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BIODIVERSITY AND PUBLIC POLICY ISSUES IN DEVELOPMENT-BRAZIL AS A CASE STUDY[*]

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Abstract - In Brazil, biotechnology is important in agriculture, in health and in the protection of natural resources. It involves research that responds to public policy issues in development and environmental conservation. Being one of the new generic technologies at the base of present world industrial growth, biotechnology development greatly increases the emphasis in Intellectual Property Protection (IPP). Brazil has an immature industrial innovation system and traditionally neglects IPP regulation. Such condition aggravates old problems and brings forth new ones. Among the old ones are the low level of innovation and the disjoining of research and the productive sector. Among the new ones are the economic losses with bio-piracy and the challenges of opening biodiversity resource exploration to foreign initiatives. Analysis of data from the USPTO, show that the number of registered biological patents by Brazilian residents have significantly increased since 1990 and the country has launched large scale biotechnology R&D initiatives since 1996. At the same time, there is great controversy around bio-prospecting agreements with multi-national corporations, legal issues involving monopoly of natural resource exploration and interpretations of macro-agro-ecological zoning results. These and other facts suggest a new relationship between biological research and innovation in Brazil. It also exposes conflicts of interests that characterize the challenges of development and of participating in a globalized economy.

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INTRODUCTION – IT'S NOW OR NEVER

The new millennium has promoted Intellectual Property in Biotechnology to a central position in Brazilian foreign policy, international trade, development strategies and domestic environmental, health, agricultural and industrial policies. It would be ripe time, if it weren't for the fact that Brazil lacks the institutional mechanisms to support technology transfer from public research institutions (which concentrate the bulk of Brazilian research) to industry. The country has the basic requirements to launch biotechnology industrial innovation initiatives: it has biotechnological capability, a surplus of research trained personnel, an experienced Patent and Trademark Office, committed to the fostering of domestic innovation, and pharmaceutical companies interested in developing domestic inventions. Furthermore, the Congress and government are active in promoting legal incentives for technology transfer and innovation. Finally, there is an extensive demand for technology transfer assistance from public research institutions all over the country. Brazil lacks, however, technology transfer management experience and Intellectual Property expertise. We argue that these factors and the lack of objective policies have prevented the development of Biotechnology transfer from public institutions to industry and will remain an obstacle unless the proper mechanisms, training and institutional support are provided. Moreover, we believe that objective policies cannot be developed or implemented without these.

The questions at stake in this paper are simple: 1. What will Brazil do with its much disputed "greatest biodiversity region in the world"? 2. Having decided that, which obviously includes the biological exploration of natural resources known as "bio-prospecting", how will it organize the activity? 3rd and most complicated question: having made the previous decisions, how will the country handle its international affairs and its development priorities?

Obviously, we have no intention of *answering* any of these questions. That doesn't prevent them from being at stake and, more than that, from taking a very, very large bite into public concerns as regards media coverage. Finally – and that's what it makes these questions relevant to science studies – all the questions above involve the interaction between scientists (or research institutions) and society.

Will Brazil, and, hopefully, the rest of Latin America, overcome its historical inertia and develop technology management expertise in the speed of light needed for a decent participation in the Free Trade agreements? We have no idea, but we are part of the story and we surely hope so.

It is, as our master Jean Jacques Salomon has put it once, an "uncertain task". But we are facing it.

Some explanations: not surprisingly, the seeds of change in innovation derived from Public Research Institutions (PRI from now on) are heavily concentrated in biotechnology. This trend is similar to that observed in the United States after the Bayh-Dole Patent and Trademark Amendments Act of 1980. In the Brazilian case, there is a further stimulating factor for such concentration: the combined effect of the “biodiversity-bioprospecting race” and the privileged position the country holds in the agricultural market.

Therefore, we will only deal with biotechnological research in this paper.

A second statement is advisable: the situation is changing on a day-to-day basis. The moment you read this paper, a new world catastrophe, World Trade Organization (WTO) panel against Brazil, UN meeting with Brazilian surprises may be happening. Watch out.

BIOTECH AS A NEW GENERIC TECHNOLOGY

The components of the “world technological system” (the production, diffusion, application and protection of new technology) have been deeply transformed in the last decades. The *new generic technologies* (Van Wijk, Cohen and Komen 1993), with wide economic applicability, have accelerated technological development in areas that were not research-intensive. As a result, the patterns of international competition are changing These technologies may open great areas for investment with a diffuse impact over an economy’s productivity. Among them are biotechnology, information technology and microelectronics, and technology of new materials (Van Wijk et al. 1993).

The introduction of new generic technologies has strengthened the concerns over IPR. With higher R&D investments, there is more need for protection. With economic globalization, there are more actors to defend one’s intellectual property from. With higher costs, research collaboration increases, requiring clear rules concerning the benefits derived from resulting products. Finally, with such wide-ranging technologies, the protection of a process or invention at the base of a new industrial activity has long lasting effects.

The concept of biotechnology is inseparable from IPR issues: the term was coined when the US Supreme Court conceded that man-made micro-organisms were patentable, in 1980. This decision caused a wave of new biotechnology firms to be formed, among them Genentech, Biogen, New England BioLabs, Cetus and Genex. The legal protection of biotechnological innovations is complex, controversial and recent – it has been in debate for approximately two decades (Van Wijk et al 1993).

Developing countries are, generally, still crawling in this discussion and way behind in adopting measures to either defend themselves or to take part in the fiery biotechnological commercial war. In 1998, ISNAR conducted a study about agricultural biotechnology developed in the national agricultural research systems of four countries: Mexico, Kenya, Indonesia and Zimbabwe (Falconi 1999). Only a few institutions in each of these countries use sophisticated techniques. Biotechnological research still represents a small part of agricultural research there. Almost all biotechnological research is public. Almost all funding comes from the government. Investment in biotechnology has grown in the four countries.

Nevertheless, growth is not balanced: the number of researchers has grown more than financial resources, making research efforts hardly sustainable.

Lacking adequate legislation to regulate the access to national biodiversity, and no clear policy concerning biotechnological development and IPR issues, Latin American countries face enormous difficulty. According to Falconi and Salazar (1999), researchers in the continent are deficient both in information and awareness about IPR. These factors make Latin American countries, in general, and Brazil, in particular, vulnerable to bio-piracy.

