

## THE BRAZILIAN SYSTEM OF INNOVATION IN BIOTECHNOLOGY: A PRELIMINARY STUDY

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### Abstract

In order to prepare a preliminary analysis of the Brazilian National Innovation System in Biotechnology (NISB), we conducted several interviews and used e-mail questionnaires with different kinds of actors in the system, i.e. university teachers, financing agents, businessmen, etc. The study suggests that Brazil has a few important strong points, like the scientific tradition in biotechnology, the financing to basic research and the strength of the agricultural sector in the last decade. But there is still a long way to go; sector regulation, the start up companies financing and the cultural aspect of business aversion by researchers seem to be the main obstacles for the country to become a significant player in this sector

Keywords: biotechnology; national systems of innovation; Brazil.

### 1. Introduction

Modern biotechnology has been suggested as the new economic wave following the Internet wave. Several countries have tried to establish a national system of innovation in biotechnology that would allow the optimization of scientific and economic resources and would generate products based on a national biotechnology. Bartholomew (1997) has suggested a model for analyzing systems of innovation in biotechnology in various countries, listing their common factors. Based on that model, we have prepared a preliminary analysis of the Brazilian system of biotechnology innovation, in order to point out its strong and weak points.

Through interviews and questionnaires we establish a general picture of the situation in the country according to the several players who are involved in the system –

graduate students, professors, promotional and regulatory agents, business people and policymakers.

Our results suggest that Brazil still has a long way to go in organizing its innovation system in biotechnology. Sector regulations, the financing of start-up companies and the aversion of researchers to businesses appear as the main obstacles to establishing the country as a significant world player in this sector. The strong points include the country's scientific tradition and the financing of basic research.

## 2. National Innovation Systems

The National Innovation System (NIS) concept is based on the principle that the relationships between different players involved in innovation are determinant for improving the performance and utilization of technology. Innovation and technical progress are the result of a complex set of relationships among those who produce, distribute and apply various types of knowledge. A country's innovative performance largely depends on how these players relate with one another. The players are private companies, universities and public research institutions and the people within them. Relationships can result from cooperative research, personal exchanges, co-patenting, the purchasing of equipment, and a variety of other possibilities. On the other hand, there is no consensual definition concerning a national innovation system (OECD, 1996; OECD, 1997). Various definitions have been offered by different authors (e.g. Freeman, 1987; Lundvall, 1992; Nelson, 1993; Patel and Pavitt, 1994; Metcalfe, 1995). Thus, many analysts have created methods for analyzing NISs, looking for national patterns that may be adapted by other nations in order to improve the local NIS.

In the present study we are concerned with national innovation systems in Biotechnology. Modern Biotechnology has been receiving great emphasis nowadays. The economic possibilities, the ethical issues involved in manipulating live organisms, the issue as to whether or not transgenic foods are harmful, and the possible treatment of diseases that had formerly been considered incurable are making headlines all over the world.

However, contrary to other economic sectors, Biotechnology is not an activity *per se*. It deals with a set of techniques, knowledge and technologies that may be productively used in other sectors. As a rule, this knowledge and these techniques are developed in academia and in other research institutions, while their utilization occurs in industry. As such, the diffusion of new technologies has become the key factor for a country's success in this field, making it necessary the use of somewhat different tools for the analysis of this specific innovation system. It is no wonder that the majority of first world countries have already set up a specific innovation system for Biotechnology<sup>1</sup>.

The objective of this study is to present an analysis of the current state of biotechnological development in Brazil, using the model developed by Bartholomew in 1997 for national systems of innovation in Biotechnology. Through interviews and e-mail questionnaires submitted to individuals working in the area, a preliminary picture was

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<sup>1</sup>See <http://www.sussex.ac.uk/spru/biotechnology/ebis/> for a view of the systems established by European countries.

obtained, concerning the country's strong and weak points in the area.

