cinve

centro de investigaciones económicas

Biotechnology services in Latin America by small and medium enterprises
A study of Argentina, Brazil, Chile and Uruguay

Jorge Niosi
Tomas Gabriel Bas

Documento de trabajo/Working Paper N° 2013(SS-IP)-01

Special Series "Promoting Innovation in the Services Sector: Towards Productivity and Competitiveness" (SS-IP)

August, 2013

cinve
Centro de Investigaciones Económicas

WORKING PAPER
N° 2013(SS-IP)-01

"Promoting Innovation in the Services Sector: Towards Productivity and Competitiveness"

Biotechnology services in Latin America by small and medium enterprises A study of Argentina, Brazil, Chile and Uruguay*

Jorge Niosi
Professor
Department of Management and Technology
Université du Québec à Montréal
Canada Research Chair on the Management of Technology

With the collaboration of

Tomas Gabriel Bas
Professor
Faculty of Administration
University of Sherbrooke
Sherbrooke, Canada

August, 2013

This publication reports on a research project financed by
Canada's International Development Research Centre (www.idrc.ca).

IDRC | CRDI
International Development Research Centre
Centre de recherches pour le développement international

Canada

* *The opinions expressed in this publication are those of the authors and do not necessarily represent those of* **cinve**

Table of contents

Executive summary

This paper is about a specific type of Knowledge Intensive Business Services (KIBS), namely R&D services in biotechnology, and their growth in four Latin American countries: Argentina, Brazil, Chile and Uruguay. Like other emerging and developing countries, the four countries in the Southern Cone are slowly adopting biotechnology. Well over a hundred dedicated biotechnology firms are already providing services in the region, from R&D to bioinformatics, to gene identification and stem cell databank storage services. We interviewed some 23 firms in the region, as well as a few policy makers and other public servants, we analyzed the policy environment, conducted the analysis of the data and linked them with the theoretical framework and hypotheses.

The paper starts with a theoretical discussion about KIBS, draws a few hypotheses, then presents the survey and its methodology, the science, technology and innovation (STI) policy framework in the region, and concludes by proposing several policy additions for science and technology: increasing public R&D expenditures, designing and implementing venture capital, academic recruitment and procurement innovation policies**,** in order to increase the supply and demand of biotechnology services. Finally, the quality and quantity of biotechnology statistics (and all R&D statistics) need to be seriously reconsidered and revamped. External advice (i.e. from OECD and/or Statistics Canada), and quality control may be useful.

1. **Theory and hypotheses: innovation in Knowledge Intensive Business Services**

Most of the theory and empirical studies on innovation has focused on innovation in the production of goods, mostly in manufacturing. However, the service sector has become most important in terms of employment and production; in addition, it is increasingly seen as a major factor in R&D and innovation (Gallouj and Savona, 2009). This is particularly so in such innovation intensive sectors as computer software, and R&D services like biotechnology, nanotechnology, and clinical research, to name a few. Not all Knowledge Intensive Business Services (KIBS) are innovation intensive. We can see a clear spectrum in terms of innovativeness. Some, such as accountancy services are at the low side of the spectrum. R&D services are at the other extreme. Engineering services lie in the middle. This paper is about the most innovation intensive services: R&D services.

Whatever the specific sub-domain, the quantitative analysis of innovation in services – particularly on the side of the outputs – poses several serious problems as Griliches (1992) underlined.

- What is exactly sold? The knowledge produced by the R&D services firm? Is it a prototype in the case of the software program? The installation of the software in the clients' hardware? The plan of the new car or building, in the case of a design or engineering firm?

- What is the role of the user? Up to a certain degree, the user participates in the definition of the service, thus in the framing of the service innovation itself. When a pharmaceutical firm requests R&D services from a dedicated biotechnology firm (DBF) it is clear that the large corporation is participating in the innovation it requests from the smaller service firm.

- The quality of the service is more difficult to measure. This is a clear problem in the analysis of education or health services, and in R&D services. The client itself may not have a clear understanding of the quality of the services he/she is buying.

Today we may add some other conceptual and measurement problems. The innovation produced by the service firm may have large positive productivity impacts on the users of the innovation, be they agricultural farms using new genetically modified organisms (GMOS), pharmaceutical corporations using new knowledge produced by a human health R&D services firm, or a manufacturing company using a new piece of software. On a second line of users, the R&D knowledge can generate positive impacts on the balance of payments through the export of the new products and services, and other even more remote positive impacts on the increased life expectancy of the population through better access to food and medicines. Under these conditions, it becomes more difficult to measure the impacts of service innovation (Pilat, 2001).

Other issues are also relevant. KIBS are often produced within networks, involving not only the service producer and its client, but also other knowledge producing institutions such as government laboratories, universities and other R&D active firms. The efficiency and effectiveness of the KIBS firm depends up to a certain point on the size, and the resources it can find in its environment. The issues of open innovation are relevant at this point.

In addition, public institutions and policy incentives compose a good part of the environment of the KIBS firm. The quantity and quality of policy incentives, public institutions and regulations will affect the nature and quality of the services produced by the KIBS firm.

Muller and Zenker (2011) have shown that KIBS not only depend on the quality and quantity of public policies and incentives at the national and regional levels; they are a key component of these national and regional innovation systems. In the same direction, Pilat (2001) suggests that KIBS are a second knowledge infrastructure, one that complements the public one of universities and public laboratories.

Several authors have found that in OECD countries, these KIBS experience very rapid growth, and they are among the fastest growing sectors of the economy (Pilat, 2001; Mueller and Zenker, 2001). Yet, drivers of growth in these KIBS are not confined to public policy and incentives. The size and the nature of the market for these services are very important determinants of KIBS innovation (Miles, 2005). It may be the case that agricultural countries have a market for some types of agricultural biotechnology, yet policy regulations (i.e. policy restrictions to field tests or commercial uses of GMOS) will set limits to the size of those markets.

Policy incentives for innovation and policy evaluation have been built over the years with manufacturing innovation in mind. Innovation in computer software and related services or in R&D business services is too often neglected both in policy and in statistical offices.

Under these considerations, the two general hypotheses of this work become clearer and well justified.

Hypothesis 1: Innovation (including innovation in services, and particularly KIBS) generates positive impacts in the economy

Hypothesis 2: Public support activities have positive impacts on innovation in services and particularly on KIBS. Public incentives to R&D and innovation, but also public regulations of different kinds may represent positive factors but also barriers to innovation.

To these general hypotheses we may add a few others.

Hypothesis 3: KIBS are major components of national and regional innovation systems, as their positive impacts occur at many different layers of the economy.

Hypothesis 4: The size and regulation of the markets represent drivers (and eventually obstacles) to innovation in KIBS.

Innovation in KIBS

Several authors distinguish between traditional professional services (p-KIBS) such as accountancy, advertising and legal services, and technology based KIBS (t-KIBS) such as computer software, R&D services and engineering consultancy. The former are not innovation intensive, the latter are very much so (Freel, 2005). Table 1a and Table 1b show the main types of KIBS in their industrial classification codes.

Table 1a: Industrial classification of KIBS in the Mercosur

Actividades profesionales, científicas y técnicas	
69	Actividades jurídicas y de contabilidad
70	Actividades de las oficinas centrales y consultoría de gestión empresarial
71	Servicios de arquitectura e ingeniería
72	Investigación y desarrollo
73	Publicidad e investigación de mercados
74	Otras actividades profesionales, científicas y técnicas

Table 1b: Industrial classification of KIBS in North America

54 Professional, scientific and technical services	
5411	Legal services
5412	Accounting, tax preparation, bookkeeping and payroll services
5413	Architectural, engineering and related services
5414	Specialized design services
5415	Computer design and related services
5416	Management, scientific and technical consulting services
5417	Scientific research and development services
5418	Advertising, public relations and related services
5419	Other professional, scientific and technical services

Source: Statistics Canada: North American Industry Classification System Canada (NAICS), 2012.

These two types of KIBS display similar patterns of human capital employment: all of them are skilled capital employers. All of them often collaborate with their clients. Yet, they show very different patterns of innovation. In terms of inputs, t-KIBS firms have a high percentage of sales devoted to R&D, while p-KIBS usually do not conduct R&D. In terms of outputs, t-KIBS often request intellectual property (IP) protection such as patents for their inventions, as well as copyrights and industrial design (and integrated circuit design) and trademark protection. P-KIBS firms seldom need this IP protection because seldom they have any IP to protect.

Thus the innovation activities of t-KIBS can be tracked and traced easily. The more the t-KIBS firms are innovative, the more their innovation activities are visible, even if the impacts of these activities are difficult to find out.

Finally, KIBS, and particularly t-KIBS are notoriously concentrated in large metropolitan areas, where they can obtain complementary knowledge from public research institutions, hire skilled professionals and recruit clients and users (Muller and Doloreux, 2009).

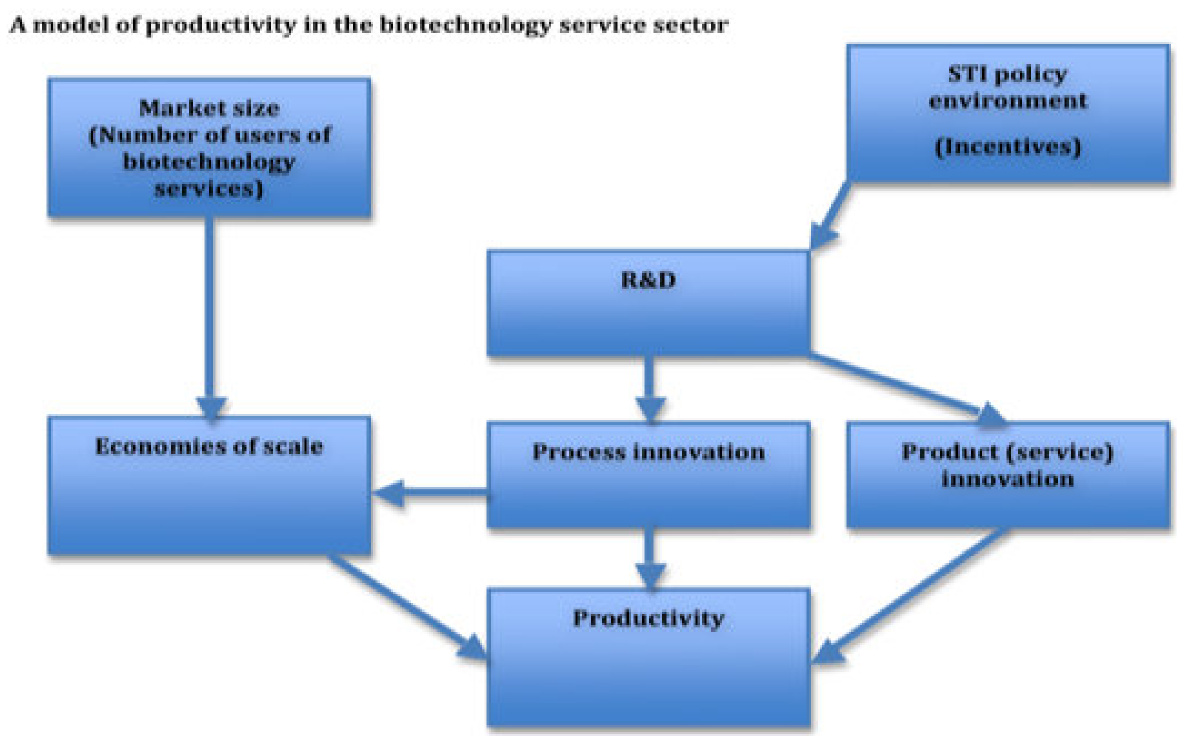
From these considerations we draw the following supplementary hypotheses:

Hypothesis 5: t-KIBS firms will be traceable and their innovativeness can be measured both by inputs (R&D expenditures on sales) and outputs (IP devices used)

Hypothesis 6: t-KIBS will be located in large metropolitan areas.

Figure1 summarizes the main arguments and hypotheses.

Figure 1: innovation and productivity in the KIBS technology based sector



2. Sector context: Biotechnology and its international diffusion

Biotechnology is not an industry but a set of general purpose technologies applied to many industries such as agriculture, environmental remediation services, food, mining, pharmaceuticals, and other industrial activities (OECD, 2009).

2.1 The birth of biotechnology

Modern biotechnology was born in the early 1950s, when James Watson, Francis Crick and Maurice Wilkins discovered the structure of DNA at Cambridge, United Kingdom (UK). Other major landmark events were the development of technologies to conduct genetic engineering in 1973 by Herbert Boyer and Stanley Cohen, respectively at the University of California, in San Francisco and at Stanford University. Again in Cambridge, UK, Cesar Milstein and his postdoctoral fellow, George Köhler, developed hybridoma techniques to produce monoclonal antibodies used to fight cancer, among other diseases. Many other scientific and technological developments followed, and biotechnology came to be able to genetically modify microorganisms, plants and animals to produce such human proteins as insulin, human growth hormones, interferon and interleukins, as well as monoclonal antibodies. In the area of agriculture, biotechnology was used to produce genetically modified organisms (GMO), thus increasing productivity and introducing plants resistant to pests, drought, and contaminated soils. Lands unsuitable for agriculture became productive. In mining, biotechnology was used to produce bacteria that assist mining companies to leach out minerals from ores. In environmental remediation, microorganisms are used to treat waste and contaminated water. Genetically modified plants are used to decontaminate lands containing large amounts of minerals. Gene identification techniques are used for a large variety of applications including those in the pharmaceutical industry, but also, in legal suits and criminal identification, and animal and plant reproduction. In the near future, gene therapy will introduce a whole new set of therapeutic possibilities.

2.2 The international diffusion of biotechnology

Biotechnology as a science was born in the United Kingdom and the United States (USA), but its commercial applications were first developed in the USA. The first commercial biotechnology firm, Genentech, was established in 1976 in California by venture capitalist Robert Swanson and biochemist Herbert Boyer. In the following years thousands of dedicated biotechnology firms were founded in the United States, Western Europe, Canada, Japan and elsewhere. In OECD countries, they were funded by government subsidies at first and by venture capital afterwards (Kenney, 1986). Most of the products and services invented by these companies require major funding and skills in order to be developed. DBF specialized in human health products allied with large pharmaceutical corporations to obtain approval and market them. DBF specialized in new seeds often gave licenses to large grain traders such as Monsanto and Syngenta. Biotechnology firms cooperated with mineral corporations to produce new genetically modified bacteria. Some types of service firms, though, remained independent for reasons we will examine later.

In biotechnology, the underlying science base evolves very fast and major breakthroughs open new commercial opportunities for small and medium-sized enterprises (SME). Thus, in 2003 the sequencing of the human genome allowed the creation of a new area of biotechnology (genomics). Using this information and technology, small and medium-sized dedicated biotechnology firms (DBF) could remain independent and offer gene-sequencing services to pharmaceutical corporations, farms, governments and individuals. The very large number of documents (millions of patents, scientific publications and approval applications) supported the growth of bioinformatics, a service industry that retrieves, stores and analyses the millions of pieces of genetic information stemming from the use of increasingly powerful and rapid sequencing equipment. Bioinformatics also analyses information about collateral effects of drugs, information that rapidly leads to the discovery of new medicines.

Genomics was followed by proteomics, the study of thousands of proteins that are produced by organisms. Proteomics also deals with protein purification and mass spectrometry. New companies specializing in this new discipline were created.

The United States remains the leader in scientific publication and commercial application of biotechnology. Australia, Canada, Israel, Europe and Japan are striving to catch up with the leader (Niosi, 2011). A series of emerging countries in Africa, Asia, and Latin America are entering the fray (Niosi et al, 2012). They include Argentina, Brazil, China, India, Mexico, Singapore, South Africa and South Korea. Their publication patterns show that their scientific base is catching up, but they seem to lack adequate complementary institutions, such as public and private venture capital organizations and public policy incentives, that would allow them to catch up in commercial biotechnology.