As we will see, however, Brazil is a special case: no tech transfer expertise but, yes, unquestionable biotechnological expertise. To top it all, until 1996, Brazilian legislation actively prevented pharmaceutical technology and biotechnology from any type of Industrial protection.

BIOTECHNOLOGY, BIODIVERSITY AND DEVELOPMENT

The Convention of Biodiversity is a key to the understanding of IPR issues and biotechnological development in Latin America. It was established at the UN "Environment and Development" conference in 1992, in Rio de Janeiro. The Convention is an agreement between developing and industrialized countries. It determines that developing countries commit to the conservation of their bio-diversity in exchange for a share of the benefits resulting from the exploration of the genetic resources collected in their countries. It is understood that the shared "benefits" will be both financial and in terms of technological transfer and learning. The convention establishes, however, that access and transfer of technology must be consistent with IPR regulations, which is still a touchy issue. Finally, granting rights to access and research activities that make use of traditional communities' resources and knowledge is a very sensitive matter. All things considered, the Convention is still controversial, to say the least. It raises old questions regarding national sovereignty and international trade, among others.

For developing countries and, especially, for tropical countries with great bio-diversity, developing biotechnological capability became crucial, as much as devising strategies to handle international interactions. In these countries, there are two significant sectors regarding biotechnological capability: agriculture and pharmaceutical industry. Latin American countries are in the process of devising policies to establish bio-prospecting[1] initiatives. Two strategies stand out at present, represented, in one hand, by Costa Rica, and on the other, by the ICBG (International Cooperative Biodiversity Groups) program.

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[1] Bio-prospecting is the biotechnological exploration of a country's natural resources.

Costa Rica has adopted a policy to protect its bio-diversity and acquire biotechnological capability at the same time. The Instituto Nacional de Biodiversidade (INBio) is responsible for the application of this policy. The INBio was created in 1989 as a non-profit private institution.

INBio has a library of chemical substances of potential commercial interest. The institution basically brokers the commercial exploitation of the country's biotic richness. Allincome beyond costs is to be used to protect and manage the country's natural resources. In October 1991, Merck Pharmaceutical celebrated an agreement with INBio according to which it would pay one million dollars for the opportunity to screen INBio's samples. INBio trusts that the contractual arrangements are sufficiently strict to inhibit Merck from benefiting from the collaboration without honoring the sharing commitment. It is foreseen that royalties will be paid for every product directly or indirectly derived from INBio, with no time limit.

Four universities and one institute from Mexico, Argentina and Chile are part of the ICBG (International Cooperative Biodiversity Groups) program. This is an American government supported program granted to the University of Arizona. The program provides the funding for the "Bioactive Agents from Dryland Biodiversity of Latin America" project. Besides the "source countries" in Latin America and the "host country", represented by the University of Arizona, the project involves three commercial partners. The project organized traditional information with the involvement of local communities, who participated in exchange for techniques they needed to cultivate their plants. The team created a data bank to organize all the information and they produced 6.900 extract samples from collected plants. Most of them have already been subjected to primary and secondary assays. They developed cheaper biological activity screening procedures in order to provide alternatives for the source-countries. They determined the chemical structure of selected compounds, besides many other research and training activities.

The contract includes protection mechanisms against possible pitfalls in the relations with the commercial partners. Among them are confidentiality of all information about the plants and source-country monopoly in the collection and manipulation of plant material. The eventual patents will be registered by the program and preferentially offered to the commercial partners for licensing. The eventual royalties will be divided among inventors, collectors and conservation activities in source-countries. The commercial partners have also agreed with other forms of payment, such as high power computers and publication funds for the host-country institution, and specimen collections and microbiological training for the source-countries. Publications are always collaborative. The group is realist about the program's chances of commercial success, which are small. Today, for each drug approved for commercialization, 5000 compounds have been screened. The chief goal of the program is to build scientific and technological capability in, and technology transfer to the source-countries (Timmermann 1999).

Other Latin American countries have set up institutions to foster biotechnological research, to promote technology transfer, to bring together university government supported research and private firms, and to develop legal procedures for bi- or multi-national agreements in which all partners benefit. Examples of these institutions are the CONABIO, in Mexico and the Humboldt Institute, in Colombia.

THE BRAZILIAN PARADOX: BIOTECH CAPABILITY AND THE TECH-TRANS DILEMMA

Anyone reading the papers recently has noted the new emphasis in the Brazilian claim as participant in the world biotechnological race. It started with the Nature-cover Xyllela fastidiosa story. But, of course, it doesn't end there.

Brazil is depicted as a strong player in the sequential genome race and now, also in the structural genome and proteome race. Projects focus major human health problems and the fight against agricultural pests.

The major stars are the phyto-pathogen genome studies, preceded by Xyllela Fastidiosa and followed by many others. Brazil surprised the world last February, when it deciphered the genetic code of the Xillela fastidiosa, a bacterium that attacks orange trees, causing losses of around $ 130 million a year in Brazil, according to the Foundation for the Defence of Citrus-growers. X. fastidiosa was the first disease-causing microorganism in the world to have its genome completely mapped out. Brazil chose to start out by studying X. fastidiosa due to its small size -- less than 3,000 genes -- as well as its significance to the national economy. The aim was to train researchers and laboratories organized in networks to carry out genome studies in the state of Sao Paulo -- the richest and most populous state in Brazil, the world's eighth largest economy -- while contributing to the fight against a major agricultural pest. The mapping of X fastidiosa genome may allow the development of more resistant orange trees, and to act directly on the Xilella by modifying it in such a way that it is no longer a pathogen, or by turning it into a killer of the insect that transmits it.

On Dec. 21, FAPESP announced a new four-year, $ 8 million project to decode the genetic map of four viruses. One of them is HIV-1, the most common local strain of HIV, which causes AIDS. The others are viruses that cause hepatitis C and serious respiratory and lung diseases.

FAPESP is also financing research on the genomes of other bacteria that cause losses to local farmers. A larger program regards the decoding of the sugar cane genome, which will soon become the first plant to have its entire sequence -- comprised of 80,000 genes -- completely mapped out.