## 3. Biotechnology

Biotechnology is one of humankind's oldest areas of knowledge. Contrary to what is normally suggested, techniques for manipulating living beings have existed for many centuries. Bread, beer and wine, perhaps the oldest products ever manufactured, are nothing more than products originating from the fermentation of microorganisms in a favorable medium, in this case, wheat or grapes. However, modern biotechnology, capable of manipulating an organism and its own genetic code, of modifying tissues and cells *in vivo*, has captured the attention of the media, economists, policymakers, researchers and scholars. Modern biotechnology was developed over the course of the 20<sup>th</sup> century, with explosive growth towards its last quarter and promising to create a new economic boom. One could present a long list of areas in which biotechnology is used today but it would certainly not be exhaustive. From the point of view of economic potential, the areas of greater impact nowadays and in the near future, according to several authors, are proteomics (the identification of spatial structures in proteins), pharmaceuticals, bioengineering, biomaterials and genetically modified foods. It is this modern biotechnology that is the object of the present study.

## 4. Bartholomew's Model for Analyzing an NIS of Biotechnology

The idea of a national innovation system differentiated for Biotechnology has already been discussed by various authors (e.g. Balazs and Twardowski, 2000; Senker et al., 1999; Chen and McDermott, 1998). Biotechnology generates ways of *attaining* new products, not products *per se*. Such ways may then be utilized in other sectors (e.g. the pharmaceutical, food and agricultural industries). As such, the system has become much more complex and the diffusion of new technologies has become critical for its success (Senker et al., 1999).

Bartholomew (1997) proposed a model for analyzing national systems, making it possible to find strong points and obstacles in each country by analyzing eleven factors with historical, social, economic and political causes that are specific to each country, and which will provide a greater or lesser ease in the development of Biotechnology. This model was well received by the academic community (an earlier version won the Haynes Prize of 1996, sponsored by the AIB Foundation and the Eldridge Haynes Memorial Trust), and we believe it allows for the inclusion of most of the critical factors suggested in the literature on NSI in Biotechnology. The model (see figure 4.1) is based on 11 factors influencing the innovation system. The factors

are self-explanatory, but a detailed description can be obtained in Bartholomew (1997).