2.3 Biotechnology business models

The literature on biotechnology business models has become fairly abundant in the last years (Casper, 2000; McKelvey, 2008; Konde, 2009; Rasmussen, 2010).

"A business model is a way to create value for a business and then at least to capture some of that value for the organization" (Chessbrough, 2011, p. 90). Generally speaking**,** two major business models are recognized among dedicated biotechnology firms: the product and the service models. In the product business model, the DBF conducts R&D services in order to create a new or improved product such as a medicine, a diagnostic kit, a tool, or a GMO. Its goal is either to sell it directly to the market or, more often, to license out the new technology to a larger corporation that is able to obtain approval for the product, and is able to manufacture it on a large scale and market it internationally. The product business model requires large investments, involves extensive project costs and risks, and is scarcely adapted to DBF in developing countries.

The service model, on the other hand, is based on a platform technology that allows the company to deliver services to a variety of different clients. Bioinformatics and gene identification are among two of the most common business service models among dedicated biotechnology firms. Compared to the product model, the main advantage of the service model is that it requires a smaller initial investment, and generates returns much faster. Service approvals are quicker or not required, while biotechnology product approval is a lengthy and costly process. For these reason, some companies adopt "hybrid" business models, providing services to produce income in a short period of time and developing products on a longer timeframe.

Several authors have examined the stability of all types of biotechnology business models (Pisano, 2006; Rasmussen, 2010). The sustainability of the companies adopting the first business model depends on their capacity to continuously generate new products. The sustainability of the service firms, on the other hand, depends not only on their ability to innovate, but also on their ability to generate processes that allow them to gain market share on the basis of decreasing costs and prices. If and where these increasing returns processes are not set up, competition would bring profits down, as the firm's services can be imitated much faster than in the product model.

In biotechnology services, company turnover is lower than in other types of service SMEs. Yet, both types of dedicated biotechnology companies sometimes disappear either because they are successful and able to repeatedly generate new products and are acquired by larger firms (this was the case for Biochem Pharma, Chiron, Human Genome, Medimmune, Serono and others), or because they are unable to repeat the success of their first discoveries**,** and run out of funds. In bioinformatics, competition and imitation have sometimes destroyed leading firms (Rasmussen, 2010).

In Latin America, as in Europe, North America, China and India, generic pharmaceutical corporations are adopting biotechnology most often through the acquisition of DBF operating in human and animal health R&D. Acquisition has been a fast and cost-effective method of incorporating skilled personnel and technologies in order to compete in the expanding biosimilar market. Larger firms are acquiring all types of biotechnology firms in order to widen their offer of products and services. Yet the dynamic evolution of the underlying science continuously allows the production of new goods and services aimed at different markets.

2.4 Policy incentives

Because the underlying science base is highly dynamic and increasingly costly, biotechnology requires strong government incentives and support. It also creates many goods, services and products such as new medicines, new seeds, key genetic information and environmental services.

There are few figures regarding the public funds spent on biotechnology in different countries. The reason is that many countries do not publish information at the company or sector level about tax credits, direct subsidies or other public funding for R&D. Reid and Ramani (2012) published figures collected from the OECD, showing that in 2005 the United States was leading the world with 23.2 US$ billion in public support, followed by Japan with $1.9 billion, Korea with $1.2 billion, Canada and Singapore with $0.6 billion, China with $0.5 billion, and India with $0.2 billion**.** For 2009, the OECD (2011) put Germany at $7.6 billion, Korea at $2 billion, Spain at $1.3 billion, Russia at $760 million and Canada at $724 million[1]. These figures show that the biotechnology sector is far from being inexpensive for the public purse, and that the design of policy incentives is crucial if such large amounts are to be followed by economic results.

Because biotechnology has had a great impact on many different industries, most notably agriculture and pharmaceuticals, OECD governments have used a large variety of incentives to nurture the creation and growth of these firms. They include academic research grants, public venture capital and public incentives for the development of private venture capital, direct subsidies to SBF, tax credits for R&D, public R&D laboratories and others (Niosi and Bas, 2004).

The design, implementation, assessment and fine-tuning of these incentives requires a permanent, sophisticated, meritocratic and professional bureaucracy. Most OECD countries have had for decades, or longer, this type of professional public service. In Latin America, this is a necessary structure to be completed in the future; the link between economic development and professional public services has been well established (Evans and Rauch, 1999).

At this time, it is important to underline the fact that other developing and newly industrialized countries are also vying to enter this industry. Since the late 1990s, Singapore has focused on the biomedical sciences. For this purpose it built a seven- building, 18.5 hectare, 300 million US$ complex called Biopolis, and invited foreign biotechnology and pharmaceutical firms to build R&D laboratories in the cluster. It also created a series of large public laboratories such as the Institute for Molecular and Cell Biology, the Bioinformatics Institute and the Bioprocessing Technology Institute, which are part of the cluster. Over 5000 researchers work in the area, and private and public expenditure is in excess of 800 US$ billion annually. Paying high salaries, Singapore has been able to attract top scholars from around the world and increasing the human capital pool in the sector. Another formerly poor country, South Korea**,** has decided to enter biotechnology through another set of incentives. In 1994, the government of South Korea decided to make biotechnology its next rapid growing sector. From 2000 to 2007, the South Korean government invested over 4.4 US$ billion in the field. Also, the government created a Korean Food and Drug Administration (KFDA) modelled on the US FDA, with the goal of entering the US and EU biotechnology markets with high-quality products and services. A late entrant in biotechnology, by 2010 South Korea had some 900 DBFs, mostly SMEs (OECD, 2011). Total biotechnology expenditure in the country was over 1 US$ billion.

[1] All figures are in millions, current US dollars at PPP.

In China and India as well government support has helped to create a vibrant set of DBFs. Strong government support – particularly strong in China – contributed to rapid economic growth and demand for biotechnology goods and services. In China, the national and the provincial governments fund biotechnology. At the national level, funding involves different ministries and agencies such as the Ministry for Science and Technology, the Ministry of Agriculture, and the Ministry of Health (OECD, 2008). In order to accelerate learning, China has invited large MNCs to set up R&D labs in China, out of which new DBFs will spin off.

2.5 Government regulation

In biotechnologies, government regulation is a major determinant of the contours and the strength of the industries that apply these technologies. These include:

- Patenting: what can be patented, how long is the exclusivity conferred by the patent to the applicant.
- Health and food; what transgenic crops and animals can be accepted for human consumption and how are the new biopharmaceutical drugs be authorised in the domestic market.
- Environment: under what conditions are new plant varieties, bacteria or animal can be released in the environment
- Trade: what principles frame international trade in biopharmaceutical drugs, GMOs and microorganisms.

Because the United States has taken the lead in all these technologies, it has also be the first one to implement regulation on new products stemming from these technologies. As such, the United States has an advantage of potentially framing the regulation of the different industries adopting these biotechnologies. However, this priority does not mean that US regulations are the universal best practices that backward countries have to adopt blindly. An example will suffice to illustrate the point. Most new transgenic plants and biopharmaceutical drugs have been invented in the United States; as such this country is the most reluctant to share its technology with other less advanced countries, and open its trade to biological comparable drugs or crops produced elsewhere. “Elsewhere” includes the European Union, Japan, South Korea, India, Israel, China or Latin America. The United States protects their technological advance through different means. Backward countries need to implement different policies in order to catch up with the global leader.

2.6 Regional concentration and biotechnology clusters

Like other technology based KIBS, biotechnology activities and firms are strongly concentrated in large metropolitan areas where research universities and government R&D institutes are located (Swann et al, 1998). In addition, venture capital tends also to be located close to these research universities that spun-off large numbers of technology based firms. In the United States, San Francisco, Boston, New York, and Los Angeles concentrate a large proportion of dedicated biotechnology firms (Romanelli and Feldman, 2006). Similarly, in Canada, Montreal, Toronto and Vancouver are they key centres of biotechnology innovation (Niosi, 2005). In the United Kingdom, Cambridge, London, Oxford concentrate the largest numbers of British biotechnology firms (Shohet, 1008).

2.7 Skilled human capital and star scientists

Lynn Zucker and her team at the University of California Los Angeles found that US biotechnology firms tend to be created by star scientists (those that appear as inventors in a large number of patents and as authors in a large number of patents (Zucker et al, 1998; Zucker and Darby, 2007). The same conclusion was found in Japan (Darby and Zucker, 2001) and in Canada (Niosi and Queenton, 2010). This fact is due to the fact that the production of knowledge is highly skewed, and a small number of scientists are responsible for a large number of inventions. In addition, venture capitalists tend to follow the activities of these stars and fund the companies in which these scientists are working or have founded.

2.8 Innovation in biotechnology services

The innovation activities of dedicated biotechnology firms are basically R&D activities. They include process innovation (how to produce new GMOs, new medicines through genetic engineering, genomic analysis and the like), and product innovation (new or improved GMOs, drugs, or services such as gene identification, bioinformatics software or other). New-to-the world products and processes are almost entirely created in rich advanced OECD countries.

In biotechnology, ***open and flexible innovation*** is almost mandatory. The rapid additions to the scientific and technological knowledge, from genetic engineering to genomics and proteomics, make that no university, public laboratory or private company, no matter their size or resources, can store and use all the information available. Alliances and cooperation are overwhelming in biotechnology (Baum et al., 2000; Niosi, 2003). Both dedicated biotechnology firms and large industrial corporations conduct R&D in collaboration with other firms.

2.9 Conclusion

Biotechnology is a science-based set of technologies used in many different industries. In the R&D service sector, SMEs represent the vast majority of firms using these technologies. Dedicated biotechnology firms, classified as R&D service companies, tend to cluster in large metropolitan areas and around research universities, in order to get close relationship to institutions where new knowledge is generated. Over the last three and a half decades they have adopted several business models. One finds similar models in both advanced OECD countries and emerging countries. If the sums invested by DBF and governments in OECD and Latin American countries are fairly different, the modus operandi of these firms is quite comparable, and the models present similar advantages and disadvantages in both groups of countries.

3. Methodology

In a nutshell, the study was done through the identification of suitable DBFs using modern biotechnology, conducting interviews with company executives and government and incubator officials using a proven questionnaire.

3.1 Population and samples

The number and distribution of dedicated biotechnology firms in each Latin American country is not exactly known. Estimations vary widely from one author to the next. The reason is that no statistical office in the region studies the R&D services sector, and individual researchers using different methods and definitions to make their own estimations.

Fortunately, several sources have nominal lists of companies. The most reliable one is Biotecsur, the organization of biotechnology-active companies in the region. In a previous study on biotechnology in developing countries (Niosi, et al, 2012) we had found the same problem, and used the same solution: to build a list of companies using different sources, companies that can be considered DBFs and request interviews with them. The company questionnaire (see Annex 1), built on the basis of Statistics Canada one, solves the problem of identifying DBFs from other biology-using firms, as one of the main and first questions asks what modern biotechnologies the company uses. In a few minutes the interviewer knows whether he/she is visiting a modern biotechnology firm or not. Our samples, yet, have no pretension to be representative ones. But the companies we have interviewed are modern dedicated biotechnology firms.

Whatever the source, it was clear that biotechnology companies are located in the largest agglomerations in each Latin American country: Buenos Aires and Rosario in Argentina, Belo Horizonte, Sao Paulo, and Rio de Janeiro in Brazil, Santiago in Chile and Montevideo in Uruguay. In this sense, the localization patterns closely resemble those in advanced OECD countries.

As to policymakers, in each of these countries several government departments have a say on the development of biotechnology. They include the Ministries of Agriculture, Education, Environment, Health, and Industry, and independent regulatory agencies such as ANMAT in Argentina and ANVISA in Brazil. In addition, in federal countries such as Argentina and Brazil, some provinces (states in Brazil) have their own incentives and regulations. Finally, a key component of the incentive toolkit are company incubators, usually linked to the large national universities. To interview them all would require months of intensive work in the field. We decided to interview a few of them in each country, selecting the ones that seem among the most active in biotechnology. Annex 1 gives the relevant information on the ones that were selected and accepted to be interviewed. It is clear that the information they provided was about the existing programs and the resources invested in them. We counted on the executives of the biotechnology firms to give their appraisal of these programs.

3.2 Questionnaires and variables

The questionnaire used is an adaptation of the one used by Statistics Canada in their bi-annual study on biotechnology firms. It contains variables on the technologies used, products and services in the markets, R&D and other innovative activities, skilled personnel, employment and sales. It contains 24 questions that may be converted into over 100 variables.

3.3 Field work

The interviews were requested well in advance, and most of the companies invited to participate accepted, as well as government officials and incubator executives. Dr Bas conducted the interviews in Chile in August 2012, and Dr Niosi in Uruguay (June), Brazil (August), and Argentina (September). The following insert and Annex 1 (Questionnaires) summarize the fieldwork.

Country	DBF	Government Laboratories	Government Departments	Company Incubators	Total
Argentina	7	2	1	1	11
Brazil	9	2	1	1	13
Chile	4	1	1	0	6
Uruguay	2	0	1	0	3
Total	22	5	4	2	33

3.4 Descriptive statistics

The majority of the 22 DBFs interviewed were active in human health (15 or 68%), plus three others active in human and animal health. In every country except Chile, human health was the most common application. Less than half of the interviewed firms (10 or 45%) were university or public laboratory spinoffs; the others were start-up firms. The average age was 10 years, and the median age was 8,5 years, but the Chilean and Uruguayan firms were much older.

In each country there are one or two firms over 100 employees. The average firm had 50 employees and the median number of employees was 22; the average numbers show the impact of some very large firms on the mean sizes. Table 2 shows the main statistics.

Table 2: Summary of descriptive statistics

Variable	Argentina	Brazil	Chile	Uruguay	Total
Interviewed DB firms	7	9	4	2	22
Active in human health	4	8	1	2	15
Active in human & animal health	1	1	1	0	3
Active in Ag-Bio	2	0	1	0	3
Active in mining, environment	0	0	1	0	1
University/public lab spin-off	3	6	0	1	10
Average age	9	9	14	15	10
Median age	6	8	11	15	8,5
Oldest firm	29	16	22	c	29
Youngest firm	1	3	4	c	1
Average employment 2011	60	51	54	22	50
Median employment 2011	12	30	15	c	22
Average sales 2011 (US$M)	9	0,2	7	0,2	3,2
Median sales 2011 (US$M)	0,2	0,2	2,5	0,2	0,2
Firms that exportedin 2011	1	2	3	2	8
Problems with regulation cost	0	5	0	0	5
Problems with regulation speed	3	5	0	0	8
Problems with regulation norm	1	4	1	1	7
Problems with other regulation	0	4	0	1	5
Firms using public funds	5	8	2	1	16
Firms using private funds	7	9	4	2	22
“Successful” firms*	5	7	3	1	16

C= confidential

** Successful means growing firms in terms of employment and /or ssles*

In 2011, average sales were US$3,2 million, but again, a few large companies biased the averages. Over one third (8/22) of the interviewed firms were exporting products and/or services. Not by chance, the smaller the country the higher the percentage of companies that export. In Argentina and Brazil, firms can survive without exports, counting on the domestic market, not in Chile or Uruguay, were exports are mandatory and a condition of survival.

Regulatory problems were fairly abundant. In comparative terms, there were more abundant in Brazil, followed by Argentina and Uruguay. Speed and the quality (or the absence of) regulations were the most frequent complaints. In each country, though, the more the firms were advanced in the product and/or process development, the more they requested authorizations, and the more they found difficulties. Very young firms usually do not completed their products or processes, thus did not request any authorization. Also, the more complex the product, or the more innovative, the more the authorizations took time and the lack or inadequacy of regulations became evident.