The idea is to apply the newfound biotechnological knowledge to boosting sugar cane production over the next few years in order to further strengthen Brazil's global leadership -- which is essentially Sao Paulo's leadership -- in output of sugar and fuel alcohol based on sugar cane.

In the case of sugar cane, of which Brazil is the world's leading producer, the prospects are broader, because the genome of the plant is in the process of being deciphered, as well as that of a bacterium that attacks sugar cane. This is Brazil's most ambitious genetic study involving a plant, because sugar cane is estimated to have some 50,000 genes.

The project to map out the genetic code is to be completed by the end of 2001, and the resulting knowledge will permit modifications that could accelerate the metabolism of sugar cane, increase the sugar content, and boost resistance to disease. (Mario Osava

“Science/Agriculture: Brazil Narrows Technological Divide” Gazeta Mercantil, Rio de Janeiro, Oct. 11)

The Human Cancer Genome Project is also a promising one, with several international cooperative initiatives involved. By the number of mapped sequences, Brazil accounts for one-third of the total human DNA sequences mapped worldwide, surpassed only by the United States' National Cancer Institute.

The network of scientists financed by the State of Sao Paolo Foundation to Support Research (FAPESP) to decode genomes has stimulated an innovative technique. With the Orestes -- "Open Reading frame Expressed-sequence Tags" -- strategy, researchers focus on the central coding portions of genes, while scientists in industrialized countries focus on the extremities. The technique was developed by Emmanuel Dias Neto, a 33-year-old biologist.

The Ministry of Science and Technology has also decided to launch a nationwide Brazilian Genome Project, organizing a network of 25 laboratories, and choosing for its first genetic sequencing project a bacterium found in the Amazon jungle region of Rio Negro. C. violaceum produces a substance believed to be effective in treating several kinds of cancer, as well as Chagas disease, a tropical trypanosomiasis that attacks the vital organs and is caused by a flagellate, the Trypanosoma cruzi. The disease is common throughout the interior of Brazil and other parts of Latin America.

Three universities and two research centers in Rio de Janeiro, meanwhile, have grouped together to decipher the genetic code of Gluconacetobacter diazotrophicus, a bacterium that absorbs nitrogen from the air and transfers it to plants like sugar cane and coffee, enabling farmers to save money on chemical fertilizers.

Another institution in Rio de Janeiro, the Oswaldo Cruz Foundation, has decided to begin studying the DNA of the parasite that causes malaria. The aim is to develop medicine against the disease that attacks 600,000 Brazilians annually and causes millions of deaths worldwide, mainly in Africa.

The University of Campinas, in the state of Sao Paulo, will focus on mapping the genome of the Crimipelis perniciosa fungus, the cause of "witches'-broom," which reduced cacao production in the eastern state of Bahia by two-thirds in the space of a decade. (Inter Press Service December 29, 2000, Friday “Brazil: in the Vanguard of Genome Research” Mario Osava)

The Chemistry Institute at University of Sao Paulo (USP) is opening a new front in the study of genomes, inaugurating December 4 its laboratory for microarrays, or DNA chips. The institution will analyze and compare sequences of DNA. The objective of the initiative is to understand possible consequences of gene mutations. (Laura Knapp, Gazeta Mercantil October 18, 2000, Wednesday SECTION: Business & Company News “USP opens new front in genome study” - Translated by James Bruce)

A group of reforestation companies has organized to map the genome of the eucalyptus tree. The eucalyptus is an important source of income in Brazil because of the paper and cellulose industries. Their researchers have devised a project that seeks to map the genome of the eucalyptus tree. It would be the first attempt to decodify the DNA of the tree in the world. (Laura Knapp, Gazeta Mercantil October 11, 2000 “Brazil begins project seeking eucalyptus genome”, Wednesday - Inter Press Service Translated by James Bruce)

Brazil is the world's second-largest producer of soybean, in which it is competitive despite a climate and soil previously considered less than ideal, thanks to the development of new strains and, especially, to a singular contribution by microbiologist Johanna Dobereiner. Dobereiner discovered over 30 years ago a bacterium that fixes nitrogen in the soil: the "Azotobacter paspali." By inoculating soybean with the bacterium, the need for nitrogen-fixing fertilizers was eliminated, saving the country an estimated total of $ 30 billion since then.

The same principle was applied in the case of sugar cane, which thus benefited the environment with a higher output of fuel alcohol to replace petroleum derivatives, and a reduction of emissions of greenhouse gases that contribute to the phenomenon of global warming.

Dobereiner passed away on Oct. 5 at the age of 75, after decades of work with the National Center of Agrobiology, located near Rio de Janeiro. In 1996, she was nominated for the Nobel Prize in chemistry. But she was not selected.

Brazil became the world's leading exporter of orange juice after many struggles with natural hazards. In the 1930s and 1940s, it lost 80 percent of its orange groves to a plague dubbed "tristeza" (sadness), spread by a virus which scientists were unable to fight. The surviving trees provided clues for the production of more resistant strains, and of a "natural vaccine.

Brazil's citrus-growing sector, which expanded and began to export in the 1960s, still fights pests and plagues. Besides the citrus canker and "amarelinho" -- the local name for the disease caused by the Xilella fastidiosa -- Fundecitrus has identified 12 other biological threats.

It also has a list of 10 insects, bacteria and fungi that threaten the country's citrus crops, some of which are already present in countries in the Amazon jungle region. (Mario Osava “Science/Agriculture: Brazil Narrows Technological Divide” Gazeta Mercantil, Rio de Janeiro, Oct. 11).

The anecdotal evidence above illustrates Brazilian biotechnology’s visibility. It is not only visible, but large and well organized for reproduction (Table 1.). It has strong graduate programs and hardly sends doctoral students abroad, giving preference for post-doctoral studies.