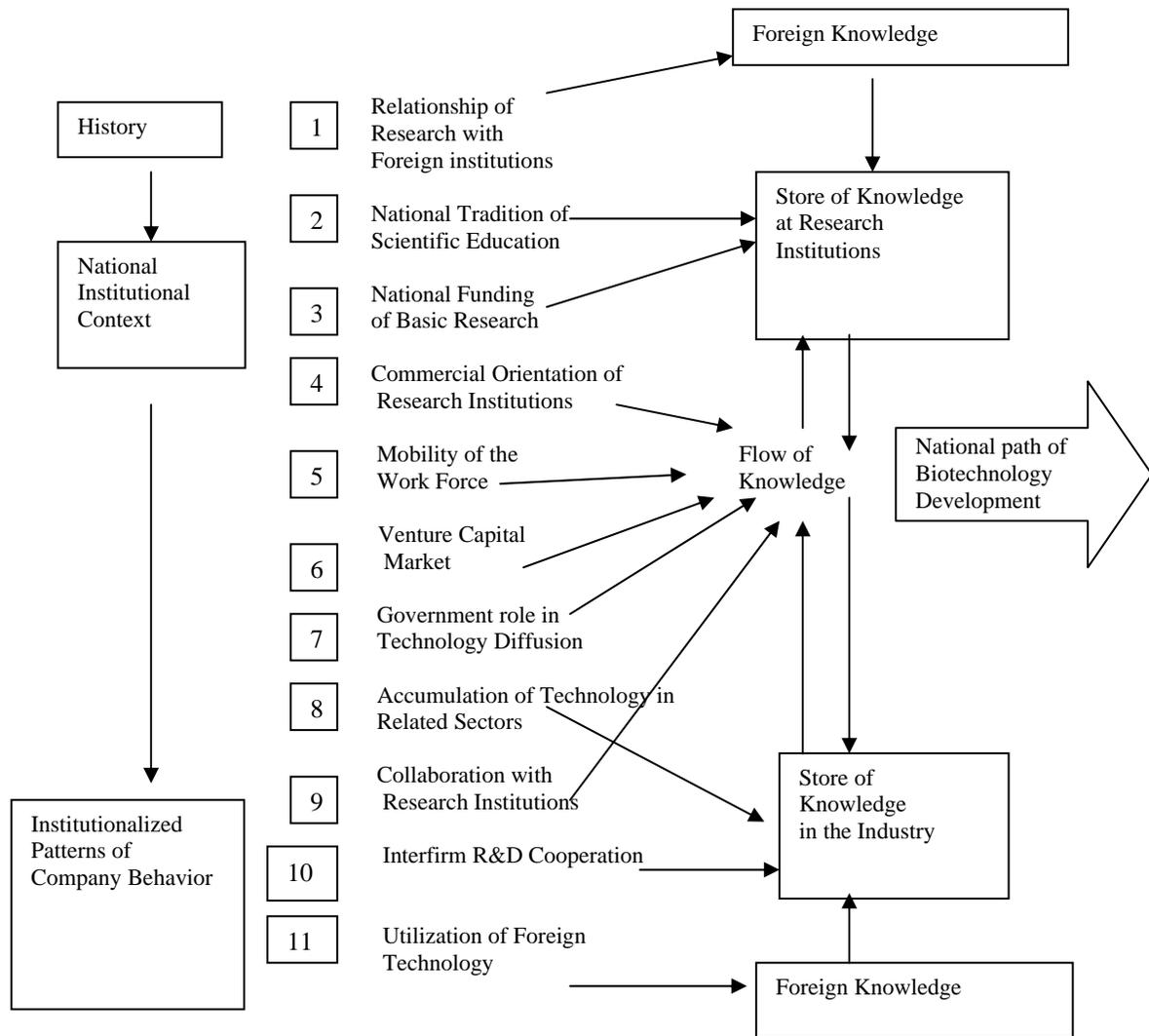


Figure 4.1 – Model for analyzing an NIS of Biotechnology, with factors critical for its success (Bartholomew, 1997).

## 5. Analysis of the Brazilian NSI in Biotechnology

### 5.1 Data collection

As already mentioned, three different tools were used to collect data, including interviews, e-mail questionnaires and bibliographical research. Unfortunately, there are no lists of “experts” in the area and we had to start building our own list relying more heavily on the academic community. Such *ad hoc* list was obtained from several sources: a biotechnology company database generated by Biominas (a

not for profit organization for the development of biotechnology in the State of Minas Gerais); graduate students and university professors in Molecular Biology (obtained by means of a search in the internet) of 4 Brazilian universities and affiliated areas; a list of researchers from the 4 main research institutes in biotechnology in Brazil; a list of patent analysts from the National Institute for Industrial Property and the National Sanitary Agency in the area of Biotechnology; members of the internal Biotechnology network of FINEP (a federal government agency for the financing of projects in technological innovation); Biotechnology project analysts

from the National Council for Scientific and Technological Development and the Ministry of Science and Technology. We used open interviews, trying to cover all the points discussed on in the model. The interviewees and

respondents were guaranteed anonymity and only their area of involvement is mentioned here. The number of interviewees and respondents to questionnaires can be seen in table 5.1.

Table 5.1 – Interviewees and Questionnaires respondents

	Interviews	Questionnaires
Graduate Students	2	5
University Professors	2	8
Research Institute Researchers	-	3
Venture Capital Professionals	2	1
Biotech Professionals in Start-up Companies	1	2
Biotech Professionals in Large Companies	-	3
Government Officials	1	12
Total	8	34

## 5.2 Results

Respondents were asked to give their opinions about the eleven factors of the Bartholomew model on a Likert scale varying from 0 (non-existent) to 5 (excellent). Results are

presented in Table 5.2 and will be discussed below. The discussion will also take into account the opinions expressed in the interviews.

Table 5.2 – Perceptions of respondents about the situation in Brazil in the area of Biotechnology (0 = nonexistent; 1 = bad; 2 = weak; 3 = average; 4 = good; 5 = excellent).

