.

that comprise the Internet, using of a variety of protocols and software as old as the FTP (file transfer protocol) and as recent as the BitTorrent protocol. On top of these data transfer systems, community layers organize the social and operational aspects of file sharing, providing space for one-to-one/many-to-many interaction and metadata management. Community layers make heavy use of social software such as forum and blog engines, content management systems and wikis. A good example of community layer software is the open source BitTorrent tracker software TBSource, which is used on many torrent communities for tracking and indexing torrent files and for managing a community website, in which users can browse through content for download/upload and interact.

Online file sharing has come a long way since Napster. The power of new technologies—such as BitTorrent—has greatly advanced the effectiveness of the data transfer layers. The greatest boost in sophistication, however, has occurred in the community layer, which now provides a rich source of regulation through both code and norms.<sup>15</sup>

To date, this extremely complex ecosystem has not been adequately appreciated content industry, policy makers and academic literature. Studies have focused on matters related to information policy, copyright reform and litigation strategies. File sharing has generally been used only as one of many examples of how law is challenged by technology. The phenomenon has yet to be studied in true analytical depth and breadth, without a judgmental stance. There has been too much focus on the individual, sometimes with a very disapproving moral tone (e.g. Kovacs 2001). Less attention has been

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<sup>15</sup> We follow Lessig's theory of four modalities of regulation (law, norms, architecture, and market) for the following analysis (Lessig 1998, 2006).

given to the complex realities of how file sharers interact and build communities that, in turn, are the source of intense normative production (Strahilevitz 2003).

The legal and technological campaign against file sharing has also fostered the creation of organized file sharing communities and the strengthening of sharing norms.<sup>16</sup> File sharing communities are much more than platforms for the exchange of content. They are also platforms for the production of social norms, which amount to a strong parallel version of copyright law. Indeed, the parallel version of copyright advanced by file sharing communities appears to be much stronger than the official state-backed copyright law. New laws and self-help by means of TPMs and DRM systems and global police raids and arrests have hardly left a dent on file sharing. There is organized, collective action backing up the file sharing phenomenon, based on an ethos that is in direct contrast with key elements of copyright law—the exclusive nature of the rights of reproduction and distribution of content. If strong copyright is taken for granted by content industry actors, file sharers take the opposite stance: unlimited access to content for non-commercial ends is supposed to be the norm.

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<sup>16</sup> No matter how open to criticism the term “sharing” is, and how different accounts for the motivation to “share” can be brought up, the “file sharing” label has stuck, and is not going anywhere. It does not matter if sharing is explained through a gift culture model (Giesler and Pohlmann 2002), or a “self-interest masked by the use of code” model (Strahilevitz 2003). File sharing communities’ self-image is one of sharing, and social norms tend to be conceptualized in those terms, even if motivations for participation and reasons for the high rates of success in the enforcement of norms vary.

## Norms versus law

Despite being a new phenomenon, the normative basis for file sharing culture has a long tradition in Brazil and elsewhere. Practices involving the sharing of cultural goods are far from novel. People everywhere are accustomed to sharing information, whether by lending a book, making someone a mixtape, or telling a campfire story. “Culture is public,” as Clifford Geertz puts it, “because meaning is” (Geertz 2000). Taking this basic fact of human culture into account, the use of new technologies allowing for easy reproduction of content for cultural transmission seems inevitable.

By attacking Napster and the services that immediately followed, the content industry only accelerated the growth and construction of file sharing communities. What had been a single community became dozens as meeting spots multiplied and new technologies were tested. File sharing did not cease but intensified, evolved and became more sophisticated (Oram 2001, Maymounkov and Mazières 2002, Cohen 2003, Kulbak and Bickson 2005). Suing individual users was even less helpful. These served only as another catalyst for the shaping of the sharing ethos, further facilitating the construction of a body of norms in direct competition with established copyright law. Content industry actors are not unaware of this normative dynamics underlying file sharing, however, their moral arguments against the sharing ethos have so far not been effective (d’Astous et al 2005, Lantagne 2004). Indeed, attempts to curb the growth of sharing norms through publicity or “educational” initiatives have in some cases backfired.<sup>17</sup>

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<sup>17</sup> In 2006, the Canadian copyright licensing agency, Access Copyright, launched a copyright awareness campaign targeted at children, using the mascot Captain Copyright. The campaign was notably mocked by Canadian legal scholar and

As file sharing grows, the public becomes increasingly aware of the problems with current copyright law.<sup>18</sup> Diversity of opinion on copyright legislation becomes unavoidable and paves the way for legal reform. Although public debates remain industry-dominated, a body of social norms continues to evolve in the opposite direction. The effects of technological development have clearly been stronger in aiding free reproduction and distribution than in restraining it. The practice of file sharing is still growing, and communities are increasingly more organized.<sup>19</sup>

Until recently, file sharing received little attention in Brazil from the domestic or international content industries. Although RIAA and MPAA's legal actions against file sharing in other countries do get coverage in Brazilian media, Brazilian nationals involved in file sharing faced no opposition. In 2006, however, the International Federation of the Phonographic Industry (IFPI) revealed that it would work with the Brazilian Association of Record Producers—*Associação Brasileira dos Produtoras de Discos* (ABPD)—to extend RIAA's litigation campaign into Brazil (Araújo 2006).

According to IFPI's press release, Brazil is now among "17 countries" where "a total of more than 13,000 legal actions" have taken place (IFPI 2006). IFPI chairman and chief executive John Kennedy warns: "They all thought they were unlikely to be caught,

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public-interest advocate Michael Geist (2006). The Captain Copyright website is no longer functional.

<sup>18</sup> As Drahos and Maher note, "the rise of international civil society has meant that regulators everywhere have to deal with much more interest group activity than in the past" (Drahos and Maher 2004, 5).

<sup>19</sup> The darknet thesis (Biddle et al 2002) has so far been correct: "There seem to be no technical impediments to darknet-based peer-to-peer file sharing technologies growing in convenience, aggregate bandwidth and efficiency. The legal future of darknet technologies is less certain, but we believe that, at least for some classes of user, and possibly for the population at large, efficient darknets will exist."

but teachers, postal workers, IT managers, scientists and people in a host of other occupations, as well as parents, have ended up having to dig deeply into their pockets” (IFPI 2006). “[I]n Argentina,” he continues, “one mother made her son sell off his car to pay her back the settlement fee” (ibid.) This strategy has been accurately described as “the marketing of fear” (Falcão 2006). Even the president of Brazilian government’s National Anti-Piracy Council—*Conselho Nacional de Combate à Pirataria*—went on record against IFPI/ABDP’s actions (Rangel 2006).

Little is known so far of IFPI/ABDP’s litigation strategy for Brazil, because no one has come forward claiming to be at the receiving end of a lawsuit. From what IFPI/ABDP revealed to the press, only twenty uploaders are being targeted, each sharing a library of 3000 to 6000 songs. Despite the broad potential for criminal prosecution under Brazilian law, only civil damages will be sought (Folha Online 2006b). For now it seems, Brazilians sharing fewer than 3000 files will be safe from prosecution, and downloaders are not being targeted at all.

There are strong reasons to predict that prosecution of file sharers in Brazil will not have much impact. First, the probability of a lawsuit is still negligible. Furthermore, in the Brazilian legal system there is barely any pressure for reaching a settlement before a case is judged. What so far has been the dominant strategy in the U.S. context—scaring targeted users into settling without a trial (Channel 2004)—will not be applicable in Brazil. Whatever ABDP’s legal arguments are, they will certainly have to be put under the evaluation of a judge. Providing adequate evidence of infringement can be difficult, particularly if Brazilian courts require convincing proof tying a particular defendant to an implicated IP number. According to the most recent IIPA Special 301 Report, “industry’s first attempt to take

action against major individual uploaders met a negative ruling. The judge, considering the recording industry's request to ISPs to identify the uploaders, decided that such an action would violate the individuals' privacy rights; the case is under appeal" (IIPA 2008).

### **Community criticism of industry enforcement efforts**

Even more interesting, however, is how file sharers have been reacting to the enforcement campaign. The ABDP's insistence that anyone engaging in file sharing of protected content is engaged in criminal activity does not seem to be acting as a deterrent. Indeed, it may serve as a further incentive for disobedience—civil or otherwise.<sup>20</sup> Since there has not been opposition to file sharing in Brazil up until October 2006, the parallel version of copyright that is fostered by file sharing communities has reigned peacefully (Mizukami 2007). Now that this understanding is finally being called into question, users revolt and start looking at copyright law—many for the first time in their lives—with a critical eye.

This is particularly true of Brazil's large communities dedicated to the sharing of American TV shows and foreign language movies. There is a substantial lag between airdates in the US and Brazil, so file sharing is the preferred alternative for those who cannot wait to see their favorite shows.<sup>21</sup> All of the most popular

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<sup>20</sup> Framing file sharing as a matter of civil disobedience is not simple, when one considers that civil disobedience requires actual knowledge that one is disobeying the law (Rawls 1999). Most Brazilian file sharers, however, appear to have no idea what the law says.

<sup>21</sup> Movies also suffer from very late release dates—sometimes DVDs are released into the film's original country before a release date is set for Brazilian theaters. In addition, many Brazilian cities lack theaters showing films except for recent American blockbusters. This too feeds the demand for file sharing as a way to access cultural materials not available in the mainstream marketplace.

American TV shows—and even some more obscure ones—have communities of fans dedicated to them in Brazil. The online social networks organized around fandom often overlap with video file sharing communities.<sup>22</sup>

Looking at these communities, one finds large networks of users who simply download files, frequently organized around a core group of fans who are active in subtitling them.<sup>23</sup> The decentralized nature of subtitling—adding a layer of meaning generated by the file sharing community itself onto the pre-existing video file—creates unique opportunities for normative criticism within file sharing communities.

When the IFPI/ABDP legal actions were announced, another content industry association followed suit. The Association for the Defense of Intellectual Property—*Associação de Defesa da Propriedade Intelectual* (ADEPI)—began to send cease and desist notifications to subtitle providers, which had up until then been left undisturbed.<sup>24</sup> The largest Brazilian community devoted to ABCs TV

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<sup>22</sup> A good example is [www.9thwonders.net](http://www.9thwonders.net), the Brazilian community of fans of NBC's show *Heroes*. Even when fan communities are not as organized as 9th Wonders, they can be found at the most popular social networking sites, such as Orkut, which provides tools for easy fan community building. Since episodes and subtitles are available within the reach of a click, the file sharing option is simply too tempting for most fans to pass on.

<sup>23</sup> See, for example, [www.legendas.tv](http://www.legendas.tv). Individuals who take on subtitling work assume important community roles in the Brazilian file sharing ecosystem, much along the lines of fansubbers of Japanese animation. For an example of a popular fansub community, visit [www.animesuki.com](http://www.animesuki.com). The Fansub Wiki, [www.fansubbers.org](http://www.fansubbers.org), is also a good source of material on fansub culture.

<sup>24</sup> ADEPI has since been dissolved and fused with the Association for the Protection of Intellectual Phonographic Rights—*Associação Protetora dos Direitos Intelectuais Fonográficos* (APDIF)—into the Association Against Cinema and Music Piracy—*Associação Antipirataria de Cinema e Música* (APCM). For more information, visit [www.apcm.org.br](http://www.apcm.org.br).

show *Lost*, Lost Brasil, had been a central provider of subtitles for *Lost* episodes, but ceased these activities as soon as ADEPI came into action. This had no effect, of course, on the unlicensed subtitling and distribution of *Lost* episodes: other members of the fan community quickly picked up the job and kept on translating the shows (Folha Online 2006b, Globo.com 2006a). The backlash to ADEPI's actions could be seen in forums, blogs, and even within the very subtitles that ADEPI was opposed to.<sup>25</sup>

Messages of distaste directed towards ADEPI's actions began to appear in fan-made subtitles for a variety of shows (Lopes 2006). Examples include: "Subtitles made in honor of ADEPI" (*Lost*, episode 3.05); "For each site going down, 100 more will be created" (*Lost*, episode 3.05); "To celebrate author's rights is not to steal them" (*Lost*, episode 3.05); "Don't make bad use of this subtitle. Legendas.TV is against piracy" (*The O.C.*, episode 4.02); "Corruption is allowed. Culture isn't. Down with ADEPI" (*Prison Break*, episode 2.10); "The only necessary condition for the perpetuation of oppression is that people remain actionless" (*Dexter*, episode 1.06); "Thank you for every message of support" (*House*, episode 3.05) (Globo.com 2006b).

A few important points about the Brazilian file sharing communities can be inferred from these comments. First of all, users do not consider themselves to be in the wrong, and do not see

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<sup>25</sup> A video was also produced and posted to YouTube, entitled "E agora, ADEPI?" ("What now, ADEPI"). The video shows the use of fan-made *Lost* subtitles in Globo Television's news show *Fantástico*, when scenes of a yet-to-be aired in Brazil *Lost* episode were broadcast. Snippets of news reports on ADEPI's actions are also shown in the video, in an attempt to provide proof of the widespread acceptance of the subtitling and downloading of TV shows by Brazil's largest mass media conglomerate, and to depict ADEPI as hypocrites. The video may be viewed at: [www.youtube.com/watch?v=4RkBKrgBVfc](http://www.youtube.com/watch?v=4RkBKrgBVfc).

themselves as pirates. Second, users do not think of what they are doing in terms of a violation of author's rights, but as a celebration of these same rights. To further complicate matters, users want to react against what they see as a violation of their rights but do not know how to put their feelings into legal terms, and moreover, do not know exactly what they are revolting against.

### **New opportunities for public debate on copyright**

It is easy to revolt against ADEPI, since it was the source of the cease and desist notifications, but revolt against the law itself is more unusual. Many file sharers look at the law to find arguments to support their activities. Since the legal text is far from user-friendly, interpretation issues inevitably arise. Some people read the law and get the impression that what they are doing is perfectly legal, since there is no commercial intent.<sup>26</sup> Others mistakenly find support for the legality of fan-made subtitles in Article 8, V of Lei 9.610/98, which is in fact not applicable.<sup>27</sup>

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<sup>26</sup> Google searching for three words—“*séries*” (TV shows), “*illegal*” (illegal), “*legendas*” (subtitles)—reveals dozens of blog and forum posts trying to tackle the issue of the legal status of file sharing and fan-made subtitles, with a variety of views on the subjects. It is not rare for people to simply declare “I have no idea what the law says,” but a common misperception of Brazilian copyright law is that any non-commercial use of copyrighted works is permitted as a general principle. See, for example, the comments left at: <http://teleseries.com.br/blog/2006/11/01/lostbrasil-e-soseries-sao-preSSIONADOS-a-tirar-legendas-do-ar/>.

<sup>27</sup> Lei 9.610/98 excludes from copyright protection “common use information, such as calendars, organizers, and subtitles” (Article 8, V). The term “subtitles,” however, does not refer to movie subtitles—context excludes this interpretation, even though what is exactly meant is not altogether clear. It is very common, though, for members of the file sharing community to read a permission to subtitle in the provision. In fact, however, the dialogue of a movie is part of it and hence under copyright protection; translations of dialogue can be considered to be derivative works, and thus prohibited unless authorized by the rightsholder. This

The Brazilian population in general knows that copyright law exists, but actual copyright rules are not well understood.<sup>28</sup> Since many times not to reproduce content makes absolutely no sense—such as taping a TV show for time-shifting—Brazilians keep on breaking the law and shrug it off as being at worst an inconsequential offense and at best not an offense at all. In the end, the criterion popularly used to separate “copyright infringement” from an acceptable use is basically its non-commercial or private nature, despite the formal existence of a strict list of limitations which does not necessarily follow the same logic. This normative instinct underlies file sharing in Brazil. Copyright law is imagined as targeted towards pirates as illegal re-sellers of copyrighted material, and any private use is taken to be a right, even when the law says otherwise.