Very often companies (72% of them) used public funds, in addition to private funds (100% of them did). As to public funds, companies complained about the scarcity of government loans, venture capital, or non-reimbursable R&D subsidies. In terms of private funds, in over 50% of the companies, managers had invested personal funds, family funds, or had obtained capital or loans from private investors.

Over two thirds of the firms (16/22) interviewed were “successful”. By success we mean that they grew over the 2007-12 period, usually both in terms of employment and sales. The other companies were not, including two in Argentina, two in Brazil, one in Chile and one in Uruguay. Of course companies may grow and still be not profitable, and also some may not grow and yet be profitable. But we did not ask whether the companies had profits or not, a very sensitive question that is not usually responded.

3.5 Innovation indicators

In biotechnology-active companies, R&D is a routine activity. All the companies we visited were conducting R&D. Yet the amounts they spent were – on average – very low: US$0,9 million. The median amount is even lower: US$ 300,000. Such amounts show that government incentives were modest, to say the least, and probably highly skewed: a few firms were obtaining large amounts of public support, and most firms obtaining small amounts or no public funds at all. Table 3 presents the main innovation statistics of the sample.

Table 3: Innovation statistics

Variable	Argentina	Brazil	Chile	Uruguay	Total
Interviewed DB firms	7	9	4	2	22
University/public lab spin-off	3	6	0	1	10
Collaboration with universities	7	8	4	1	20
Collaboration with public labs	7	8	1	0	16
Cooperation with other firms	5	7	3	2	17
Average R&D expenditure (US$M)	1.3	1.3	0,11	0,15	0,9
Median R&D expenditure (US$M)	0.25	1	0,12	c	0,3
Patenting firms	4	3	2	1	10
Firms with US, EPO or PCT patents (new to the world innovations)	2	2	1	0	5
Firms with trademarks	4	4	2	2	12
Product innovation in the market (New to the country)	6	6	3	2	18
Process innovation (New to the country)	6	6	3	2	18

Open innovation was paramount. Almost all the firms (20/22) collaborated with research universities and over two thirds of them cooperated with public laboratories. Over three quarters of the interviewed firms cooperated with other biotechnology of pharmaceutical firms, and most of them collaborated with foreign private partners.

In Latin American countries there are few new-to-the world innovators, as attested by the reduced number of patents. Only five companies had US, EPO or PCT patents. Yet in a few cases, these companies are conducting breakthrough research and development that may result in radical novelty. Most often than not, however, DBFs in Latin America are service providers linked to agricultural, pharmaceutical and environmental firms. Some of them are entirely or partially controlled by these companies to which they become captive service providers.

Trademarks are indicators of some level of innovation (Mendonça et al, 2004). They play a key role in the marketing of innovation, as they allow potential and actual consumers to identify the product or service and its producer. In our sample, over 50% of the firms have requested trademarks, both for their products and their services, and in all the four countries. In addition, there is a strong correlation between having trademarks and patents: basically, almost all the companies with patents had trademarks, but two companies with trademarks had no patents.

4. Biotechnology in Latin America

This study focuses on two of the largest countries in Latin America (Argentina and Brazil), one medium-size country (Chile) and a small country (Uruguay). These are among the countries with the highest human development index and the highest Gross Expenditure on R&D (GERD) as a percentage of Gross Domestic Product (GDP) in the region. Because biotechnology requires a skilled labour pool and strong expenditures on R&D, we considered that these countries were more likely than others to have undertaken some biotechnology service activity.

4.1 Argentina's biotechnology

Argentina had a leading start in biotechnology in the region. In the early 1980s, it had a prompt entry in the science, with Dr Cesar Milstein, future Nobel Prize winner and discoverer of the methods to produce monoclonal antibodies. Argentina also had strong demand for both GMO from its large agricultural sector**,** and for biopharmaceutical drugs produced by a large generic pharmaceutical industry (Niosi et al, in press).

Even if Argentina spends little funds in R&D in comparative terms, particularly when compared with South East Asia, there has been some progress in the recent years and the national statistical institute indicates that the Gross Expenditure on R&D (GERD) has moved from 0,41% in 2003 to 0,61% in 2010. Researchers' salaries were raised, non-reimbursable subsidies to R&D were increased and close to 1000 Argentinean researchers working abroad were repatriated. As a consequence, Argentina's scientific publication has increased, even if the number of locally owned patents has barely augmented.

Main activities and locations

The number of dedicated biotechnology firms (DBF) in Argentina, like in other Latin American countries, is a well-hidden secret. According to BIOTECSUR[2], the MERCOSUR website for biotechnology, there are some 80 DBFs in Argentina, mostly dedicated to human and animal health and agricultural biotechnology. By contrast, Anlló et al (2011) found some 120 DBFs in Argentina for 2008-9.

Buenos Aires, the capital city, is the main location of these DBFs, followed by the Province of Buenos Aires; just three of them are located in the main cities of the Province of Santa Fe, Rosario and Santa Fe. Córdoba hosts only two. The geographical distribution of Argentinean DBFs mirrors the distribution of the Argentinean population, as well as its academic and industrial activity.

Firm sizes and revenues

Most DBFs are small firms with total employment between 5 and 10 employees. The average is 25 employees**,** according to Anlló et al (2011). Multinational corporations (including one domestic MNC) dominate the agricultural biotechnology sector for the main crops (corn, soya beans, and sunflower), where few small DBFs still operate. One can still find small DBFs mainly in micro-propagation of cultures, the discovery of microbial inoculants and the development of GMO varieties in agricultural species that are not among the main crops. Only ten companies have more than 50 employees.

According to Anlló et al (2011)**,** Argentinean biotechnology firms produce some 1 billion US$ in sales annually, and export nearly 25% of what they produce. However, some of these firms may not be service companies; the OECD would classify them as biotechnology users operating in the pharmaceutical manufacturing industry, or trading companies, due to their main activity.

[2] www.biotecsur.org

Government financial support

In the early 1990s, Argentina created the National Agency for Scientific and Technical Promotion (ANCYPT), which started supporting a series of advanced science-based industries such as biotechnology. In 1993, Argentina established the FONTAR (Argentinean Technology Fund: the acronym is in Spanish).

FONTAR distributes subsidies to dedicated biotechnology firms using both national and multinational funds (i.e. from the Inter-American Development Bank). Also, FONTAR attributes tax credits for R&D: Argentina spends annually some US$ 10 to 14 million for all industries in the entire country, but also uses funds transferred to it by the federal government or the public banks. Table 4a and 4b give some information about the funds distributed by FONTAR in biotechnology between 2000 and 2004. Biotechnology received some USD 2 million a year, and the average R&D project received USD 57 000.

Table 4a: Argentina: Funds distributed by FONTAR to biotechnology firms, 2000-4

	Biotechnology		All sectors	
Functional goal	Number of projects	Total amount in millions of USD	Number of projects	Total amount in millions of USD
R&D	114	6.5	1480	80.6
Infrastructure	12	2.5	48	13.8
Total	126	9	1528	94.4
Biotechnology as a % of all sectors	*8.25%*	*9.7%*	*100%*	*100%*

Source: Biotecsur

Table 4b: Argentina: Biotechnology R&D projects supported by FONTAR by area of application (2000-4)

Area of application	Projects		Amounts	
	Number	Percentage	Millions USD	Percentage
Human health	43	38	4.5	67.6
Animal health	34	30	1.3	19.5
Food	16	14	0.5	7.7
Vegetal health/inoculants	16	14	0.3	4
Environment	4	4	0.1	1.3
Total	*114*	*100*	*6.5*	*100*

Source: Biotecsur

FONAPYME is a fund created in the 2000s to support small and medium-sized enterprises (SME) with loans for productive and R&D investment. In 2005 the loans for new firms amounted to about US$ 5000, and for existing firms up to 70% of the investment and US$ 60 000.

Moreover, in 2006, the Central Bank supported soft credit lines (with interest rates around 50% that of private banks) for SMEs, with amounts up to US$ 3 million, and reimbursement periods up to 10 years. Argentina, unlike countries like Brazil or Canada, has no national development bank.

Also, in 2007 Argentina approved a National Biotechnology Plan, but the law was not implemented and thus no financial support was provided to Argentinean DBFs on the basis of this Plan.

On the whole, Argentina's support for biotechnology is meagre not only compared to what Canada, the European Union, Japan, South Korea or the United States bring to the sector, but even compared to its giant neighbour Brazil.

The public sector incubation of new technology-based firms is a new activity in Argentina. The largest and most research active university, the National University of Buenos Aires (UNBA), has a technology incubator called INCUBACEN, based on technologies developed at the Faculty of natural sciences. A new company, NEOINOCS, is developing microbial inoculants for plants. Another one, Biocodices**,** is working on bio-informatics. A third one, POLICLON, is developing biological reagents for animal health. Another incubator at the UNBA, INCUBAGRO**,** counts no new firm among its accomplishments[3]. The second Argentinean university, La Plata (UNLP)**,** has a science and technology park where six new companies are located, including a biotechnology company, Biotecnologías Argentinas, producing microorganisms for the wine industry[4].

Government laboratories

Argentina's two main government laboratories – the **National Institute for Agricultural Technology** or INTA, and the **National Institute for Industrial Technology** or INTI – were founded in 1956. In 2010, INTI inaugurated a new biotechnology laboratory with close to 30 employees. Its priority areas are the development of food enzymes to replace imported enzymes, and nanotechnology development for the controlled delivery of medicines.

INTA hosts an Institute of Biotechnology, founded in 1989, and the Genetics Institute "Ewald Favret" (founded in 1992, on the basis of a previous Fitotechnical Institute), both close to the City of Buenos Aires. The Institute of Biotechnology hosts some 100 researchers and conducts research projects in the areas of bioinformatics, biomarkers, the genetics of plants resistant to different types of pathogens, as well as animal microbial infections. INTA collaborates with private firms as well as with universities and non-profit organizations. Its funding comes from appropriations from the national government, competitive national and international funds (including US NIH and European Union funds) and also from contracts offered by private firms. Because of the scientific training and affiliation of some of its staff, INTA does not have a culture of patenting its research results, and is keener on publishing articles and reports than on patenting. Patenting is more costly, takes more time and spends scarce resources needed to conduct research. Also, some of its results are probably not patentable.

Besides these two large research centres, Argentina boasts an institution largely based on the Spanish CSIC, the French CNRS and the Italian CNRS: CONICET, the National Council for Scientific and Technical Research. Founded in 1958, it had a budget of US$400 million, and in 2011 it enrolled 6,500 researchers and 2,500 technical personnel. It coordinates research conducted both in universities and at its own research institutes; many of its researchers are also university professors. It is impossible to know how many of them are working on biotechnology, as no such division of disciplines exists.

Government regulations

Argentina has since the 1980s had a permissive attitude towards biotechnology, both in its agricultural and health applications. In the 1980s, Argentinean pharmaceutical firm Sidus was producing recombinant insulin. In the 1990s, Argentinean agriculturists were experimenting with transgenic crops. Regulation came at a leisurely pace. New plant varieties can be registered since 1987. Between 1987 and 2006, some 903 varieties were registered in the National Register of Varieties, mostly from international companies, but also some from local ones. New genes in plant varieties can be patented since 1995. In a few years, both locally produced GMOs and imported ones were circulating in

[3] www.agro.uba.ar/incubagro
[4] www.unlp.edu.ar/articulo/2008/5/27/parque

Argentina. Argentina is today (2012) the third country in the world, after the USA and Brazil, in the area planted with transgenic crops. Most transgenic plants used in Argentina show resistance to herbicides and insects.

In the area of health, Argentina only requires bioequivalence or comparability, based on the European Union model of 2005/6. In all cases the company trying to get a biological follow-on approved, must show through clinical and non-clinical trials, its comparability with a given originator (reference product).

The companies we visited found that Government regulations are not expensive but they are slow. The authorization of a new-to-the-world human drug takes eight years, a biologic follow-on between 18 and 24 months, and a new animal drug takes four years. Legislation on clinical essays seems another area of contention. There is no legislation on the number and quality of clinical essays required by an innovative drug, a situation that, according to them, hampers their entry into highly regulated markets in the North.

Academic training

Several Argentinean universities offer training and degrees in biotechnology. They include:

- Graduate studies: National University of Buenos Aires – The Faculty of Agriculture offers a Master degree in biotechnology. A private university (UMAZA) in the Province of Mendoza also offers a master's degree in bio-security.
- Undergraduate: the National Universities of Litoral and Rosario (Province of Santa Fe) both offer undergraduate degrees in biotechnology. Also, the National Universities of La Plata, San Martin, Quilmes (province of Buenos Aires), as well as the National University of Tucumán (Province of Tucumán) offer similar degrees.

Academic publication

Five institutions concentrate over 60% of Argentinean publication in biotechnology: they are CONICET, the National University of Buenos Aires, the National University of La Plata, INTA and the National University of Córdoba (Table 5). Yet, a more complete picture would show that the number of biotechnology-activity research institutions increases every year.

Table 5: Argentina: Main institutions producing biotechnology publications (1996-2011)

Institution	Number of articles	%
CONICET	1720	32
National University of Buenos Aires	1024	19
National University of La Plata	537	10
INTA	318	6
National University of Córdoba	232	4
Five largest	3831	71
All others	1511	29
Total	*5342*	*100*

Source: SCOPUS; figures produced by Science Metrix

NB: There is some level of double counting as some researchers have multiple affiliations

Some relevant private service and hybrid DBF and their innovation

Argentina has had for decades a fairly strong generic pharmaceutical industry, and a similarly strong agricultural industry. Both of them have invested in biotechnology and are large users of biotechnology services.

Some of these users have created or acquired biotechnology R&D service firms. **IND** (located in Rosario, Santa Fe province) is a subsidiary of Bioceres, a private firm with over 200 shareholders, mostly innovative farmers. Founded in 2004, IND hosts some 150 researchers, working mostly on soya, sunflower and wheat seeds. IND has obtained 27 patents, granted in Argentina, Australia and the USA, mostly on new or improved organisms. It conducts collaborative R&D with public institutions in Argentina (such as CONICET, INTA, INTI and research universities) and in neighbouring countries. It has also transferred technology to India. Its services include a platform for genomics and bioinformatics, the analysis of environmental impacts on microbial communities, RNA sequencing, and others[5].

Located in Buenos Aires and founded in 2006, **AB** is a successful private R&D product and service firm conducting innovative research on biosimilar drugs (follow-on biologics having lost their patent protection)[6]. AB produces twelve Active Pharmaceutical Ingredients (API) for biopharmaceutical drugs, as well as seven finished biosimilar drugs sold under the names of different Argentinean pharmaceutical firms. AMEGA is now conducting innovative R&D on five different monoclonal antibodies (MABs) and will build another plant to produce them. These products are exported to unregulated markets in Africa, Asia and Latin America. Thus, AB is a hybrid product and service company, which will soon conduct new services such as quality control and preclinical essays for other pharmaceutical firms. Hosting over 200 employees, AB is also growing fairly fast both in terms of employment and revenues.

BC is an emerging bioinformatics firm being incubated at the National University of Buenos Aires. One of seven firms incubated by INCUBACEN, **BC** was recently launched by this incubator organization. The aim of the new company is to develop bio-informatics services using imported arrays and creating its own arrays. It will also customize R&D services and genomics diagnostics. It has already received an A$ 2 million grant (US$ 400 000) from ANCYPT[7]. Bio-informatics is insufficiently taught in Argentinean universities and its researchers are trained either abroad or on the job.

Another emerging biotechnology R&D service firm is **IM**. A spin-off of the FIL, its goal is to produce several vaccines (for human and animal health) and license them out to pharmaceutical and veterinary companies. **IM** has received funds from the private equity market and is growing fast according to its R&D plan.