Table 1 – Brazilian Biotechnological Indicators

Area	Research Lines (L)	Researchers (R)	Research Groups (G)	L/G	R/L	R/G	Percentage of researchers in the Biotechnology Sector
Agronomy	477	1,070	207	2.3	2.2	5.2	0.140678
Biochemistry	604	1,041	298	2	1.7	3.5	0.12806
Microbiology	441	831	223	2	1.9	3.7	0.102227
Genetics	407	778	217	1.9	1.9	3.6	0.095707
Veterinary Medicine	311	618	137	2.3	2	4.5	0.076024
Medicine	269	567	129	2.1	2.1	4.4	0.06975
Immunology	201	463	116	1.7	2.3	4	0.056957
Food Technology	154	350	84	1.8	2.3	4.2	0.043056
Pharmacology	136	305	81	1.7	2.2	3.8	0.03752
Botanic	133	289	79	1.7	2.2	3.7	0.035552
Parasitology	120	279	75	1.6	2.3	3.7	0.034322
Physiology	112	194	53	2.1	1.7	3.7	0.023865
Collective Health	53	184	32	1.7	3.5	5.8	0.022635
Biophysics	103	181	58	1.8	1.8	3.1	0.022266
Ecology	72	167	49	1.5	2.3	3.4	0.020544
Pharmacy	70	156	41	1.7	2.2	3.8	0.019191
Biomedical Engineering	59	133	35	1.7	2.3	3.8	0.016361
		7,606	1914				

(data from the Directory of Research Groups of the CNPq – www.cnp.br)

The leading areas are Agronomy, Biochemistry, Microbiology and Genetics. Each of these areas has a different profile concerning institutional setting, production and community reproduction (table 2.). Agronomy is strongly practiced in Public Research Institutes, while Biochemistry is chiefly undertaken in universities, for example. Agronomists circulate their findings in publications that sometimes are formal editions of research reports, which accounts for their high national production and low international production.

Table 2 - Complete articles published in specialized journals

Area	National circulation (1)	International Circulation (2)	International article / Technological Product (2)/PT
Agronomy	15,240	3,894	7.22449
Biochemistry	720	3,940	1313.333
Microbiology	1106	2503	89.39286
Genetics	921	2,301	1150.5

(data from the Directory of Research Groups of the CNPq – www.cnp.br)

But a basic question comes to mind as one reads about all the heroic accomplishments made by young Brazilian biotechnologists: who will benefit from them? In other words, how will they become innovative?

Up to now, they have not. Genomes have been sequenced, drugs have been found but they have not been commercialized. They have not gotten out of their scientific environment.

The question that eats researchers up and drives them to desperation is: how do we get our inventions out of the laboratory?

Some have tried. Let us examine why Brazil has failed to do it in ANY area.

THE TECH-TRANS DILEMMA: BEYOND WHINING

Many contemporary authors have studied industrial innovation and development (Dosi 1982, Nelson & Winter 1977, Rosenberg 1976, Albuquerque in press (a) e (b)). Industrial innovation can be approached according to corporate competition dynamics or according to the institutional structure for Science and Technology (S&T) support. In this second approach, Nelson e Winter (1993) focused the "national innovation system". It is defined as the institutional structure and policies to stimulate innovation.

Patel and Pavitt (1994) created a typology of innovation systems, used by other researchers to investigate the dynamics of technological innovation in specific countries. According to this system, there are three types of national innovation systems: 1) the *mature systems* comprising, among others, the United States, Germany and Japan, forefront countries in technology; 2) the *intermediary systems*, specialized in absorbing and disseminating innovations generated in mature systems. They also explore specific niches in the international technological market. This category comprises countries such as Sweden, Denmark, Holland, Switzerland, South Korea and Taiwan; 3) the *incomplete systems*, technologically less dynamic. Their national S&T systems are poorly articulated with the productive sector. Investments in S&T are low and inefficient because of that disjunction. They comprise countries such as Brazil, Argentina, Mexico and India.

The historical, social, political and economic factors that keep these countries as incomplete systems were analyzed by some authors. Schwartzman has described the chronic difficulties met by the Brazilian S&T system in achieving a relevant role in society (Schwartzman 1991, 1995). One reason for this is that short-sighted elites never permitted successful research activities to continue beyond immediate needs (Schwartzman 1991, Coutinho 1999, Coutinho & Dias 1999). Schwartzman described the setting up of the largest Latin American S&T establishment in military-ruled Brazil, between 1968 and 1980. Scientific and technological research were endowed their largest federal appropriations until then. These funds were chiefly absorbed by public universities, which concentrate Brazilian research up to now. This accelerated growth in the S&T establishment was related to a development project based on economic self-sufficiency. The project was unsuccessful, research failed to stimulated relevant industrial sectors (except in isolated cases, such as agriculture) and the disjunction between national S&T research and the productive sector remains. Schwartzman believes that the project's failure was due to the poor response from the private productive sector. According to him, the high costs and low reliability of domestic technology were unattractive to private corporations.

Vessuri (1997) explained the relationship between import substitution policies in Latin America and the poor results in Research and Development (R&D). Vessuri stressed that these policies were implemented without a systematic concern for technological development. Most of the technology transfer to Latin America was done through equipment and procedures. R&D was ignored, as well as other forms of technology transfer that could foster technological learning. Moreover, the lack of IPR regulation made technology import cheap and attractive for corporations. The lack of protection for the production of capital goods and the inexistence of R&D incentives made the development of domestic technology expensive and risky. Vessuri believes this combination of factors explains the evolution of a non-competitive industry in the continent (Vessuri 1990, 1997).

As a result of the research-production disjunction in the continent, its scientific community became encapsulated in university environments. The excessive politicization and unionization as well as the difficulty to mature merit-based procedures at the universities are further consequences of this condition, feeding back into it and aggravating the isolation.

Matesco and Hasenclever (1998) have analyzed the economic determinants of Latin America's low innovative activity. They have also studied the S&T-productive sector disjunction. They reached three explanations: the first is related to the economic instability of the region. This would hinder the establishment of more permanent support mechanisms for technological development in the productive sector. The second explanation concerns the protective policies adopted for national industry. As a result, it became isolated from foreign competitors, thus deactivating the technological development chain based on competition. The third explanation concerns local workforce's low level of qualification (Matesco & Hasenclever 1998, Matesco 1994).

As a first attempt to overcome the chronic difficulty in efficiently exploring local biodiversity, the Brazilian government created the PROBEN (Programa Brasileiro de Ecologia Molecular para o Uso Sustentável da Biodiversidade da Amazônia – *The Brazilian Molecular Ecology Program for the Sustainable Use of Amazonia's Biodiversity*) in a partnership between the Ministry of the Environment, the Science and Technology Ministry, universities, research institutes, private companies and governments from the Amazonian region (Secretaria de Coordenação da Amazônia http://www.mma.gov.br/port/SCA/fazemos/

outros/probem.html). The program was coordinated by the social organization BIOAMAZÔNIA.