Factors	Average
Relationship of Research Institutes with Foreign Institutions	3.1
National Tradition of Scientific Education	3.2
National Financing for Basic Research	2.7
Commercial Orientation of Research Institutes	1.4
Mobility of Work Force	1.8
Venture Capital Market	2.0
Government Involvement in Diffusion of Technologies	2.4
Accumulation of Technology in Correlated Sectors	3.0
Collaboration between Industry and Research Institutes	2.1
Cooperation among Companies in R&D	2.0
Strategic Utilization of Foreign Technology	2.4

### *Relationship of Research Institutes with Foreign Institutions*

According to the interviewees and respondents, our research institutions and universities have a good relationship with foreign institutions. The average score obtained on our questionnaires for this factor was 3.1, the second highest among the 11 factors assessed. The strong point of this relationship is in research, where the flow of scientists and students abroad is constant and embodies all the areas related to Biotechnology. There is a large contingent of students working on their doctoral who spend from 6 months to a year doing research in foreign universities, as well as a large number of post-doctorates,

especially in the U.S. and Europe (notably France and England).

### *National Tradition of Scientific Education*

According to respondents (and interviewees) this is the country's strong point in the Biotechnology area. This factor achieved the highest average score of all 11 factors, 3.2.

Brazil has always produced a large number of professionals in the area of Biotechnology. According to the interviewees, the problem with this factor is not supply, but demand; there is a lack of risk capital, commercial orientation by companies and even public financing (as we shall soon see); as a consequence, there is a surplus of

qualified professionals, who are often lost to other sectors of the economy due to a lack of places at universities, research institutions and companies.

#### *National Financing for Basic Research*

This factor, in spite of having received a good average score (2.7) presented a large variability of responses, not only among the questionnaire respondents but also among the interviewees. While some of them consider it to be good and, in some cases, “exceptional,” a good part of the respondents find government involvement in supporting research quite weak or “barely tolerable.” The main complaint of the interviewees was the government’s lack of constant financial support. According to the interviewees, funds are always late in coming and quite often projects that are already underway fail to receive the agreed budget.

#### *Commercial Orientation of Research Institutions*

The lack of commercial orientation seems to be as main deficiency in the national system of innovation in Biotechnology. Both in the interviews and in several spontaneous opinions presented in the questionnaires, it became clear that the cultural aspect is the first barrier to biotechnology in Brazil. For them, researchers seem to believe that their only job is to practice science, and that the idea of trying to earn money as a product of their research is not proper. The scientific community looks down on researchers who turn to a career in industry or who become entrepreneurs and create their own business. It was further cited that Brazilians generally have an aversion to entrepreneurs, associating their image to those who take advantage of others to get money, as opposed to researchers, who have an image of pure dedication, persistence, accomplishment and honesty.

#### *Workforce Mobility*

This factor received the second lowest mean score (1.8). However, the majority of the interviewees, as well as some of the respondents, stated that they were not adequately familiar with the subject. Several suggested that Brazilian mobility was rather low as compared to European or North American mobility, a suggestion which may well be right (for a discussion of mobility in Brazil, see Pastore & Valle Silva, 2000; Scalón, 1999).

Although the cultural aspect may be a major factor for low mobility, some interviewees also suggested that the (lack of) demand from industry (e.g. pharmaceuticals) could also be blamed; many companies prefer to develop new products at headquarters and/or research centers abroad.

#### *Venture Capital Market*

New Biotechnology companies are born in universities and research centers when researchers see the possibility of creating an innovative and lucrative business. In the overwhelming majority of cases, researchers’ own funds are insufficient for creating a new company with equipment, personnel and funding for research continuity. Thus, there is a strong dependence on capital investment.

On top of that, unlike sectors such as information technology, where a group of software developers can develop an excellent new product “in their garage” and put it on the market to generate revenue, in Biotechnology the initial investment required is very large (Robbins-Roth, 2000).

But venture capital is still embryonic in the country (average score was 2.0) and faces a serious obstacle in the particular area of Biotechnology: legislation. If the “rules of the game” are not well defined, it is not possible for the investor to assume further risks, with possible changes in the Biodiversity law, the biotechnology product patent law, and regulations concerning the functioning of companies based on biotechnology. Researchers and students showed concern about the fact that the (small) supply of risk capital has become restricted to the Rio – São Paulo hub.