PADN is a captive R&D service and product firm linked to the largest pharmaceutical Argentinean company. Founded in 2006, PADN was acquired by the pharmaceutical group in 2008. The private pharmaceutical company has 8000 employees across the world, and R&D activities in Argentina, China, India Italy and Spain. It manufactures products in Argentina, China, India, Italy, Spain and Uruguay. PADN is growing very fast, conducting collaborative research with Argentinean and foreign universities. Its funding comes from both its corporate owner, and national and international public agencies. In a few years, PADN will become a manufacturer of its own biopharmaceutical products**,** including first generation biosimilar drugs and its own MAB. It is important to note that its pharmaceutical owner is the only Argentinean group trying to produce new-to-the world biopharmaceutical drugs; PADN is part of that effort.

---

[5] http://www.indear.com
[6] http://www.gemabiotech.com
[7] http://incubacen.exactas.uba.ar/?page_id=1493

BE is a biotechnology firm focusing on plant biotechnology products and services. Founded in 2000, its employment and sales have experienced strong fluctuations, as the company moved from one area (large crops such as corn and soya) to more specialized products such as blueberries, capers and flowers, as well as functional food additives. The case illustrates the difficulties of plant biotechnology firms competing in key crop markets with multinational companies such as Monsanto, Pioneer or Syngenta; and in food additives with companies such as Natraceuticals.

In short, five out of seven Argentinean companies in the study are growing in terms of both employment and revenues, either by adopting a service model, or a hybrid product-service one. Their productivity is also increasing. Two are not growing, and represent our less successful cases.

Conclusion on Argentina

Argentina has a strong agricultural and pharmaceutical industry able to demand bio-informatics, genomics and R&D services and products stemming from biotechnology. Its scientific institutions have long been the best in Latin America, and the only ones in the region that produced three Nobel prizes in science. However, some of its Latin American neighbors, particularly Brazil, are investing more than Argentina in biotechnology and may soon leave Argentina behind. Also, Argentina is notorious for its fast and unexpected changes in industrial policy: think of the 40-year lead Argentina had in aircraft, nuclear energy, and oil production and refining over other Latin American countries, and how this lead was suddenly lost.

Lack of continuity in policy is reinforced by inadequate funds and idiosyncratic academic practices. Argentinean academic salaries are mediocre in a discipline that is developed by attracting the best and the brightest, research funds are increasing but are still reduced and industrial incentives for R&D are minimal compared not only with the United States and Western Europe, but also with emerging Asian countries such as China, India, Singapore, South Korea and Taiwan. Entire areas of biotechnology from bio-informatics to stem cell therapy are thus still underdeveloped.

In the OECD countries, the venture capital industry has always developed thanks to smart government incentives such as national development banks or pension fund incentives (Gompers and Lerner, 2004). Yet, the design and implementation of these polices, like all other innovation incentives, need careful crafting and continuous monitoring (Lerner, 2009).

Argentina, as opposed to Brazil, has no national development bank that could launch a venture capital industry. The National Development Bank of Argentina was closed in 1976, a few years after it was founded. The private pension fund system, that helped both the United States and Canada to launch a venture capital industry, was nationalized in Argentina in 2008 in order to fund the federal government's current expenditures.

There are few signs of an implementation of the National Biotechnology Plan announced in 2007. Policy incentives appear scattered, and they lack continuity and solvency. Under these conditions, both dedicated biotechnology firms and industrial biotechnology users may have to count on themselves.

Government financial support it is not very large, but companies got some funds from the Sector Funds, Banco de la Nación, but also from different programs run by the MINCYT. More serious is the fact that the national government is slowing its payment transfers to the provinces, thus rendering provincial hospitals unable to pay the drugs and services to domestic firms.

4.2 Brazilian biotechnology

As in many other industries (aircraft, automobile, nuclear, oil, etc.) Brazil had a later start compared to Argentina, but catches up and moves ahead fairly fast. Brazil GERD has increased from 0,85% of GDP in 2000 to 1,19% in 2011. Its public laboratories have a strong presence in agricultural and human health biotechnology. And the number of its university graduates, particularly at the master and doctoral levels far outstrips Argentina. Its scientific publication in biotechnology is now in the top 15 in the world. In addition, Brazil has created many technology-based firm incubators in its national universities and is also catching up in the number of biotechnology patents invented in the country.

Main activities and locations

Like in other Latin American countries, the precise number of biotechnology active firms in Brazil is unknown. The reason for this confusion is that three different types of firms are grouped together[8]:

a) Dedicated biotechnology firms: companies producing R&D services, usually small and medium sized enterprises;

b) Users of biotechnology products: these are usually large corporations operating in such areas as agriculture, environmental remediation services, food products, pharmaceuticals and other industries.

c) Traditional biology services and products firms such as those discovering, reproducing and selling microorganisms that help plants to absorb nutrients and grow faster, or those that improve animal species and plants through hybridization.

The interviews in Brazil showed that some of these companies (even some that boast the name "biotechnology") are traditional biology firms and users of biotechnology.

Thus, in 2009, according to the Biominas Foundation, there were 102 bioscience firms using biotechnology in Brazil (Biominas, 2010). Human health, agriculture, environment and energy, and animal health were the key application areas. The details of their activities are as follows (see Table 6):

Table 6: Brazilian biotechnology companies by main activity

Area	Activity	N	%
Human health	R&D for new therapies and vaccines	18	
	R&D for in vitro diagnostics	13	
	Contract research organizations	8	28%
Agriculture	Biological control of plagues	11	
	Seed improvement	9	19%
Hybrid	Molecular diagnostic services	10	
	R&D for several areas of application	5	15%
Inputs	Reagents	8	8%
Environment	Bioremediation and effluent treatment	8	8%
Animal health	R&D for recombinant vaccines	4	
	Animal genetic diagnostic services	4	8%
Energy	Improvement of plants to produce biodiesels	4	4%
Total		*102*	*100%*

Source: Biominas (2010): Estudo das empresas de biociências, Belo Horizonte.
NB: there is no quality control on these figures; the number of DBFs may be lower.

Another study, for 2011, found information about 145 users of biotechnology and dedicated biotechnology firms in Brazil, with a similar distribution of main areas of application (BR Biotec, 2011). In this more recent study, the three main clusters were located in the sates of Sao Paulo (SP)(40.5%), Minas Gerais (MG)(24.5%) and Rio de Janeiro (RJ)(13.1%). Three states, according to Biominas, concentrated 78% of the biotechnology firms. In human health, SP, RJ and MG were the three main clusters. RJ was the main region for environment and energy, followed by SP. MG, SP and

[8] The North American Industrial Classification System (NAICS) has different codes for these industries.

RJ (together with Santa Catarina and other states) hosted agriculture DBFs. In sum, biotechnology was flourishing in the South of Brazil where the main universities and research centres are located.

A more recent book suggests that there are some 40 to 60 dedicated biotechnology firms in Brazil, but also argues that SP, RJ and BH are the three main hubs for this activity (Uziel, 2012).

As for users, Brazil, like Argentina, has a well-developed agricultural sector and a growing pharmaceutical sector, both of which can demand innovations from the domestic DBFs. In June 2012, Brazil announced the merger of four generic pharmaceutical companies into a new large firm called Bionovis, located in Sao Paulo.

Firm size and revenues

Most DBFs and UBFs in Brazil are small firms. In 2011, 56% of them had revenues up to US$ 1.5 million and around 85% of them had no more than 50 employees. Some 65% of them had 20 employees or less. Some 86% of them imported products (reagents, equipment and/or services) but only 25% exported services or products. Half of the DBFs were or had been in business incubators, and almost 95% conducted collaborative research with universities or government laboratories, or shared their equipment (BR Biotec, 2011).

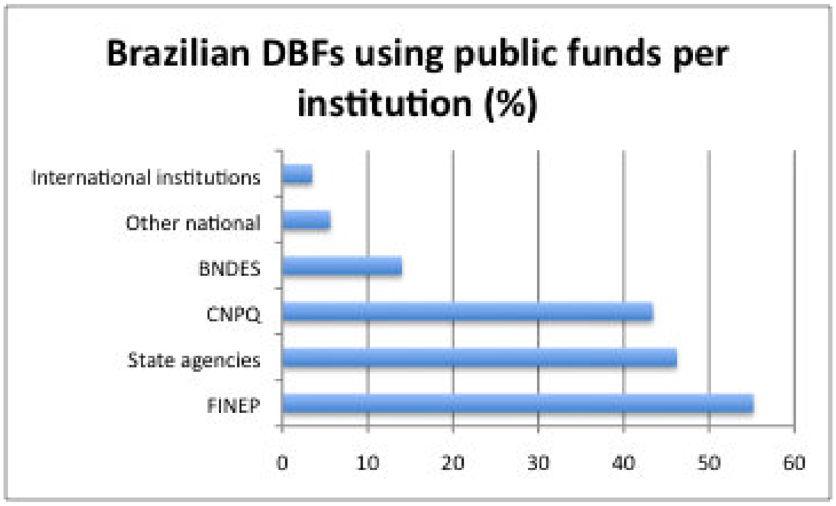
Government funding

Since the late 1970s**,** the Brazilian government has supported research in biotechnology. The first funds aimed at the development of human resources and academic research were handled by Financiadora de Estudos e Projetos (FINEP), created in 1967, and the Conselho Nacional de Desenvolvimento Científico y Tecnológico (CNPQ), established in 1951. In 1999, the federal government created sector funds (FS) that linked science, technology and innovation under the aegis of FINEP, with a hint at industrial policy. Among these Sector Funds, two aimed directly at biotechnology: the Biotechnology Fund and the Health Fund. Other funds, aimed at Agro-Business, Energy, Infrastructure and other industries also occasionally supported biotechnology projects. These Funds handled over R$2481 million(US$1.2 billion) in 2010. The amount supporting biotechnology projects was not disclosed. In addition, FINEP also had a program of reimbursable loans for innovation (representing R$ 1 billion) and in 2006 it instituted a program of non-reimbursable grants, the value of which represented R$ 500 million in 2010. All in all, in 2010 FINEP handed over some US$ 2 billion to different projects; based on a conservative estimation, 10% of that amount went to biotechnology.

Also, two new laws were approved to support innovation: the Innovation Law (L. 10973/2004) and the Goods Law (L. 11196/2007). The first allowed the state to support innovation by means of non-reimbursable subsidies. The second put forward a tax credit for R&D incentive.

Over 78% of Brazilian biotechnology firms used public finds in order to conduct R&D (BRBiotec 2011). The main funds used came from FINEP, from other state agencies, from CNPQ, BNDES and other national and international institutions, including the Inter-American Development Bank (see Figure 2).

Figure 2: Brazil: biotechnology firms using public funds per funding institution (%)



Source: BRBiotec (2011)

Because they represent the main public support, we will concentrate our attention on FINEP, CNPQ and BNDES, as well as the incubating universities and government laboratories producing knowledge.

BNDES is the National Development Bank of Brazil. BNDES has several funds supporting biotechnology, the main one being FUNTEC, with emphasis on human health. Up to April 2010, the BNDES had invested some R$150 million (about 75 million US$) in human health biotechnology projects. Out of this amount, 56 million US$ were disbursed by FUNTEC.

The CNPQ is the federal agency responsible for distributing financial support for academic research and fellowships for graduate students. CNPQ reports to the federal Ministry of Science and Technology and is the first source of support for new scientific development in Brazil. Its 2012 budget (composed of both internal funds and funds transferred from FS and other public sources is around US$ 1 billion (CNPQ 2011). It also distributed 43 000 fellowships to graduate students in all disciplines. Unfortunately, biotechnology funds are not shown as a separate category and are distributed across human health, agriculture, chemistry, energy, environment, and other sectors. Yet, biotechnology is one of the CNPQ strategic areas. Biobrás, the first Brazilian producer of insulin, was one of the Council's grantees.

Government support for biotechnology is not confined to grants and loans to private firms or grants for academic research. Public laboratories are part of the program. Two main laboratories should be mentioned**:** EMBRAPA (Empresa Brasileira de Pesquisa Agropecuária) and Foundation Oswaldo Cruz (FIOCRUZ), which are key beneficiaries of public support.

Government laboratories

EMBRAPA was founded in 1973. It hosts 8275 employees, of which 2113 are researchers with either Master's or PhD degrees. EMBRAPA has 38 research centres, 3 service centres and 13 central divisions. Areas of biotechnology research include biopharmaceuticals, bio-fertilizers, bioinformatics, bio-remediation, cloning, genetic engineering, gene therapy, molecular markers and GMOs. EMBRAPA also produces and distributes transgenic seeds to poor local peasants at no cost to increase their productivity and thus their revenues.
FIOCRUZ was originally launched in 1900 in Rio de Janeiro, to produce vaccines against the bubonic plague. Over the years it saw much expansion and the addition of new research centres and

manufacturing activities. Today, FIOCRUZ hosts 7500 employees, working in 15 institutes across Brazil. Many of them work in biotechnology in one way or another, but Bio-Manguinhos (the Immunobiology Technology Institute) is key. Bio-Manguinhos is the largest producer of vaccines in Latin America. Its production includes vaccines against diphtheria, yellow fever, meningitis, measles, poliomyelitis, tetanus, and other infectious diseases, as well as reagents for AIDS, Chagas, rubella and other diseases. It is also located in Rio de Janeiro.

Technology transfer between both EMBRAPA and FIOCRUZ and private firms is extensive, though no aggregate figures were available. Some publicized examples include the transfer of the technology used to produce a vaccine against Schistosomiasis (an illness caused by a parasite found in poor areas and affecting 200 million people in Brazil and elsewhere) to Alvos Biotecnologia, a Brazilian DBF, in 2005.[9]

Government regulations

Brazilian regulation of biotechnology products has started later than in Argentina. In agriculture, Brazil passed from a position of cautious resistance to transgenic crops to a warm approval of them starting in 1997. In a few years, Brazil became the second producer of GMO in the world. Again, like in Argentina, both local varieties and imported ones are circulating. EMBRAPA is producing most of the local transgenic varieties and distributing them mostly to poor farmers. The Ministry of Agriculture and Fisheries regulates the production and trade of transgenic crops.

ANVISA regulates the approval of new drugs and other human health material. Brazil imports most of its biopharmaceutical drugs from the United States and the European Union. When it comes to biological follow-on products, like Argentina, Brazil has adopted the same regulations as Europe, namely that companies that want to introduce a biosimilar drug must prove their comparability with the most used drug in the country. Such regulation puts Argentinean, Chinese, Indian and other producers of biosimilar drugs at a disadvantage, because the drug that they have compared with in their own market, may not be the same used in Brazil.

Some interviewed companies complained about the slow rhythm of approvals in Brazil and the incomplete character of legislation concerning different biotechnology products, particularly in the area of human health products.

Universities

Brazil has developed a very extensive system of public and private universities. The public institutions are considered the best, particularly the federally funded universities like the Federal Universities of Sao Paulo, Rio de Janeiro, Rio Grande do Sul, Minas Gerais, Brasilia and Santa Catarina. Some state-funded universities such as UNICAMP (the State University of Campinas, in Sao Paulo state) and UNESP (Sao Paulo State University) are also in the top ranks. Among the private universities, the Catholic Pontifical University of Sao Paulo (PUCSP) and the PUC of Rio de Janeiro (PUCRJ) are among the best ranked. All these universities are conducting teaching and research in biotechnology, as attested by their biotechnology incubation and publication activities.

Brazilian universities – together with public laboratories - produce some of the knowledge used by domestic biotechnology firms. Firms also gather knowledge from foreign articles and patents, as well as scientific collaboration with foreign universities and public laboratories.

[9] http://www.biominas.org.br/blog/2012/06/18/alvos-biotecnologia-a-company-created-by-biominas-brasil-had-an-effective-participation-in-the-development-of-a-brazilian-vaccine-against-schistosomiasis

Most Brazilian DBFs were incubated in universities. Some thirteen incubators are operating in Brazilian universities and municipalities. The results of such incubation activity are very positive, if one judges by the large number of biotechnology firms housed in these organizations (see Table 7).

