Current Issues of IP Management in Health and Agriculture in Brazil

CLAUDIA INÊS CHAMAS, *Researcher, Oswaldo Cruz Institute, FIOCRUZ, Brazil*
SERGIO M. PAULINO DE CARVALHO, *Researcher, National Institute of Industrial Property (INPI), Brazil*
SERGIO SALLES-FILHO, *Professor, Geopi, State University of Campinas, Brazil*

ABSTRACT

This chapter presents Brazil's intellectual property (IP) system and identifies relevant experiences of IP management in the fields of health and agriculture. Brazil takes advantage of the flexibilities offered by relevant international agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and attempts to implement an equitable system. During the 1990s, Brazil revised its industrial property and copyright laws, and other related laws, and enacted new legislation that includes provisions for plant variety protection and for access to biological resources.

1. INTRODUCTION

Brazil is considered to be an innovative developing country,[1] with a robust scientific research structure in both health and agriculture. The Brazilian trend toward innovation will become even more relevant in the years ahead as a result of the recent Policy for Industry, Technology, and Foreign Trade of 2004, which prioritizes these economic sectors. In addition, the country has engaged in continuous revision of its IP policies to keep up with advances in science and technology, approved an Innovation Law in 2004, and continues to strengthen its presence in international research and innovation.

IP is a social institution, changing in form and function through, for example, the Paris Convention in 1883, the Bern Convention in 1886, the UPOV Convention in 1961, the Convention on Biological Diversity of 1992, and the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These international agreements are the instruments of such changes.[2, 3, 4, 5] An important characteristic of a system of IP protection is its impact on various industries and countries. The degree of impact depends on, among other factors, infrastructure and the level of training of individuals working in technology and science. Thus, the National System of Innovation places the IP system in context, providing necessary substance.[6] Heterogeneity of national laws also impacts IP protection as a function of the differences in terms of the way laws are applied in each country, because, in spite of the homogenization process that has accompanied TRIPS, flexibility in the formulation and implementation of national laws is possible.[7]

The reform of the legislation related to IP, which took place in Brazil in the second half of the 1990s as a consequence of TRIPS, brings with it opportunities as well as obstacles. These relate to the type of protection (including, for industrial property: patents, trademarks, geographical indications; for copyrights, in general; for computer programs; and for sui generis protection of plant varieties and biological diversity), or to the

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national scientific and technological capability to generate new and useful knowledge.[8, 9]

An important aspect of TRIPS is its linking of IP protection to international commerce. Traditionally, agreements in the field of IP, especially the Paris Convention, linked IP to the technological and economic development of the countries participating in those agreements. This change in emphasis gave rise to some relevant issues. One issue is the enlargement of asymmetries between countries, in terms of the kinds of economic development occurring. These asymmetries can be of obvious concern to developing countries, particularly those that are lacking the infrastructure, scientific, technological and industrial capability for assimilating the technologies more strongly protected pursuant to TRIPS standards.[10, 11]

There is a new structure of international trade regulation that restricts the use of incentive policies for stimulating local production. This is similar to industrialization in developing countries, especially where import replacement is based upon direct subsidies and the closing of national markets. In addition, policies supporting industrialization, competition, and scientific and technological growth embed innovation, converging towards policies of science, technology and innovation. In the context of innovation and industrial policy, IP is important, augmenting the positive impacts and reducing the potential embarrassment that might be caused by restrictions to technological development deriving from the TRIPS agreement.[12]

Specific policies can and should be developed by nation states, particularly starting from the national scientific and technological asset base. Brewster and colleagues[13] believe that the promotion of access to innovations in the fields of health and agriculture to groups of lower income in developing countries should be the basis of those IP policies.