#### *Government Involvement in Diffusion of Technologies*

Diffusion is the process by which an innovation is communicated over time through determined channels by members of a specific social system (Rogers, 1995). Since Biotechnology is strongly dependent on basic research, its success in any country is strongly connected to government policies concerning science and its diffusion. This is not a very simple matter because biotechnologies seem to diffuse differently in different sectors of the economy. This was confirmed by respondents to the questionnaire who indicated differences in diffusion between the agro-business and the pharmaceutical sectors (good diffusion in agro-business and not good in pharmaceuticals). The average score was 2,4

#### *Accumulation of Technology in Related Sectors*

Similar to diffusion one finds a clear distinction between different sectors of the economy (here, the agricultural sector and the health sector) with respect to accumulation. Both the interviews and the comments provided in the questionnaires indicate that although in the average this factor is well rated (3.0), it is clear that agriculture enjoys much more accumulated knowledge than health. In several questionnaires,

### *Company Collaboration with Research Institutions*

Industrial innovation depends on the integration of applied research and development. However, such integration does not occur automatically and the efficiency with which a company transfer applied research to final products and processes is a key factor for success. Biotechnology is still strongly dependent on basic research (generated, as a rule, at universities).

This factor did not receive a good evaluation from both interviewees and respondents. With a 2.1 average, the common feeling is that industry and universities do not communicate with each other, creating a barrier to Biotechnological development. It is important to mention that there were some very positive comments about the interaction between some non-academic research institutions and local industry (EMBRAPA and the rural producers and Fiocruz and pharmaceutical companies in drug development).

### *Cooperation among Research and Development Companies*

In modern industries, competition is now seen as a race for learning. Collaboration among organizations (companies, universities and others) has grown over the last few years, especially in sectors such as Biotechnology. But this does not seem to hold in Brazil. The interviews suggested that there was very little cooperation and the explanation was that the biotechnology industry is still quite small and new. Respondents to the questionnaires also indicated that this may be so; 15% of the respondents did not answer this question and some 20% mentioned that their answer applied to the general collaborative situation among companies in the country, but not to Biotechnology companies.

### *Strategic Utilization of Foreign Technology*

Similarly to the previous factor, size and age of the industry seem to diminish the importance of the strategic use of foreign technology. The majority of the interviewees showed that they did not know of practical cases where technologies in the productive sector were strategically utilized. In research, however, all pointed out the constant search by researchers for new methodologies, and to the fact that each year many doctoral students go abroad to be trained in new methods. Quite naturally, this transfer of knowledge applies only to the field of research. It will be used by the productive sector only in cases of company start-ups initiated by the student him/herself or by his/her professor. As one interviewee pointed out there is some use of foreign technology by the Fiocruz Foundation for the production and development of new vaccines. Although of

great importance for the country, the volume of the operation in industrial terms is still small.

### 5.3 Strong and Weak Points of Biotechnology in Brazil

As mentioned before, the main objective of this paper is to discuss the strengths and weaknesses of the Brazilian NSI in Biotechnology. In other words, what are the strong and weak points for the development of a national system of innovation in biotechnology in Brazil?

According to our results, we are still quite far from those countries that are on the cutting edge of biotechnological development. Not one single factor was considered "excellent" (five) or "good" (four). The best factor (National Tradition of Scientific Education) was rated just a little above "average" (3.2).

Nevertheless, there are positive aspects in the current state of the situation. The scientific tradition is a favorable point in the development of new technologies and processes. Financing of basic research, in spite of being less than what is desired by the scientific community, is another positive factor. We suggest that a good supply of human resources coupled with a reasonably good financing of research, represent a very good start for the creation of a strong internal knowledge, which is the support for the entire innovation system.

The current state of agriculture in the country was also emphasized during several interviews and (written) comments in the questionnaires. The system formed by the universities, EMBRAPA, and the diffusion to the producer was highly approved by the respondents.

