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Commercial biotechnology in Latin America: Current opportunities and challenges

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Abstract

The unparalleled growth of commercial biotechnology in the USA and Europe during the past two decades has also been marked by its steady development in Latin America. Brazil, Cuba, Argentina, Chile, Mexico and others have made significant strides in building their research and production capacity in modern biotechnology. As these countries have pioneered new biotechnology applications in agriculture, mining, biofuels, human and animal healthcare a number have also launched national biotechnology plans with long-term investment commitments. Newly formed biotechnology trade associations in the region are expanding their membership and rapidly gaining international visibility. Along with the growth of commercial biotechnology in Latin America comes the need to address a series of issues associated with public perception, regulatory framework and intellectual property protection, financing mechanisms, workforce development and more. Government agencies and related public institutions are challenged to adjust their policies and operations to address these changing needs. The private sector and the international community at large will continue to play critical roles in the region through knowledge networks, technology exchanges and joint business investments.

A GROWING REGIONAL PRESENCE

A 2005 report by PricewaterhouseCoopers¹ on pharmaceutical potential in Latin America states that the region 'is becoming much more appealing as a place in which to conduct development and production.' Factors that contribute to this perception include recent healthcare reforms and major development plans, backed by substantial public and private sector investment.^{2,3} Additionally, there is a visible increase in economic and political stability and long-term investments in qualified human resources.

As of 2004, the combined GDP of Latin America and the Caribbean stood at US\$1.9 trillion (Table 1).⁴ Although the data are compiled from only 19 of Latin America's 33 countries, it illustrates the dynamic nature of the region's economic picture. Together with a significant increase in the size of Latin America's

population of more than 500 million people, there has also been an upward shift in the age profile and all the age-related health issues this implies. Clinical trials in the region have shown a tenfold expansion in recent years.

US biotechnology firms now recognise the huge market potential and 'business-friendly' outlook in Latin America. Genzyme Corporation's Senior Director of Marketing for Latin America, Carolina Vallucci, is active in several countries in the region. According to Ms Vallucci:

Latin America presents an excellent potential market for biotechnology products. This is an area that is just starting to develop in the various countries and the respective governments appear to be very interested in supporting its growth and expansion. In the area of health, the authorities have demonstrated much openness in understanding what

Table 1: Economies of Latin American and Caribbean countries

	Economy (US\$bn)	Population (million)
Mexico	676.5	106.2
Brazil	599.8	179.1
Argentina	151.9	37.9
Venezuela	107.5	26.2
Colombia	95.2	45.3
Chile	93.7	16.0
Peru	67.9	27.5
Ecuador	29.9	13.4
Guatemala	26.1	12.7
Dom. Rep.	19.4	8.8
Costa Rica	18.5	4.2
El Salvador	15.8	6.7
Panama	13.8	3.2
Uruguay	12.0	3.4
Bolivia	9.4	8.8
Honduras	7.4	7.0
Paraguay	7.0	6.0
Nicaragua	4.4	5.6
Haiti	3.6	8.1
Total	1,959.8*	526.1*

Notes: Real GDP in current prices in US\$.

*Excludes Cuba.

Sources: IMF,⁵ Population Reference Bureau,⁶ Latin Business Chronicle⁷

Chile plans to achieve a level of R&D investment of 1.5 per cent of its GDP

biotechnology can offer. In several of the Latin American countries, Genzyme is working jointly with the governments to develop legislation which will allow the citizens to have access to biotechnology-based therapies for genetic diseases for which no alternative exists.⁸

A country-by-country study carried out during the past few years on 14 Latin American nations shows that there are over 430 biotechnology firms in the region. Currently Argentina, Brazil, Chile, Colombia, Cuba and Mexico are the Latin American countries most active in commercial biotechnology. In order of importance, the most frequent areas of application are agriculture, followed by human and animal healthcare, food processing, environmental applications and industrial biotechnology. In the case of Mexico, nearly one-third of the approximately 90 biotechnology firms in the country focus on agriculture. Large international firms with biotechnology-

related activities also operate in the region.⁹

SELECTED NATIONAL INITIATIVES

A review of national initiatives in selected Latin American countries illustrates how the diverse approaches to biotechnology development has created working coalitions of public, private and academic sectors appropriate to each country's situation. The following sections offer brief profiles of Chile, Brazil and Mexico as examples of countries with significant forward movement in commercial biotechnology.