Brazil presents two outstanding examples of IP policy applied in those specific sectors in the controversy over the drug cocktail for the AIDS program of the Brazilian government: (1) the role of EMBRAPA (Institute of Agricultural Research of the Ministry of Agriculture) in the Brazilian seeds market; and (2) the role of FIOCRUZ (an institute of the Ministry of Health that works in research, education, technological development, and production in the field of the human health). In the first case, supported by an IP policy in the area of plant varieties, EMBRAPA was able to assemble partners, both public and private, who worked on the development of new plant varieties, allowing the country to keep the majority of national plant varieties after the promulgation of the Plant Variety Protection Law in 1997, pursuant to TRIPS requirements. FIOCRUZ, through Far Manguinhos, its drugs production unit, provided the Ministry of Health with a cost structure for the drugs that constitute the drug cocktail used in the AIDS program and identified the necessary technology for production of the drug cocktail.[14]

In both FIOCRUZ and EMBRAPA, a new standard of research organization is being implemented: the search for partnerships and the sharing of proprietary results. The search for complementing competences, which would be impossible to find in a single research institution or national economic agent, is a main factor. The rationale underlying the role of public research may be centered in the relevant markets, without losing focus on the mandate and rationale for the generation of technical and scientific knowledge.[15]

2. RECENT DEVELOPMENTS

2.1 *Legal aspects*

In Brazil, TRIPS is viewed as representing an initiative on the part of developed countries to increase the protection of IP. Further, TRIPS is seen as having sought to expand international commerce and the technological content of these exports, as well as to consolidate the new concepts of global production, where the control of technology obtains a differentiated qualitative dimension as compared to the environment in which the Paris Convention was ratified. (Brazil was one of the originators of that convention and has adhered to all of its revisions[16]). Two benefits of TRIPS, however, seem unequivocal: first, the maintenance

of compulsory licensing with the possibility of implementing parallel import mechanisms, and second, the use of sanctions panels within the World Trade Organization (WTO), which minimizes the negative effects of unilateralism. Importantly, both of these elements can be exploited to the greatest advantage of developing countries if the countries have a certain level of technical and scientific capacity.

Prior to the present Industrial Property Law of 1996 (Law No. 9279), Brazil had already reformed its legislation concerning the protection of industrial property, instituting the Industrial Property Code in 1971 (Law No. 5772). The code prohibited the patenting of chemical products, food- and chemical-pharmaceutical products or processes, and did not recognize transgenic microorganisms as patentable. Due to Article 27 of the TRIPS agreement, the new Industrial Property Law recognized these fields as patentable matter.

Further relying on TRIPS, Brazil introduced a new legislation for authors' rights (the Authorship Rights Law of 1998 (Law No. 9610), a Computer Programs Law of 1998 (Law No. 9609), and the Plant Variety Protection Law of 1997 (Law No. 9456). The latter aims to encourage private investment in plant breeding. The law is widely perceived in Brazil as a radical change with regard to the protection of IP.

2.2 *Institutional aspects*

The following federal agencies are responsible for the administration of IP systems in Brazil:

- **for industrial property and computer programs**. Instituto Nacional da Propriedade Industrial (National Institute of Industrial Property [INPI]), an economically self-sufficient and independent government agency subordinate to the Ministério do Desenvolvimento, Indústria e Comércio Exterior (Ministry of Development, Industry and Foreign Trade [MDIC]). The INPI handles the processes for the granting of patents for inventions and utility models, the protection of trademarks, the protection of industrial designs, the protection of geographic indications, and the registration of computer programs. Furthermore, the country's legal dispositions established the requirement of prior approval by the Agência Nacional de Vigilancia Sanitária (National Health Surveillance Agency [Anvisa]), subordinate to the Ministério da Saúde (Ministry of Health[MS]), to subsidize the analysis process of patents on drugs, in accordance with the prerequisites established by Law No. 9279/96.
- **for plant variety protection**. The Serviço Nacional de Proteção de Cultivares (National Plant Varieties Protection Service [SNPC]), created by Law No. 9456 (of 1997) and subordinate to the Ministério da Agricultura, Pecuária e Abastecimento (Ministry of Agriculture, Livestock, and Food Supply [MAPA]), is accountable for its administration.
- **for authors' rights**. This is a field of protection that does not demand registration in order to guarantee rights. Computer programs, which are included in this category of IP protection, are registered at the INPI, as mentioned above. All other work protected by authors' rights, may be registered at various institutions, however, registration is not required. Works can be registered at the National Library (literary works), the Councils of Engineering and Architecture (plans, maps, and designs), and the School of Music of the Federal University of Rio de Janeiro (music, musical arrangements), and at other institutions. The policies for authors' rights are established by the authors' rights board within the Ministry of Culture. Additionally, the Interministerial Committee Against Piracy, subordinated to the Ministry of Justice, coordinates and implements enforcement policies, focusing on those works that are protected under the various fields of protection (that is, plant variety protection, industrial property, and so on) with greatest emphasis being placed on authors' rights.
- **genetic resources**. With the publication of Provisional Measure No. 2186-16 (of