As for the main difficulties one can point to the lack of consistency in financing for research, the cultural reaction to entrepreneurial activities, the difficulty of finding financing for the final steps of product development and company start-ups, the legislation now in force, the lack of a specific policy for diffusing technologies in the area of health, the non-commercial orientation of research institutions, and the lack of labor mobility between the university and the productive sector. Two of such difficulties were strongly emphasized by respondents and we will comment on them next.

## **6. Two major Difficulties in the NIS in Biotechnology in Brazil: Venture Capital and Legislation**

As mentioned previously, a large number of problems were identified in this study. Many of them were circumstantial, such as the discontinuity in public financing for research, while some affect only certain activities, such as the lack of a specific policy for diffusing technologies in the area of health.

However, some of the problems identified seem to be very relevant and have a great potential for making the development of the system very difficult. Two of such problems were (i) the issue of financing a start-up company, which in the rest of the world is traditionally done in the form of venture capital (Robbins-Roth, 2000; Senker, 1996); and (ii) the country's as yet undefined legislation. The frequency and emphasis with which they were mentioned suggest that they are the main obstacles to biotechnology in Brazil. These two problems deserve our special attention and are presented next in greater detail.

## 6.1 Venture Capital

### 6.1.1 *Technological Based Companies and the Need for Venture Capital*

The traditional financing mechanisms available through financial institutions are not the most appropriate for base technology companies. This is due to the risky nature of the activities of such companies, which involve intense investment in Research and Development, and the profile of their founders, who do not usually possess enough real assets to secure a loan.

Risk capital, besides not requiring security, implies that returns for investors depend on the growth and profitability of the company in question, which is contrary to traditional credit where the creditor has legal rights in terms of interest and amortization, regardless of the success or failure of the business. Furthermore, such a financing mechanism differs from other traditional sources because it provides long-term capital and offers managerial and administrative support (British Venture Capital Association, 2000).

### 6.1.2 *The Venture Capital Market in Brazil*

Venture capital in Brazil started in the 1970s, primarily through two public institutions, *BNDES*, the National Bank for Economic and Social Development and *FINEP*<sup>2</sup> (Gorgulho, 1997).

Support from *BNDES*, through its subsidiary, *BNDES-Participações* (*BNDESPAR*), is one of the pioneering experiences in Brazil in terms of financing the process of innovation through risk capital. Especially in the cases of small and medium-sized companies, support is relatively recent (beginning in 1988) through the Capitalization

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<sup>2</sup> Financiadora de Estudos e Projetos — *FINEP* (Research and Projects Financing), also known as the Brazilian Innovation Agency, is a publicly owned company subordinated to the Ministry of Science and Technology — *MCT*.

Program for Technology Based Companies (*CONTEC*) (Gorgulho, 1997). Nowadays the main program for diffusing Venture Capital in the country is *FINEP*'s Project *INOVAR*, which has already put together nearly one hundred companies and their risk investors.

### 6.1.3 *Biotechnology Companies and Venture Capital*

For a Biotechnology company to grow, several rounds of ever-increasing investments are generally necessary. It is usual for such investments go over the \$30 million mark (Robbins-Roth, 2000). This need for large quantities of resources may be explained by the fact that the great majority of biotechnological companies in the U.S. are geared toward developing new medicines, which implies the need for FDA approval. This is a long process and consumes a large amount of resources.

Therefore, it becomes evident that the entrepreneur will hardly possess enough personal resources to set up his company. Since the Brazilian pharmaceutical industry is quite limited (in terms of investment funds) and developing new drugs is usually done abroad, Brazilian companies do not have the financial ability to subsidize the needed expenses.

Without the help of State Financing Organizations (which are ill equipped to deal with this kind of investment) and considering that the term of investment and the volume of resources are outside the usual limits of bank financing, the alternative for potential entrepreneurs is the traditional financial credit

It has become clear that the country's Biotechnology development depends on the creation of (unsecured) long-term financing mechanisms on the part of the government, or else on the growth and consolidation of the Venture Capital industry.