The traditional practices of information sharing, amplified and organized through modern file sharing, reflect a public opinion environment that is extremely hostile to the content-industry version of copyright law, which prohibits even non-commercial sharing. When copyright awareness was still absent from most people, industry discourse was taken as common sense, and yet ignored when actual information reproduction and sharing came into practice. Now that industry is adopting increasingly more aggressive strategies in going after users, however, the situation is different. People are now being forced to think about copyright law, and to compare it to the

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often goes unnoticed by file sharers. See the following lengthy discussion in the boards of one Brazil’s largest film news and reviews websites: [http://www.cinemaemcena.com.br/forum/forum\\_posts.asp?TID=12648&PN=1](http://www.cinemaemcena.com.br/forum/forum_posts.asp?TID=12648&PN=1).

<sup>28</sup> The situation is not very different from Jessica Litman’s evaluation of public perception of copyright law in the US: “people do seem to buy into copyright norms, but they don’t translate those norms into the rules that the copyright statute does; they find it very hard to believe that there’s really a law out there that says the stuff the copyright law says” (Litman 2001, 112).

parallel copyright norms that actually guide their behavior, as reflected most clearly in file sharing communities. Since so many Brazilians behave as if an exception existed for non-commercial reproduction and derivative works, the question must soon arise whether such an exception should be written into law.

Information policy considerations are only now being placed where they always belonged: at the center of public discourse, and within reach of the ordinary citizen. If questions such as “What is copyright for, anyway?” and “What should my rights as a user of copyrighted content be?” start to appear in everyday conversations, there is still hope for reform. The public’s embrace of a presumed “right” of non-commercial use and distribution, however, have yet to be conceptualized as a problem related to exceptions and limitations. Ordinary users are beginning to get in touch with copyright law and trying to use it to argue in the defense of the sharing ethos, but they lack the conceptual repertoire that is necessary for rational public discourse over information policy matters. As the next section discusses, this effort has so far found little support from legal scholarship.

## **The role of Brazilian legal scholarship**

If a perspective of criticism and questioning is emerging among the Brazilian public, it has yet to find reflection in the legal profession. Scholarly debates over copyright exceptions and limitations in Brazil are almost non-existent. The idea that high copyright protection is essential to motivate cultural production and protect the dignity of authors, and that any exceptions and limitations that the law establishes are to be strictly construed, is the consensus scholarly position. The reasons for this unanimity—and the strategies

adopted by scholars in order to sustain an academic barrier to policy debates—deserve to be examined more closely.

### **A failure of inquiry**

Teleological reasoning is prevalent in Brazilian legal thought because of continental European influences.<sup>29</sup> In this tradition, the question of “What are the functions exerted by exceptions and limitations?” should immediately come to mind, closely followed by the question of “What are the functions exerted by copyright itself?” Once these two questions are posed, vigorous discussions are unavoidable, providing a fertile breeding ground for scholarly debate.

Looking over the most widely-read Brazilian texts on copyright law (e.g. Bittar 2003, Abrão 2002, Hammes 2002), however, one would be hard-pressed to find any depth of discussion on these matters. Reasons for copyright protection are briefly, but forcefully, stated. Then the authors proceed to dry efforts of textual exegesis which remain oblivious to these controversial issues.<sup>30</sup> A

<sup>29</sup> This influence is particularly due to the works of German legal philosopher Friedrich Carl von Savigny. Savigny’s much-discussed four elements of interpretation— grammatical, logical, historical and systematic—although taken out of the context of his broader system of legal methodology, have had a marked impact on Brazilian legal thought. The idea that an adequate interpretation of legal texts involves the correct handling of the four aforementioned “methods” is ubiquitous among Brazilian lawyers and law professors. Teleological reasoning is often mentioned as a fifth element, or simply derived from what corresponds to the logical element in Savigny’s theory. For the standard text on legal hermeneutics in Brazil, see *Hermenêutica e Aplicação do Direito* (Maximiliano 2001).

<sup>30</sup> For example, all that notable copyright scholar Bruno Hammes has to say about the rationale for copyright protection in a reasonably lengthy book, for instance, is the following: “Authors create culture. Literature and art are fruits of human intellectual activity. By protecting authors, the country promotes and increases the cultural patrimony” (Hammes 2002, 34); “Culture is a factor of progress. A learned people progresses on all points of view. Economic progress is directly dependant

rationale for copyright protection is clearly assumed by Brazilian scholars, but often stated as an unquestionable fact which is not open to debate and never to be examined beyond a paragraph or two.

Brazilian copyright scholarship is also regrettably limited in scope. There is a paucity of copyright-specific literature in Brazil. Copyright scholarship consists of an isolated corpus of texts—written by only a handful of scholars—dealing primarily with the strict exegesis of Lei 9.610/98 and occasionally branching out to Lei 9.609/98, the Penal Code and international treaties.<sup>31</sup> Copyright is studied as a self-sufficient, closed body of rules rather than as part of a broader legal system. The wealth of interactions between copyright legislation and other civil law norms<sup>32</sup> remains largely unexplored, to say nothing of the constitutional law.

The insularity of copyright scholarship is one of the major barriers to a more rational discussion of exceptions and limitations in Brazil. Lack of numbers has led, in the Brazilian case, to homogeneity of discourse. In addition, most of Brazil's copyright scholars are also copyright lawyers working for the content industry. This alignment

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on culture. Author's rights are a source of economical riches. There are important economical sectors that depend on author's rights" (ibid., 36).

<sup>31</sup> Courses on copyright are not part of the curricula of the overwhelming majority of Brazilian law schools. Copyright is studied only as part of elective course offerings, which are seldom available. This fact is sometimes noted by conventional copyright scholars, as part of discourses that blame the "social acceptance" of piracy in Brazil on the absence of proper education (see, e.g., Kretschmann 2006). The most serious consequence of this deficiency, however, is that copyright scholarship remains largely unexamined by the academic community.

<sup>32</sup> A good example is the interaction between copyright licenses and consumer law. Any license demanding that rights be unilaterally waived by consumers is unauthorized by Brazilian consumer law (Lei 8.078/90, Article 51, I). That would make any licensing arrangement making use of DRM technology in order to impose barriers to exceptions and limitations to copyright automatically against the law.

may be responsible for legal scholarship's decidedly industry-oriented stance on copyright matters.<sup>33</sup> As a result, the content industry not only writes copyright law in Brazil but also, effectively, interprets it.

### **Exaltation of the Romantic author**

In order to understand how this works, it is necessary to see how strong natural rights-based justifications for copyright are woven into legal doctrine by Brazilian scholars in order to push the theory that the public is well served by the status quo.

Studies on the foundational arguments for intellectual property protection usually mention two strands of justification, grounded on either utilitarian or natural rights-based theories (Menell 2000). Regardless of a particular country's copyright tradition—Anglo-American copyright or continental European *droit d'auteur*—both strands can be found and are actively used (Ginsburg 1990, Goldstein 2001). Yet countries such as Brazil that have been exposed for a longer time to Berne-style rhetoric and continental European *droit d'auteur* are inclined to make much heavier use of natural rights arguments.

The traditional utilitarian justification considers the legal monopoly established by copyright a necessary evil, justified by its ability—over the long run—to facilitate public access to works that authors otherwise would not have had the incentives to create. Brazilian scholars offer a narrower version of this utilitarian

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<sup>33</sup> Textbook author Plínio Cabral, for instance, adopts ABDR rhetoric when criticizing the reprography of excerpts of protected works for educational purposes: “On universities, so-called ‘professors’ folders’ can be found in which, without any order, indication of title or authors’ names, copies of excerpts of protected works pile up in haphazard fashion. This is true pedagogical junk, an attack on culture and an offense to the education of our youth, besides a gross violation of author’s rights” (Cabral 2003, 72).

argument: authors need incentives so that they can create, and that is the end of the story. Culture is not seen as a matter of necessity, of human needs related to communication and the very development of a society, but as part of a hierarchical worldview in which authors are valued above non-authors.<sup>34</sup>

Instead of being the result of a bargain between public and private interests, then, copyright is seen as a means of protecting authors from the public. The neo-utilitarian justification of providing a living to creators comes along with further appeals to protection of the author's personality and dignity. In this view, the entire universe of copyright law on the figure of the mythical Romantic creator who—despite the theoretically non-transferrable and non-waivable nature of moral rights—can be and usually is replaced by a corporate agent through contractual means. In other words, authors deserve protection as an incentive for creation, but more importantly, just because they are authors. Discussion of the direct and collateral damage commonly associated with intellectual property protection is completely avoided.

### **Strict interpretation of exceptions and limitations**

The logical consequence of the Romantic-inspired *interpretatio in favorem auctoris* in Brazilian copyright literature is the idea that lists of exceptions and limitations are to be strictly construed, with absolutely no room for judges to decide on broader principles (Abrão

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<sup>34</sup> Authors, in this case, also means industry, but this is rarely explicitly mentioned. The fact that we have “author’s rights” legislation instead of “copyright” immensely helps the protection of industry through the proxy of authorship, by centering the entire universe of copyright law on the figure of the mythical, Romantic author/creator.

2002, 146).<sup>35</sup> Whatever is written under article 46 of Lei 9.610/98 or article 6 of Lei 9.609/98 is to be interpreted in the strictest and most restrictive way possible, and any controversy in interpretation must be decided in favor of the author. The strict interpretation dogma has acquired the status of common sense. It is never questioned.<sup>36</sup>

Two lines of reasoning are commonly used to defend strict interpretation. The first argues that Article 4 of Lei 9.610/98 expressly mandates this approach (Bittar 2003, 71; Cabral 2003, 15-16). Article 4, however, clearly refers to the interpretation of copyright *contracts*, and not interpretation of the statute itself. Unlike copyright legislation in the Dominican Republic,<sup>37</sup> for example, Brazilian law does not explicitly call for strict interpretation of exceptions and limitations. The second line of argument maintains that strict interpretation is logically required, since exceptions and limitations deal—by definition—with exceptions to the general rule (Abrão 2002, 146). Viewed from another angle, however, copyright itself is an exception to the rule of public access to content and public domain. Thus an argument from logic might equally conclude that exceptions and limitations for public use should be interpreted from the broadest perspective possible. Despite the flaws of both

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<sup>35</sup> The only notable author who seems to partly disagree with this is Eduardo Vieira Manso. Writing about the 1973 statute, Manso analyzes strict interpretation of exceptions and limitations in a purely commercial context, and states that any use of protected content with non-commercial intent should be considered a free use (Manso 1980, 132-133 and 152).

<sup>36</sup> As Norman Fairclough writes, when ideologically charged discourses such as the entire rhetorical apparatus required for the defense of the strict interpretation dogma acquire enough power to be taken as common sense, they also assume a semblance of neutrality which turns them into an “official” version of the truth, and consequently become very difficult to be challenged (Fairclough 1990).

<sup>37</sup> Ley 65-00 (Ley sobre Derecho de Autor), article 30.

arguments, the conviction that exceptions and limitations are to be interpreted as narrowly as possible dominates traditional copyright scholarship in Brazil.

### **The birth of dissent**

This is Brazilian legal scholarship on copyright so far. But signs of a more nuanced future are on the horizon. Digital reproduction is here to stay and so is content distribution through the Internet. Collaborative authorship, commons-based peer production, free software and open content licensing are on the rise despite technological and legal threats. Scholarship cannot remain oblivious to these facts.

For the first time in Brazil's history, a schism can be seen in copyright scholarship. This is a result of challenge from outside the community of established authorities.<sup>38</sup> Instead of operating on strictly doctrinal grounds, this new body of literature takes a critical approach to the conceptualization of copyright law in general and the interpretation of exceptions and limitations in Brazilian law in particular. It remains to be seen if these re-interpretations will gain traction. Support for them is strong, however, when copyright law is viewed in light of Brazilian constitutional law.

### **Copyright and the constitution**

The maximalist approach to copyright protection that currently dominates Brazilian statutory law and legal scholarship

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<sup>38</sup> This has been due in significant part to the influence of recent American scholarship, particularly the works Lawrence Lessig and Yochai Benkler. Domestic scholarship by authors with broader interests in intellectual property and international law, however, is also playing an important role. See, for instance, Lemos 2005 and Barbosa 2003.

emphasizes the rights of copyright-holders while minimizing the rights of users seeking access to knowledge. It is questionable, however, whether this approach is acceptable when viewed in light of the broader constitutional framework.

While the Brazilian constitution requires protection of authors' rights, it also contains provisions requiring protection of other public interests that may be affected by copyright law. These include guarantees related to free speech, education rights, access to culture, antitrust law and consumer law. The constitution specifically mentions goals such as the "production, promotion and diffusion of cultural goods" (Article 215, II), the construction of a society that is "free, fair and grounded on solidarity" (Article 3, I), the "eradication of poverty and marginalization and the reduction of social and regional inequalities" (Article 3, III). It charges government to promote "full employment" (Article 170, VIII), to "provide the means of access to culture, education and science" (Article 23, V), to "promote scientific development, research and technological capacitation" (Article 218) and to secure the "full exercise of cultural rights" (Article 215). Fulfillment of these rights calls for greater use of exceptions and limitations to strike an appropriate balance in copyright law.

One possible path to an alternative approach to copyright exceptions and limitations begins with the constitutional clause on the "social function of property."<sup>39</sup> While there has been resistance in the past to the idea of applying the clause to intellectual property

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<sup>39</sup> Brazilian Constitution, Article 5, XXIII: "Property shall fulfill its social function." The social function of property is also mentioned as one of the principles that guide economic activity under Article 170, III, alongside private property (article 170, II), consumers' rights (Article 170, III), competition (Article 170, IV), and the reduction of social and regional inequality (Article 170, VII).

(Bastos 1998, 210), recent literature is more receptive to the idea (Souza 2006, Carboni 2006, Guerrero 2006, Oliveira 2006, Branco 2007, Mizukami 2007). Although the exact meaning and extent of this clause is open to debate, current Brazilian constitutional scholarship provides a welcoming environment for the analysis of competing property interests, individual rights and state goals. This can serve as an intellectual basis for considering a more systematic framework exceptions and limitations to copyright.

Brazilian scholarship on constitutional law has been very open in the past years to recent German legal theory.<sup>40</sup> This framework makes it quite easy to defend the use of the social function of property clause as a source for exceptions and limitations to copyright. Reasoning based on the Dworkin-inspired rules/principles distinction proposed by Robert Alexy (2000, 2002, 2003) makes a particularly productive strategy for arguing for a more extensive and permissive system of exceptions and limitations. The Brazilian constitution is also structured in such a way that it is possible to easily defend the existence of the horizontal effect of constitutional rights.<sup>41</sup> There is thus broad opportunity to argue for the direct enforcement of constitutionally derived exceptions and

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<sup>40</sup> The works of Robert Alexy and Friedrich Müller—which despite being deeply incompatible are usually seen as component parts of a single unitary approach—have been particularly influential. This is mostly due to the great influence of Portuguese author José Joaquim Gomes Canotilho’s constitutional law textbook, *Direito Constitucional e Teoria da Constituição* (Canotilho 2002).

<sup>41</sup> Brazilian constitutional law does not present a “state action” requirement to find a violation of constitutional rights—actions of other citizens or of corporations can also be found to violate constitutional rights. Indeed, the text of the Constitution is so open to the concept of horizontal effects that the controversy surrounding them is limited to how exactly effects should be considered (da Silva 2005, Steinmetz 2004, Sarmiento 2006).

limitations, either alongside the ones that have been statutorily established or in place of those limitations.