2001), legislation relating to genetic assets was altered with respect to the conservation of biological diversity, the integrity of genetic assets, and associated traditional knowledge. As with Provisional Measure No. 2186-16 and Decree No. 3945/2001, access to and dispatch of the country's genetic assets are determined by the Council for the Management of Genetic Assets, whereby the benefits are liable for distribution, and the exchange and dissemination of components of genetic assets as well as associated traditional knowledge of indigenous and other local communities are preserved, provided doing so benefits them and is based on common practice.

One action that has had, and should continue to have, repercussions in the field of health and agriculture research is the promulgation of the Innovation Law of 2004 (Law No. 10973). An increase in the number of partnerships between companies, universities, and scientific and technological institutes is expected. The greater likelihood of attracting university researchers to establish companies dedicated to innovation is also expected. The law serves as a stimulus to the creation of technology-based companies that would be capable of marketing the results of research undertaken in universities and research institutes. Participation of these researchers in the management or administration of private companies is now allowed, so the new law provides the freedom for these professionals to realize their entrepreneurial potential. In addition, the law allows the sharing of space and infrastructure between public research and private companies. The law promotes the elimination of various bureaucratic hindrances, such as the requirement of a bidding process for the licensing of patents when these belong to a public agency.

The Innovation Law demands the establishment of technological innovation offices at universities and research centers. This innovative and potentially powerful incentive is expected to encourage the protection and commercialization of academic inventions, fostering economic dynamism and new job opportunities.

3. ISSUES CONCERNING HEALTH AND AGRICULTURE

3.1 *IP in agriculture*

The use of biotechnology as a tool for the improvement of traditional plant varieties has been an important issue. Expectations concerning the implementation of the Plant Variety Protection Law were very diffuse at first. Some authors argued that the law would promote the privatization process derived from the recognition of proprietary rights, thus displacing the public research sector, cooperatives, and producers' associations.[17] Others argued that the impact tended to be differentiated, in terms of the dynamism of the cultures and of the technical and scientific conditions. The technical and scientific training of the public sector and synergy among associations and producers' associations, would help it to maintain its production release capacity of new plant varieties.[18] Either way, only time will tell how the impact of the law will play out.

Currently, the main assignees of protected plant varieties are the national public research institutes (39%), foreign private companies (38%), and producer associations or related foundations (20%) (see Table 1). Local companies and universities each hold marginal positions, with a participation of less than 2% of the total protected plant varieties. Seven of the protected plant varieties are among the 10 most important in terms of the amount harvested during the 2001–2002 harvest season.

EMBRAPA is the economic player of greatest relevance in the production of protected soy seeds. Individually, it holds 23% of the registered protected plant varieties of all cultivated species. If its partnerships are included, EMBRAPA's participation increases to 36%. By itself, EMBRAPA holds the registry of 27% of the protected plant varieties employed in the production of seeds, and, including its partnerships, EMBRAPA's participation amounts to 41%.

For the harvest of 2001–2002, in terms of bearing registration of protected plant varieties, Monsanto Co., through the firm Monsoy, has a position superior to that of EMBRAPA, when the latter is considered on its own. Monsoy is the bearer of 55 protected plant varieties (30% of the

total), 13 of which are genetically modified. This participation, however, falls to 23% when considering only the protected plant varieties used as seeds. Thus, Monsoy assumes second place in terms of the protected plant varieties used in the production of seeds and third place in terms of the quantity of seeds produced using protected plant varieties.

Another relevant economic player is the Central Cooperative for Agricultural Research (Coodetec), linked to the Cooperative Organization of Paraná (OCEPAR). For the harvest of 2001–2002, Coodetec participated with 10% of registered protection for soy plant varieties, having three intended for derivation and three genetically modified. The company's participation was slightly more than 13% when considering the use of protected plant varieties. Coodetec's participation in the amount of seeds of protected plant varieties was 12%.