BIOAMAZÔNIA's first action – taken without the approval of its Technical-scientific Counsel – was deeply upsetting to the Brazilian scientific community: on May 30, 2000, the institution signed a contract with the Swiss corporation Novartis Pharma AG, granting exclusive access to Amazônia's biodiversity to the company. The agreement gave Novartis full access to all information related to bio-prospecting. This included taxonomy, genetics, culture media, replication technology, among others. The company would have exclusive rights, including those of patenting and commercializing, over all the products developed from Amazonian micro-organisms, fungi and plants. In exchange, Novartis would pay US$1.200.000 and, for the duration of the agreement (three years), additional payments in case research with the screened material generated commercially relevant products. The Brazilian scientific community pointed out that reaching a commercially relevant final product takes more time than the contracted duration of the program. Besides that, the commercial product is frequently a modified form of the original organism or compound, in which case Brazil would lose its right to financial compensation. There is no legal or simple mechanism to prevent that.

The reactions to the Novartis episode were not restricted to the scientific community's protests: José Sarney Fo., Minister of the Environment, immediately barred the agreement. BIOMAZÔNIA's Administrative Counsel insisted on its interest in Novartis and elaborated adjustments to the original contract, which were submitted to Novartis in August 2000 (Bioamazônia Organização Social 2000 http://www.bioamazonia.org.br/). In October, the government announced the formation of an inter-ministerial commission to control all bio-prospecting activity in Brazil, the Conagen (Conselho Nacional de Gestão do Patrimônio Genético – *National Counsel for Genetic Resources Management*). According to bill 2.052, which established the Conagen, all new products derived from bio-prospecting must be sanctioned by this commission. It has the power to veto contracts, apply heavy fines and establish royalties to be paid to indigenous communities. Foreign corporations may only carry out research in Brazil if in association with a national institution. Biological material samples may only be sent abroad with Conagen authorization. All bio-prospecting agreements were temporarily suspended (MMA – sala de imprensa 2000).

The government has, in reality, adopted a monopoly policy in regard to natural resource management. The results of this choice are not clear at this point.

After the first disaster, the big question still remains: what's missing to accomplish the predicted blockbuster success in bioprospecting in the country (Ricardo Arnt even said Brazil would be the next Saudi Arabia in the Bio-OPEP)?

First, we have to see how Tech trans works and then identify the missing links.

Brazil is definitely not the first country to face this dilemma: concerns with technology transfer from universities have been growing since the 1980's in most industrialized countries (Lederman 1994, Fujisue 1998; Licht and Ner-. linger 1998). The US are the most illustrative and developed case. Since 1980, the American Congress has passed eight policy programs to foster technology transfer. University Technology Transfer has developed into a professionalized and complex field. At least one journal, the Journal of Technology Transfer, is devoted exclusively to ''technology transfer'' (Bozeman 2000). Several professional organizations appeared. The Association for University Technology

Managers is one of them. AUTM was created in 1994 and is now a growing organization with more than 2,700 members increasing at a rate of 10% per year. AUTM's members are representatives of universities, nonprofit research institutions, government, and industry who work in the fields of licensing, new business development, patent law, and R&D. ‘‘Technology transfer agent’’ is a job title now listed in many government employee and civil service manuals all around the world.

The American experience in fostering university technology transfer is illustrative of the requirements for setting up and developing the innovation chain. Until 1980, TT was not intensive in American universities. The lack of interest in inventive activity among faculty is attributed to the compulsory licensing of all public funded research production that prevailed. The Bayh-Dole Patent and Trademark Amendments Act of 1980, amended by Public Law 98-620 in 1984, eliminated this requirement and stimulated university TT. This legislation shifted the responsibility for the transfer of federally funded research inventions from the federal government to the research universities. According to Sandelin (1994), at least 60 percent of all invention disclosures at universities arise from federally funded research, and so university offices of technology transfer have defined their role on the basis of the Bayh-Dole Act.

Also since the early 1980’s, the rise of biotechnology R&D and, more generally, of research in the life sciences, stimulated inventive activity. TT increased and so did the number of research universities with offices of technology licensing. Incomes earned by these offices have been on the rise in the 1990’s (Mowery, Nelson, Sampat & Ziedonis 1999). Today, at least 70 percent of all license income earned by universities comes from the life sciences (AUTM 1998).

Since the Bayh-Dole, most American universities have created not only TT offices but also incentives to faculty inventors. Rogers et al (2000) report that most UTT offices are becoming more proactive in seeking innovation disclosures from faculty members, in patenting technologies, and in marketing the intellectual property rights to these technologies to private companies.

Technology transfer from public research institutions (PRI) involves several steps and actors (Figure 1). The chain starts with the researcher-inventor, at her laboratory. A research product must be identified as an INVENTION. The conceptual transformation of a research result into an INVENTION is increasingly being the UTT agent’s concern. It involves monitoring research activity and constantly contacting researchers to access their awareness about the commercial potential of their work. The first step in the process is an invention disclosure: information about a new technology developed by a faculty member, a graduate student, or a staff member in a PRI is conveyed to the TTO. The second step is patenting. It is the TTO’s responsibility to devise the commercial strategy and, consequently, the basic aspects of the patent documents (claims and description). It is also the TTO’s role to choose the patent agent that will represent the PRI by writing the patent document, applying for the patent in the Federal Patent and Trademark Office and defending the PRI’s rights in litigation. Once a new technology is patented by a research university, the university owns the intellectual property rights and can license the patented technology to another organization. Once again it is the TTO’s role to take action. The next step in the process is the contact and negotiation of a license agreement between the PRI and a commercial partner. After this licensing agreement is executed, and, given commercial uses of the licensee, the research university may begin earning income from the transferred technology

Patent application and litigation must be done by local agents in each country in which the PRI decides to protect its intellectual property. Licensing, especially in biotechnology, is becoming increasingly international. TTO managers must be comfortable with different languages and cultures.