## Conclusion

As the preceding account of exceptions and limitations reveals, Brazil is a nation of criminals when it comes to copyright infringement. Moreover, this situation is not going to change in the foreseeable future. In opposition to the dominant cries for stronger copyright protection and enforcement, this chapter argues that instead of scandal directed at Brazilian citizens, scandal should be directed at the inadequate state of the law and of legal scholarship. What is needed now is a critical re-evaluation of the essential role of exceptions and limitations in balancing the interests of copyright holders and the larger public, particularly in light of Brazil's constitutional guarantees.

Exceptions and limitations in Brazilian copyright law are inadequate on many accounts. They are excessively restrictive and anachronistic—in some cases incoherent—and offer no opportunity for balance through interpretation. To make things worse, they are often misinterpreted by the content industry to pose even greater limitations on users. As a framework for public rights of use and access to culture and information, the current lists of exceptions and limitations are unacceptably limited.

Although the scenario we have described is bleak, there is also hope on the horizon. The Internet and digital technologies have turned culture and information policy into the focus of popular attention. The new efforts of the Ministry of Culture to create a genuine public discussion of copyright policy are a sign of these times. Prior to leaving his post as Minister of Culture in July 2008,

Gilberto Gil initiated a series of public debates on copyright legislation through the Fórum Nacional de Direito Autoral. This series of multistakeholder conferences aimed at a long-overdue overhaul of copyright law. So far two conferences have been staged, with debates broadcast over the Internet to encourage broad public participation. This is unheard of in the history of Brazilian copyright lawmaking, and all things considered, a positive development. Although public participation has been negligible so far, the fact that there is an open forum for copyright reform at all is welcome change.

At the same time, old habits die hard. Under the pretense of protecting Brazilians against identity fraud and child pornography, a bill currently under congressional discussion would create even more criminal offenses related to the reproduction, distribution and modification of copyrighted content online (Doctorow 2008). Under Senator Eduardo Azeredo's proposed "cybercrime" legislation, even accessing a website while disregarding its terms of use could be punished with one to four years of imprisonment. A new system of private surveillance—charging Internet service providers with notifying the police of potential criminal activity and providing identity records of users—is also a part of the package.

Together, these two recent initiatives illustrate well the crossroads at which Brazilian copyright law currently stands. While the outcome of these battles is not easy to predict, at least copyright law is now on its way to being properly debated in Brazil.

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# BIOTECHNOLOGY IN BRAZIL: PROMOTING OPEN INNOVATION

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**T**his chapter examines the current efforts of the Brazilian state to promote the biotechnology sector, leveraging the nation's immense biodiversity as a resource for economic development. The analysis focuses on a case study of the ONSA Network's Genoma Program, which adopted a collaborative approach to basic research in biotechnology. This experience may be considered a success story in open innovation. Critical questions emerge, however, when examining the prospects for commercial application of these discoveries. Will scientific analysis of Brazil's vast natural resources propel rapid innovation in

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agriculture, medicine and other fields? Or will multiplying intellectual property claims result in a “patent thicket” that holds back development in Brazil’s biotechnology sector? Our discussion of these issues develops in three parts:

**Part one** reviews the political context of the biotechnology sector’s development in Brazil. In 2003, federal policy-makers identified this high-technology industry as a promising site for development. In 2007, a national biotechnology policy was issued, along with a commitment to a significant investment in public funds.

**Part two** presents a case study of a foundational Brazilian experience in biotechnology research: the Genoma Program developed by the Organization for Nucleotide Sequencing and Analysis, or ONSA Network. This effort demonstrated the promise of an open, collaborative approach to biotechnology research, leveraging the “wealth of networks” to jump-start a new field in a developing country.

**Part three** examines the importance of intellectual property policy for the future of Brazil’s biotechnology sector. This part discusses the tensions between biotechnology patenting, and the opportunities for collaboration that characterized the ONSA Network’s Genoma Program. The chapter concludes by examining the prospects for promoting more open innovation in the Brazilian biotechnology sector.

## The Biotechnology Development Policy

The Brazilian state plays a fundamental role in shaping the field of biotechnology, acting as networker, financier and producer. Highly conscious of its position as the nation with the greatest biodiversity in the world, the Brazilian government views

biotechnology as a critical element in its global competitiveness strategy. Although firmly committed to market-based development, the Brazilian state's view is that private companies must have the support of a national innovation system to jump-start development in this strategic sector.

According to Brazil's 2003 Industrial, Technological and Foreign Trade Policy—*Prospectiva Consultoria Brasileira de Assuntos Internacionais* (PITCE)—“the global scenario is characterized by new economic dynamics based on an increase in the demand for unique products and processes, made possible by the intensive and accelerated development of new technologies and forms of organization. This new dynamic sees innovation as the key element for industrial and national competition growth” (Governo Federal 2003, 4). Among other measures, the 2003 economic strategy document identified biotechnology as a key sector for development. Also in that year, the government established the Biotechnology Competitiveness Forum—*Fórum de Competitividade de Biotecnologia*—to bring together researchers, industry and labor to define sector-specific policy goals and opportunities (Furlan et al 2007). Four years later, the federal government formally launched its Biotechnology Development Policy—*Política de Desenvolvimento da Biotecnologia* (Governo Federal 2007).

In a speech announcing the new policy, President Lula encapsulated its ambitious goals: “by holding twenty percent of all global biodiversity and vast forests, Brazil stands out as an important country in this new development vector. The goal of the Biotechnology Policy is to fully exploit this potential so that in the next ten to fifteen years, Brazil will rank among the five greatest research, services and biotechnological production centers in the world” (Lula da Silva 2007, 3). Driving home the centrality of high-

technology innovation to national development aims, the president promised, “Brazil is not and will never be again a mere supplier of raw material to the global market. Rather, the Brazilian Growth Acceleration Program and Biotechnology Development Policy have looked towards another direction, defining other priorities for Brazilian development in the twenty-first century” (ibid., 5).

In announcing its new biotechnology policy, the government was building upon several successful experiences with publicly-funded research over the last three decades (Valle 2005). The Brazilian state’s investments in scientific innovation have ranged from chemistry and pharmaceuticals (Vitolo 1999), to geosciences (Assad 2000), to agriculture and environment (Bin 2004). A point of particular national pride has been the nation’s success in developing new biofuels to protect its energy independence and create new markets for major crops (Ayarza 2007).

The political rhetoric surrounding the Biotechnology Development Policy made this connection explicit. Quoting again from the president’s address:

Our objective is to take up a leadership position in [the biotechnology field] similar to that already assumed by the biofuel area. This has become a partnership of indisputable success between the scientific community and the efficiency of the Brazilian entrepreneurial society. Our greatest challenge, my friends, is to repeat this successful collaboration in other areas of the economy and production. We must begin to produce affordable drugs and vaccines, biodegradable plastic, develop more effective and less polluting

industrial enzymes, more nutritious food, medicines and cosmetics from our bio-diverse environment and techniques of environment recovery. In addition, in the future, we must focus on biotechnology by investing in DNA sequencing research, the neurosciences, stem cell research, nano-biotechnology, [and] biopharmaceuticals... (Lula da Silva 2007, 3).

Similar points were made in accompanying announcements from government ministers responsible for implementing the new policy (Furlan et al 2007). These also gave more detail on how the efforts would be carried out:

[T]he Biotechnology Development Policy... means focusing on innovation and the integration of research and production... Efforts and resources will be allocated for the production of vaccines and hemo-derivatives, plus other specialized products and services to meet the demands of public health; development of processes connected to biomass and food, cosmetics and environmental uses... development of strategic agricultural and cattle raising products, and to reach new competition and food safety levels by introducing innovations and product differentiation to win new markets. ...To do so, Brazil [also] needs to address key industrial consolidation issues, from the establishment of stable and safe

regulatory boundaries to fiscal and credit policies” (ibid.).

Within this framework, the federal government committed R\$6 billion—approximately USD 3.5 billion—in public funds to support biotechnology research and development over ten years. The government aims to have private companies contribute an additional R\$ 4 billion. The efforts will be guided by two institutions. The National Biotechnology Committee—*Comité Nacional de Biotecnologia*—is composed of researchers, government officials and members of civil society, including representatives of indigenous groups. The Biotechnology Competition Forum, established in 2003, continues to represent the interests of the business sector.

The National Biotechnology Policy reflects the Brazilian state’s belief that collaborative partnerships in scientific research and development can yield benefits for business and for society as a whole. A crucial element in this effort is state support for basic science, which is understood to yield not only technological discoveries necessary for product innovation, but also to serve as a training ground for human capital—in the form of skilled researchers and scientists—upon which this new sector depends. Although the National Biotechnology Policy has only recently been formally announced, state-sponsored research has a long tradition in Brazil including in the field of biotechnology. A critical evaluation of these prior experiences will shed light on the challenges and opportunities presented as the government prepares to expand these efforts through the National Biotechnology Policy.

## **An open research model for biotechnology**

This section presents a case study of São Paulo’s “virtual institute” for genomics research: the Organization for Nucleotide Sequencing and Analysis, or ONSA Network—*Rede ONSA*. Launched in 1997, the ONSA Network’s Genoma Program represents the beginning of genomics research in Brazil. Developed in São Paulo—the state with the highest degree of industrialization and the densest university network—the Genoma Program has tackled a series of genetic sequencing challenges over the past decade. Through these projects, the ONSA Network was developed and technical capacity for genomics research in Brazil greatly expanded.

The following analysis focuses on the collaborative and open dimensions of the ONSA Network’s practices, examining whether it is possible to characterize these efforts as consistent with an access to knowledge approach to open innovation. This analysis will show that collaborative practices in the biotechnology field can promote access to knowledge across two dimensions: broader dissemination of technical capacity, and more democratic control over the products of basic research. The democratization drive at the research stage may still give way to privatization later on, however, as entrepreneurial actors seek to appropriate the downstream benefits of research.

### **Conception of the ONSA Network’s Genoma Program**

The São Paulo State Foundation for Research Assistance—*Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP)*—established the Genoma Program in 1997. The program had two objectives: first, to discover new biotechnological methods for improving local agriculture; and second, to develop expertise in genomics in the State of São Paulo (Dal Poz 2000; O Estado de São

Paulo 1997). To achieve these goals, FAPESP established a network of thirty university laboratories. These laboratories would act as “a virtual genomics institute” to collaborate in sequencing the complete genome of *Xylella fastidiosa*, a bacteria responsible for significant damage to the region’s citrus crops (FAPESP 2008).

The ONSA Network’s Genoma Program offers an example of alternative production models and the “wealth of networks.” According to Yochai Benkler’s wealth of networks theory, new digital technologies facilitate collaborative production of information goods, enabling less centralized, less capital-intensive production models (Benkler 2005). Whereas the traditional model for jump-starting genomics research was to establish a single national genomics research facility, the Brazilian experiment sought to coordinate the efforts of many smaller laboratories. This decentralized production model was facilitated by the contributions of a distributed network of researchers to a central data repository through the Internet. In this way, the project’s founders sought to build comparable genomics research capabilities, but at a lower cost and shorter start-up time (Macilwaine and Neto 2000, 440).

Consistent with this capacity-building approach, the ONSA Network was designed to create opportunities for researchers to receive training in genetic sequencing techniques. The project’s announcement stated: “This joint effort should significantly increase the number of laboratories in the state capable of using modern molecular biology techniques. The project also intends to provide contemporary training in basic molecular biology to graduate students to develop the biotechnology field and the ‘genome culture’ in Brazil” (ONSA 1997). Even laboratories without established expertise in molecular biology were invited to participate in the

ONSA Network, provided they submitted a clear proposal for how the skills acquired would be applied in future research activities.

### **Results of the ONSA Network's Genoma Program**

In 1999 the Genoma Program achieved its original goal, producing the world's first complete genomic sequence of a plant pathogen. The striking accomplishment led to a feature in the respected scientific journal *Nature* (Macilwaine & Neto 2000). The ONSA Network's collaborative efforts, however, did not end with the *xylella fastidiosa* breakthrough. Two new goals were set in 1998: sequencing 50,000 sugar cane genes involved in plant development and sugar content and investigating their roles in resistance to diseases and adverse climate and soil conditions.

The ONSA Network began its first project with human health applications in 1999. The Human Cancer Genome Project identified one million sequences of Brazil's most frequently-occurring tumors before the end of the following year. The Clinical Cancer Genome Project was later established to develop new diagnosis and treatment methods based on these genetic insights. Soon thereafter, ONSA Network established a project to sequence genes of a parasite responsible for schistosomiasis, an under-researched disease endemic to parts of Brazil.

In addition to achieving ever more ambitious sequencing goals, the Genoma Program's objectives in the area of technical capacity-building were also a success. At the beginning of the program, few members of the ONSA Network had ever sequenced DNA. Five years later, more than 450 researchers had training and experience in DNA sequencing (Camargo & Simpson 2003). The Genoma Program's success in developing this capacity provided the

necessary human capital foundation for the national Biotechnology Development Policy to be launched in 2007.

The ONSA Network's Genoma Program also demonstrated the feasibility of a decentralized, network approach to advanced biotechnology research in a developing country context. This open research model has since been successfully applied to other public research goals, notably the BIOTA Program, an initiative to survey and catalog the biodiversity of the state of Sao Paulo for the purposes of environmental preservation and sustainable exploitation.<sup>1</sup>

Given the potentially broad applications of this innovative open research model, its contours deserve more detailed discussion. The open research model developed by the ONSA Network has three key elements: (i) coordination between universities and public funding agencies, (ii) decentralized, democratic organization of production and (iii) virtual publication of data via the Internet.

### **Coordination between universities and public funding agencies**

The foundation of the ONSA Network's collaborative approach to biotechnology research is a new system of coordination

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<sup>1</sup> The Biota Program, also funded by FAPESP, adopted a collaborative research approach to mapping out the state's biodiversity. Its organization is based on "the culture of collaborative research," facilitated by standardization of data (Biota.org 2008). This conception is its core and in this respect, it is a more improved and self-aware experience than its predecessor, the Genoma Program. Taking advantage of the expertise of the previous project and the wider network of professionals familiar with its organization and methods, the Biota Program aimed, since its beginning, to build a broad and continuous block of information collectors, with a wide geographical and thematic reach. The program is considered to have been a success and has involved some 500 researchers from São Paulo, who are participating in 50 research projects. The information produced by this research effort was instrumental in shaping later environmental policies.

between laboratories, facilitated by public funding. The Genoma Program's work was centrally guided by a five-member steering committee, composed of three international experts in genome sequencing and two scientists from the state of São Paulo. A single Project DNA Coordinator was charged with generating the fragments of the genome assigned to each laboratory for sequencing and coordinating the flow of completed sequences from the laboratories to the Bioinformatics Center.

Membership in the network was granted by means of a contract between the participating laboratory and the São Paulo State Foundation for Research Assistance (FAPESP). Under the terms of the contract, sequencing laboratories received DNA material, equipment, and training. In return, they were obligated to share sequence specific DNA fragments—assigned by a central research coordinator—at a prescribed standard of quality, within one year. The resulting mapped information would be fed back into a common repository associated with the project, which could then be accessed by any interested party. As soon as a laboratory successfully delivered a sequence, it could apply for a second assignment.

### **Decentralized, democratic organization of production**

Although the research environment was stimulated by a state agency, its actual implementation was decentralized. Individual laboratories were responsible for their own project management. Under the terms of the contract, laboratories received a specified payment per base pair of finished sequence. This was set at R\$4 per base pair in the initial research stage to cover start-up costs. Of this payment, 70% was advanced before the service was rendered, and 30% was paid upon delivery of the sequence to the Bio-Informatics center. Laboratories could allocate their funds for equipment,

supplies, third party services and travel as they saw fit. An incentive was provided for efficient work, in the form of research stipends proportional to the amount of work successfully completed. Participating laboratories could also advance in stature according to the scale of their contributions to the project.