Table 1: Protected Plant Varieties of Soybeans in Brazil, by Bearer and According to the Number of Plant Varieties and Use as Seeds, 2000–2001 Harvest

Main bearers	Description					
	Protected plant varieties		Plant varieties used as seed		Approved production	
	Unit[a]	%	Unit[a]	%	1,000 metric tons[b]	%
EMBRAPA, with partners[3]	67	37	43	41	217	51
Monsoy	55	30	24	23	89	21
Coodetec	19	10	14	13	94	22
Pioneer Hi-Bred International, Inc.	8	4	6	6	11	3
Fundação mato grosso (fmt)	10	5	5	5	1	0
Other bearers	25	14	13	12	15	3
Total of protected plant varieties	**184**	**100**	**105**	**100/52[c]**	**427**	**100/56[d]**
Nonprotected varieties (as percentage of total)	0	0	96	48	338	44
Total	**184**	**100**	**201**	**100**	**765**	**100**

Source: Carvalho[19]

a Number of protected plant varieties and varieties in use as seeds

b Volume of basic seed obtained from plant varieties in use as seeds

c FMT, CPTA, Epamig, Agrop. Boa Fé, Copamil, APSEMEG, Emater-GO, Agrosem, Ag. Rural-GO, CPTA, Empaer-MS

d Percentage of protected plant varieties as part of total plant varieties harvested of 2000–2001

Participation of the players may be understood by reviewing the trajectories of EMBRAPA, Coodetec, and Monsoy with regard to soy production. Both the public research institutions and the rural producer organizations tend to have a relevant role in the generation and adoption of new technology processes, particularly where the capacity for the appropriation of the generated innovation tends to be small. With the exception of seeds for hybrids, where biological characteristics increase the capacity for appropriation, private companies demonstrate little interest in the improvement of autogamous species, the seeds of which are capable of being reused by the rural producer.

The three economic players mentioned maintain trajectories with supplementary involvement that allow a highly competitive environment. There is a coevolution process of these players paralleling the institutional changes, particularly those changes that have affected statutes for the protection of plant varieties.

However, the introduction of new Brazilian players and economic units fuels the debate on the range of protection of innovations in the agricultural field, and, especially, the role of the national company. When prohibiting gene sequence patenting in 1996, the Brazilian legislation of industrial property aimed at ensuring the preservation of the national industry, as it was thought that it would not otherwise be able to compete with mostly transnational companies of larger size and more invested in technology.

The initial investment effort in scientific and technological training in the identification and genome sequencing in Brazil (*Xylella fastidiosa* and *Xanthomonas citri* among others) brought about conditions for the establishment of companies as a result of this research, for example, the venture capital fund of Votorantim Ventures, linked to the huge homonymous Brazilian industrial group, Scylla Bioinformática and Alellyx Applied Genomics.[20]

Scylla Bioinformática was formed by a group of researchers from the State University of Campinas (Unicamp)[21] and offers computing solutions and software development for companies and research centers that use or develop biotechnology. Alellyx Applied Genomics is a research and development company in applied genomics. The company's initial investment was around US$2 million. It is currently focused on research with soy, orange, eucalyptus, and sugarcane. Complementarily, the company performs contracts for the use of the genes by customers, invests in the development of an IP culture, and monitors global databases. Alellyx uses public domain information as well as information that is internally generated. IP is considered fundamental to the company's growth, particularly with respect to patent protection for genes. The strategy of the company has been to apply for patents in the United States on genes with potential value.

Evidently, restrictions on gene patenting in Brazil are somewhat of a bottleneck, because the Brazilian legislation on industrial property does not protect the genes themselves, but only the genetically modified organisms. Besides, the Brazilian Plant Variety Law forbids double protection, making the legislation on plant variety protection the only form of protection for plants.

In one sense, the current institutional picture tends to affect those activities in a regressive way, because the system of IP protection does not create incentives for those companies.

3.2 *IP in health*

3.2.1 *Antiretroviral access*

Since the end of the 1980s, the Brazilian Ministry of Health has supported policies for the provision of antiretroviral drugs as well as drugs for opportunistic infections. In 1991, Zidovudine was already provided with government support to serum-positive patients, although the supply suffered from eventual discontinuities. Decree No. 9313 (of 1996) ensured to all HIV-infected patients free access to all the medication necessary for their treatment. The distribution of drugs for triplex therapy with protease inhibitors began in December 1996.