In biotechnology, it might take five or more years since the licensing agreement for any income to be earned by the PRI.

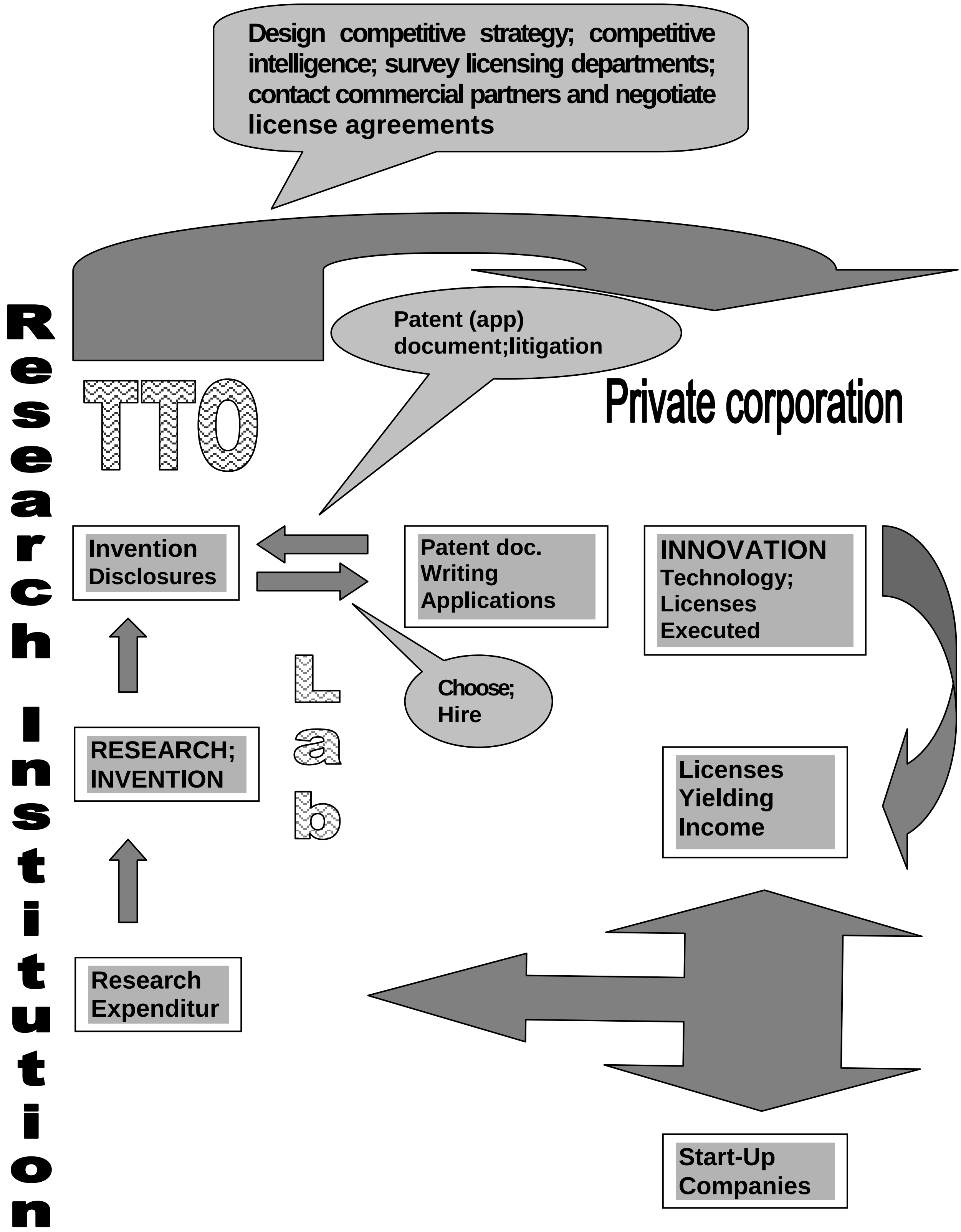

Figure 1 – Technology transfer system from Public Research Institutions to Private Corporations

Figure 1. sketches the steps involved in pharmaceutical innovation, which we may use as a proxy for biotechnology innovation in general.

Brazilian institutions are equipped –in infra-structure as well as in expertise – and have been carrying out biotechnological innovation up to the pre-clinical stage. Intellectual protection may take place before or after this point. A patent application document is a requirement to start negotiations with a commercial partner.

