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CHAPTER FOUR

Biotechnology in Brazil: Promoting Open Innovation

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This 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 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 policymakers 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.

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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. 2006). 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. 2006). 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. (Furlan et al. 2006, A-3)

Within this framework, the federal government committed R\$6 billion – approximately US\$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 – *Comitê 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 2006). 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 with a 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.¹

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: 1) coordination between universities and public funding agencies; 2) decentralized, democratic organization of production; and 3) 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 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

1 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.

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 their 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, 28–29)

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 who had worked on the *xylella fastidiosa* sequencing and other ONSA Network projects – the company specializes in software solutions for genomics research.² 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.³

² <http://www.scylla.com.br/>

³ <http://www.alellyx.com.br/>

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 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.⁴ 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

4 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 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. 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 is: (1) concerned with broad problems of public welfare; (2) initiated and funded by the state; and (3) 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 Act⁵ – actively encouraged university researchers to seek and commercially exploit patents on their academic discoveries (Amorim 2004). Such privatization and enclosure of knowledge may have important consequences

5 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 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).

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 classified as biotechnology companies”⁶ (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 (*ibid.*). 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 (*ibid.*). 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.*).

6 The Biominas survey differentiates between biotechnology and life science companies: “Biotechnology companies were defined as companies whose main commercial activity depends 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).

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 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 (WTO 1994). According to one of the authors of the current Industrial Property⁷ 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 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

7 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.

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 organisms⁸ 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.

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

8 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.”

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 bio-technology, 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 policymakers' 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 4.1 (Chamas 2008, 87–88).

Table 4.1 : 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;
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 2576 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 of creating 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, 698).

Instead of uncritically harmonizing Brazil’s intellectual property regime with those of more developed countries, policymakers 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: 1) there is a past of unorthodox practices for creating genomic science, involving public funding and public universities with decentralized management; 2) there exists a strong relationship between universities and companies as a result of the biotechnology incubators; 3) 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 policymaking 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 opportunities 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 fewer 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 were complete, project managers felt they were 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, policymakers

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, policymakers should consider these lessons carefully.

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