Currently, 17 antiretrovirals (ARVs) are available from the Ministry of Health, eight of which are produced locally. Some are not protected by patents, entering the market before

Law No. 9279 was enacted. The ARVs that have patent protection are considerably more expensive. There is a natural tendency for newer drugs to overtake older ones (in the marketplace), because many patients develop resistance to drugs and begin to seek out new (drug) treatments. Access to drugs has become increasingly expensive.

The strategy for maintaining the antiretroviral access policy has various dimensions:

- systematic follow-up of patents in force
- monitoring what is in the public domain
- negotiations with suppliers
- local production and importation of generic medicines
- intensification of local R&D activities in an effort to minimize the technological gap
- adjustments in the legal procedures to facilitate access measures

Five companies in Brazil have industrial and technological capabilities for the production of generic ARVs. The national access policy also includes intense participation by various public laboratories.

Government expenditure for its access policy was around US$34 million in 1996 and has grown steadily to US$332 million in 2000. In 2004, government expenditure with the acquisition of ARVs jumped to US$238 million (80% from imports, 20% from local production). The increase in expenditure is mainly due to the increase in the number of patients under treatment, the increase in the proportion of patients needing more complex therapies, and the updating of therapy recommendations. The threat of compulsory licensing, a government recourse, forced the dropping of the price of three drugs in 2001: indinavir, produced among others by Merck and Co., Inc., (by 64.8%); efavirenz, also from Merck (by 59%); and nelfinavir, from Roche, (by 40%).

Aside from the direct benefits of the Brazilian program to individuals in Brazil infected by the HIV virus, as evidenced by the reduction in the AIDS mortality rate and the rate of opportunistic infections, the program has indirectly benefited other countries by providing a model in their efforts to combat AIDS. These countries include Angola, Nigeria, Venezuela, Guyana, and Mozambique, all of which are in now cooperating with the Brazilian government to develop production capability for antiretrovirals.

3.2.2 *Intangible assets in health biotechnology*

Concerning health research evolution indicators in Brazil, the most indicative at this stage is the number of publications. A recent article, published by the National Science Foundation (NSF),[22] indicates the increase of scientific publications in Latin America. The number of Latin American articles tripled during the period from 1998 to 2001, with most articles being written by Brazilian, Argentine, Chilean, and Mexican authors. Considering only the Brazilian contribution, the number of articles quadrupled during this same period.

In the last two decades, Brazil rose from 27th to 18th place in the world ranking for science and technology publishing. There were 1,887 articles published in periodicals indexed by the Institute for Scientific Information (ISI) in 1981, which corresponds to 0.44% of the world output. By 2001, this number had risen to 10,555 articles, or 1.44% of the world total. The number of articles in the medical and biomedical research areas has also increased.

In Brazil during the period from 1997 to 2001, the medical research community produced 7,365 articles (0.9% of the worldwide total) and ranked 23rd in the world. Medical research was 3rd in an internal ranking, representing 16.9% of the total articles indexed for the country on the basis of the ISI figure. The biomedical community had an even greater output than did medical research, with 8,366 articles for this period (0.9% of the worldwide total). With this output biomedical research was in the 21st place in the world ranking and second place in the internal ranking. Biomedical research contributed 19.0% of all the country's articles indexed on the basis of the ISI Deluxe.[23,24] Despite a large part of Brazilian scientific production taking the form of published articles, it *is* possible to protect knowledge by means of IP rights.

Other indicators are somewhat less positive. Brazilian participation in triadic patents[25] remains very low at 0.2%. This low participation reinforces the necessity of developing specific incentive programs for technological research. In Brazil, the assessment of projects undertaken by agencies still judges researchers chiefly by their results in terms of publications. Progressively, the matter of IP is beginning to be incorporated into the analysis criteria of researcher productivity, but this is not an established routine in the academic community yet.

Data from the Directory for Research Groups of the National Council for Scientific and Technological Development (CNPq) indicates that groups that undertake health research produce a considerable amount of work with predominantly bibliographic-academic characteristics. Among each 10 published works only one represents research of a technical nature that results in some kind of protection for the purpose of eventually obtaining IP rights. Not all institutions have adequate support for providing protection to IP or for the identification of patentable subject matter.

The low participation by companies, in the areas of science, technology, and innovation (ST&I), and the lack of ability to transfer knowledge generated in universities to industry and various service sectors, partly explain the predominance of bibliographic-type work production. The ST&I activities are relatively concentrated in the university setting and in some research institutions that are dedicated to specific purposes. The development of these activities inside private companies of the productive sector is small despite efforts aimed at their expansion.