Chile

The former president of Chile, Ricardo Lagos, pledged that, by the year 2010, that country's government planned to achieve a level of R&D investment of 1.5 per cent of its gross domestic product (GDP).¹⁰ Now standing at 0.7 per cent of GDP (up from 0.56 in 2000), this continued increase in support for research innovation in Chile symbolises the country's commitment to building the infrastructure conditions needed for boosting technology commercialisation. The government is also creating financial incentives for increasing private sector investment in R&D along with a continuing effort to strengthen universities and international linkages.^{11,12}

Specific to the biotechnology area, Chile has designed several competitive research programmes, one of which involves consortia centred on major export sectors of agriculture, aquaculture, mining, forestry and others (Figures 1 and 2).¹³ Chile's national strategy for biotechnology development was launched in 2003 with the objective of increasing the country's competitive standing in the above-mentioned areas. This national biotechnology strategy responds in part to the needs of its existing biotechnology community and provides ways to address the opportunities and challenges emerging on the global front. The more than 30 private biotechnology firms in Chile

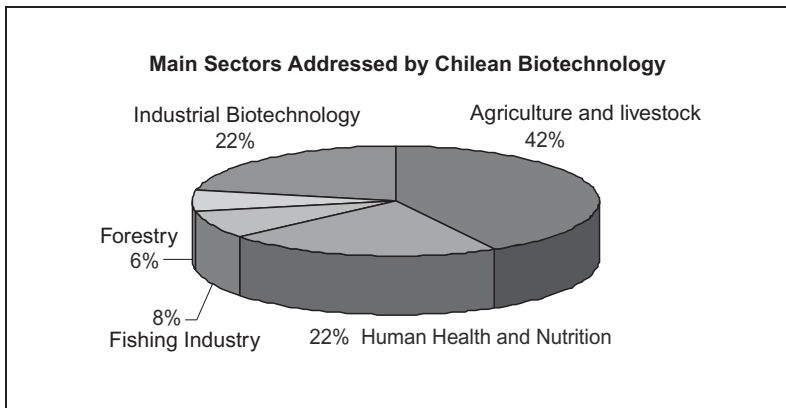


Figure 1: Main sectors addressed by Chilean biotechnology
Source: Alvarez¹³

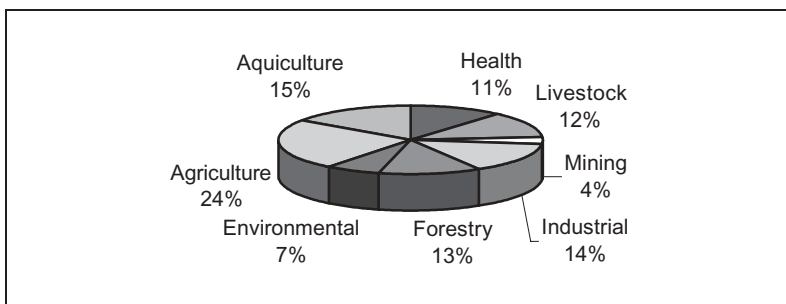


Figure 2: Main research areas in biotechnology
Source: Alvarez¹³

Brazil's leadership in biotechnology is widely recognised

should benefit from these efforts and serve to contribute to the overall technology innovation in the country.

The four specific objectives outlined in Chile's national biotechnology strategy are entrepreneurial development, training of human resources in science and technology, modernisation of the regulatory framework, development of public institutions and citizen participation. Chile has long had a strong tradition in the area of medical research and services. In recent years the country has increased its funding commitment to technological innovation. During 2004, new consortia were formed for selected sectors of the economy including forestry, fruit culture and human health industries. A genome programme has been formed with applications to renewable natural resources and to 'bio-mining' respectively.

An example of a private biotechnology company in Chile is BIOSONDA. Founded in 1992 by a group of Chilean scientists, this company carries out research, production and commercialisation of selected biotechnology products. It provides special services in the areas of protein chemistry, immunology and molecular biology and has capabilities in the production of polyclonal and monoclonal antibodies. BIOSONDA is headquartered in Santiago and works in close association with Chilean Universities, research institutes and other biotechnology companies.