The ONSA Network empowered peripheral laboratories in two ways. First, participation in the project was open to laboratories with no previous experience in DNA sequencing. The project funding enabled such laboratories to purchase state-of-the-art DNA sequencing machines, and to train their student technicians in its operation. In this way, research tools and the relevant technical expertise spread throughout the state university system. Second, because the participating laboratories were encouraged to work in tandem on a common project, the joint accomplishments were of a scope that none of the laboratories could have achieved independently. The scale of these accomplishments helped forge a reputation for Brazilian science in a field previously dominated by researchers in more developed countries.

### **Virtual publication of data via the Internet**

The choice to create a network that was physically spread over several research centers, with modest central coordination, was partially motivated by limitations. There were few Brazilian researchers working in the genomics field before the Genoma Program, and these few researchers were spread out across several institutions. As Brazilian innovation policy analyst Maria Ester Dal Poz has written,

The [ONSA] network allowed for links to be established between researchers, in

a scientific learning system, with the development of genetic protocols, an exchange of information, the solving of common problems, the adaptation and adjustment of techniques and improvements in the productivity of DNA sequencing. The union of many laboratories developing their own broad-scope research with a single scientific objective was an important learning factor for generating expertise in refined molecular and genomic biology techniques. This research organization encourages the spreading of research throughout the whole State, which would not have happened if a single center had been set up (Dal Poz 2000, 28-9).

To support such collaboration between physically, technically and economically distant laboratories, new communications protocols were developed to enable faster information dissemination. Centralized support for bio-informatics was made the responsibility of the Computing Institute of the State University of Campinas—*Universidade Estadual de Campinas (UNICAMP)*. This body oversaw a great evolution in the use of the ONSA data network, which achieved full technical maturity during the Human Cancer Genome Project. This project represents the Genoma Program's technical and political apex, wherein delivery of sequencing results was combined with quality control measures to achieve a rigorously accurate database (Kimura and Baía 2002).

In addition to meeting the communication needs of the ONSA Network, the assembly of this IT network also led to the creation of two Brazilian bio-informatics companies. Scylla

Bioinformática was established in 2002 at the initiative of five people that had worked on the *xylella fastidiosa* sequencing and other ONSA Network projects—the company specializes in software solutions for genomics research.<sup>2</sup> Alellyx Applied Genomics was founded in the same year by five molecular biologists and informaticists involved in the ONSA Network, with the assistance of Brazilian venture capitalists. This company focuses specifically on genomics applications for agriculture and currently employs more than one hundred people.<sup>3</sup>

### **Learning from the ONSA Network experiment**

The open research model described above created a new system of incentives for scientific research. In the traditional market-based research model, research is conducted within one firm, with the aim of accruing profit. In this model, the incentive system only works if the resulting knowledge is tightly controlled, either through secrecy or intellectual property, to ensure that the resulting value flows back to the firm. In the traditional academic research model, individual laboratories conduct research to advance their reputations through publication and increase their ability to secure future grants. In this model, laboratories may be reluctant to share any data until the research is ready for publication. The open research model relies on a different incentive system, wherein contributors receive payment according to their research output, as well as valuable skills training and reputational benefits.

Within the ONSA Network model, the incentives for knowledge production are provided through a system geared toward

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<sup>2</sup> <http://www.scylla.com.br/>

<sup>3</sup> <http://www.alellyx.com.br/>

encouraging wide participation, coordinated collaboration and full public access to research outputs. This incentive structure does not require excluding others from access to the knowledge produced, but rather rewards researchers precisely for their contributions to a shared knowledge pool. In this model, the public has paid for the research through the state funding agency, and the research outcomes are returned to the public, enabling their maximum utilization by future researchers and product developers.<sup>4</sup> Its success demonstrates that non-proprietary approaches to scientific research can be highly successful and efficient.

While similarities can be noted between this open research model and the business model of open source software, there are also significant differences. In the case of open source software, software developers perform work-for-hire for other private actors, motivated by market-based incentives. No source of public funding is required to stimulate the work, as a private market exists for these services. These developers share the knowledge and innovations produced by their for-hire work with the larger software development community because they have no financial incentives not to—their income is derived from customization services, not from ownership of the underlying code—and because sharing one's good work benefits one's reputation. In the ONSA Network model, however, the incentives for the original knowledge-production labor did not exist in the market. Rather, they were provided by a public funding agency.

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<sup>4</sup> Note that although the investment was made by the São Paulo government, it also produced benefits to the broader Brazilian public, and to actors outside Brazil who were able to use the resulting research for their own uses. This may argue for a greater degree of international collaboration in the funding of open research initiatives.

The practice of sharing was ensured as a contractual requirement of participation.

This model's success shows an alternative approach to the production of socially necessary knowledge. Here, the research (i) is concerned with broad problems of public welfare, (ii) is initiated and funded by the state, and (iii) is managed in a decentralized and collaborative manner. The ONSA Network's unorthodox approach proved to be a viable institutional alternative for solving knowledge problems that overwhelm the simple rationality of individual agents. By channeling research energies through an alternative system of incentives, a functional non-proprietary approach to the production of knowledge was achieved. This has important implications for the wide diffusion of socially necessary knowledge, in line with the goals of access to knowledge.

Nevertheless, the ONSA Network case study also demonstrates some tensions within the logic of access to knowledge. The Genoma Program's guiding principle was the sharing and diffusion of discoveries through publication of all sequencing information in a public domain database. Many other types of knowledge, however, were also generated through this publicly-funded research. In areas less politically visible and of more immediate economic value than sequencing data, much of the knowledge produced by the Program was privately appropriated. This was true, for instance, of some of bio-informatics software tools mentioned above, as well as of certain sequencing techniques developed by laboratories. Indeed, Brazil's 2004 Innovation Law—strongly inspired by the U.S. Bayh-Dole Act<sup>5</sup>—actively encouraged

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<sup>5</sup> United States Public Law 96-517, Patent and Trademark Act Amendments of 1980. The Bayh-Dole Act set the modern framework for licensing of university

university researchers to seek and commercially exploit patents on their academic discoveries (Amorim 2004). Such privatization and enclosure of knowledge may have important consequences for downstream innovation in the biotechnology sector, as will be further explored in the final part of this chapter.

## **From research to development**

The ONSA Network experiment demonstrates the potential of an open approach to biotechnology research. Brazil's goal, however, is to be a leader not only in biotechnology research but also in product development, creating a new export market for biotechnology-based goods and services. Can the open innovation model that was so successful at the research stage also find application in development? What implications does this have for the National Biotechnology Development Policy, particularly as it relates to intellectual property derived from the Brazilian biodiversity? These questions are examined in the following part.

### **The emerging Brazilian biotechnology sector**

In the last ten years, the biotechnology sector in Brazil has grown rapidly. According to a recent report, "nearly 200 life science companies in the country were identified, 40% of which were

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discoveries in the United States. Previously, any patentable discoveries stemming from federally-funded research were to be made property of the U.S. government, which would license them non-exclusively. Since the Bayh-Dole amendments, American universities are allowed to retain ownership of these patents and license them at their discretion, with revenues shared between the university and the individual inventors. Proponents of the new system point out that it has been remarkably successful in increasing university applications for scientific patents. Critics argue that rapidly proliferating scientific patents may ultimately harm, rather than promote, technology innovation (Rai and Eisenberg 2002).

classified as biotechnology companies”<sup>6</sup> (Biominas 2008, 9). According to the Biominas survey, Brazilian biotechnology firms offer products in the following sectors: Agriculture (22.5%), Reagents (21.1%), Animal Health (18.0%), Human Health (16.9%); Environmental (14.1%), Bio-energy (4.2%) and Mixed Activities (2.8%). Overall, the sector is young, and has an accelerating growth rate. Only 28% of the biotechnology companies surveyed were founded before 1997; 51% were established after 2002 (Biominas 2008). Consistent with the youth of the sector, a high percentage of companies were not yet profitable, or were generating only modest revenues. Only 5.4% of firms—generally the longest-established ones—had revenues greater than R\$10 million (Biominas 2008). The Biominas survey also revealed that the biotechnology field is concentrated in the states that have made the greatest public investments in this field. “The Southeastern states, Minas Gerais (29.6%) and São Paulo (42.3%), are home to most of the companies. Together, both states are home to seven out of ten biotechnology companies” (ibid.).

These data reflect the crucial role that incubator institutions play in the establishment and growth of biotechnology companies. Incubators are generally public universities or laboratories that become home to biotechnology research projects, which ultimately have for-profit aims. Such projects rely initially on public funding and

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<sup>6</sup> The Biominas survey differentiates between biotechnology and life science companies: “Biotechnology companies were defined as companies whose main commercial activity depend on the application of biological organisms, biological systems or biological processes, either in internal research and development, in manufacturing or in the provision of specialist services (adopted from Nature Biotechnology). Companies that did not fit into the biotechnology category but develop activities in human and animal health, agriculture or environment were defined as life science companies” (Biominas 2008).

may be dependent on the physical, technical and personnel structure of universities or public laboratories for several years. Over time, however, the objective is for these projects to become independent and succeed in selling some product or service on the market. According do the Biominas report, “Incubators play a very important role and are responsible for a growing number of biotechnology companies in several states throughout the country. Incubated biotech companies account for 35.2% of the total number.” (Biominas 2008, 13). Taken together, these data reveal an industry still in its infancy, and very much dependent on state investment for its development and growth.

### **The current intellectual property framework for biotechnology**

The emerging Brazilian biotechnology industry will be strongly shaped by the intellectual property regime in which it develops. Brazil’s intellectual property regime, in turn, is strongly shaped by the global regulation of intellectual property, particularly the terms of the World Trade Organization’s TRIPS Agreement. According to one of the authors of the current Industrial Property<sup>7</sup> Law (Lei 9279/96), “It is impossible to ignore the fact that the problem [of intellectual property law] began to be analyzed by the international community from the point of view of its implications for world trade. The subject, the norms of which were established within the scope of a long-negotiated agreement, constitutes the principles and rules to which the country owes an obligation, because

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<sup>7</sup> Following international practice, the Brazilian intellectual property regime recognizes two categories of intellectual property: copyright and industrial property. The latter encompasses patents, trademarks, mechanical designs and trade secrets.

of their international commitment and their incorporation within the domestic legal order” (Del Nero 2004, 139).

Where the TRIPS Agreement provides flexibility, however, the Brazilian Industrial Property Law often adopts a less IP-maximalist approach than is practiced by many other countries. The issue of patents on genetic sequences and other issues related to biotechnology was an area of particular controversy in the negotiations that produced the TRIPS agreement, on which the parties ultimately “agreed to disagree.” As the Brazilian legislature revised the Industrial Property Law to implement TRIPS in 1996, it chose to continue a relatively restrictive approach to the scope of allowable patents in the field of biotechnology (Chamas 2008, 89; Del Nero 2004, 165). Under Brazilian law, no patents may be taken out on “the whole or any part of living beings, except transgenic organisms<sup>8</sup> that meet the three requirements of patentability—something that is new, an inventive activity and an industrial application...and that is not a mere discovery” (Lei 9279/96, § III, Art. 18). Also specifically excluded from patentability are “operational or surgical discoveries, techniques and methods, as well as therapeutic or diagnostic methods for application in human or animal bodies, and all or part of natural living beings and biological materials found in nature, or even isolated from it, including the genome or germplasm of any natural living being and natural biological processes.” (ibid., at Art. 10, VIII & IX). Unlike many countries, therefore, Brazil does not allow for patenting of gene sequences.

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<sup>8</sup> Lei 9279/96 dated May 14, 1996 – the Industrial Property Law. The only paragraph of Article 18 establishes what transgenic micro-organisms are: “(...) they are organisms, except the whole or any part of plants and animals that, as a result of direct human intervention in their genetic composition, express a characteristic that is not normally achievable by the species under natural conditions.”

### **Proposals to expand biotechnology patenting**

The status quo, however, is precarious, as IP-maximalist arguments emerge from two quarters. Advocates of the international and liberalizing policies of the 1990s—motivated by the doctrine of New Institutional Economics—accept the view that greater protection yields greater investment, innovation, jobs, and general well-being. Advocates of national industry development policies—based on the theories of neo-Schumpeterian economics and Latin American structuralism—suggest that Brazil should provide more IP protection to avoid having its knowledge exploited in other countries, to the detriment of Brazil's international competitiveness.

Members of the party that sponsored the international and liberalizing reforms of the 1990s, the Brazilian Party of Social Democracy—*Partido da Social Democracia Brasileira* (PSDB)—have already presented two bills proposing changes to these patent ceilings. In 2003, Congressman Wilson Santos (PSDB-MT) presented Legislative Bill 2695 to change Article 10, IX of the Industrial Property Law to permit patenting of genetic material, biological samples, seeds and natural biological processes. The project was, however, removed from consideration in 2007. In 2005, however, Congressman Antonio Thame (PSBD-SP) presented a second bill with similar objectives that has already been approved in preliminary procedures and since May 4, 2007 has been with the Environment and Sustainable Development Committee.

The structuralist argument is put forward by scholars who maintain that current Brazilian policy benefits the corporate complexes of central countries, at the cost of Brazilian research. By presenting restrictions to the patenting of genetic sequences—while at the same time making sequencing available in public international

databases—Brazil may be allowing foreign actors to patent these sequences in more lenient jurisdictions. Advocates of this view note:

In Brazil, the first technological results of the Sugar Cane Genome, such as processes that reduce production costs for sugar cane and alcohol production chains, are being negotiated with international partners. In practice this means placing the research results in innovation systems that are more open to genomic-based patenting of biotechnology, through American and European patent offices. The patent protection impediment on genes in Brazil encourages the internationalization of genomic research and development (Dal Poz and Barbosa 2008, 132-133).

According to these scholars, a contradiction exists in Brazil's approach to genetic patenting:

On the one hand a mega-diverse Brazil would agree to fight internationally for maintaining its industrialization principle in order not to run the risk of having material from its biodiversity used for generating genomic innovations in other countries. On the other hand, genomic research significantly contributes to international gene-banks, by depositing DNA sequences and proteomic data that increase the opportunity for other countries, which have sufficient inventive capacity to choose the appropriation logic that refuses the industrialization

principle, to take advantage of these resources in order to monopolize the pre-technical knowledge phases by countries (ibid).

If advocates for relaxed patent protection standards in biotechnology win this debate, based on either of these arguments, Brazil's model will become closer to that seen in most of the countries that already have significant biotechnology industries.

### **Intellectual property in the Biotechnology Development Policy**

The Biotechnology Development Policy also contains language setting forth the policy-makers understanding of how intellectual property may be leveraged to stimulate the biotechnology sector. Decree 6041/2007 establishes a broad set of objectives related to intellectual property, listed in Table 1 (Chamas 2008, 87-88).