One of the more important effects of modern biotechnology is that it has greatly contributed to the closing of the gap between science and the market.[26] Because of this, academic medical and biomedical research may be viewed as appropriable technology, subject to formal IP protection. A lack of appropriation of academic research in Brazil, however, indicates both that the culture for IP is still undeveloped in academic institutes and that the sponsors of medical and biomedical research have a biased perception, still bound by the obsolescent dichotomy between basic research (freely disseminated) and applied research (appropriated for IP protection). This is reflected by the scant participation of Brazilian patents in the area of unquestionable scientific and technological competence (assuming that the inventions in these areas have a strong academic component).

Our research group is presently evaluating protection by means of patents in biotechnology in Brazil. Preliminary research was undertaken in some of the fields of the International Patent Classification related to the protection of biotechnological inventions. Despite being in the early stages of the research, our analysis of the database of the National Institute of Industrial Property (INPI) revealed patent applications and/or patents in all the verified fields. The research involved overall numbers, regardless of the origin of the application priority and numbers relating to the application priorities of Brazilian origin. Table 2 summarizes the results collected for a period from 1992 to 2005.

The correlation between publications and applications for patents is not linear. However, as the above data show, in the field of biotechnology in health, the volume of Brazilian publications grew intensely. The numbers of patents or patent applications shown (Table 2) having Brazilian priority are relatively modest. In all the fields of patents, the ratio of Brazilian priority to overall priority is low. Despite the very early stage of our research, it is possible to discern that biotechnological inventors seeking patent protection are predominantly foreign. It can be noted that there is a bias for protection in fields C12M, C12P and G01N33/50 with regard to patent applications being first filed in Brazil (which can be interpreted as technology developed in Brazil). Thus, the data seems to indicate that Brazilian technological production is focused in enzymology, microbiology, fermentation, or chemical analysis of biological material. Applications in the field of genetic engineering represent a mere 8.8%. These figures should be investigated more closely, as should the reason for these results. Deeper analysis may explain the disparity between scientific domain (publications) and technological domain (patents).

The recent approval of the Innovation Law and the structuring of technological innovation

offices in universities and research centers indicates that patenting intensity of biotechnology should soon increase.

4. CONCLUSIONS AND FUTURE DIRECTIONS

One of the most important elements of the regulatory process is the area of IP rights. Especially since the 1980s, the results of research in biotechnology have been liable to protection through various mechanisms of IP. There is a trend toward a progressive increase in the scope of what can be considered patentable. The patent proves to be the most relevant and controversial asset; with other assets also being considered as such: trademarks, plant varieties, traditional knowledge, geographical indications, trade secrets, and so on. Common practice shows an intensive and complementary use of several of these assets; the possible combinations depend on the sector of activity (human health, animal health, agribusiness, and so on).

In the recent reorganizations of IP systems, countries and blocks seek to adopt more or less consistent positions in accordance with industrial and technological development. Both the 1980s and 1990s were marked by strong propatent movement tendencies; however, this approach was heavily criticized by many groups. The passing of the Bayh-Dole Act prompted the opening of more than 200 IP offices in U.S. universities.[27] Patenting with academic ownership became aggressive, altering standards of generating restrictions for the access to research results. University patents started to become the subject

Table 2: Health Biotechnology Patents in Brazil

Section, class, subclass, main group, or subgroup*	Patent or patent applications overall	Patent or patent applications, Brazil priority	Brazil priority (percent of total)
C12M	228	58	25.4
C12N	4,020	353	8.8
C12P	1,521	318	20.9
C12Q	940	82	8.7
C07K	2,523	171	6.8
G01N33/50 (including subdivisions)	171	27	15.8
A61K39	1,290	128	9.9
A61K48	260	7	◂0.1
A01H	710	63	◂0.1
Others	n/a	42	3.5
Total	**11,663**	**1,249**	**100.0**

* Fields of International Patent Classification

of negotiations between the academic and corporate fields. Universities began to be summoned to court, being frequently questioned concerning the exaggerated broadness of the scope of various patents, which hindered access to certain markets (very high royalty rates, questionable conditions of exclusivity, and so forth). In this context, benefits such as the research exemption faced extinction. The patent race U.S. universities entered into was also taken up by European institutions and, on a smaller scale, by Brazilian institutions. In Brazil, during the mid-1990s, a series of legal mechanisms motivated the IP protection of academic inventions. More recently, the Innovation Law was enacted.