Table 7: Brazil: Business Incubator or Technology Park

Name	Location (city and state)	Area
Bio-Rio (Pólo tecnológico de Rio de Janeiro)	Rio de Janeiro (RJ)	Created in 1988 as the first Latin American high-tech park. Located at the UFRJ, it counts over 40 life science firms[10]
CDT	Brasilia (DF)	Incubates companies in different high tech areas. Located at the University of Brasilia[11]
CENTEV	Viçosa (MG)	Located at the University of Viçosa, hosts some 45 firms including 10 DBF[12]
CIETEC	Sao Paulo (SP)	Founded in 1998, hosts some 150 companies including 18 DBF. Located at the USP[13]
HABITAT	Belo Horizonte (MG)	Founded in 1997 and specialized in biotechnology. Has incubated 20 DBF already in the market
IE-CBIOT	Porto Alegre (RS)	Established in 1992, located at the UF Rio Grande do Sul, has incubated 7 biotechnology firms[14]
INCAMP	Campinas (SP)	Associated with UNICAMP has 37 companies in the incubator, of which 7 in life sciences[15]
INOVA	Belo Horizonte (MG)	Has 50 incubated companies, of which ten in biotechnology[16]
PADETEC	Fortaleza (CE)	Located at the UF de Ceará, some 44 companies associated or graduated, including some DBFs[17]
TECHNOPUC	Porto Alegre (RS)	Launched in 2003 in the Catholic University of Rio Grande do Sul, it hosts 77 companies; biotechnology is one of its areas[18].
POSITIVA	Recife (PE)	Located at the UF de Pernambuco, established in 2005, it hosts 5 DBFs
PROSPECTA	Botucatu (SP)	Established in 2005, supported by UNESP, has 6 DBFs, in ag-bio and environment[19]
SUPERA	Riberâo Preto (SP)	Focus on life sciences, established in 2003, has 10 resident firms in the incubator. Located at the USP campus in Riberâo Preto

Sources: BRBiotec (2011) and web sites

[10] http://www.biorio.org.br/
[11] http://www.cdt.unb.br/
[12] http://www.centev.ufv.br
[13] http://www.cietec.org.br/index.php?id1=10
[14] http://www.cbiot.ufrgs.br/iecbiot/
[15] http://www.incamp.unicamp.br/
[16] http://www.inova.ufmg.br/
[17] http://www.padetec.ufc.br/
[18] http://www.pucrs.br/agt/tecnopuc/
[19] http://www.prospecta.org.br/

Yet, almost without exception, their web sites are basically in Portuguese – a major difference between them and South East Asian universities and incubator portals, which aim to attract human capital and venture capital from the entire planet[20]. Brazilian incubators would benefit (as all Latin American science, technology and innovation institutions) from opening up to international ideas. Presenting themselves in the international language of investment, science and technology (English) would be a good practice to imitate.

Publication shows a similar distribution. Over 40 educational institutions and several public research laboratories have had biotechnology articles in refereed journals since 1996. Yet only six of them concentrate more than 50% of their scientific publication in biotechnology according to SCOPUS databases (see Table 8).

Table 8: Brazil: Biotechnology publication by research institution (1996-2011)

Institution	Total biotechnology articles	%
University of Sao Paulo	3826	22
UNICAMP	1624	9
State University of S. Paulo	1394	8
Federal Univ. of Rio de Janeiro	1388	8
EMBRAPA	1241	7
Federal Univ. of Minas Gerais	993	6
Subtotal 6 main institutions	10466	59
Top ten institutions	13645	78
Total Brazil	17591	100

Source: SCOPUS, compilation by Science Metrix for Canada Research Chair on the management of Technology
NB: There is some level of double counting as some researchers have multiple affiliations

The University of Sao Paulo is Brazilian and Latin American top higher education institution. It was established in 1934 and enrols over 90,000 students. It also hosts Brazil's largest incubator, and publishes more scientific articles than any other Latin American institution, including in biotechnology. The National University of Campinas (UNICAMP, also in the State of Sao Paulo) and the National University of Rio de Janeiro (UFRJ) follow in its trail – at certain distance. Among public research institutes, FIOCRUZ is number one in terms of scientific publication in biotechnology, closely followed by EMBRAPA and Institute Butantã.

The interviews

Twelve firms were interviewed, but during the interviews it appeared that only eight of them were DBFs. The others were either manufacturing users or traditional biology firms.

Location: These eight DBFs were located in Rio (four), Sao Paulo (three), Belo Horizonte (one) and Porto Alegre (one). In addition, the manager of the Bio-Rio incubator was also interviewed[21]. The Rio interviews were conducted personally and the others by phone, because of the short schedules allocated for the project.

Applications: All these companies are active in R&D for human health biotechnology, including therapeutics, functional additives for food products, health cosmetics, diagnostics and other areas. One of these companies is also conducting R&D in animal health. All these companies – except one, which

[20] See the Shanghai incubator at http://www.tic.stn.sh.cn/en
[21] The names of the companies and the interviewees are kept confidential as agreed upon with the interviewees.

was acquired by a North American firm - are owned and controlled by Brazilian entrepreneurs. A majority of these DBFs were university spin-offs from such universities as the USP, UFRJ and UNICMP. Some of them were also incubated in their respective universities.

Axis may be the most relevant firm in Rio de Janeiro. The group has adopted a hybrid product/service model, and is active in several lines of biotechnology products and services. The group includes a pharmaceutical company producing traditional generics (Sylvestre, founded in 1989), a stem cell databank service company providing stem cell storage and studying regenerative medicine (Cryopraxis, established in 2001), Cell Praxis (2007) and Pharma Praxis (2008), a recent biopharmaceutical company conducting R&D on biosimilar drugs that are not yet on the market.

Another very relevant company is **PN**. Based in Sao Paulo, a spin-off from the University of Sao Paulo, it was founded in 2003, conducts R&D and produces products and services related to dermatology. PN is one of the few Brazilian biotechnology companies to have received funds from both domestic angel investors and BNDES. In 2012, the Toronto based biotechnology company Valeant took a minority position in the Brazilian DBF.

BiOC was founded in 2004. Based in Belo Horizonte, State of Minas Gerais, it received local angel and venture capital. The company is an R&D service biotechnology firm working for both domestic and international clients, mostly in Canada, Europe and Latin America.

Government Funding: The vast majority of these firms had received some financial help from FINEP, and one received a major venture capital amount from the BNDES. Most of these firms had requested funds from both FINEP and BNDES. Only two of them have had BNDES funds. Firms were critical about BNDES because the Bank devotes three quarters of its loans to large enterprises and just one quarter to SMEs. Also the firms criticized the fact that BNDES tends to refuse loans to support projects involving technological and/or commercial risk. FINEP was also criticized for its lack of continuity at supporting emerging technology-based firms: some programs were interrupted and resumed several years later, but biotechnology projects often span over several budgetary periods. Also, company executives in these DBFs underlined the fact that FINEP spends the vast majority of its funds on academic research (95%)**,** and little (5%) on new technology-based firms. A majority of the funds gathered by seven of these eight companies came from the founders, family and friends. Just one of them received a major portion of its funds from BNDES. In Sao Paulo, the Foundation for support of Research at Sao Paulo State (FAPESP) was the main government-funding agency. Companies of that state were positive about the cost, and efficiency of FAPESP.

Government regulations: one company complained about having spent 8 years to get a Brazilian patent. Government regulatory agencies (ANVISA for drugs), IBAMA (for environment) and Ministry of Agriculture (for genetically modified plants) are not knowable about these new products and services and are slow to proceed with the authorizations. Another company said that sometimes they have to teach ANVISA what to do to examine a new microorganism, and even more with stem cells. Another company underlined the fact that the Brazilian regulations (unlike the US law) do not allow registering a second use for the same or slightly modified drug. At least two companies mentioned the fact that regulatory norms are not clear in Brazil particularly when it comes to human health drugs.

Government laboratories and universities: companies were unanimously positive about EMBRAPA and FIOCRUZ as having large portfolios of technologies, and a long experience of collaboration with DBFs. However, Brazilian universities are seen as engines of social mobility, not of economic development. Brazilian universities tend to block the modification of GMOS they have co-invented with private firms. They have little experience and no models of sharing intellectual property with private firms.

Conclusion about Brazil

Brazil has several advantages over all other Latin American nations, including its larger internal market, higher public expenditures on R&D, and more scientific publication on biotechnology than any other country in the region. Also, Brazil has a national development bank (BNDES), a type of institution no other country in the region has established. In addition, Brazil has developed a bio-fuel expertise unparalleled in the region, and it leads the region in the number of biotechnology incubators. However, in key areas of commercial biotechnology, Brazil seems to lag behind Argentina in many respects.

In fact, even if the figures may not be entirely reliable, Brazil seems to have a smaller number of DBFs than Argentina. Also, the large size of Brazilian government laboratories (EMBRAPA and FIOCRUZ) may have discouraged private sector investment and entrepreneurship. In addition, the pharmaceutical industry of Brazil is not as advanced as that of Argentina, particularly in the development of biosimilar medicines. Thus, in Argentina there may be more private-sector demand for biotechnology R&D services than in Argentina.

However, if historical trends over the last century offer some perspective on the future, Brazil has always started behind Argentina, whether on agricultural biotechnology, aerospace, or oil and gas exploration and refining, only to forge ahead several decades later. It is our impression that Brazil will catch up with Argentina in biotechnology products and services in the years to come.

4.3. Chilean biotechnology

Chilean biotechnology is fairly different from that of Argentina and Brazil. The main reason is that there are few users from agriculture and pharmaceutical industries. Unlike its largest neighbours, Chile has no large crops, a reduced animal stock, and a small generic pharmaceutical industry. In Chile, other sectors have the potential to fuel the development of biotechnology; they are: salmon farming, the fruit industry and the mining industry. Thus, the profile of Chilean biotechnology shows different specialties than those of Argentina and Brazil. However, the most distinguished biotechnologist in Latin America is Dr Pablo D. T. Valenzuela, former professor at the University of California, and co-founder and Vice-president of Chiron Corporation. Valenzuela created the vaccine against hepatitis B, discovered the virus of hepatitis C, and developed a process to produce recombinant insulin using yeast. In 1997, Dr Valenzuela went back to Chile where he founded Fundación Ciencia para la Vida, and several new DBFs in human and animal health.

Number, location and application of biotechnology firms

According to the association of Chilean biotechnology firms, ASEMBIO, there are ninety-three manufacturing users of biotechnology in that country, as well as sixty-one SMEs based in universities and twenty-two firms producing specialized services[22]. Chile also hosts some fifteen incubators prioritizing biotechnology, and ten academic technology transfer centres. Like in other countries, it is difficult to assess the accuracy of these estimations. According to this association, the key application sectors are mining, fishing (the salmon industry), fruits and sylviculture (plant pathologies and genetic markers for plant selection), and energy (mainly biofuel and biomass). The biotechnology sales of these firms would represent some 100 million USD.

Santiago, the national capital is the main location of Chilean biotechnology firms, as well as the host of most research universities in the country.

[22] http://www.asembio.cl/biotecnologia

Government support

Chile's biotechnology policy focuses mainly on natural resources: forestry, mining, fruit, aquaculture, small animals and legumes are the main sectors. Issues include quality improvement, resistance to pathogens, biotic stress and gene selection. In mining, companies are interested in the development of bacteria that allow bioleaching, the separation of valuable minerals - in particular the recovery of copper - from other minerals.

Between 1991 and 2001, the Chilean government supported 408 biotechnology R&D projects, for a total of 73.4 million USD[23]. Since then, public backing has been continuously growing, particularly after the creation of Innova Chile.

Innova Chile (IC) is now the main fund supporting the development of Chilean biotechnology firms. IC was established in 2005 following the merger of two public funding agencies: FDI and FONTEC. Its missions are promoting innovation in private firms, stimulating innovative entrepreneurship and strengthening the national system of innovation. Biotechnology is one of its seven key areas of funding. The mechanisms through which support is provided are seed capital, business incubators, and the establishment of a network of angels. IC supports new technology-based firms with up to USD190.475 for three years.

Government regulations

Chile forbids the introduction of transgenic crops for both human and animal consumption, but allows their production for exports as seeds. This regulation has made Chile an important producer and exporter of GMO in international markets. Also, Chile forbids the liberation of living transgenic animals in domestic waters. Yet there is some R&D taking place on the genomics of Chilean plants and animals for purposes of finding cures to different plagues and diseases such as those that affect Chilean salmon fisheries.

In terms of biopharmaceutical drugs, Chile allows their patenting and imports most of its products from original innovators.

Universities

Four Chilean universities dominate the landscape in biotechnology publication: Universidad de Chile, Pontificia Universidad Católica de Chile (PUCC), Universidad de Concepción, and Pontificia Universidad Católica de Valparaíso (PUCV).Table 9 gives some details about their publication activities.

Table 9: Chile: academic publication in biotechnology, main universities 1996-2011

University	Total biotechnology articles	%
Universidad de Chile	636	31
Universidad de Concepción	316	15
PUCC	306	15
PUCV	202	10
All other institutions	596	29
Total	2056	100

Twenty other universities have some publications on biotechnology, as well as several university hospitals and foundations.

[23]Chile: Comisión nacional para el desarrollo de la biotecnología (CNDB), 2003: p. 8.

Research laboratories

Two main laboratories conduct research on biotechnology and publish their results in refereed journals: the National Agricultural Institute (INIA) and the Milenio Institute of Fundamental and Applied Biology (MIFAB).

INIA was founded in 1964 as a private organization reporting to the Chilean Department of Agriculture, that funds some 44% of its revenues, the remaining coming from the sale of services and seeds. In 2010, INIA hosted 600 employees, working in several stations across the country[24]. INIA conducts biotechnology research aiming at the genetic improvement of legumes and fruits. It also aims at preserving the genetic heritage of the country and transmitting its research results to universities, DBFs and other research centres. INIA is not working on genetic engineering but rather on gene identification of useful plants and plant pathogens. INIA appears in 9^{th} rank in terms of scientific publication on biotechnology in Chile.

The Milenio Institute (MIFAB), founded in 1999, focuses its work on human pathology, more precisely on the molecular basis of cell regulation and cell functions. Among its research projects, some focus on cancer, diabetes and obesity. MIFAB also works on the pathogens of salmon. It hosts eleven senior researchers, including Dr Valenzuela, its director. However, neither Milenio nor INIA have received any US patents yet[25]. MIFAB's main researchers are active in one or the other of two Chilean universities (Andrés Bello and PUCC) as well as the Foundation for life sciences. MIFAB appears in 11^{th} rank in Chile in terms of scientific publication.

Dedicated biotechnology firms

Four dedicated biotechnology firms were interviewed in Chile, all of them in Santiago. Three of them were active in human health and one in mining biotechnology. The mining DBF is the result of a consortium of a large domestic copper company and a foreign multinational corporation; its goal is to develop bioleaching processes for the copper industry. This biotechnology company, founded in 2002, has already been granted seven US patents, since 2009. It sells its services to its two major shareholders and to financial supporters.

By far the largest Chilean company, Grupo Bios[26] operates in human and animal health R&D. It was founded in 2008 by Dr Pablo Valenzuela, and already has 130 employees. It has developed molecules for diagnostics kits for several human and animal diseases. It is now trying to export products (molecules and kits) to the United States. It is offering custom-made MAB services. Its funding initially came from public funds, and now comes from sales in the domestic market. This company has also licensed its molecules to a large multinational pharmaceutical corporation. However, the firm has no patents, either in the country or in other OECD nations.

A smaller DBF is operating in the same areas as the one above: human and animal health. Mostly supported by government funds, its growth has been less spectacular than that of Grupo Bios. Yet it exports to the United States and its productivity is also showing strong growth.