**Table 1. Intellectual Property Objectives, Decree 6041/2007**

- Increase the number of biotechnological patents that are owned by Brazilians, both in Brazil and abroad;
- Encourage the development of individual and managerial skills for the effective use of intellectual property rights;
- Encourage the adoption of best practices with a view to increase in the competitiveness of Brazilian industry;
- Foster communication between research groups and industry relating to the handling and management of intellectual property rights;
- Propose the adoption of mechanisms for spreading the culture of intellectual property that involves all players that participate;
- Include legislation and the management of innovation and intellectual property in academic biotechnology education;

*Continued...*

*...continued*

Provide scientists and technicians with the necessary skills in technological management and in strategies for protecting intellectual property and technology transfer;

Strengthen the structure of the Brazilian intellectual property system and the centers for technological innovation;

Increase the spread of the use of the biotechnological information made available by the intellectual property system;

Harmonize practices for managing the intellectual property of the federal and state research and development support agencies so as to facilitate the transfer of the technologies developed by science and technology institutions to the private sector, while preserving the rights and remuneration due to such science and technology institutions and, when applicable, to the supporting agencies;

Harmonize intellectual property management practices with value for traditional knowledge and a respect for the rights of traditional communities and indigenous people

Propose the establishment of specialist courts for dealing with matters relating to intellectual property;

Stimulate the adoption of mechanisms for managing intellectual property in national science and technology institutions so as to increase the competitiveness of Brazil's bio-industry;

Propose the adoption of mechanisms for spreading the culture of intellectual property that involves all players that participate either directly or indirectly in innovation activities, including representatives from the Judiciary Branch and the Government Attorney's Office;

Revise and strengthen national legislation for protecting cultivated plant species, especially concerning protecting crops for plant reproduction, strengthening the rights of patent holders and developing new descriptors for plant crops that can be protected;

Encourage the adoption of intellectual property mechanisms for the effective protection of strains derived from the genetic improvement of animals.

The language of these objectives reflects a sympathy with those who advocate an expansion of intellectual property protections in biotechnology. This view is also reflected in the call for a “program for accelerating protection and patenting,” as mentioned by President Lula when launching the policy (Lula da Silva 2007, 4-5). These indicators suggest that the Brazilian government views greater intellectual property protection as unequivocally desirable for the development of the biotechnology sector. The reality, however, is more complicated.

### **How much intellectual property protection is too much?**

As the ONSA Network’s Genoma Project shows, patent privileges are not necessarily the most effective incentive for biotechnology research. Other institutional and incentive arrangements can also drive research and innovation, without excluding any parties from access to the end results.

Too much patent protection, in fact, may stifle research and development in the biotechnology sector. The piling up of intellectual property claims in a field can result in what some scholars have referred to as a “tragedy of the anticommons” (Heller 1998). The traditional phrase “tragedy of the commons” refers to a situation in which unrestricted access to a finite resource owned by no one—a commons—results in the exhaustion of the resource, an ultimate loss to all (Hardin 1968). The “tragedy of the *anti*-commons,” however, refers to an opposite situation, in which the proliferation of too many ownership claims over a resource makes it impossible for anyone to use it. This problem has also been referred to as the “patent thicket,” describing a situation wherein an excess of intellectual property claims makes it too difficult to legally maneuver in a given field (Shapiro 2001). Several scholars have suggested that biotechnology

may be a field particularly prone to this type of problem (Heller and Eisenberg 1998; Shapiro 2001; Hope 2006).

From a global perspective, life sciences research has undergone a dramatic process of commercialization over the past three decades, driven by changes in intellectual property law since the 1980s (Hope 2008). The result has been a rapid increase in filing of biotechnology patents, as Hope demonstrates by taking the U.S. patenting figures as an example. “In 1978 the USPTO granted fewer than 20 patents in the field of genetic engineering. By 1989 the total number of biotechnology patents being granted each year had risen to 2,160, increasing even further to 7,763 new patents in 2002” (Hope 2008, 35). A similar trend is evident at the European Patent Office. In 1993, individuals and corporations from the twenty-seven EU Member Countries filed 920 biotechnology patent applications with the EPO. In 2003 the same countries filed 2,576 such applications (Félix 2007, 5).

The increasing number of patent applications should not, by itself, be interpreted as evidence that an anticommons has emerged (Adelman & Deanglis 2007). Concern exists, however, because biotechnology patents increasingly apply not only to end product inventions, but also to many essential research tools. This greatly increases the transaction and licensing costs associated with biotechnology research (Hope 2006). The ability to patent genetic sequences themselves—permitted in some countries—holds particular risk to create an anticommons because these sequences are the foundational point from which an entire field of biotechnology research and development might proceed. This presents a danger:

In theory, in a world of costless transactions, people could always avoid commons or anticommons tragedies by

trading their rights. In practice, however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants, with success more likely within close-knit communities than among hostile strangers. Once an anticommons emerges, collecting rights into usable private property is often brutal and slow (Heller and Eisenberg 1998, n. 10-15).

Instead of uncritically harmonizing Brazil's intellectual property regime with those of more developed countries, policy-makers should consider whether a lesser degree of patent protection might provide a competitive advantage to Brazil's emerging biotechnology industry, by reducing the costs of research and avoiding a biotechnology anticommons. This prospect seems particularly promising in the case of Brazil where (i) there is a past of unorthodox practices for creating genomic science, involving public funding and public universities with decentralized management, (ii) there exists a strong relationship between universities and companies as a result of the biotechnology incubators and (iii) there is a recently developed policy framework, which is not yet fully defined in favor of the logic of enclosure.

In addition to carefully limiting the scope and term of genetic patents, another way to avoid the tragedy of the anticommons is to pursue an open source approach to biotechnology development (Hope 2004, 2006, 2008). This proposal is based on the experience of the open source software industry, discussed in an earlier chapter in this volume. Replicating this experience in the field of biotechnology would require university researchers or a public body to obtain patents on inventions, and then subject these to a special license

specifying the terms under which other researchers and developers are free to use and build upon that invention. The existence of clear licenses associated with existing intellectual property dramatically reduces the transaction costs that would otherwise be spent in contacting and contracting with the owner or owners. This benefit is magnified when—as is the case with open source software—a substantial portion of useful inventions within a field have identical or compatible licenses attached. This compatibility dramatically facilitates research and development projects that utilize many different components to enable more complex research or develop more sophisticated technologies.

### **Prospects for open innovation in Brazil's biotechnology sector**

Brazil's current situation provides a unique opportunity for institutional imagination and policy experimentation. At present, the Brazilian biotechnology sector is still characterized by a collaborative culture, which has yielded visible and practical results through the ONSA Network's Genoma Program. Some policy-making institutions—like the Brazilian Institute of Industrial Property, the National Economic and Social Development Bank, and the Brazilian Industrial Development Agency—tend to adopt an IP-maximalist rhetoric, and may be suspicious of open innovation models. Other institutions, however, may be more open to the open innovation concept. The economic-industrial health complex, for example has countless public players, and a well-established historical practice of sharing information, tools and products. Companies in the Brazilian biotechnology sector may similarly see open source approaches as opportunity to free themselves from transaction costs and successfully compete with more established foreign players. Adopting an open source approach to biotechnology development could

provide Brazil with a competitive advantage relative to nations with more rigid patenting systems. Because discoveries in this system would be patented—and subjected to open licenses—this approach would also alleviate concerns that Brazil's natural resources and government-funded research results end up unfairly appropriated by foreign biotechnology companies.

An examination of the value chain of scientific research and development yields three points of leverage where the public interest might be protected: 1) conception and funding of research, 2) publication of and access to resulting data, and 3) patenting of technologies invented by publicly funded actors. Each of these points of leverage offers an opportunity to promote open innovation through appropriate licensing.

Working from the first point of leverage, public funding for research may be used as an opportunity to require open innovation practices. An existing example of this approach is the requirement instituted in the United States that all journal articles based upon research funded by the National Institutes of Health (NIH) should be deposited into an open access digital archive. Early data suggests the initiative has been successful (NIH Public Access 2008). In 2006, an average of less than 500 publications per month were deposited. In January 2007, immediately after the mandate took effect, more than 1000 articles were deposited. Eighteen months later, monthly submissions to the archive topped 2500 articles (*ibid*). Although the NIH initiative deals with academic publications rather than patent applications, it is an example of how federal funding can be leveraged to ensure practices of openness.

The second type of leverage is exercised at the point of data publication. The International HapMap Project offers an example from the field of genomics research. This internationally-funded

project made its data on genetic variation in global perspective available to the public at no cost. To access the data, however, users had to agree to licensing terms that prohibited them from using the accessed data to file genetic patents (National Human Genome Research Institute 2004). Once the data was complete, project managers felt it was sufficiently protected from private appropriation under the “prior art” principle alone, and opened the data to public access without licensing restrictions. This allowed the data to be integrated with other genomic databases, ensuring that the project could achieve the full scientific value of maximum openness (*ibid.*). This example illustrates both the power of a strategic approach to licensing at the moment of access, but also the challenges of aligning licensing regimes with the interest of maximum openness.

Finally, an example of leverage at the point of patenting is offered by the BiOS Initiative for Open Innovation, a project of the Australian organization CAMBIA. This effort encourages biotechnologists to license their patented inventions in socially responsible ways (Red Herring 2006). It also promotes the development of open source tools for biotechnology research, and has drafted a model license to facilitate a “protected commons” for biotechnology researchers (BiOS 2008). These three initiatives are all targeted at the community of individual biotechnology researchers based in universities. Similar initiatives developed at the university level to promote licensing regimes advancing the public interest also hold promise, although many challenges remain (Rossini 2007).

## **Conclusion**

As the twenty-first century begins, Brazil seeks to transition from being an exporter of raw materials toward a modern knowledge

economy based on innovation in high-technology fields. A central strategy for achieving this goal is leveraging the nation's natural resources in the area of biodiversity to position itself among the world leaders in biotechnology research and development.

The task of designing an appropriate intellectual property framework to promote biotechnology research and development is a challenging one. More intellectual property protection does not necessarily lead to more innovation. Indeed, in the case of the biotechnology sector, there is good reason to believe that the opposite holds true. Proliferating patent claims by competing companies can create obstacles for biotechnology research and development. Careful attention must be given to the structure of intellectual property regulations to avoid stifling Brazil's emerging biotechnology sector in a patent thicket. Particular attention should be paid to the regulation and promotion of licensing regimes to encourage open innovation.

The tragedy of the anticommons is a challenge facing biotechnology globally. The success of Brazil's biotechnology development effort will depend in large part on the extent to which its scientists, policy-makers and entrepreneurs are able to take the lead in developing new solutions, rather than merely follow global trends. The country's successes in this field to date have been achieved through open research models that generated, organized and distributed economically valuable scientific knowledge, while also developing and diffusing technical capacity. By realizing the "wealth of networks," the ONSA Network's Genoma Program was able to transform peripheral university facilities into centers of advanced biotechnology research. As the National Policy on Biotechnology Development gets underway, policy-makers should consider these lessons carefully.

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# ACCESS TO MEDICINES: PHARMACEUTICAL PATENTS AND THE RIGHT TO HEALTH

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**T**he concept of “access to knowledge” encompasses a variety of values, including access to knowledge goods (Shaver 2008, 253-256). These goods may

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be “better, more plentiful or cheaper because of some technological advance embedded in them or in their production,” and their affordability is greatly influenced by patent regimes (Benkler 2006, 311-312). This chapter focuses on access to medicines in Brazil, with particular attention to the impact of recent legislative reforms that implemented the TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights).

For some time, Brazil has been a world leader in the area of access to health—and in particular, access to medicines. The country has developed a comprehensive national system that aims to secure access to health as a constitutional right to all Brazilian citizens. There is, however, a complex story behind the implementation of this constitutional provision. Lessons may be learned not only from its successful results but also from its failures. The objective of this chapter is to outline and assess how—and if—access to medicines is assured in Brazil, with particular attention to the role of information policy, including the pharmaceutical patent regime. The chapter is divided into four parts:

**Part one** presents the legal framework governing access to medicines in Brazil. Starting from the constitutional text on the right to health, this part reviews the federal legislation that specifically implements a right of access to medicines, as part of the constitutional right to health.

**Part two** examines Brazilian case law on access to medicines. Brazilian courts have traditionally been very generous in ordering the government to supply medicines sought by special petition, regardless of cost. Recently, however, the courts have shown signs of rethinking this approach, as the financial impact of high drug costs has become increasingly unsustainable.

**Part three** takes a closer look at the dynamics underlying these financial pressures, examining the role played by pharmaceutical patenting in the rising cost of medicines. This part concludes that the Brazilian government made three mistakes in implementing TRIPS: opting for early implementation, approving pipeline patents, and prohibiting parallel imports.

**Part four** examines the efforts Brazil has made to control drug costs post-TRIPS, including: price negotiations and compulsory licenses, the prior consent mechanism, the Bolar exception and the Popular Drugstore program. This part concludes that Brazil's experiences do provide some success stories, but further efforts are still needed to control rising costs.

## **Access to medicines as a constitutional right**

Access to medicines in Brazil must be viewed within the broader context of the national legal framework on the right to health. As we will see in this section, several sources of Brazilian law guarantee the right to health, with specific reference to a universal right of access to medicines.

### **The constitutional right to health**

In 1988, as a result of the redemocratization process and civil society pressure (Escorel et al. 2005, 59-81; Labra 2005, 260-262), Brazil approved a new federal constitution.<sup>1</sup> Article 196 of the

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<sup>1</sup> The full texts of all constitutional, statutory, and regulatory materials cited in this chapter may be accessed online in Portuguese. Please consult the list of references for direct links.

Brazilian Federal Constitution—*Constituição da República Federativa do Brasil de 1988*—states that:

Health is the right of all and the responsibility of the State, to be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards, and at the universal and equal access to actions and services for its promotion, protection and recovery.

The constitution also qualifies health as a fundamental right, thus giving it an instantly binding application.<sup>2</sup> The right to health in Brazilian law is not understood as an aspirational development goal, but immediately creates citizen rights and state obligations.<sup>3</sup>

To implement the constitutional right to health, Lei 8.080/90 and Lei 8.142/90 established the National Health System—*Sistema Único de Saúde* (SUS). This single public health system guarantees universal health care coverage to all Brazilian citizens, providing access to health care to 60 million people who had been excluded from the previous national public health services (Sobrinho 2002, 7).

The legislation established three foundational principles of the Brazilian National Health System. First, it should be universal—meaning that no citizen can be excluded from SUS coverage. Second, it should be characterized by equality of access—with no

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<sup>2</sup> Art. 6 (Title II, “*Fundamental Rights and Guarantees*,” chapter II, “*Social Rights*”): “*Education, health, work, leisure, security, social security, protection of motherhood and childhood, and assistance to the destitute, are social rights, as set forth by this Constitution.*”

<sup>3</sup> Art. 5, para. 1: “*Rules defining fundamental rights and guarantees have instantly binding application.*” For further information on the “instantly binding” nature of fundamental rights, see Silva (2005 177).

discrimination regarding the public health services and products provided to users. Third, it should provide *full* health care coverage—from the most basic to the most complex health care needs. The three principles of universality, equality and integrality define the Brazilian state's promotion of health as a fundamental social right (Cohn 2005, 387).

### **The right of access to medicines as part of the right to health**

The constitution does not specifically mention access to medicines as part of the right to health, but this understanding is established by the implementing legislation. Article 6(I)(d) of Lei 8.080/90 specifically provides that SUS “*must be responsible for promoting full medical assistance, which includes pharmaceutical assistance.*” Several other national laws and regulations also address the issue of access to medicines in Brazil.

Ordinance 3.916/98 created the National Policy on Medicines, aimed at guaranteeing access to medicines through affordable prices, as well as their safety, efficiency and quality. The National Policy on Medicines also directed the Ministry of Health to issue a list of essential medicines—*Relação Nacional de Medicamentos Essenciais* (RENAME).<sup>4</sup> The RENAME list is to be periodically updated by the Ministry of Health according to criteria of drug effectiveness, security and costs of the medicines available in the market. The list includes all drugs needed for the treatment and control of the main diseases in the country. Drugs necessary for the treatment of less common and very expensive-to-treat conditions—

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<sup>4</sup> According to article 3.1 of Ordinance 3.916/98, “*essential medicines are those considered to be basically indispensable to dealing with most of the population's health problems. These products must be permanently available to those in society who need it, under proper pharmaceutical conditions.*”

such as chronic kidney failure, organ transplants or refractory schizophrenia—are not included on the list. The RENAME list represents an important framework for public health policies, including: (i) the granting and revision of drug certificates; (ii) the analysis of information that public health professionals must communicate to the population; and (iii) the standardization and modernization of drug labeling and package inserts.