In accordance with evidence advanced by several authors, patents have a crucial role in the biomedical industry.[28, 29, 30, 31] The introduction of a new drug demands great expenditure for research, development, and preclinical and clinical tests. There exists a relative ease of imitation without requiring the same amount of investment made by the innovating company, especially if the imitator possesses a technological capability similar or even close to that of the innovator. Patents, therefore, serve as the equivalent of a mediation contract between public and private interests. Thus, having made a technique public through publication of a patent document, the bearer of the patent is granted the right to exclude third parties from exploiting the invention.

The biomedical sciences also see the fractioning of existent rights, chiefly patent rights. Heller and Eisenberg[32] point to an intriguing phenomenon concerning the present commercialization of patents in the biomedical field. The grant of broad-scope patents and the grant of many patents with overlapping claims, whereby the determination of the exact limits of each one is difficult, has lead to what the authors term the "tragedy of the anticommons."

The metaphor corresponds to a situation in which many persons fight for the rights of exclusion in an environment of meager resources. The negotiations to ensure the rights of different bearers may stall, imposing obstacles to further development of the invention. The development of new drugs dependent on the multiple patents referring to DNA fragments and other intermediaries and research tools becomes vulnerable due to this "patent thicket." The eventual payment of the various license rates raises costs, making many products far too expensive.

The group of patents to be negotiated to make a product viable may belong to one or several bearers. If the bearers of the rights to be negotiated are distinct companies or institutions, there arises a further difficulty: that of dealing with a heterogeneous environment, each party having its own purpose, culture, and administrative experience. It should not be forgotten that the area of biomedical research is a heterogeneous environment composed of multinational corporations, small- and medium-sized technology-based companies, universities and research institutes. A further obstacle exists in the form of each invention as such. After licensing a biotechnological invention, the investor still has much work to do, with development needed—and uncertainty concerning success ever present—until the final product is marketed.

In Brazil, IP rights are consistent with a specific level of technological and industrial development. The country takes advantage of the (now, almost minimal) degree of freedom offered by the international agreements for the conformance/harmonization of IP rights (the TRIPS Agreement, for example) to innovate more equitably at the national level. Since the 1990s, Brazil has promoted a broad and deep revision of various legal instruments (Industrial Property Law, Copyright Law, and so on) and has inaugurated certain approaches (for example, through the Plant Variety Law and the Regulation for the Access to Biological Resources).

IP protection in biomedical fields differs from protection in the agricultural field due to the distinctive nature and dynamics of each. In health biotechnology, patents perform a fundamental role. The agents organize themselves to achieve protection (especially simultaneous protection, through patents and trademarks) and try to maximally extend the term of protection. On the other hand, the rationale of the developing countries is confounded by the dilemma of prices and the access to technologies. The issue of access has been

broadly described in literature and in practice. The Brazilian Antiretroviral Access Policy reflects these dilemmas and difficulties. Thus, is it possible to reconcile IP protection and also provide the population with access to advanced technology at prices compatible with the local economies?

The impact of the incentive brought about by the IP is idiosyncratic, differing in terms of sections, of industries (and inside of a same section and a same industry), of companies (differing in their use of the strategies in different markets and segments), and of countries. Thus, the ability to appropriate innovation will equally present variations. The protection offered by the different protection fields (in the case in analysis, industrial property and plant improvers' rights) is different and related to the scientific and technological qualification and to the market and industrial structure in Brazil. Equally important is the way that institutional structures for the formulation and execution of public policies differentiates in the economic sector impact as linked to the protection fields.

In this way, specific characteristics of creation and incorporation of inventions/innovations tend to develop different intervention backgrounds. In the case of inventions/innovations in plant varieties, willingly or not, sponsored or not, there is no way for a foreign organization to introduce plant varieties that are not adapted to the area and the productive pattern where the plant variety will be used. This is a fundamental distinction between the areas of health and agriculture. In the case of the health, the companies do not find themselves under the contingency of setting up R&D structures in the countries where the drugs will be used.