Brazil

With over 75 active biotechnology companies, Brazil's leadership in biotechnology is widely recognised (Tables 2 and 3).¹⁴ The country initiated its national biotechnology programme in 1981, enabling long-term investments in building its human resource base and technological platform. The state of Minas Gerais, with its capital city Belo Horizonte, is one of the most important biotechnology centres in Latin America. Since its earliest involvement, the country has made deliberate efforts to integrate institutions and budgets relating to biotechnology applications in agriculture, energy and health. In 1997, a combination of federal and state funding enabled the development of a virtual genome institute made up of 30 laboratories. This institute (named the

Table 2: Brazilian biotechnology companies by state

State	Percentage
São Paulo	42
Minas Gerais	29
Rio de Janeiro	9
Paraná	5
Distrito Federal	3
Rio Grande do Sul	2
Others	10

Source: Stat-USA¹⁴

Table 3: Brazilian biotechnology companies by sector

Sector	Percentage
Human health	24
Government and international biotechnology companies	22
Consumables suppliers	17
Equipment	17
Agribusiness	12
Animal health	4
Environment	4

Source: Stat-USA¹⁴

Organization for Nucleotide Sequencing and Analysis) successfully sequenced a fruit disease-causing bacterium (*Xylella fastidiosa*), which affects some of the country's major export crops. In 2000, the Brazilian Genome Project was launched in part from this experience. FAPESP, the State of São Paulo Research Foundation, in concert with the Ludwig Institute for Cancer Research, is working on a Cancer Genome Project. Started in 1999, six sequencing teams from the University of São Paulo are contributing to public databases. In addition Brazilian researchers are actively working to map the bovine genome.

Brazil's biotechnology trade group, the Association of Brazilian Biotechnology Businesses (ABRABI), plays a key role in bringing together the principal players in the country's biotechnology community to address issues that affect biotechnology development in Brazil. Recently this group has taken an interest in the area of patent legislation and biosafety regulations. According to the organisation, there are approximately 300 companies involved with biotechnology in Brazil. Founded in 1986, ABRABI itself has 21 associates including pharmaceutical companies, ag-bio companies, and bioinformatics firms as well as government agencies and universities. ABRABI works closely with its counterpart associations in Argentina, Chile, Mexico and Uruguay on region-wide initiatives and programmes through an umbrella group, the Latin American Federation of Biotechnology Companies

(FELAEB). In August 2006 these organisations will hold a joint congress in Buenos Aires entitled 'BIOLATINA 2006'.

Brazil established its first bio-company incubators in Brazil in 1984–86, in Florianopolis, São Carlos, Campina Grande and Brasilia. According to the Brazilian Association of Business Incubators and Technology Parks (ANPROTEC), founded in 1987, there are now 283 fully operational incubators in Brazil. The most active incubators are: Biominas Foundation, Minas Gerais, Incubation Center of Technology Companies (CINET), São Paulo, Managerial Center for the Elaboration of Advanced Technologies (CELTA), Santa Catarina and the Technology Plant Foundation, Paraíba.

At the end of the last decade many Brazilian biotech companies invested in gene mapping, 100 million BRL (US\$43m) had been invested to sequence the genomes of a number of plants. The Federal Agricultural and Horticultural Research Institute (EMBRAPA) is working with the Alellyx company, which is part of the Votorantim group, Brazil's largest industrial conglomerate with revenues of (US\$6bn). This group has invested heavily in agricultural biotechnology including the area of ethanol from sugar cane. Brazil is a leader in the production of bio-fuel usage and currently produces more than 13 billion litres of bio-ethanol from sugar cane. Principal investments have been in the areas of plant genomes and sugar cane breeding.¹⁵ Some 25 per cent of world production of sugar cane comes from Brazil. In addition to sugar, this group has interests in soy, coffee and rice, which are staples of the Brazilian economy.¹⁶

Mexico

Mexico represents the tenth biggest economy in the world today and is a destination for significant foreign direct investment. Currently US-based Merck & Co. is sponsoring a comprehensive study of the life sciences sector in Mexico.

Mexico is a destination for significant foreign direct investment

By providing a major grant to the Council on Competitiveness in Washington, DC, Merck has demonstrated interest in assessing the national and regional policy environment for life sciences innovation in Mexico. The study will determine areas of strengths and weaknesses in the Mexican life sciences sector and provide specific recommendations for the establishment of a 'cluster' in the life sciences.

At a recent biotechnology conference in the USA, Grey Warner, Merck & Co.'s Senior Vice President for Latin America described this effort and offered his view of Mexico's potential for innovation in biotechnology and related fields.¹⁷ He pointed out that by creating the enabling conditions in which innovation can flourish (such as free trade, respect for intellectual property, market-based healthcare reform and rule of law), Latin America can deliver on the promise of prosperity for its people. The ability to innovate and absorb innovation and turn it into marketable goods and services has become essential. He said that establishing these conditions will 'enable countries to

use innovation as a platform to improve the health status and standard of living of their citizens while allowing them to compete more effectively in the global marketplace.'