In order to comply with the constitutional right of integrality of access, SUS must give assistance not only to those who suffer from the most common diseases but also to patients who suffer from diseases that only affect a limited number of people and are most costly to treat. To provide for this type of treatment, Ordinance 2.577/06 established the National Program for Exceptional Medicines. This framework supplies strategic medicines for the treatment of HIV/AIDS, malaria, tuberculosis, influenza and meningitis.

In addition to these general frameworks, some laws have been specifically enacted for particular diseases or populations. Lei 8.069/90 explicitly provides that children and adolescents were entitled to full medical care. Lei 9.313/96 compels SUS to provide free medicines to all citizens infected with HIV/AIDS. Lei 10.741/03 requires that SUS accord full medical care to the elderly, and devotes special attention to their unique health needs—for example by means of specialized clinics and the availability of homecare services. Lei 11.347/06 guarantees free medicines to all diabetes patients.

## **Judicial enforcement of access to medicines**

As the previous section demonstrates, the Brazilian State's duty to provide full health care to all its citizens is well defined by the

law. Implementing this duty, however, has proven to be a major challenge, particularly in regard to the provision of medicines. The tension between universal access to medicines and limited state resources has already found expression in several important court cases. An analysis of the judicial holdings in these cases will be the focus of this section.

In theory, Brazilian citizens should be able to access whatever medicines their doctors prescribe through SUS. In practice, however, the medicines sought are sometimes not made available. When this is the case, individuals may seek access by going to court. Depending on the case, such petitions may be based either on the constitutional right to health or on specific laws and statutes. These lawsuits usually demand: (i) medicines that are included on one of the Ministry of Health's supply lists but that, for a number of reasons,<sup>5</sup> are not available; (ii) medicines that are not included on the supply lists due to considerations of cost, including those for which cheaper generic versions are available; and (iii) medicines that have not yet been established as safe and effective through national testing. Regardless of which category an individual's request falls into, Brazilian courts almost always rule in favor of the petitioner and order the State to provide the medicines sought.

### **The traditional approach: ruling in favor of access**

In general, Brazilian courts have ruled in favor of petitioners demanding medicines. The judicial consensus is that, every time the government denies a medicine, it violates a fundamental

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<sup>5</sup> Reasons for unavailability may include: insufficient budgets to purchase all drugs approved for distribution, lapse of time between purchase and arrival of the drugs due to complicated administrative procedures, or simple logistic incompetence.

constitutional right. The study of Brazilian case law shows that most judges: (i) consider the right to health individually, and not collectively; (ii) interpret the right to health and the principles of SUS as the individual's right to any health-related expense; (iii) ignore that the fulfillment of such rights is costly, that the needs of the health system as a whole are enormous and that the scarcity of public funds makes budgetary trade-offs necessary; and (iv) do not take into consideration the already existing medicine distribution policies (Wang 2006, 42-79; Marques et al. 2007, 103-106; Ferreira et al. 2004, 38-41).

When analyzing the Superior Court of the State of São Paulo—*Tribunal de Justiça de São Paulo* (TJSP) case law concerning specific demands for HIV medicines, Ferreira et al. (2004, 22) found that, in 84.7% of the cases, the Court considered the provision of health care to be an individual right, without any regard to further social and economic consequences. Marques et al. (2007, 105-106), analyzing the same Court from 1997 to 2004, came to a similar conclusion: in more than 80% of the cases that demanded medicines, judges considered that the right to health should be universally guaranteed but did not take into consideration other issues relevant to the discussion of public policies, such as the scarcity of resources.

The Brazilian Superior Court of Justice—*Superior Tribunal de Justiça* (STJ) is the second most important Court in the Brazilian legal system, receiving cases on appeal from all state courts. An analysis of its case law shows a similar pattern of judgment. In the great majority of the cases, the STJ decided that the State must provide the medicines demanded, regardless of: (i) their cost; (ii) the scarcity of public resources; (iii) the priorities established by the National Health System's pharmaceutical policy; (iv) Lei 6.360/76 forbidding distribution of medicines not registered by the Ministry of Health;

and (v) doubts regarding the effectiveness of the treatment (Wang 2006, 44-46).

The exception to this pattern is that the STJ has proved willing to deny requests for medical treatments outside of Brazil (Superior Tribunal de Justiça 2003a, 2003b, 2004 and 2005). In such occasions, the typical line of reasoning was as follows: (i) the payment of such treatments would impose great difficulties on public authorities and make the public health system impracticable; (ii) the scarcity of resources could not be ignored; and (iii) the technical and administrative criteria chosen by the public administration to elect priorities for public health policy should be respected in order to promote a more rational spending of public funds and benefit as many citizens as possible. Some members of the court, however, still voted in favor of granting the requests. Wang (2006, 54-58) relates that these members' considerations arrive at the conclusion that financial and economic issues cannot outweigh the constitutional right to health. It is interesting to note that this court did credit budgetary concerns when deciding lawsuits that involved treatments abroad, but not when it came to domestic treatments and access to drugs. In many cases, however, providing access to high-cost medicines can be just as expensive as providing treatment abroad.

In granting the vast majority of individual petitions for access to medicines, both the TJSP and the STJ were following the lead of the Supreme Federal Court—*Supremo Tribunal Federal* (STF).<sup>6</sup> The STF is the highest court in Brazil and must judge appeals of decisions

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<sup>6</sup> Lower courts are not, however, required to follow the STF's lead in these matters. A 2004 amendment to the Brazilian constitution gives the STF power to approve binding synopses—*súmulas vinculantes*—of its jurisprudence (Constituição da República Federativa do Brasil de 1988, art. 103-A). No binding synopsis concerning the right to health or access to medicines has been approved yet.

that: (i) are contrary to the provisions of the Federal Constitution; or (ii) validate a statute or act of local government that may be interpreted as contrary to the Federal Constitution. Most of the lawsuits demanding access to medicines that have reached the STF are related to anti-HIV treatments, followed by phenylketonuria, Duchenne muscular dystrophy and cancer (Wang 2006, 67-79; Wang et al. 2007, 7-13). The STF has traditionally upheld all lower-court decisions that granted the medicines demanded.

In this line of cases, the STF's decisions portray the judiciary as a powerful tool for protecting the constitutional right to health. In the Court's understanding of its role, such lawsuits protect citizens against government irresponsibility and omission in regards to health issues. This stance is highlighted in a decision often cited as precedent by lower courts (Supremo Tribunal Federal 2000b):

FREE DISTRIBUTION OF MEDICINES TO PEOPLE IN NEED. When recognizing the legal validity of programs that distribute medicines free of charge to people in need (...) this Court puts the rules contained in the Constitution into effect (...). It is not enough for the State to merely proclaim the recognition of a right. It becomes essential that the constitutional declaration be completely respected and fully complied with, especially in cases where the right – such as the right to health – qualifies as a judicial prerogative that ensures the right of the citizen to demand from the State the implementation of constructive actions (...). The importance of the right to health (...) legitimizes the actions of prosecutors and the Judiciary in those situations where State bodies refuse to respect the constitutional commandment, thus betraying legal and social obligations,

whether by default, or by any other form of governmentally deviant behavior.

Traditionally, the STF precedents have understood budgetary considerations as a “secondary governmental interest” (Supremo Tribunal Federal 2000a), and of “minor importance” (Supremo Tribunal Federal 2001). The quote below exemplifies this rationale (Supremo Tribunal Federal 1998):

Forced to choose between protecting the essential right to life – an unalienable right assured by the Constitution (art. 5º) – or overruling it in favor of secondary or financial interests of the State, I understand, as this dilemma is set out, that judicial ethics dictate to the judge only one possible option: to decide in favor of the undeniable right to life.

The year of 2007, however, set a new landmark, as the STF started to reconsider its stance.

### **Courts at the crossroads: rethinking the right to medicines?**

In 2007, the pattern of STF decisions regarding individual demands for medicines or medical treatments shifted significantly, as the court started to deny some petitions, perhaps in recognition of the increasingly critical pressure the earlier approach was placing upon public health budgets. In this new line of cases, arguments that had not been considered relevant in previous decisions appeared: (i) public resources are limited, so there needs to be rationalization of public spending in order to provide health care to most people; (ii) the right to health cannot be seen from an individual perspective, but as a right to be made concrete through public policies for collective,

equal and universal access; (iii) the administration's funding allocation decisions should be respected.

The first two decisions denying medicines were issued in February and March of 2007 (Supremo Tribunal Federal, 2007a and 2007b). In her March vote, Minister Ellen Gracie, then President of the STF, stated that:

The administration of national health policies – which is done on a regional basis – must search for a better rationalization between the costs and benefits of treatments available for free, in order to reach the largest number of beneficiaries. It is my understanding that art. 196 of the Constitution, that assures the right to health, refers mostly to the carrying out of policies that reach the population as a whole, assuring them universal and equal access, and not in individual situations. The responsibility of the State to provide the resources necessary to the health care of its citizens cannot endanger the public health system. In the present case, by conceding the effects of guardianship to determine that the State provides the related medicines (...) the possibility of offering basic services to the rest of society is being diminished.

Immediately after these first two decisions were issued, there was a strong reaction from NGO activists, who criticized the STF and strongly advocated in favor of the right to health in the media. Local health officials, on the other hand, filed new suits to interrupt medicine provisions previously ordered by lower courts. Subsequent decisions issued by the STF show an attempt to deal with these conflicting pressures from public health managers and civil society activists. Several decisions return to the prior pattern, concluding that

it is indeed the government's obligation to provide the medicines demanded (Supremo Tribunal Federal, 2007c, 2007d, 2007e, 2007h, 2007i, 2007j and 2008). Others emphasize the limitation of resources and the need to respect public managers' funding allocations (Supremo Tribunal Federal, 2007f and 2007g).

From 1988 to 2006, therefore, the Brazilian judiciary strongly supported citizens' attempts to demand the right of access to medicines through the courts. At all levels, the courts decided the vast majority of these cases in favor of the petitioners. In 2007, however, the first hint of serious judicial rethinking of this approach was seen in the STF, as the court started to deny some petitions for access, in light of public budgetary considerations. In the face of criticism, however, the STF has been inconsistent; from mid-2007 forward, some decisions have continued the new approach, while others reflect the traditional one.

### **Discussion: policy considerations facing the courts**

The debate concerning judicial protection of the right to health in Brazil touches upon two particularly delicate issues: access to medicines and access to justice. Some consider these lawsuits to be a constructive means by which the government is pressured to play a more active role in ensuring access to medicines—an important mechanism to fight against governmental delay and omission. Litigation can also be an effective way to pressure the government towards better public policies. Several non-governmental organizations (NGOs) and Brazilian state and federal attorneys have successfully used the courts to pressure the government to make certain drugs more easily available through SUS (Scheffer et al. 2005, 127). The pressure of litigation has also been one of the reasons why Brazil's HIV/AIDS program has been so successful.

It is important to keep in mind, however, that such judicial remedies do not benefit all people equally. With very few exceptions, successful legal claims in this field are brought by plaintiffs who can afford to hire a good lawyer (Silva 2007, 7). This is certainly not the profile of the great majority of Brazilians, who rely on the public health system as their only option for medical care. Empirical research has verified that most of those who go to courts demanding a certain drug or medical treatment not available through SUS hire private lawyers and live in high-income districts (Silva 2007, 7). A second study found that most people that went to court had medical prescriptions from private doctors and were assisted by private lawyers; moreover, those with the highest incomes were the ones who demanded the most expensive drugs (Terrazas 2008, 40-43). It thus appears that the system of individual petitions works relatively well for wealthier individuals, but fails the poor majority, which does not have access to the justice system.<sup>7</sup>

Given this reality, court decisions that grant medicines to individual patients may be harmful to the planning and execution of public health policies as a whole. When examining individual petitions, most judges do not take the public health budget into account (Vieira and Zucchi 2007, 8). Therefore, each time that an individual petitioner obtains costly medicines by judicial order, a portion of the public health budget is diverted towards benefiting that individual, at the expense of other patients.

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<sup>7</sup> Research shows that the main reasons why poor people do not benefit from such lawsuits are: (i) lack of resources and information (Lopes 1994, 74); (ii) lack of efficient pro-bono legal assistance in Brazil (Ministério da Justiça 2004); and (iii) the fact that attorney offices have only recently directed attention to public health issues (Lopes 2006, 221-222).

In recent years, lawsuits ordering the public administration to distribute medicines have dramatically increased, placing a heavy burden on the public health budget. According to the Brazilian Ministry of Health, expenses to comply with successful petitions increased 211.4% from 2005 to 2006. In 2006, the city of São Paulo alone spent R\$ 65 million on medicines to settle lawsuits that benefited only 3,600 people (Terrazas 2008, 38). This represents an average cost of R\$ 18,000 per patient, in a country where the total public health budget is only R\$ 450 per capita (Ministério da Saúde *Datasus* 2006).

The increasing scale of individual litigation asserting the right of access to medicines presents the Brazilian judicial system with a great challenge. On one hand, the success of these suits has facilitated activist efforts to push for better public health policies through the courts. In recent years, however, the number of individual suits has become overwhelming and resulted in enormous costs for the public health system. Access to the courts is mostly limited to the wealthy, and total budgets for drug procurement are not increased each time the courts order a particularly expensive medicine to be provided. This litigation has distorted the cost-effective allocation of resources, and exacerbated unequal access to public health resources.

Although ruling against petitioners is politically unpopular, pressure for courts to do so is likely to build in the near future, as rising costs of medicines make the current system unsustainable. There is an urgent need for a better balance between individual and collective rights in the administration of Brazilian laws concerning the right to health.

The impact of private litigation, however, is not the only source of financial pressure facing public provision of medicines. Indeed, the expanding scale of litigation may be a symptom of a more

fundamental problem threatening the right to health in Brazil: the skyrocketing price of medicines.

## **TRIPS and the rising costs of medicines**

The increase in health care expenditure is a worldwide phenomenon (Organization for Economic Cooperation and Development 2007; Berkman et al. 2005, 1171; Cohen et al. 2005, 217; Ford et al. 2007, 22). Following this global trend, Brazilian expenditures on public health care by federal, state and municipal authorities have increased significantly in recent years (National STD and AIDS Program 2008, 14). The Brazilian Ministry of Health's budget for 2003 was R\$ 30.5 billion. Four years later, this figure rose to R\$ 46.4 billion, a 51.6% increase. Between 2003 and 2004, the expenditures of the DST/AIDS National Program alone increased 97.6%, going from R\$ 689 million to R\$ 1.36 billion (ibid., 24).