In the case of the seeds industry, companies are structured either alone or in partnership with public and/or private research institutions. To be granted protection, plant varieties must pass tests that evaluate performance in the actual conditions of the country. Furthermore, the way legislation was negotiated, for the international treaties (TRIPS and UPOV), differs from negotiations for industrial property, hence creating more favorable conditions for a national project in the particular sector. For that, one should recognize the crucial contribution of institutional training by EMBRAPA, which organized partnerships for the development and licensing of new proprietary varieties, allowing for the main agents (public research, multinational corporations, and rural producers organizations) to establish complementary, yet synergistic, paths.

The drug market presents a rather different situation. It is worthwhile to stress the point concerning the need for the pharmaceutical industry to maintain R&D structures, either alone or in partnership. To enter the Brazilian market, multinational corporations do not need such structures locally. Besides, before the 1996 Industrial Property Law, national industries manufactured similar products, in other words, copies, modified or not, of the innovative products launched in both foreign and internal markets. As from 1997, when the new legislation came into effect, the traditional national producers' catalogue of drugs tended toward obsolescence as copying became illegal except for drugs already available (that is, nonpatented).

The government policies universalizing drug distribution to serumpositives in Brazil, on the other hand, was unable to foster the development of the national industry (national capital private companies) even with a massive government purchase program. The rationale underlying the negotiations on the industrial property legislation resulting in the current legislation, was highly regressive, with respect to industry and the national interest. Giving up the flexibilities offered by the TRIPS Agreement, especially the possibility of obtaining up to 10 years for the recognition of new drugs (even adopting the pipeline) the country's local production of active principles by the national industry was vastly hindered.

In spite of the contradictions of the adopted policies, they were able to answer the challenges imposed by the industrial property legislation. The country managed to overcome much embarrassment, transforming industrial development opportunities. Those opportunities, however, will not be sustainable long without a clear articulation between industrial property and the innovation policy, focusing on the enlargement of the competence and training of the national

private companies in the maintenance of the present standard of excellence of the state laboratories and, mainly, in the creation of incentives, inductive or mandatory, to the international pharmaceutical companies, so that they focus R&D efforts toward the national scientific and technological structure. The protection instruments to the IP will play a central role in that process.

On the other hand, there are business opportunities consequential to the national scientific and technological training, as well as the venture investment in innovation undertaken by national companies, that are not protected by Brazilian laws. This creates a contradictory picture, in which fear of occupation of economic space in the Brazilian market by transnational corporations inhibits the activities of the national companies. That phenomenon is clear in the case of Alellyx Applied Genomics. Perhaps, the best way to ensure the access of developing countries to technology is less in the legislation and more in the defense against competition and in market regulation. The case of Brazilian agriculture seems to point in that direction.[33] On the other hand, the impact of IP in the field of health is central. Any discussion on the subject of protection should take into account the deep technological dependence of Brazil in the field. IP policy should be linked to scientific, technological development, and innovation and, also, be an integral part of the agricultural, health, industrial, and foreign trade policies.

Countries that present rich biodiversity, such as Brazil, still need to acquire the ability to act more actively in the dynamic environment of protection and exploitation of IP, whether to protect local inventions or to gain the knowledge to acquire technology developed by third parties. The demand for highly qualified professionals in this field of work is most urgent, as is the strengthening of the National Institute of Industrial Property. More energetic and integrated actions on the part of Brazil's public administration would contribute to a more mature policy in the area of industrial property and to the development of a configuration for a more competent system for innovation and IP management. ■

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CLAUDIA INÊS CHAMAS, *Researcher, Oswaldo Cruz Institute, FIOCRUZ, Ministry of Health, Av. Brasil, 4365, Mourisco, 4365, sala 122, Rio de Janeiro RJ, 21040-900, Brazil. chamas@ioc.fiocruz.br*

SERGIO M. PAULINO DE CARVALHO, *Researcher, National Institute of Industrial Property (INPI), Praça Mauá 7, Rio de Janeiro RJ, 20083-900, Brazil. sergiom@inpi.gov.br*

SERGIO SALLES-FILHO, *Professor, Geopi, State University of Campinas, Instituto de Geociências/Unicamp, Caixa Postal: 6152, Campinas SP, 13083-970, Brazil. sallesfi@ige.unicamp.br*

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