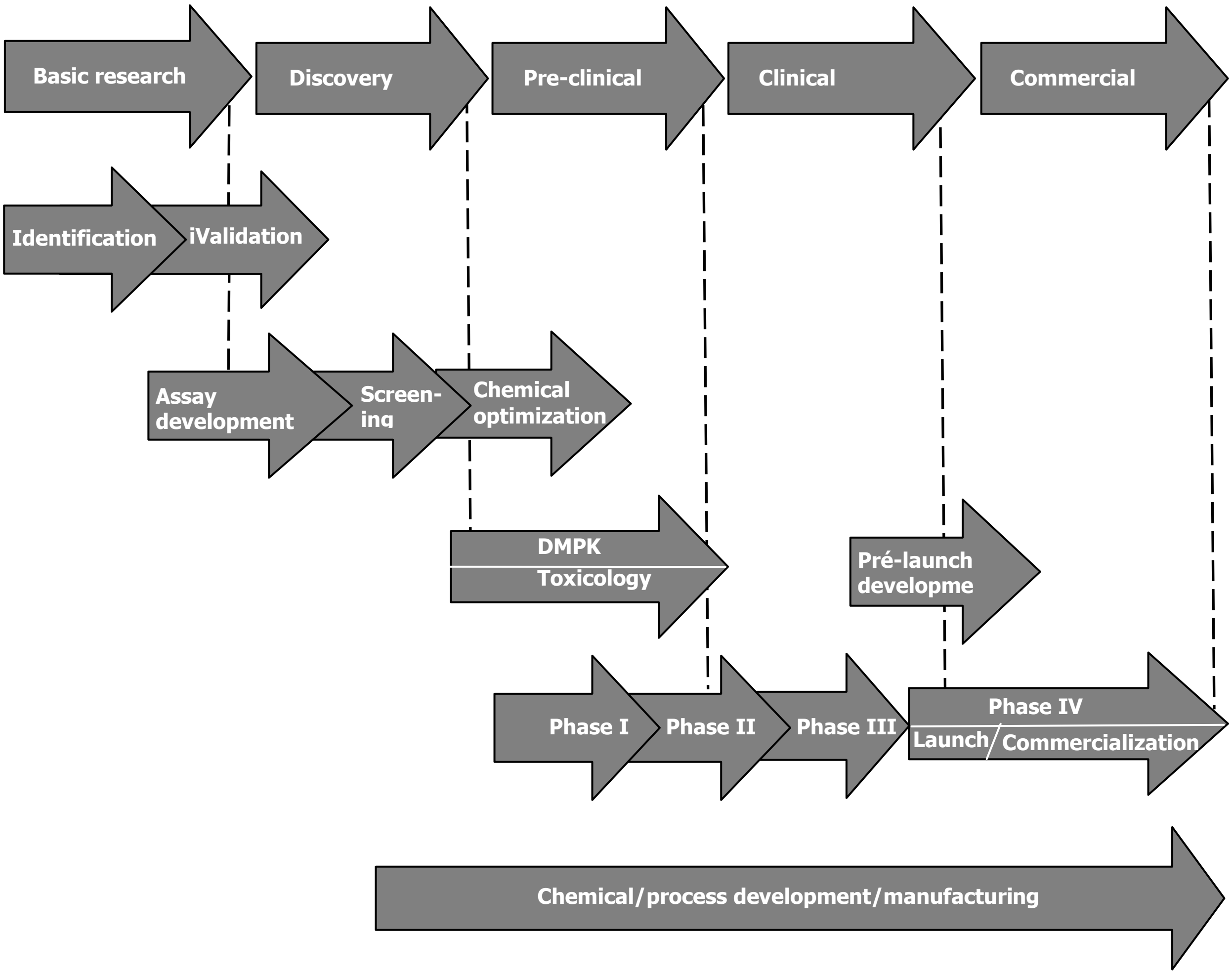

Figure 2 – Drug discovery and Innovation Chain

The whole process, from screening to a "drug", might take more than 10 years and easily a few million dollars. It must be clear that bioprospecting drug discovery is a long term investment.

In a recent survey of TT in public research institutions, the INPI (National Institute for Industrial Property) observed that most Brazilian PRIs lacked either a formal organism or the expertise to carry out the job. Even the most prestigious research university in the country, the University of São Paulo, suffers with lack of support and high quality personnel.

Except for strong and traditional applied research institutions such as FIOCRUZ and EMBRAPA, or innovative bioprospecting programs such as CAT, biotechnology research in public institutions lacks the basic elements for technology transfer. Links and elements in the innovation chain are missing from one end to the other.

Step	Problem
From research to invention	Researchers are not trained to identify potential inventions in their research. Biotechnology researchers have no background in industrial innovation and do not understand its mechanisms.
Invention disclosure	When a research product is identified as an invention, researchers have no recognized institutional channels to take action. They lose a great deal of time searching for alternatives. There is no accord in the TT activities of universities and funding agencies. There is often conflict in their procedures. The researcher is at a loss and has no means to decide between different institutional strategies.
From invention disclosure to patenting	a. Specialized data base searches are never performed. The inventor, unskilled for the job, carries out most of it. In spite of the large number of industrial property agents in São Paulo, whether any of them is competent to handle biotechnology innovation is unknown.
From patenting to licensing	a. There is no licensing expertise. Either the commercial partner is involved from the beginning, or licensing efforts will be done with no strategy or knowledge of the licensing procedures. There are no studies concerning contract formats and contract negotiation strategies regarding bioprospecting activity.
From licensing to commercialization	Research institutions are not prepared for the reality of licensing success and royalty sharing. Strategies predicted in employment and funding agency contracts are contradictory. Funding agencies and institutions have no skill to handle commercial relationships with industry

The first bottleneck in PRI innovative activity is the lack of TT institutional structure and skilled personnel. It would be unfeasible to initiate high quality technology transfer programs even in a small number of Brazilian public research institutions. While by no means denying support to on-going local initiatives, urgency recommends an alternative strategy. The most effective measure would be to create or “transform” a centralized Technology Management Office to handle biotechnological innovation stemming from PRIs.

Brazilian biotechnological innovation is done now and in the predictable future in public institutions. Yet, the incipient but rising private biotechnology industry must also be considered. Portugal (1996) points out the large number of corporations and research institutes formed in Brazil between 1981 and 1992. The relationship between these new private companies and public institutions is noteworthy. Biobrás, for example, one of the first private biotechnological initiatives in the country (founded in 1976, specialized in human insulin and products for diabetics), is also involved with BIOAMAZÔNIA and develops collaborative projects with important public institutions, such as FIOCRUZ (Biobrás S.A. 2000, Projetos de Pesquisa, Instituto Oswaldo Cruz http://dcc007.cict.fiocruz.br/projetos/protozoologia014.htm).

This example of proximity between public research and the private sector is paradigmatic. The entrepreneurial clusters and “company incubators”, such as the Polo Bio-Rio, are also part of this new reality of growing private interest in biotechnology and its dependence upon public research.

This reality makes it even more urgent to acquire Technology Transfer and Management Expertise.

We have studied the Brazilian residents patents registered at the USPTO. The number is minuscule, but a trend is visible. The number of patents at the USPTO with Brazilian residents as inventors was determined. Registered biological and pharmaceutical patents with Brazilian resident inventors from 1990 to 1999 were examined. Patents retrieved as "biological" overlap with those retrieved as "pharmaceutical", with two exceptions. There are 40 patents in this period (fig. 1).