Companies had some complaints about regulations in Chile. Speed and cost were not issues. There is no regulation on biotechnology diagnostics in the country, and this fact represents an obstacle to exports to other countries.

[24] www.inia.cl
[25] www.mifab.cl
[26] Grupo Bios (2011): Servicio de anticuerpos monoclonales murinos a pedido, Santiago, 6 pages (www.grupobios.cl).

These DBFs had experienced productivity growth of over ten percent in the last five years, besides increasing total employment by between 14% and 50%. In Chile, supported by a developmental state, growth is taking place, at least for the largest DBFs.

4.4 Biotechnology in Uruguay

Compared to its larger neighbours, Uruguay has a less significant human capital pool, a more reduced internal market and smaller government funds to support the domestic development of a set of costly and complex technologies. Yet, the country has managed to introduce biotechnology services and products through small and medium-sized enterprises. Because its economy and government policy is similar to that of Argentina, there are striking similarities in the distribution of biotechnology among biotechnology firms in both countries.

Number, location and application of biotechnology firms

Like in most developing countries, particularly in Latin America, there are no official statistics on the number of dedicated biotechnology firms. The Biotecsur website[27] publishes a list of 13 biotechnology Uruguayan companies. However, a more detailed analysis of this list finds that most of them are either pharmaceutical corporations (such as Clausen), producers of recombinant animal health vaccines (i.e. Santa Elena) or companies producing inoculants for edible plants. In fact**,** the latter are considered biotechnology users, manufacturing specific lines of products. Once the list was analyzed, one is left with only four dedicated biotechnology firms producing R&D services.

Government support

In 2012**,** Uruguay published a national Biotechnology Plan[28], but like in Argentina, no practical implementation or funding followed. Yet, the Plan contains some figures and forecasts about what biotechnology was in 2012 and what it could aspire to be in 2020. The training of human resources, creation of an adequate regulatory framework for biotechnology, and a better coupling of industry and academia were among the goals for the next decade. The Plan did not publish any figures about what the government might invest in the next decade. Uruguay, like Argentina, has no National Development Bank.

In Uruguay, government support is more reduced than in Argentina, Brazil or Chile. Support for innovation is confined to the National Agency for Research and Innovation (ANII is the Spanish acronym). ANII uses mostly external funds, provided by the national government, the Banco de la República Oriental del Uruguay (BROU), or external agencies such as the Inter-American Development Bank, UNESCO, World Bank, the UN Development Fund, the European Commission and others.

ANII is a private organisation under government control. It is the key actor in the implementation of the National Strategic Plan for Science, Technology and Innovation. ANII supports innovation in private companies through different schemes. It also distributes grants to local students for graduate studies in the United States. Its total annual budget through government appropriations in 2011 was about US$ 26 million (plus US$ 3 million in funds coming from foreign sources). Even if the funds are modest (US$ 0.75 per inhabitant) they have grown exponentially from US$ 8.5 million in 2008, to US$ 18.5 million (2009), and US$ 21 million in 2010.

Several programs support biotechnology firms. The reader may be astonished by the modest amounts involved.

[27] www.biotecsur.org
[28] Uruguay (2012): Gabinete productivo, Plan Sectorial de biotecnología, Montevideo, 48 pages.

(a) The Sector Funds for Agriculture, Energy, and Health could finance biotechnology projects. The 2011 ANII Annual Operative Plan reports that 6 projects were supported: two in energy for US$ 238,000 (almost US$ 120 000 per project) and four in agriculture for US$ 359 000 (or US$ 90 000 per project) . But the Plan does not specify whether these were biotechnology projects[29].

(b) The "Clemente Estable" Fund for fundamental research, which may also support biotechnology research**,** was forecasting total disbursement in 2012 for all disciplines of about 1.7 million USD for 77 projects, or US$ 22 000 per project.

(c) In 2010**,** the "Maria Viñas" Fund for applied research had approved 65 projects for all disciplines for a total of 1 225 million, or 18 800 USD per project.

A program aimed at promoting alliances among universities, private innovative firms and government laboratories in the life sciences was implemented in the late 2010. But according to a well-known Uruguayan expert, the program was not successful for the simple reason that few companies conduct R&D in Uruguay, and the handful of government laboratories and research universities in the country are seldom involved in biotechnology research.

Uruguay has no tax credit for R&D, but it has a tax credit for investment, the average amount granted being around US$ 80 000. Some biotechnology companies interviewed have used this investment incentive. None had received funds from the sector or from the other R&D funds.

Uruguay has not promoted the development of a venture capital industry; there are no incentives for angel investment either; thus, the country cannot use the more traditional mechanism to support new biotechnology firms.

Government laboratories

Uruguay has two government laboratories that mirror Argentina's INTA and INTI. They are the National Institute for Agricultural Research (INIA),and the Uruguayan Technology Laboratory (LATU). Neither of them has biotechnology research among its missions. At a given moment, INIA obtained some funds (US$ 50 000 to 100 000) for agricultural biotechnology**,** but had no personnel to conduct that research. Similarly, for a short period of time**,** LATU obtained some funds to acquire biotechnology equipment but had no budgets to hire the specialised personnel required to use them, or scientists to ask relevant questions or propose relevant research projects.

Universities

Uruguay has developed a National System of Researchers (NSR), giving bonuses to the most productive academics in their system. But the NSR has a clear preference for fundamental research and articles, not for applied research and patents. Such a bias, according to a responsible person from the Department of Industry**,** makes links between university and industry difficult.

Two universities in Uruguay teach and conduct some research on biotechnology. The largest is the Universidad de la República (UDELAR). Founded in 1949, there is some research and teaching at the Faculties of Sciences, Medicine and Agriculture. Between 1996 and 2011, Uruguayan scholars published a total of 356 scientific articles. UDELAR was responsible for 61% of them, followed by the Ministry of Education, the Louis Pasteur Institute (a private non-profit research centre) and INIA. No other institution had biotechnology publications.

The Universidad ORT, founded as a pre-university private college in 1942, became a university in 1985. In 2010, ORT created the first and only university degree in biotechnology in the country, under

---

[29] ANII (2011): Plan Operativo Anual 2011, Montevideo.

the supervision of Mr Carlos Sanguinetti, M. Sc., one of the most distinguished Uruguayan biotechnologists. This 4-year undergraduate program teaches molecular biology, agricultural biotechnology, bioinformatics, bioprocesses and other relevant disciplines. After the first 3 years, the program grants a degree of Technician in biotechnology.

The Pasteur Institute in Montevideo was founded in 2004 and inaugurated in 2007, through an agreement with the French Pasteur Institute. It focuses on three main areas: protein chemistry, molecular biology and structural biology, linked by bioinformatics. The Institute will conduct research and train local and regional human resources in biotechnology. The French government supported the new Institute through a € 5 million grant and the Uruguayan government contributed € 1 million. Its annual budget will be US$ 650 000. In 2007 an international committee selected three competitive research projects, which started their work the same year. Two other research teams were added the following years.[30]

Scientific publication in biotechnology is modest but it exists, particularly at the Universidad de la República (UDELAR), where most of it takes place (Table 10)

Table 10: Uruguay: academic publication in biotechnology, main institutions 1996-2011

University	Total biotechnology Articles	%
UDELAR	217	63
Department of Education	39	11
INIA	16	5
I. Pasteur	16	5
Others	58	16
Total	356	100

Government regulation

Uruguay allows patenting of both transgenic crops and biopharmaceutical products. Uruguay imports all of these products mostly from original innovating countries. A government supported study on the prices of biopharmaceutical drugs published in Colombia (Zapata and Steiner, 2012) showed that among the Latin American countries included in the study, Uruguay was systematically the one that paid the highest prices, followed by Brazil. Argentina was systematically the one where the prices were the lowest. The domestic competition in Argentina, against the total absence of competition in Uruguay and the reduced competition in Brazil were the main factors explaining very substantial differences in process in these countries.

Dedicated biotechnology firms

Informed respondents suggested that there are no more than five or six biotechnology firms in Uruguay. For the purposes of this project, the PI interviewed a total of six firms, but only two of them were dedicated biotechnology firms, the others being in fact manufacturers of different products (biotechnology users).

ATG was founded in 2001 as a dedicated R&D services biotechnology firm. The largest domestically controlled pharmaceutical company in Uruguay acquired ATG,a spin-off from the UDELAR that has developed expertise in diagnostics for different illnesses including Chagas, HIV and cancer. Like several companies already mentioned in Argentina, ATG has become a captive R&D service provider

[30] http://www.pasteur.edu.uy/institution/overview

for a biotechnology user. Under the umbrella of the larger firm, ATG is growing, both in terms of employment and revenues. And like its Argentinean counterparts, its productivity is also rising.

Gen, established in 1993, is a private biotechnology pure service company. Its specialty is the analysis of DNA. It started conducting service tests for herpes, moved to paternity tests and the creation of DNA banks, and now is focused primarily on gene identification in order to understand the genetic basis of the effectiveness of some drugs marketed by multinational corporations. In addition, it conducts gene identification for security services. Finally, it has diversified into gene identification of large cattle. The company exports services towards different Latin American countries, and conducts R&D in Argentina and Uruguay. Its employment, revenues and its productivity are growing fast.

LSE, not included in the statistics, is probably the largest biotechnology user in Uruguay for animal health. The company has some 80 products in the market, 60% of which are biological vaccines mostly for large animals. The company is 56 years old, and has recently passed an alliance with French Virbac, in order to gain complementary knowledge on a different set of veterinary products. Virbac also provided capital and access to new markets. LSE was a spin-off of UDELAR. Its business model is hybrid product/service, where products have the lead. LSE conducts research with UDELAR, INIA, LATU, ORT and the Pasteur Institute in Montevideo. It also collaborates with large national universities in Brazil and Argentina.

The companies that have envisaged producing follow-on biologics found that the complete absence of regulations on these products, made their investment highly risky.

Conclusion on Uruguay

Uruguay has a more reduced potential to develop science-and technology-based service SMEs. Yet some companies are growing thanks to the entrepreneurial effort of their creators, and focusing on the two major applications that are available to them: animal and human health. Like other Latin American countries, Uruguay invests little on public and academic R&D, and thus it forces companies to rely exclusively on revenues they generate. In a sector where technical change is very fast, and depends on university research, this means serious handicaps for local companies.

5. Conclusion and policy implications

In biotechnology innovation takes essentially form through R&D. all the 22 companies interviewed were conducting R&D even if it was with reduced amounts of funds due to scanty government incentives for private-sector R&D. Almost of all them were practicing "open innovation", collaborating with domestic research universities and public laboratories, and most often with foreign biotechnology and pharmaceutical firms in order to gain complementary knowledge. Over one third of the companies had patents, and five of them had been granted US, European and/or PCT patents, showing that some new-to-the world R&D is taking place in the region. This new-to-the-world innovation is most probably in the area of drug delivery, than in the composition of the drugs themselves. The use of trademarks in the largest of these biotechnology service firms and biotechnology users shows that some level of novelty is being created.

However, imitative innovation (copying) products invented elsewhere is the norm in Latin America's biotechnology. In two of our selected countries, Argentina and Brazil, domestic generic pharmaceutical companies and public government laboratories are moving towards the production of biological copies of existing biopharmaceuticals that are losing patent protection in the United States and Europe. In Chile, a start-up DBF is moving in the same direction: imitative innovation of biopharmaceutical drugs.

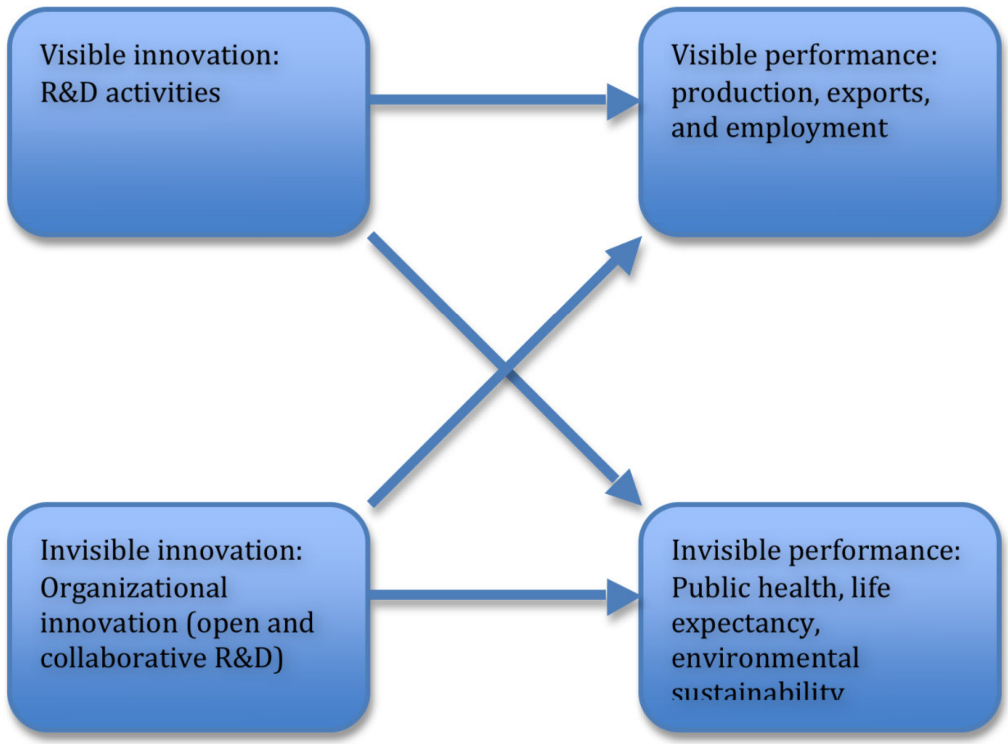
In the area of organizational innovation, imitation is also the rule: open, collaborative innovation and the creation of captive biotechnology firms is not a new-to the world organizational innovation; it is the way many large pharmaceutical companies based in Europe, Japan and North America are incorporating biotechnology.

Biotechnology services companies are being created in all the four countries, and some of them show increasing employment, revenues and productivity, despite reduced government support for advanced academic and public-sector R&D, limited domestic markets and small human capital pools, particularly at the level of star scientists. Pure service biotechnology companies are more easily established in the region than product companies. These service companies require less start-up capital, smaller investments in R&D, and are often able to develop a stream of revenues fairly rapidly.

In Argentina and Uruguay, several large pharmaceutical corporations have acquired biotechnology R&D service companies; in Argentina, a group of agricultural firms has also followed this path to internalize biotechnology R&D services. In Chile, mining companies have established their own captive R&D service provider. In the same country, the presence of a word-class star scientist is allowing Chile to propose highly sophisticated biotechnology health services to the world. But the R&D service model is not the only one existing in the region. Other biotechnology services, such as bioinformatics, gene identification and others, even more specialized, such as stem cell bank services, are also part of the biotechnology landscape in the region.

Figure 3 summarizes the innovation activities of the firms and their impacts, both in terms of visible and invisible impacts.

Figure 3 : Visible and invisible innovation, visible and invisible performance of DBF



Policy implications

User surveys are one important method of assessing the quality of public innovation policy incentives and regulations (Georghiou and Roessner, 2000).Policymakers have helped to understand the rationale of the programs. Yet, our survey of biotechnology companies, even if it is not statistically representative, points to some deficiencies in the regulatory and innovation policy environment.

Competition policy: if Argentina's health system and consumer were paying often lower prices for biotechnology drugs than those based in Brazil and Uruguay, this is because Argentina has taken some care of its pharmaceutical industry, and the industry has learned to live under little support, macro-economic turmoil and a permissive regulation. The combination of stronger public funds for innovation and a soft regulation may probably improve the situation in at least Argentina, and probably in Brazil. In sum, bringing local producers to the competitive arena, both at home and abroad, may produce welfare benefits to the region's health systems and consumers.