The financing of SUS has always been a challenge for Brazil.<sup>8</sup> The first reason for such a financial burden is the ambition of the public health system model conceived by the 1988 Constitution. Even though an increasing number of people are turning to private health insurance (as their prices become more competitive), 90% of

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<sup>8</sup> In 1996, Lei 9.311/96 created a special tax on financial transactions—*Contribuição Provisória sobre Movimentação Financeira* (CPMF)—to finance health actions and services. The tax, originally created to last only 2 years, was successively extended by Constitutional amendments. A recent study found that, between 2001 and 2006, not all the resources generated by CPMF were actually used in the health sector, but rather allocated to finance other government expenses (Santi et al. 2007, 27). The Brazilian senate has recently extinguished this tax and as of January 2008 it no longer provides revenue for the public health system.

the population still makes use of SUS (Conselho Nacional de Secretários de Saúde 2006, 64).<sup>9</sup>

Another reason for this pressure on the Brazilian public health budget is the country's demographic transition. Life expectancy has increased 32.4% in the past years, going from 54.6 years in 1960 to 72.3 years in 2006, while child mortality rate decreased 64% from 1980 to 2006 (Instituto Brasileiro de Geografia e Estatística 2008). As the population gets older, their health care needs become more complex and more expensive (Chaimowicz 1997, 185; Schramm et al. 2004, 898). Such demographic transition combined with increasing access to SUS services puts a natural pressure on the public health budget (Tren and Bate, 2006, 6). In the following section, we examine how much of the growing health budget strain can be attributed to medicine costs.

### **Impact of medicines on the public health budget**

Medicines take up a significant portion of public health spending and their public purchase has become increasingly costly over the past decade. According to the Ministry of Health, the growth of drug expenditure has outpaced the total growth in health expenditure. A study conducted by Viera et al. (2007, 10-11) found that, while total health expenditures went up 9.6% between 2002 and 2006, drug expenditures alone increased by 123.9% over the same period. The same study also found that, in order to guarantee drug

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<sup>9</sup> It is important to note that private health insurance policies typically only cover medicines provided while the insured patient is in a private hospital. High-complexity medical treatments, such as some kinds of transplantation and exceptional medicines, due to their high costs, are not offered by private health insurances. Since the high cost of these medicines also makes it less likely that patients will pay for them out-of-pocket, the public health system is primarily responsible for their supply (Vianna et al. 2005, 22).

purchases, the Ministry of Health had to re-allocate its budget, thus significantly reducing expenses in other areas.<sup>10</sup>

One of the main reasons for such increase in drug expenditure was the introduction of patent protection for pharmaceutical products in the country. The following sections examine how patents have affected access to medicines.

### **Impacts of patent protection on access to medicines**

After Brazil joined the World Trade Organization in 1995, the nation experienced a dramatic shift in pharmaceutical production policy. Prior Brazilian law forbade the patenting of pharmaceutical products and processes (Lei 5.772/71, art. 9c). This allowed the government to rely on cheap domestic copies to meet its public health needs. Under Article 27 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), however, Brazil was required to start granting patents for medicines. This was accomplished through Lei 9.279/96.

Compliance with TRIPS provisions naturally affected the cost of medicines, as it eliminated the possibility of generic production during the term of a pharmaceutical patent. This impact was exacerbated, however, by the fact that Brazil failed to take advantage of several flexibilities and opportunities that would limit pharmaceutical patents and help keep drug prices manageable.

### **Early implementation**

As a developing country, Brazil could have used the Transitional Arrangements established by article 65 of the TRIPS

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<sup>10</sup> For a complete analysis of the Brazilian Ministry of Health's expenses with medicines over the past decade, please see Vieira et al. (2007).

Agreement, to delay implementing its provisions until 2000.<sup>11</sup> Nevertheless, the country chose to implement its new Industrial Property Act as early as 1996, a decision attributed to pressure exerted by foreign pharmaceutical companies over Brazilian lawmakers (Tachinardi 1993, 19-35). Such quick implementation was in the interest of these companies, as patent protection allows industries to set monopoly prices and capture royalty revenues from their innovation. This rationale underlies the intellectual property system as a whole: the exclusive market right temporarily granted by intellectual property is intended to foster further innovation.

Within the public health context, however, these incentives come at substantial cost: patent protection results in increased drug prices and consequently, more limited access to medicines. Several studies show that the introduction of patent protection has inhibited local generic production (Hanefeld 2002, 86-88; Nunn et al. 2007, 1805-1809; Outtersson 2006, 3-5; Thomas 2002, 262-264; Vasan et al. 2006, 394). This was, of course, precisely the strategy that had previously allowed Brazil to make progress in fulfilling the constitutional right to health. Implementing TRIPS provisions as early as 1997, before new national measures were developed to adequately protect access to medicines under these new circumstances, was a clear mistake.

Between 1995—when Brazil joined the WTO—and the 1997 patent reforms, a number of companies filed lawsuits demanding the patentability of specific drugs. At the time, there was a lively debate among legal scholars over whether TRIPS provisions should be applied by the courts before implementing legislation was passed.

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<sup>11</sup> A broader interpretation of the Transitional Arrangements (part 4 of article 65) could have extended that period for yet another five years.

Some Brazilian scholars favored immediate application (Araújo 2003, 14), while others advocated a more gradual approach (Basso 2000, 283; Soares 1995, 114). The Courts, however, consistently ruled in favor of immediate patent protection (Tribunal Regional Federal 2000, 2002 and 2005a). This meant that even before the legislature passed the 1996 Industrial Property Act, TRIPS provisions for pharmaceutical products were put into effect by means of judicial decisions. Such decisions most certainly worked to the industry's advantage, but against public health interests. The majority of these judicial decisions, however, did not address public health arguments at all (Tribunal Regional Federal 2003 and 2004).

Therefore, when it comes to the implementation of the World Trade Organization's intellectual property provisions in Brazil, we can identify two major obstacles to access to medicines: (i) the legislature did not make use of the Transitional Arrangements allowed by TRIPS in revising the Industrial Property Act; and (ii) the courts applied TRIPS provisions to individual cases even before the Industrial Property Act came into effect, thus granting patent protection for pharmaceutical products as early as January 1, 1995.

### **Pipeline patents**

A second problem with the 1996 patent reforms was the recognition of a new category of patents not required by the TRIPS Agreement. Articles 230 and 231 of the 1996 Brazilian Industrial Property Act allow patent applications to be filed for previously nonpatentable subject matter with minimal administrative review, provided that the patent was already granted abroad. This TRIPS-plus mechanism is commonly known as "pipeline" review.

One of the main problems with the pipeline mechanism is that it subjects patent requests to a mere formal analysis by the

national patent office—*Instituto Nacional de Propriedade Industrial* (INPI). Article 230 (3) of the Industrial Property Act determines that “*once the provisions established in this Article have been satisfied and the granting of the patent in the country where the first application was filed has been proven, the patent shall be granted in Brazil, just as it was granted in its country of origin.*” The assumption is that the product meets the requirement of patentability, as a patent was already granted somewhere else in the world. The patent may have been granted, however, in a country that is more flexible regarding novelty, inventiveness or industrial application. Thus, some medicines that should not qualify for a Brazilian patent under a conventional analysis may be waived in through the pipeline process.

A second problem with the pipeline mechanism is that it allows for retrospective patents of medicines already invented. The traditional argument for patent protection—that high prices must be assured to provide incentives for innovation—does not carry weight when considering innovations that have already been brought to market. Companies benefiting from pipeline patents received an additional reward—at great public cost—without having to invest in any additional innovation.

In practice, the pipeline patents granted in Brazil had a strong impact on the public health budgets as they inhibited the production and purchase of generic medicines. Important drugs used in the treatment of HIV/AIDS (*lopinavir/ritonavir*, *abacavir*, *nelfinavir*, *amprenavir*) and leukemia (*glivec*) were patented in Brazil via the pipeline mechanism, dramatically raising the public cost of supplying these drugs (Instituto Nacional da Propriedade Industrial 2007). A study conducted by the Federal University of Rio de Janeiro shows that, had pipeline patents not been granted to some of the drugs

purchased by the Ministry of Health between 2001 and 2005, the country would have saved US\$420 million (Hasenclever 2006).<sup>12</sup>

In November 2007, the National Federation of Pharmacists—*Federação Nacional de Farmacêuticos* (FENAFAR)—on behalf of the Brazilian Network for the Integration of Peoples—*Rede Brasileira pela Integração dos Povos* (REBRIP)—filed a formal complaint to the General Attorney’s Office, claiming that pipeline provisions of the 1996 Industrial Property Act violate constitutional rights. The filing relies on constitutional texts asserting: (i) the supremacy of society’s interests and the pursuit of the country’s technological and economic development over intellectual property protection;<sup>13</sup> and (ii) society’s vested right to the content of certain patents, as the objects of pipeline patents were already in the public domain before the Industrial Property Act was passed.<sup>14</sup> As of late 2008, the complaint was still under analysis.

### **Parallel importation**

Parallel importation refers to trade of genuine products outside official channels of distribution.<sup>15</sup> It represents an alternative means for improving access to medicines that are lawfully sold at

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<sup>12</sup> The analysis assumes that in the absence of patents, the state would have paid the World Health Organization’s minimum drug prices for generic versions.

<sup>13</sup> Brazilian Federal Constitution, Art. 5, XXIX: “The law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, weighing the social interest against the country’s technological and economic development.”

<sup>14</sup> Brazilian Federal Constitution, Art. 5, XXXVI: “The law shall not injure the vested right, the perfect juridical act and the *res judicata*.”

<sup>15</sup> It should not be confused with trade in counterfeit goods.

cheaper prices in different countries. Article 6 of the TRIPS Agreement states that WTO Members are free to decide whether parallel imports will be allowed under national legislation.

Brazil's 1996 patent reforms, however, rule out the possibility of parallel imports, by adopting the principle of national exhaustion of rights.<sup>16</sup> This allows patent holders to prevent the importation of their products into Brazil by unauthorized parties. In practice, it means that pharmaceutical companies may set and enforce drug higher prices in Brazil when the same product is lawfully sold a cheaper price somewhere else in the world.

Allowing parallel imports could effectively increase access to essential drugs. A number of developing countries—including Argentina, Thailand and South Africa—have enacted laws permitting parallel imports of pharmaceutical products. When analyzing the implications of parallel imports in pharmaceuticals for competition and prices, Maskus (2001, 2) points out that the mere threat of accessing parallel import drugs could be sufficient to provide governments enough negotiating leverage with original manufacturers so that they would accept lower prices. Although most developed countries maintain significant restrictions on parallel imports, recent initiatives by policy-makers in several OECD countries have been favorable to international exhaustion (Fink 2005, 176).

By ruling out parallel imports, Brazil failed to make use of an important tool considered legitimate by the WTO, which could improve access to medicines. Similar to the pipeline mechanism and

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<sup>16</sup> Art. 43 “The provisions of the previous Article [the right to prevent a third party from, without his consent, producing, using, offering for sale, selling or importing the product subject to patent protection] do not apply: (...) IV. To a product manufactured in accordance with a process or product patent that has been introduced onto the domestic market directly by the patent holder or with his consent.”

the early implementation of the TRIPS agreement, the impossibility of parallel imports reflects a failure to consider the public health impacts of pharmaceutical patent law.

A bill proposed by congressional representative Alberto Goldman in 1999 (Bill no. 139) would explicitly allow parallel importation, including but not limited to medicines. After 9 years, it still awaits approval. In order to fulfill the constitutional right to health, lawmakers should speed up further discussion on parallel imports. Authorizing parallel imports would not violate WTO rules to which the country is bound, and would aid the nation in meeting its public health goals at reduced cost.

## **Evaluation of current cost-cutting efforts**

As we have seen, since implementing the TRIPS agreement, Brazil has taken a number of steps that have rewarded international intellectual property holders, but undermined the country's ability to fulfill the constitutional right to access to medicines. The government has also implemented several initiatives that go in the opposite direction, however, to make medicines more accessible. The following sections discuss these mechanisms in further detail, analyzing whether they are sufficient to ensure the long-term sustainability of the public health system.

### **Price negotiations and compulsory licenses**

Brazil is widely recognized as the leading example of integrated HIV/AIDS prevention, care and treatment in a developing country (Berkman et al. 2005, 1162; Galvão 2005, 1110; Okie 2006, 1977). In 1996, Lei 9.313/96 made it mandatory for SUS to provide

free access to ARV drugs to all HIV/AIDS patients in the country.<sup>17</sup> Today, the Brazilian National STD and AIDS Program—*Programa Nacional de Doenças Sexualmente Transmissíveis e AIDS*—provides eighteen antiretroviral (ARV) drugs—as well as medicines to combat opportunistic infections<sup>18</sup>—to over 220,000 patients.<sup>19</sup>

While 1996 marked the beginning of the HIV/AIDS program, this is also the year that the Industrial Property Act was enacted. The introduction of patent protection for pharmaceutical products would raise prices of the same drugs the government was now obliged to purchase for thousands of patients. Until 1996, these medicines were in the Brazilian public domain and could be reproduced without licenses. The Brazilian network of public pharmaceutical laboratories thus played an important role in the cost-effective implementation of the program. Today, of the eighteen drugs supplied by the government, only eight are produced by Brazilian laboratories (National STD and AIDS Program 2008, 80).

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<sup>17</sup> Brazil's highly successful HIV/AIDS treatment experience, it should be noted, is the result of access to medicines demands from civil society. Prior to 1996, hundreds of lawsuits demanding access to HIV drugs were filed in Brazilian courts. The lawsuits, in this case, worked in favor of all. The government not only provided ARV drugs to individual petitioners who had access to the courts, but introduced a comprehensive program to make the drugs easily available to all Brazilians.

<sup>18</sup> Opportunistic infections are those that would not usually affect healthy people, but can be deadly to persons with weaknesses in the immune system caused, for instance, by HIV/AIDS.

<sup>19</sup> Life expectancy for HIV/AIDS patients in Brazil has significantly increased since the program was put into effect. Before the availability of ARV drugs, the average survival time of an AIDS patient was less than six months; it is currently over five years (National STD and AIDS Program 2008, 69-72). The program is also responsible for reduction in health care spending to treat patients for opportunistic infections. Between 1997 and 2002, about 358,000 admissions in public hospitals have been averted by the program (National STD and AIDS Program 2008, 19).

To ensure public access to the remaining medicines, the government must purchase the drugs from the pharmaceutical companies that hold the patents. The Brazilian generic drugs industry (public and private laboratories) has thus seen a substantial reduction in its share of the national ARV market, while the international pharmaceutical industry has seen its share of this market grow rapidly (National STD and AIDS Program 2008, 81-83).

Faced with the challenge of carrying on its HIV/AIDS program at a considerably higher cost, in 2001 the Brazilian government started negotiations with the major pharmaceutical companies. Backed by the threat of compulsory licensing—a process permitted under Articles 68 to 71 of the Industrial Property Act—the government was able to effectively negotiate with pharmaceutical suppliers. The 2001 negotiations resulted in substantial reductions in prices: 64.8 % for *indinavir*, 59.0 % for *efavirenz*, 40.0 % for *neftrina* and 46.0 % for *lopinavir/r*. In addition, a technology transfer agreement was established between Merck & Co. Inc. and the Ministry's main national laboratory, FarManguinhos.<sup>20</sup>

In 2003, the Ministry of Health created a special group to negotiate further issues related to the purchase and production of ARV drugs—*Grupo de Negociação para Aquisição e Produção de ARVs*. Besides the reduction of ARV drug purchase prices, the group's mandate was to negotiate for noncompulsory licenses that could boost domestic production. In the same year, the government decided to discuss the pricing of *neftrina*, *efavirenz* and *lopinavir/r* with the industry again. This time, however, the negotiations were unsuccessful; the government accomplished neither further price reduction nor voluntary licenses. In 2005, attempting to bring down

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<sup>20</sup> For further information, visit: <http://www.far.fiocruz.br>.

the price of *kaletra*, the government commenced talks with Abbott. In this case, also, the negotiations were unsuccessful.