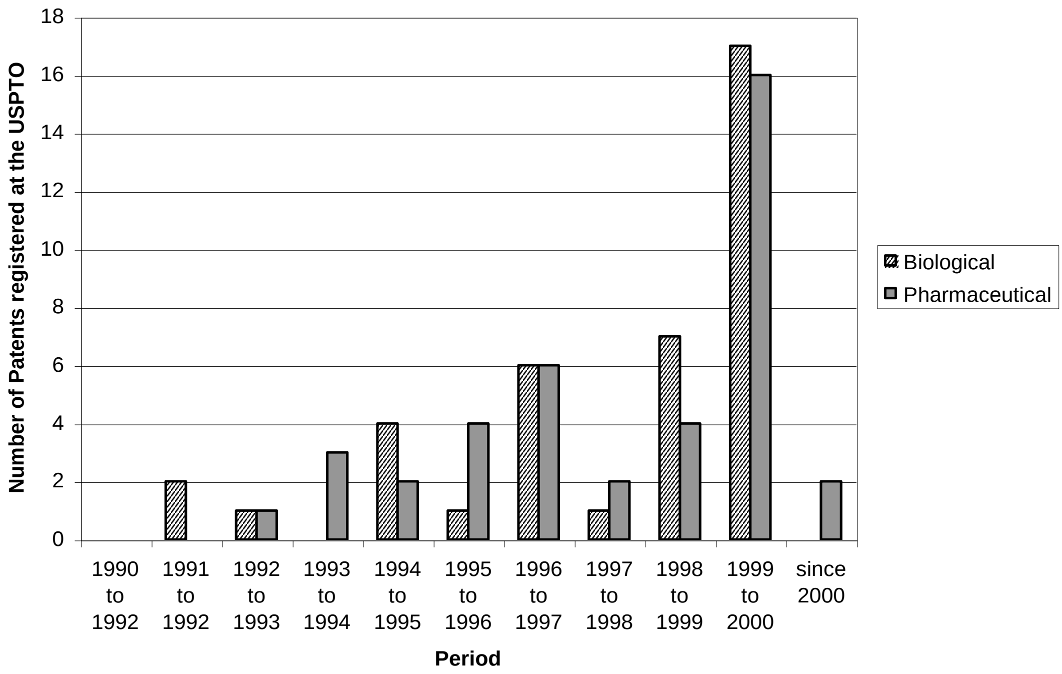

Figure 3 – Biological and Pharmaceutical Patents registered by Brazilian Residents

Of the 40 pharmaceutical patents, 13 are registered by Brazilian assignees, 26 by foreign assignees and 1 is co-owned by a Brazilian (EMBRAPA/Cenargen) and a foreign corporation (Plant Genetic Systems N.V., Ghent, Belgium). All the patents owned by Brazilians have exclusively Brazilian inventor teams, except for the bi-nationally owned one. The foreign owned patents usually have one or two Brazilians in a foreign dominated inventor team. The distribution of patents by owner category is displayed in Table 3:

Table 3 – Distribution of Patent Owner Category

Brazilian Assignee			Foreign Assignee		
Public Institution.	Private Organization	Individual	Corporate	University	Government
4	7	3	21	4	2

There are no University Assignees among Brazilians and there are no individual Assignees among foreign owned patents.

Information obtained through personal communication reveals that some of the foreign owned patents are actually the result of Brazilian research. Once the researcher finds her (him) self working in a foreign institution during sabbaticals or post-docs, the research becomes collaborative. The foreign institution is much more aggressive in protecting research products and no previous agreements are done with the Brazilian researcher's institution.

Tech-trans and public policy - What's going on now: the new law, the industry and natural resources monopoly

It is curious to trace back in time the spirit of Intellectual Property rejection in Brazil. Bermudez et al. (2000) have shown that although Brazil had industrial property legislation as soon as 1809 (one year after the Portuguese court moved to colonial Brazil), items started being excluded from patentability in the first industrialization wave. In 1945, foodstuffs, medicines or chemically produced substances were considered not patentable. In 1969, pharmaceutical products were altogether considered not patentable. These measures did foster a certain growth in Brazilian pharmaceutical industry. Nevertheless, again it was not based on domestic innovation, but rather on the production of medicines labeled "similar" to the brand name foreign developed substances. Protected by a law that excluded pharmaceutical patents, companies grew without R&D investment.

In the 1990's, as an outcome of the TRIPS (Trade Related Intellectual Property Rights) agreement, Brazil adopted a patent law that not only conforms to the multinational pharmaceutical companies demands, but even grants them the right to patent previous "public domain" substances through the pipeline procedure. The Industrial Property Act # 9279/96 was passed on May 14, 1996 (for more details on the consequences of the TRIPS agreements on Brazilian public policy, see Bermudez et al. 2000).

Ironically, a closer relationship between industry and public research began to develop in the same period. Now, unprotected researchers and Brazilian pharmaceutical industry face the threat of legalized bio-piracy: they fear medicines developed from Brazilian biodiversity will be patented by huge multinational corporations, thus crushing recent and still feeble attempts into domestic pharmaceutical R&D.

As mentioned before, the reaction to the first and clumsy attempt from a pharmaceutical multinational to dig into Brazilian biodiversity was immediate and radical: the Conagen (Conselho Nacional de Gestão do Patrimônio Genético – *National Counsel for Genetic Resources Management*) was formed and Brazil has, in practice, adopted natural resource monopoly (MMA – sala de imprensa 2000).

It would be naïve to consider this monopoly as any substantial protection from multinational take-over. Even if policemen are placed every square mile of Brazilian territory, domestically developed drugs and other substances will not reach the market without proper Technology Management expertise.

CONCLUDING REMARKS: SCIENTISTS AS INVENTORS, AS TECH MANAGERS AND DECISION MAKERS: IT'S NOW OR NEVER

Five years separate our calamitous state of lack of Technology Management expertise from the opening of the Free Trade Area of the Americas. Five years to accomplish the apparently impossible: enable the country to set up an efficient biotechnological (including pharmaceutical) innovation system.

If there are government initiatives leading to this, if scientists are dying to receive a Tech-Trans office as a Christmas present, then why don't they do it now?

The answer is not that easy. The shortest one is: "petty politics". A longer and more elaborate one would have to highlight the prevalence of a perverse practice in most PRIs: to delegate technology management to the lowest productive elements in the institutions. These tend to be both politically articulated in unions and violently opposed to any modernizing measure to allow flexible appropriations and expenditures management – both needed for such a "large dog's game" as patenting, licensing and commercializing technological innovation.

In a very short time, there will have to be a wider discussion, including different sectors from society, and a decision must be made as to whether an aggressive national policy to foster innovation will or will not be ***enforced***.

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