Venture capital: Following the experience of more advanced OECD countries, Latin American countries should be interested in building the fundamentals of a solid venture capital industry, either through their national development banks (Brazil) or the private-sector pension fund system, by allowing them to invest a small percentage of their assets in high-technology DBFs. Other paths are also available: countries such as Canada and Israel have invited well-known venture capital firms to create local subsidiaries in order to accelerate learning in this most sophisticated financial industry.

Academic research and training: biotechnology services are based on advanced human capital (Zucker et al, 1998). In order to accelerate the incorporation of highly skilled human capital in the region, several paths are possible. Brazil and Chile have relied on generous fellowships allowing students to increase their skills abroad. This practice is valuable but not very cost effective: nearly half of the students do not complete their careers, and among those that do complete their advanced degrees, half of them tend to remain in the country where they have trained (NSF, 2010). Countries like the United States and Canada offer accelerated immigration procedures to successful students having completed their graduate degrees in these countries, a practice that tends to reduce the effectiveness of the Brazilian and Chilean training policies. Singapore has taken a faster and more cost-effective route: it imports star scientists from across the globe. These scientists bring not only badly needed skills, but also research funds from national and international foundations such as the US National Science Foundation, the British Wellcome Trust, the Gates Foundation, the Volkswagen Foundation and hundreds of others in North America and Europe. In addition, these star scientists train local students in the most advanced technologies. Thus, the developing country that imports such intellectual human capital is less likely to lose its newly skilled graduates who are trained at home. Yet, this practice requires a system of private and public sector chairs open to global competition and adjudicated by international committees, a practice that is common in North America but not in Latin America, where endogamy in recruitment is often the norm in academia[31]. The salaries of these star scientists should be internationally competitive. A major change in mindsets is required in Latin American academia.

Procurement innovation policy: government hospitals and other public agencies can help the development of biotechnology service SMEs in such applications as gene identification, bioinformatics and stem cell banks by outsourcing them to the private domestic sector instead of developing them in-house. Such a practice may create a fertile ground for new companies to grow and eventually export such services to other countries.

Approval and regulations: almost unanimously, companies suggested that approval and registry of biotechnology products and services was fairly long and complex. Most important, they found that public employees in charge of these regulatory activities were sometimes unable to perform their task because of the very sophisticated and knowledge-intensive character of these activities. A more through investigation about these potential obstacles may be necessary.

Statistical offices: the region is seriously lagging in the quantity and quality of its statistics, and particularly but not exclusively concerning R&D, science and technology. No country in the region knows exactly how many dedicated biotechnology firms it hosts, or what the public and private R&D expenditure in biotechnologies is[32].

In summary, the policy incentive supply in science-based industries, particularly in the area of biotechnology services, is badly underdeveloped in the region. It would benefit from being revamped in order to diversify the economies of a region that is increasingly dependent on natural resources, and to support the development of high-technology services. A more complete survey of the users of these policy incentives and regulations could collect useful ideas on how to increase the policy tools in Latin America. More micro-evidence is needed on the impact of these incentives that, even if they are modest in comparative international terms, cost hundreds of millions of dollars to the four countries involved in this survey.

[31] For the definition of star scientists in biotechnology and their impact on industry, see Zucker et al (1998) and Niosi and Queenton (2010). Star scientists are people who have invented at least five biotechnology patents, and authored at least 50 publications in refereed journals. Under this definition, Dr Pablo Valenzuela the inventor in over 30 US granted biotechnology patents, and may well be the only biotechnology star scientist in the region.

[32] Another staggering evidence of quality deficiency came to light in 2009, when Chile was admitted into the OECD, and under the quality control of this international organization its R&D statistics suffered a dramatic reassessment. We may wonder what would occur if Argentina, Brazil, or Uruguay were admitted to the OECD and their statistical data came under quality control.

References

Anlló, G., R. Bisang and L. Stubrin (2011): Las empresas de biotecnología en Argentina, Santiago, Chile, CEPAL, 50 pages.

Baum, J., T. Calabrese and B. Silverman (2000): “Don’t go it alone: alliance network composition and start up performance in Canadian biotechnology”, Strategic Management Journal, 21 (3): 267-294.

BRBiotec (2011): Brazil Biotech Map 2011, 39 pages.

Casper, S. (2000): “Institutional adaptiveness, technology policy and the diffusion of new business models: the case of German biotechnology”, Organization Studies, 21 (5): 887-914.

Chessbrough, H. (2011): Open service innovation, New York, Wiley.

Comisión nacional para el desarrollo de la biotecnología (CNDB)(2003): Informe al Presidente de la República, Santiago, Chile.

CNPQ (2011): CNPQ em ação, Brasilia, 48 pages. (http://www.cnpq.br/documents/10157/64f81c26-639f-4e68-81ac-4b4efed24b4a)

Darby, M. and L. Zucker (2001): Change or die: the adoption of biotechnology in the Japanese and US pharmaceutical industries”, Research on Technological Innovation, Management and Policy, 7: 85-125.

De la Mothe, J. and J. Niosi (eds.)(2000): The economic and social dynamics of biotechnology, Boston, Kluwer.

Evans, P. and J. E. Rauch (1999):”Bureaucracy and growth: a cross-national analysis of the effects of ‘Weberian’ state structures on economic growth”, American Sociological Review, 64 (5): 748-765.

Freel, M. (2005): “Patterns of technological innovation in KIBS”, Industry and Innovation, 13 (3): 335-358.

Fundação Biominas (2010): A Biominas study of Brazilian biotechnology companies, Belo Horizonte.

Gallouj, F. and M. Savona (2009): “Innovation in services: a review of the debate and a research agenda”, Journal of Evolutionary Economics, 19 (2): 149-172.

Georghiou, L. and D. Roessner (2000): “Evaluating technology programs: tools and methods”, Research Policy, 29: 657-678.

Gompers, P. and J. Lerner (2004): The Venture Capital Cycle, Boston, MIT Press (2nd ed.).

Griliches, Z. (1992): Output measures in the service sector, Chicago, University of Chicago Press.

Kenney, M. (1986): Biotechnology: The University-Industrial Complex, New Haven, Yale University Press.

Konde, V. (2009): “Biotechnology business models: an Indian Perspective”, Journal of Commercial Biotechnology, 15 (3): 215-226.

Lerner, J. (2009): Boulevard of Broken Dreams, Princeton, Princeton University Press.

McKelvey, M. (1996): Evolutionary Innovation: the business of biotechnology, Oxford, Oxford University Press.

McKelvey, M. (2008): Health Biotechnology: Emerging Business Models and Institutional Drivers, Paris, OECD.

Mendonça, S., T. Santos Pereira and M. Mira Godinho (2004):"Trademarks as an indicator of innovation in industrial change", Research Policy, 33: 1385-1404.

Miles, I (2005):"KIBS: prospects and policies", Foresight, 7 (6): 39-63.

Muller, E. and D. Doloreux (2009): "What we should know about KIBS?",Technology in Society, 31: 64-72.

Muller, E. and A. Zenker (2001):" Business services as actors of knowledge transformation: the role of KIBS in regional and national innovation systems", Research Policy, 30: 1501-1516.

Niosi, J. (2003): "Alliances are not enough. Explaining rapid growth in Canadian biotechnology", Research Policy, 32 (5) 2003: 737-50.

Niosi, J. (2011): "Complexity and path dependency in biotechnology innovation systems", Industrial and Corporate Change, 20 (6): 1795-1826.

Niosi, J. and T. G. Bas (2004): "Canadian biotechnology policy: designing incentives for a new technology", Environment and Planning C, 22 (2) : 233-248.

Niosi J., T. G. Bas and J. Flores Amador (2013, in press): "Biotechnology in Latin America", Innovation and Development.

Niosi, J., P. Hanel and S. Reid (2012): "The international diffusion of biotechnology: the arrival of developing countries", Journal of Evolutionary Economics, 24 (4): 767-783.

Niosi, J. and J. Queenton (2010): "Knowledge capital in biotechnology: impacts on Canadian performance", International Journal of Knowledge-Based Development, 1 (1-2): 136-152.

OECD (2001): Second OECD Ad Hoc Meeting on Biotechnology Statistics, Paris, May.

OECD (2008): OECD Reviews of Innovation Policy China, Paris, 650 pages.

OECD (2011): Key Biotechnology Statistics, Paris.

Pilat, D. (2001): "Innovation and productivity in services: state of the art", in OECD: Innovation and Productivity in Services, Paris, pp. 17-56.

Pisano, G. (2006): Science Business: The Promise, the Reality and the Future of Biotech, Boston, Harvard Business School Press.

Rasmussen, B. (2010): Innovation and Commercialization in the Biopharmaceutical Industry, Cheltenham, Elgar.

Reid, S. and S. Ramani (2012): "The harnessing of biotechnology in India: which roads to travel", Technological Forecasting and Social Change, 79: 648-664.

Romanelli, E. and M. Feldman (2006): “Anatomy of cluster development: emergence amd convergence in the US human biotherapeutics”, in P. Braunerhjelm and M. Feldman (Eds.): Cluster Genesis, Oxford and New York, Oxford University Press, pp. 87-112.

Shohet, S. (1998): “Clustering and UK biotechnology”, in Swann, G. P., M. Prevezer and D. Stout (Eds.): The Dynamics of Industrial Clustering: International comparisons of Computing and Biotechnology, Oxford and New York, Oxford University Press, pp. 194-224.

Swann, G. P., M. Prevezer and D. Stout (Eds.): The Dynamics of Industrial Clustering: International comparisons of Computing and Biotechnology, Oxford and New York, Oxford University Press.

Uziel, D. (Ed.)(2012): Biotecnologia no Brasil, Rio de Janeiro, EDUERJ (158 pages).

Zapata, J G. and R. Steiner (2012): Pertinencia de incentivar la competencia en el mercado de medicamentos biotecnológicos en Colombia y su impacto sobre las finanzas del sector y la salud, Bogotá, FEDESARROLLO, 144 pages.

Zucker, L., M. Darby and M. B. Brewer (1998): “Intellectual human capital and the birth of US biotechnology enterprises”, American Economic Review, 88 (1): 290-306.

Zucker, L. and M. Darby (2007): Star scientists, innovation and regional and national migration, Cambridge, MA, NBER Working Paper 13547.

Annex 1: Interviews with biotechnology organizations

Country	City	Organization	Type of organization
Argentina	Buenos Aires	Biocientifica	DBF
		Biocodices	DBF
		BioExt	DBF
		Gema Biotech	DBF
		Incubacen	Academic incubator
		Inmunova	DBF
		PharmADN	DBF
		INTI	Government laboratory
		MINCYT	Government department
	Castelar	INTA	Government laboratory
	Rosario	INDEAR	DBF
Brazil	Belo Horisonte	Biocancer	DBF
	Florianopolis	LBE Biotech	Not a DBF
		WAB Biotech	Not a DBF
	Porto Alegre	FK Biotecnologia	DBF
	Rio de Janeiro	BioRio	Academic incubator
		Axis/Cryopraxis	DBF
		ENgene	DBF
		GCTbio	DBF
		StrategoBio	DBF
		Usinaverde	Not a DBF
		EMBRAPA	Government laboratory
		FIOCRUZ	Government laboratory
	Sao Paulo	Inventa Pharma	DBF
		Pelenova	DBF
		Recepta Pharma	DBF
		FAPESP	Government department
Chile	Santiago	BioSigma	DBF
		BioSonda	DBF
		Grupo Bios	DBF
		Venturelab	DBF
		Innova Chile	Government department
		INIA	Government laboratory
Uruguay	Montevideo	ATGen	DBF
		Calister	Not a DBF
		Genia	DBF
		Lab. Santa Elena	Biotechnology user
		Lage	Not a DBF
		Ministry of Industry	Government department
		ORT University	Biotechnology program

Annex 2: Cuestionario en Biotecnología

Propósito del estudio.
El estudio se centra en las características y las actividades de las compañías que utilizan o desarrollan la biotecnología como parte de su actividad.

¿Quién debe completar este cuestionario?.
Un directivo que conozca detalladamente la compañía, puede completar este cuestionario.

Confidencialidad.
Los datos serán tratados con estricta confidencialidad. Estos se utilizarán para los fines estadísticos y se divulgarán, solamente, en forma agregada.

Nombre de la persona que completa el cuestionario y su título:
………

Teléfono(s)…………………………………………………………………………………….

E-mail (s)……………………………………………………………………………………...

Fax (s) ………………………………………………………………………………………

Pagina Web……………………………………………………………………………..

Sección 1: Uso de la Biotecnologías (utilice la siguiente la tabla)

Esta sección mide el uso de la biotecnología en su compañía.

Biotecnologías	Actualmente en uso	Si las utiliza corriente, usted las utiliza para			Número de años en uso
		Desarrollo producto/proceso	Producción actual	Propósitos ambientales	
Codificación de ADN	Si…. No….				
Proteínas y moléculas - bloques funcionales	Si…. No….				
Ingeniería y cultivo de células y tejidos	Si…. No….				
Procesos biotecnológicos	Si…. No….				
Organismos Sub-celulares	Si…. No….				
Otros (ej. Bioinformática)	Si…. No….				
Nanobiotecnología	Si…. No….				
Biotecnología ambiental	Si…. No….				
Otros (Por favor, especificar)	Si…. No….				

Sección 2: Recursos Humanos en Biotecnología

2. Número de empleados en Biotecnología.

a) ¿Cuántos empleados empleó su compañía en este país el 2011? ....

b) ¿Cuántos empleados tenían responsabilidades relacionadas a la biotecnología en el 2011? ....

c) Empleados con responsabilidades en biotecnología a tiempo completo........................

Posición
Número a tiempo completo
Dirección/investigación científicas..
Técnicos ....
Asuntos reguladores/clínicos ....
Producción ....
Finanzas/comercialización/desarrollo de negocios ....
Gerencia administrativa ....
Otro, especifique por favor: ....
Empleados totales con responsabilidades en biotecnología, a tiempo completo....................

d) Empleados con responsabilidades en biotecnología a tiempo parcial (por horas)

Para cada grupo enumerado abajo, indique cuántos son empleados con responsabilidades a tiempo parcial (por horas) en biotecnología (menos el de 50% de su tiempo pasa en actividades relacionadas a la biotecnología). Si un empleado ejecuta más de una tarea, diga su responsabilidad primaria. Cuente a cada persona solamente una vez. Diga por favor el nivel de empleo típico para 2011 en los equivalentes a tiempo completo (FTE).

Posición
Número a tiempo completo
Dirección/investigación científicas...
Técnicos ....
Asuntos reguladores/clínicos ....
Producción ....
Finanzas/comercialización/desarrollo de negocios ....
Gerencia administrativa ....
Otro, especifique por favor: ....
Empleados totales con responsabilidades a tiempo completo en biotecnología ....

e) Número Total de empleados en biotecnología.

Total de empleados a tiempo completo y tiempo parcial relacionados a actividades de biotecnología………………………………………………………………………………….

f) Evolución del empleo (ETC) y de los ingresos ($ miles) en biotecnología del 2007 al 2011

	2007	2008	2009	2010	2011
Empleo					
ingresos					

3. Practicas de Personal y reclutamiento.

a) ¿Su compañía tiene cargos relacionados a la biotecnología sin completar (ocupar)?

No: **Vaya a preguntar 3 b)**

Sí: En la tabla abajo indique el número de cargos sin completar por categoría:
Número de cargos sin completar
Dirección científica/investigación...
Técnicos ....
Asuntos reguladores/clínicos ....
Producción ....
Finanzas/comercialización/desarrollo de negocios ....
Gerencia administrativa ....
Otro, especifique por favor: ....

b) ¿Su compañía tiene un programa formal de entrenamiento y desarrollo para el personal interno que desee aplicar a altos cargos?
No
Si

c) ¿Su compañía intento reclutar a cualquier empleado en biotecnología el 2011?
No…→ Vaya a la pregunta 5
Si …→ tuvo éxito ?
No…→va a la pregunta 3d
Sí… →cuántos contrato usted?

d) ¿Usted intentó contratar a personal en biotecnología que residía fuera del país el 2011?
No…
Si…→en la tabla abajo indique el número de personal en biotecnología empleado de cada región.