As negotiations for reduced drug prices became less and less effective, the government explored a new approach. In the beginning of 2007, the Ministry of Health engaged in conversations with Merck & Co. Inc. This negotiation effort focused on the price of *efavirenz*, a highly effective drug used by 38% of HIV/AIDS patients in Brazil. After several months of unsuccessful negotiations, on April 24, Ordinance no. 886 declared *efavirenz* a drug of national public interest. On May 4, Presidential Decree no. 6.108 granted a compulsory license for the drug's patents—based on public interest and for non-commercial use only. The medicine is currently being imported from India, where it is already produced off patent. Government reports state that domestic production by Brazil's public laboratories should begin soon (National STD and AIDS Program 2008, 86). Already, the government has reported a reduction of 72.2% in the cost of supplying this drug.

As the Brazilian experience with HIV/AIDS drug provision shows, compulsory licenses can be an effective means to reduce the cost of providing patented medicines, when private negotiations fail.

### **The prior consent mechanism**

The prior consent mechanism is another attempt to improve access to medicines in Brazil. Until 2001, the Brazilian Industrial Property Office (INPI) was the only body authorized to consider patent applications for pharmaceutical products. Lei 10.196/01, however, instituted the prior consent mechanism. Art. 229-C was then added to the Brazilian Industrial Property Act, providing that “the grant of patents for pharmaceutical products and processes shall

be subject to prior consent by the National Health Surveillance Agency—*Agência Nacional de Vigilância Sanitária* (ANVISA).”

ANVISA is an independently administered and financially autonomous regulatory agency. Among other functions, it administers the National Sanitary Surveillance System, monitors prices of drugs and medical equipment, regulates and inspects the production of generic medicines in the country and—since 2001—works along with INPI in the granting of patents for pharmaceutical products and processes.

When an application for a pharmaceutical patent is filed, INPI first analyzes whether it meets patentability and formal requirements, as determined by the Brazilian Industrial Property Act. The applications are then sent to ANVISA for a separate analysis. This second stage of review is intended guard against the danger that a weak examination process could lead to patent “evergreening.”<sup>21</sup>

In theory, ANVISA can deny the granting of a pharmaceutical patent or process against INPI’s recommendation. In practice, this rarely happens. The most recent report published by ANVISA shows that out of the 1,083 patent requests sent to it for analysis, 709 (65%) were accepted, 44 (4%) were not, and 330 processes (30%) are still ongoing (*Agência Nacional de Vigilância Sanitária*, 2008). In the rare cases where a patent application is not accepted by ANVISA, the applicants have a right to appeal. In the

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<sup>21</sup> Evergreening involves filing ‘new use’ patent claims of an already patented product or process. When successful, the patent term is extended, which delays the generic manufacturer’s entry into the market. A weak examination process might wrongly grant patent protection to a product that does not truly comply with the requirements of novelty, industrial application and/or creative step. This does not mean that all drug patents granted by INPI undergo weak examination processes; it only means that ANVISA becomes responsible for guaranteeing a particularly thorough examination on patents for products important to public health.

event of a conflict between ANVISA and INPI, meetings are held in an attempt to reach consensus; in the event of an impasse, the patent will not be granted.

In theory, the prior consent mechanism is important, as it could prevent the granting of pharmaceutical patents that work against public health interests. In practice, however, it is unclear that any patent application has ever been denied due to ANVISA's efforts. Administrative procedures require that, in order to be valid, ANVISA's denial of a patent must be officially published by INPI. It is not unusual, however, for such publications to be stalled for years. ANVISA's denial of patent request no. PI 9710693-3, for example, has been awaiting publication for exactly four years (Instituto Nacional da Propriedade Industrial 2008). Although ANVISA review is in fact intended to be a check on INPI's efforts, this administrative procedure effectively enables INPI to prevent ANVISA objections from taking effect.

### **The Bolar Exception**

A generic drug is identical to the reference drug in terms of active substance, dosage, manner of administration, and pharmaceutical form.<sup>22</sup> They are thus interchangeable in terms of safety and health benefit. The global market for generic medicines is US\$ 55 billion, and growing by approximately 13% a year (Pró-genéricos 2008). In coming years, the generic drugs industry expects

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<sup>22</sup> "Generic" drugs should not be confused with "similar" drugs. According to ANVISA, "similar drugs are those that contain the same active agent, the same concentration and pharmaceutical form, and are administered in the same way and with the same dosage and have the same therapeutic result as the reference (or branded drug), but which do not have the same bioequivalence as the proven reference drugs." A "generic" drug, on the other hand, has been tested by ANVISA to confirm bioequivalence (Agência Nacional de Vigilância Sanitária 2008).

that the expiration of patents of several brand medicines will render an additional US\$30 billion in drug sales susceptible to generic competition (Pró-genéricos 2008).

In 1999, Lei 9.787/99 established the legal framework for the production and marketing of generic drugs in Brazil. Subsequently, the Ministry of Health started to prioritize generic medicines when purchasing drugs. Prescription of generic medicines is mandatory within SUS, although private physicians may prescribe branded drugs even when a generic version is available. Currently, there are approximately 541 accredited pharmaceutical companies in Brazil, of which forty-two manufacture generic medicines and generic drugs currently account for almost 14% of unit sales in Brazil (Pró-genéricos 2008).

The introduction of generic versions of branded drugs in the market improves access to medicines because prices are immediately lowered through new competition. As the government spends less to buy the same drugs, it also becomes possible to buy larger quantities and bargain for even better prices (Quental et al. 2008, 623-627; Gadelha, Quental and Fialho 2003, 50). It is therefore important that generic drugs become available in the market as soon as the patent of the branded drug falls into the public domain.

To facilitate this process, national patent regulations may allow for what is known as a Bolar Exception.<sup>23</sup> A Bolar Exception allows third parties to manufacture limited quantities of patented drugs without seeking a license, specifically for drug approval purposes. Because drug approval process can be lengthy, without the

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<sup>23</sup> The name *Bolar* originates from a lawsuit brought in U.S. courts between *Roche Products Inc.* and *Bolar Pharmaceutical Co* in 1984. It is also known in literature as *early working* of the patent (Abbot 2002; Correa 2001; Love 1997).

Bolar Exception, patent periods would be effectively extended beyond the intended period (Correa 2001, 68).

In 2001, Law 10.196 created a Bolar Exception for Brazil, which was incorporated at Article 43 of the Industrial Property Act. This reform has been effective in speeding up the administrative procedures to enable the immediate entry of generic versions in the pharmaceutical market once patents expire. Even before this reform, however, several individual lawsuits had established such an exception based on a broad interpretation of article 43. The merit of the 2001 reform is to make the process of securing such an exception less complicated and time-consuming, which ultimately works in favor of public health interests.

### **The Popular Drugstore Program**

Another step taken by Brazil to promote access to medicines is the Popular Drugstore Program—*Programa “Farmácia Popular do Brasil”*—created by Decree 5.090/04. This measure was originally designed to improve access to essential medicines for patients that use the private health system, as private health insurance policies typically do not cover out-patient drug costs. In practice, however, the program has been widely used by SUS patients when public hospitals fail to provide the medicines on time (Pinto 2008, 130-137).

The program works both through state-sponsored drugstores and private drugstores that choose to participate. The Ministry of Health buys medicines from private and public industries and the participating drugstores resell them at up to 90% below market prices. According to recent government data, the Popular Drugstore Program has: (i) allowed patients to continuously afford necessary medicines; (ii) softened the impact of medicines on families’ budgets;

and (iii) reduced costs of hospitalization caused by the interruption of medical treatments (Ministério da Saúde 2007a).

Although the objective of the Program is to widen access to medicines, it has recently been the target of some severe criticisms (Conselho Nacional de Secretários de Saúde 2007, 36). One class action filed in the state of Sao Paulo, argued that the program violated the constitutional right to health by requiring citizens to pay for medicines, as opposed to receiving them free. A federal judge upheld the claim and ordered all state-subsidized drugstores to offer medicines at no charge (Procuradoria Geral da República 2005). This decision was later overruled by a higher court that considered the Popular Drugstore Program complementary—and not harmful—to public health policies (Tribunal Regional Federal 2005b). Several similar suits are still underway.

The debate over whether the government can establish a program that provides access to medicines *at some cost* when it should be providing them *at no cost at all* is a healthy one. It compels us to examine root problems of the national public health budget. It would be detrimental, however, for courts to eliminate initiatives such as the Popular Drugstore Program that fall short of the ideal constitutional expectation of free access. The popular drugstores have been effective in expanding access to medicines, especially for Brazilians with lower incomes. All 27 states of the country have operating drugstores—not only in large urban centers but also in rural areas where access to medicines has traditionally been more difficult.

Recent research shows that a growing number of people are completing their medical treatments because they have access to affordable drugs at the popular drugstores when SUS fails to provide them (Pinto 2008, 132). The existence of these drugstores may also

be a partial solution the flood of lawsuits filed by individual citizens seeking access to medicines.

## Conclusion

In 1988, the federal constitution established health care—including access to medicines—as a duty of the State and a right of all. Although wonderful in theory, this ideal has proved difficult to fulfill in practice. Drugs are not always made available, prompting a growing wave of citizen-initiated lawsuits demanding access to medicines. While these suits typically result in victories for the individual plaintiffs, the health care system as a whole loses. The drugs sought by these petitions are often extremely expensive, and the costs of litigation further strain the public health budget.

At the heart of this problem is the rapidly rising cost of medicines. Prior to 1995, public laboratories could produce generic versions of branded drugs without regard for international patents; today less than one-fifth of medicines consumed in Brazil are generics. While still managing to provide access to medicines to most of its population, the Brazilian health care system is rapidly approaching a financial crisis. Recognizing this reality, the nation's highest court has already shown signs of an interest in limiting the scope of the constitutional right of access to medicines. The high cost of patented drugs is thus a key matter to be addressed if the right to health is to be preserved.

Unfortunately, several decisions made in implementing the TRIPS Agreement aggravated this situation even further. Prompted by industry pressure and judicial action, the legislature approved patentability for pharmaceutical products almost immediately, rather than pursuing a more gradual implementation. This resulted in a

particularly difficult transition, as new policies designed to control drug costs—such as compulsory licensing, the prior consent mechanism, the Bolar exception and the Popular Drugstore Program—were introduced only later and still have not been perfected. The 1996 reforms also implemented two measures not required by TRIPS that further increased the price of medicines: the granting of pipeline patents and the prohibition on parallel imports.

The newly implemented cost-cutting measures are not sufficient to control drug expenditures, which continue to rise. Preserving the constitutional right of access to medicines will require further policy reforms to bring the price of medicines down to manageable levels. Toward this end, the authors propose the following concrete recommendations:

First, lawmakers should revise the Industrial Property Act to allow for parallel importation and eliminate the pipeline patent process for medicines. These measures significantly increase the price of medicines, and are not required by the TRIPS Agreement. The Bolar exception must also be preserved.

Second, the government must ensure that ANVISA plays its intended role in blocking inappropriate patent extensions more effectively. This requires making the patent review procedures more transparent and perhaps also limiting the power of INPI to block ANVISA objections through non-publication.

Third, the government should explore wider use of price negotiations, backed by the threat of compulsory licenses. These have been effective in the specific area of HIV/AIDS treatment. Other drugs, however, also play a significant role in the national health budget and could benefit from similar efforts.

Fourth, the courts should welcome the Popular Drugstore Program. This program has played an important role in promoting

access to medicines in Brazil, even if the medicines are not entirely free. In the post-TRIPS era, higher drug costs are inevitable. Insisting on free access to medicines—even for those who can afford to pay at least part of the cost—may not be sustainable.

Finally, the judiciary must begin to take a more holistic look at the dynamics underlying individual petitions. Simply granting every request causes great financial harm to the overall health system. A more productive approach would be to refocus judicial and legislative attention on the underlying policies that have caused rising drug costs and the structural reforms needed to address them.

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Lei 8.080/90. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. <http://www.planalto.gov.br/ccivil/LEIS/L8080.htm>.

Lei 8.142/90. Dispõe sobre a participação da comunidade na gestão do Sistema Único de Saúde (SUS) e sobre as transferências intergovernamentais de recursos financeiros na área da saúde e dá outras providências. <http://www.planalto.gov.br/CCIVIL/LEIS/L8142.htm>.

Portaria 3.916/98. Aprova a Política Nacional de Medicamentos, cuja íntegra consta do anexo desta Portaria. <http://e-legis.anvisa.gov.br/leisref/public/showAct.php?id=751&word>.

Portaria 2.577/06. Aprova o Componente de Medicamentos de Dispensação Excepcional. <http://dtr2001.saude.gov.br/sas/PORTARIAS/Port2006/GM/GM-2577.htm>.

Lei 9.313/96. Dispõe sobre a distribuição gratuita de medicamentos aos portadores do HIV e doentes de AIDS. <http://www.planalto.gov.br/CCIVIL/Leis/L9313.htm>.

Lei 11.347/06. Dispõe sobre a distribuição gratuita de medicamentos e materiais necessários à sua aplicação e à monitoração da glicemia capilar aos portadores de diabetes inscritos em programas de

educação para diabéticos. [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2004-2006/2006/Lei/L11347.htm](http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2006/Lei/L11347.htm).

Lei 8.069/90. Dispõe sobre o Estatuto da Criança e do Adolescente e dá outras providências. <http://www.planalto.gov.br/ccivil/LEIS/L8069.htm>.

Lei 10.741/03. Dispõe sobre o Estatuto do Idoso e dá outras providências. <http://www.planalto.gov.br/ccivil/LEIS/2003/L10.741.htm>.

Lei 6.360/76. Dispõe sobre a vigilância sanitária a que ficam sujeitos os medicamentos, as drogas, os insumos farmacêuticos e correlatos, cosméticos, saneantes e outros produtos, e dá outras providências. <http://e-legis.anvisa.gov.br/leisref/public/showAct.php?id=16615>.

Lei 9.279/96. Regula direitos e obrigações relativos à propriedade industrial. [http://www.planalto.gov.br/ccivil\\_03/Leis/L9279.htm](http://www.planalto.gov.br/ccivil_03/Leis/L9279.htm).

Lei 5.772/71. Institui o Código da Propriedade Industrial, e dá outras providências. [http://www.planalto.gov.br/ccivil\\_03/leis/L5772.htm](http://www.planalto.gov.br/ccivil_03/leis/L5772.htm).

Lei 10.196/01. Altera e acresce dispositivos à Lei no 9.279, de 14 de maio de 1996, que regula direitos e obrigações relativos à propriedade industrial, e dá outras providências. [http://www.planalto.gov.br/ccivil\\_03/leis/LEIS\\_2001/L10196.htm](http://www.planalto.gov.br/ccivil_03/leis/LEIS_2001/L10196.htm).

Lei 9.782/99. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. [http://www.planalto.gov.br/ccivil\\_03/LEIS/L9782.htm](http://www.planalto.gov.br/ccivil_03/LEIS/L9782.htm).

Lei 9.787/99. Altera a Lei no 6.360, de 23 de setembro de 1976, que dispõe sobre a vigilância sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. [http://www.planalto.gov.br/ccivil\\_03/leis/L9787.htm](http://www.planalto.gov.br/ccivil_03/leis/L9787.htm).

Lei 10.196/01. Altera e acresce dispositivos à Lei no 9.279, de 14 de maio de 1996, que regula direitos e obrigações relativos à propriedade

industrial, e dá outras providências. [http://www.planalto.gov.br/ccivil\\_03/leis/LEIS\\_2001/L10196.htm](http://www.planalto.gov.br/ccivil_03/leis/LEIS_2001/L10196.htm).

Decreto 5.090/04. Regulamenta a Lei no. 10.858, de 13 de abril de 2004, e institui o programa "Farmácia Popular do Brasil", e dá outras providências. <http://portal.saude.gov.br/portal/arquivos/pdf/decreto5090.pdf>.