## 6.2 *Brazilian Legislation in Biotechnology*

According to the interviewees and respondents to the questionnaires, the second major difficulty faced by entrepreneurs and risk capitalists is the Brazilian Legislation in Biotechnology. All agree that the present legislation is rather vague with reference to the development of biotechnological products (or leave room for interpretation), making it very risky for entrepreneurs and risk capitalists.

The main difficulties are:

- ❑ Patent law, which presumably protects the rights of the inventor of a new product or process, and which is fundamental for the profitability of any Biotechnological undertaking (once a new drug or cell is created, it can be easily replicated);
- ❑ Biodiversity law, which starting with the Rio-92 conference, has determined that the information on the genetic structure of the biological resources

(flora, fauna, microorganisms) located in a particular country is the property of that country. This law and its internal regulations have direct implications on the possibilities of exploiting Biotechnology in Brazil; and

- Biosecurity law, which imposes limits on the manipulation of living organisms, as well as on the way they are manipulated and the competence of whoever manipulates them.

Even in the most developed countries the legislation applying to products derived from biotechnological modifications is still a difficult subject. While the European countries have placed regulations on GMOs (genetically modified organisms) to deal with the *process*, in Japan and the U.S. there seems to be a preoccupation with regulations that deal with the *product*. The labeling of transgenic products is also still quite controversial, and it has resulted in a split between the U.S. and Europe (Chen and McDermott, 1998).

With respect to regulatory policies, it seems that all countries are concerned with the potential risks of Biotechnology, and the U.S. has initiated a process of regulating the sector with this variable in mind. Some countries have created specific legislation for Biotechnology, while others are regulating the sector based on the way other existing sectors are regulated (simply adapting already existing laws). The strictness of the laws appears to be directly linked to the public's perception of the biotechnology issue, with Germany displaying the highest degree of strictness. With respect to intellectual property, sharp differences are observed with direct implications on the industry's structure, possibilities and growth. The most controversial issue concerns the patentability of life forms. Microorganisms are patentable in all the countries studied, but transgenic animals are only patentable in the U.S. and Japan. Another issue that deserves special attention is the use of its genetic information. There is a need for strict and specific legislation and strict control over the exploitation and use of such biodiversity, or countries like Brazil may lose all its genetic wealth to countries that are further advanced in the biotechnological race.

Interviews with specialists in the area made it clear that such laws are very much open to interpretation. Without having to dwell further on the legal considerations, it seems clear that there are two main lines of thought: those who defend the patenting of basically all new molecules and organisms created in the laboratory, and those who think that they are not patentable.

## 7. Conclusion

The problems related to legislation and the financing of start-ups and small and medium-sized companies are no doubt quite difficult, and we suggest that such problems could be solved (in the long run) given the political will of legislators and Government. The cultural problem is also very difficult, with its solution only envisaged in the very long term through a change in the mentality of researchers and, in some way, of the population in general. Such a change can in fact take more than one generation to happen and never by a single leap.

Nevertheless, several measures such as the federal government proposed Innovation Law and the concern of some universities (patent protection policies) to secure their rights over research developed in their laboratories may well help to overcome the obstacle of commercial orientation.

One issue raised during some of the interviews was the fact that the scientific and technological structure of the country is based on the Brazilian scientific community. Most of the financing is decided by members of the scientific community and there is some fear that funds will be biased towards basic research. Some steps taken by the Federal Government (Innovation Law and the creation of Sector Funds) suggest however, that this picture can be changing. We suggest that an alternative to the financing of "science through science" would be to develop work plans with well-defined economic objectives and that have some impact on the country's imports and/or exports. A successful example of planning for this type of action has occurred in India with the growing of cardamom (Mehra, 2000).

Therefore, our conclusion is that policy makers, in order to develop Biotechnology in the country must:

- Work on the legislation for the sector in order to attract new investments;
- Develop new financing mechanisms that are adequate for industry know-how and with sufficiently long maturities;
- Create programs focused on the real problems of the country, seeking to develop in-house solutions with Brazilian competencies and companies, and acquiring, when necessary, foreign technology.

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