Región	**Repatriación**	**Contratación Internacional**	**Total**
Estados Unidos			
Canadá			
Europa			
China			
India			
Asia (otro de China o India)			
Otro (por favor especifique)			
Total de empleados contratados del exterior			

4. a) Alguien del personal de biotecnología dejo la compañía el 2011?
No… → Vaya a la pregunta 6
Si…→ ¿Cuantos?

b) ¿Qué porcentaje de los que partieron el 2011 fue decisión de la compañía?........................

Sección 3 – Historia de la compañía

5. ¿Cuántos años tiene la compañía de establecida? ....

6. ¿Su compañía es pública?
No… ➔ Vaya a la pregunta 8
Si…➔ ¿Que ano fue la oferta pública inicial (IPO)?

7. a) ¿Su compañía se ha fusionado con otra compañía?
No… ➔ Vaya a la pregunta 8
Si…➔ En qué año ocurre la fusión?

b) ¿Cuáles fueron las razones de la fusión?
………………………………………………………………………………………………………

8. a) ¿Su compañía es una firma nacional?
No… ➔ Vaya a la pregunta 10
Si…➔

b) ¿Su compañía tiene sucursales fuera de este país?
No…
Si…➔ ¿Su compañía realiza I+D fuera de este país?
No… Si…

9. Su compañía es un spin-off? (Un spin-off se define como una nueva compañía creada para comercializar desarrollo tecnológico en universidades, laboratorios públicos u otras compañías)
No… ➔ Vaya a la pregunta 10
Yes…➔ Su compañía es un spin-off de:
Universidad/ Hospital
Otra compañía biotecnológica
compañía no biotecnológica
Agencia o laboratorio gubernamental
Otra, por favor especifique

Sección 4: Productos Innovativos en Biotecnología

Esta sección investiga acerca del desarrollo de los nuevos productos y de los procesos de la biotecnología de su compañía.

10. a) ¿Tiene usted procesos/productos en el Mercado que requieran el uso de biotecnología?
Si… (Por favor nombre los tres procesos o productos mas importantes bajo su desarrollo)
No…

b) ¿Su compañía desarrolla actualmente **productos** que requieran el uso de biotecnología?
Si… No…

c) ¿Su compañía desarrolla actualmente **procesos** que requieran el uso de biotecnología?
Si… No…

d) ¿Considera a la biotecnología central en su compañía para sus actividades o estrategias?
Si… No…

11. **a)** En la siguiente tabla, por favor indique el Número de productos o procesos en biotecnología que su compañía tiene actualmente para cada etapa de desarrollo en el sector de salud humana. Si es "0" (cero) por favor indique "0".

Sector de Biotecnología	Número de porductos\procesos de biotecnología por etapa de desarrollo					
	I+D	Pruebas PRE-clínicas	Fase clínica I	Fase clínica II	Fase clínica III	Producción aprobada/ en el mercado
Salud Humana						
Diagnósticos						
Terapias						
Drogas						

b) En la siguiente tabla, por cada sector listado por favor indique el Número de productos o procesos de biotecnología que su compañía tiene actualmente por cada etapa de desarrollo. Si es "0" (cero) por favor indique "0".

Sector de Biotecnología	Número de productos/procesos de biotecnología por etapa de desarrollo			
	I+D	Pruebas PRE-clínicas Ensayos prácticos PRE-mercado	Fase reguladora Determinación lanzamiento Determinación final PRE-mercado	Producción aprobada/ en el mercado
Biotecnología Agrícola				
Biotecnología vegetal				
Biotecnología animal				
Agricultura no alimentaria para uso industrial				
Agricultura no alimentaria para uso medico				
Recursos naturales				
Energía				
Minería				
Productos forestales				
Ambiente				
Aire				
Agua				
Suelo				
Acuicultura				
Sanidad de peces,				

genética				
Bioinformática				
Genómica y modelización molecular				
Terapia génica				
Procesos alimenticios				
Bio procesos				
Alimentos funcionales/ nutracéuticos				
Otros (especifique)				

Sección 5: Regulación de Productos Biotecnológicos

12. a) En el 2011, ¿tenía usted productos/procesos de biotecnología en alguna etapa de I+D, pero no aun en el mercado?
No….➔ Vaya a la pregunta 13
Si…➔ Vaya a la pregunta 12 b

b) De los productos o de los procesos en biotecnología que su compañía tenia en etapas de investigación y desarrollo (no aun en el mercado) en 2011, ¿cuántos requerían la evaluación y/o la aprobación formal de autoridades reguladoras nacionales? Número……….

c) El 2010, para su principal producto en biotecnología, ¿cuál es la duración total de su proceso regulador hasta la fecha (en meses)?
…………………………………………………………………………………………………….

d) ¿Cuál era su gasto el año pasado en I+D?
……………………………………………………………………………………………………..

e) ¿Cual era su gasto el año pasado en regulación?
…………………………………………………………………………………………………….

13. ¿Ha Usted tenido problemas en los procesos regulatorios, tales como:
Costos Si….. No…..
Rapidez Si….. No…..
Normas Si….. No…..
Otros Si….. No…..

14. a) ¿Hizo su compañía contratos fuera de las actividades relacionadas a la biotecnología en el 2011?

Organización	Número de contratos
CRO (Contrato con organización de investigación)	
CMO (Contrato con industria)	
Universidad/hospital	
Laboratorios gubernamentales	
Otras compañías de biotecnología	
Otras, por favor especifique	
Total	

b) ¿Proporcionó su compañía servicio de contrato a otras compañías u organizaciones? No….➔
Vaya a la pregunta 15
Si**….➔** Por cada tipo de contrato por favor proporcione el número y los ingresos

Organización	**Número de contratos**
Otras compañías de biotecnología	
Compañía farmacéutica	
Otra forma que biotecnología o farmacéutica	
Laboratorios gubernamentales	
Universidad/hospital	
Otra, por favor especifique	
Total	

Acuerdos de colaboración.

Los arreglos cooperativos y de colaboración implican la participación activa en proyectos entre su compañía y otras compañías u organizaciones para desarrollar y/o continuar el trabajo en nuevos o procesos significativamente mejorados en biotecnología, productos y/o servicios. El trabajo de contratación externa no se mira como colaboración.

15. a) Su compañía estuvo implicada en acuerdos de cooperación/colaboración relacionados a la biotecnología con otras compañías u organizaciones en 2010? (Incluya por favor ambos casos dentro y fuera del país)
No… ➔ Vaya a la pregunta 16
Yes…➔ Proporcione el número de acuerdos por propósito y el tipo de socio.

Propósito del acuerdo	Número de acuerdos por tipo de socio				
	Compañía Biotecnológica	Compañía farmacéutica	Otra compañía que Biotecnológica o farmacéutica	Institución académica/ hospital	Agencia o laboratorio gubernamental
Conducir I+D					
Asuntos reguladores					
Acceso a otras patentes					
Producción/fabricación					
Acceso mercados					
Acceso capital					
Acceso propiedad intelectual					
Acceso a otras técnicas del conocimiento					
Bajar costos					
Otros, por favor especifique					

b) ¿En 2010, su compañía estuvo implicada en acuerdos de cooperación/colaboración relacionados a la biotecnología con otras empresas u organizaciones extranjeras (situadas fuera del país)?
No… ➔ Vaya a la pregunta 16
Si…➔ En la siguiente tabla, marque los acuerdos de cooperación/colaboración por cada tipo de socio y su ubicación geográfica:

Tipo de socio	**USA**	**Europa**	**Canadá**	**China**	**India**	**Otro**
Compañía biotecnología						
Compañía farmacéutica						
Otra compañía que biotecnología y farmacéutica						
Laboratorio gubernamentales						
Universidad/hospital						
Otro, por favor especifique						

c) Clasifique los siguientes propósitos para formar acuerdos de colaboración/cooperación con un **socio extranjero***(localizado al exterior). Liste los tres más importantes*

Propósito de acuerdo	**Listado**
Conducir I+D	
Asuntos reguladores	
Acceso a otras patentes	
Producción/fabricación	
Acceso a mercados	
Acceso a capital	
Acceso a propiedad intelectual	
Acceso a otras técnicas de conocimiento	

Propiedad Intelectual
16 a) Su compañía solicito u obtuvo patentes relacionadas a la biotecnología o tiene patentes pendientes para sus invenciones?
No… ➔ Vaya a la pregunta 16 b
Si…➔ Cuantas? Indique la distribución de patentes relacionadas a la biotecnología y patentes pendientes que su compañía tiene en la oficina de patentes:

	Nacional	USPTO	Europea	Otro
Existencia de patentes				
Patentes pendientes				
Patentes expiradas				

16 b) Su compañía tiene marca comercial relacionada a la biotecnología?
No… ➔ Vaya a la pregunta17
Si… ➔ Cuantas?......................................

17. a) Su compañía asigna o autoriza derechos de Propiedad Intelectual (PI) relacionado a la biotecnología con otras compañías?
No… ➔ Vaya a la pregunta 17 b
Si… ➔ Por cada tipo de instrumento de PI listado abajo, por favor indique el número de derechos de PI concedido según el país.

Instrumento de PI	Número compañías nacionales	Número compañías USA	Número compañías europeas	Número otras compañías
Acuerdo de licencia				
Asignación de patente				
Acuerdo de transferencia tecnológica				
Otra, por favor especifique				

17 b) ¿Su compañía ha adquirido derecho de propiedad intelectual relacionado a la biotecnología de otra compañía?
No… ➔ Vaya a la pregunta 20
Si… ➔ Por cada tipo de Instrumento de PI listado abajo, por favor indique el Número de derechos de PI obtenido por el país?

Instrumento de IP	Número compañías nacionales	Número compañías USA	Número compañías europeas	Número otras compañías
Acuerdo de licencia				
Asignación de patente				
Acuerdo de transferencia tecnológica				
Otra, por favor especifique				

Sección 7- Característica de la compañía y perfil financiero

18. Por favor complete la siguiente tabla. Si la información no esta disponible, por favor proporcione una estimación cuidadosa en US$.

	2006	2011	2008 pronostico
Total ingreso compañía (todas Fuentes)			
Porcentaje de ingreso biotecnología			
Gasto total I+D			
Porcentaje de gasto en I+D en biotecnología			

Actividades de financiamiento

19. a) ¿Su compañía intentó reunir capital para los fines de la biotecnología en el 2011?

No…➔¿Porque no?...
Vaya a la pregunta 20
Si… ➔ Porque intentó usted reunir el capital? (por favor, revise todas las respuestas que se aplican).
Propósitos de I+D
Producción
Comercialización de productos
Gastos reguladores clínicos

19 b) ¿Fue exitoso en reunir el capital?

No…➔ Vaya a la pregunta 19d
Si…➔ Cuanto capital reunió usted el 2011? …………

19 c) ¿Alcanzo usted su objetivo?
No…➔ Vaya a la pregunta 19 d
Si …➔ Vaya a la pregunta 19 e

19 d) ¿Que razones hicieron que el prestamista/proveedor limitara los fondos o rechazara el pedido del capital?
……………………………………………………………………………………………………

19 e) ¿Que Fuentes proporcionaron el financiamiento?

Fuente	%
Capital de riesgo nacional	
Capital de riesgo US	
Capital de riesgo europeo	
Capital de riesgo de otros países	
Capital otros (ej. Bancos)	
Inversionistas ángeles, familia, amigos	
Gobierno	
Colocación privada	
Oferta Privada Inicial (IPO)	
Oferta Privada secundaria (SPO)	
Fondos propios de fundadores	
Alianzas	
Total	

20. Solicito su compañía créditos fiscales para I+D?
No…➔ Porque no?
Si

21. ¿Exportó su compañía productos de biotecnología en el 2011?
No…➔ Vaya a la pregunta 22
Si…➔ Por favor diga las exportaciones a:
US
Europa
Latino América
Japón
China
India
Otros (por favor, especifique)

22. a) Importo su compañía productos de biotecnología el 2011?
No…➔ Vaya a la pregunta 23
Si…➔ Por favor diga las importaciones desde:
US
Europa
Latino América
Japón
China
India
Otros (por favor, especifique)

b) ¿En 2010, cuáles eran los usos principales finales previstos de los productos biotecnológicos importados por su compañía? (Indique por favor “sí” o “no").
Uso final.
Reventa como producto final.
Uso como producto intermediario o materia prima en:
Siembra y plantación.
Utilización comida/alimentos.
Biología veterinaria.
Droga/farmacia.
Otro por favor, especifique.

Sección 8: Uso de estrategia en el 2011

23. Indique por favor la importancia de cada una de las siguientes estrategias de su compañía en el desempeño del 2011, por "sí" o "no".

Conocimiento de estrategias de desarrollo

	Sí	**No**
Captura y uso del conocimiento obtenidos de otras fuentes de la industria tales como asociaciones industriales, competidores, clientes y surtidores.	☐	☐
Captura y uso del conocimiento obtenido de instituciones de Investigación pública incluyendo universidades y laboratorios Gubernamentales.	☐	☐
Desarrollo de nuevos conocimientos a través de acuerdos de Colaboración con otras compañías u organizaciones.	☐	☐
Uso y actualización de base de información científica y base de Datos.	☐	☐
Desarrollo de políticas y prácticas de la firma en la PI.	☐	☐
Desarrollar o alentar el aumento de la educación del personal.	☐	☐
Conducir una intervención de PI para asegurar la protección de los Productos y procesos en todas las etapas de desarrollo.	☐	☐
Usar la PI como signo de competitividad	☐	☐

Estrategias de negocios

Aumenta el tamaño de la compañía a través de la adquisición o fusión de una empresa adjunta.	☐	☐
Reducción de operaciones de la compañía.	☐	☐
Promover productos o servicios de otras compañías basados en descubrimientos interinos o aumento de I+D para generar flujo de ingresos	☐	☐
Ingresar productos o procesos de ensayo/adaptados para aumentar el ingreso al mercado.	☐	☐
Comienza nuevas investigaciones y desarrollo de proyectos.	☐	☐
Expandirse a los mercados extranjeros	☐	☐

Otro, por favor especifique……………………………………………

24. ¿Cuáles son los planes de la compañía para los siguientes 5 años?

………

………

………

…………………………………………………………………………………………

Gracias

Protocolo entrevistas con funcionarios públicos en programas accesibles a empresas de biotecnología

1. ¿Cuál es el presupuesto anual que su organismo dedica a la biotecnología?
2. ¿Por medio de qué trámites se distribuye esa ayuda?
3. ¿Cuál es el objetivo de la ayuda (ejemplo: I+D, obtención de patentes, control de calidad, contratación de personal altamente calificado, compra de equipo…)
4. ¿Qué tipo de empresa recibe esos incentivos (grande, pequeña o mediana, sector, región…)?
5. ¿Qué otros programas similares existen a nivel nacional, provincial o municipal?
6. ¿Cuántas empresas recibieron esa ayuda en los últimos tres años? Por favor especifique año por año.
7. ¿Cuál es el monto promedio de la ayuda, por empresa?
8. ¿Cómo se compara ese programa con otros programas de incentivos dentro del país?
9. ¿Cómo se compara ese programa con otros similares en América Latina? En otros países?
10. ¿Cuánto personal cuenta esta oficina?
11. ¿Cuál es la duración del personal de esta oficina en el empleo?

cinve
Centro de Investigaciones Económicas

Avda. Uruguay 1242 - Montevideo CP 11100 - Uruguay
Tel./ fax (598) 2900 3051 / 2908 1533 - E mail: cinve@cinve.org.uy
http://www.cinve.org.uy