In Mexico, the issue of genetically modified (GM) organisms has been the subject of extensive debate with proponents and opponents arguing both sides. After lengthy deliberations in Mexico's Congress and as a result of considerable public protest, the Mexican government published its new Biosafety Law for Genetically Modified Organisms in March of 2005 (Figure 3). Complying with Mexico's obligations under the Cartagena Protocol, this law regulates the creation, development and marketing of GM products. The law essentially removes previous restrictions on the use sale, import, export and farming of GM organisms and provides for governmental coordination of the oversight and permitting processes.

One of the groups that seek harmonisation of regulations affecting biotechnology in Mexico is the country's widely respected professional association

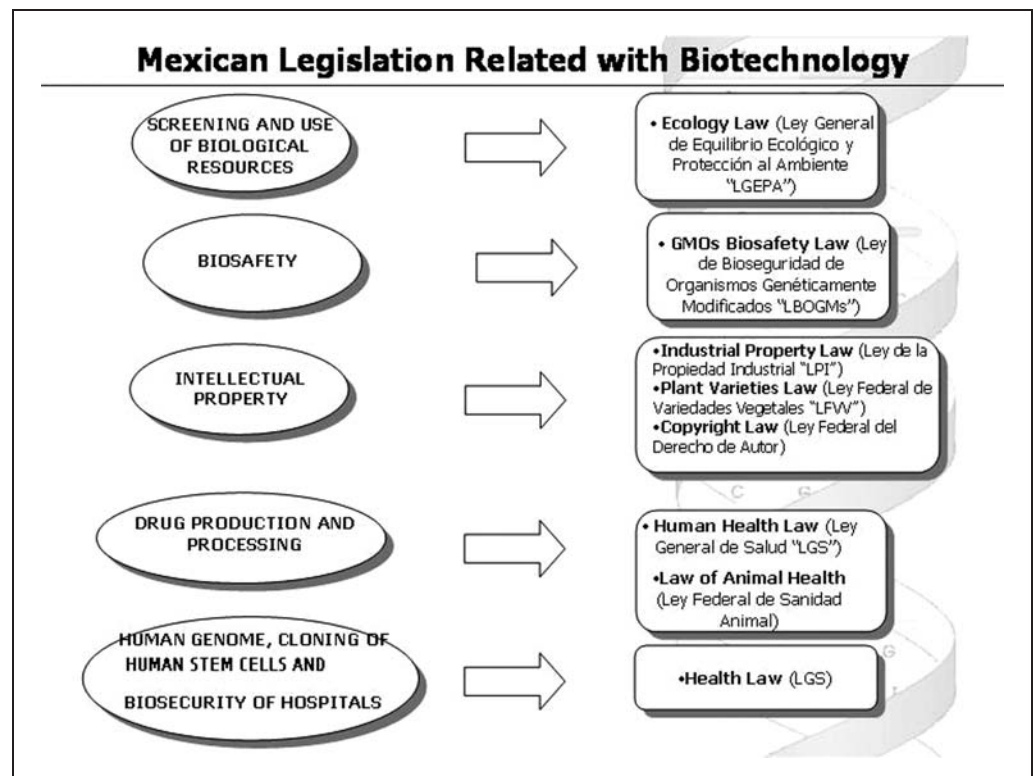


Figure 3: Mexican legislation related with biotechnology
Source: Arriaga¹⁸

for biotechnology. Founded in 1982, the Mexican Society of Biotechnology and Bioengineering (SMBB) promotes technology transfer between the private and public sectors. Its membership includes more than 800 associates who are practising professionals and students.

Commercial biotechnology companies in Mexico are researching a number of areas. These range from the work of Laboratorios Silanes in new technologies for the diagnoses of metabolic disorders to the work of companies such as ProBioMed which is developing bioactive products for human use. Others are dedicated to fermentation and downstream processing.¹⁹ In this latter category, Fermic S.A. de C.V. is a Mexican firm that operates a fermentation and synthesis facility approved by US FDA GMP (Food and Drug Administration's good manufacturing practice). With one of the largest fermentation plants in Latin America, Fermic is currently producing and supplying bulk active ingredients for production of pharmaceuticals. It is relevant that a US firm, Diversa Corporation, has entered into a long-term contract with Fermic, to provide manufacturing capacity for the production of Diversa's enzyme products.²⁰

OPPORTUNITIES AND CHALLENGES AHEAD

The opportunities for biotechnology-related collaboration in Latin America are gaining visible momentum through creative initiatives from business, government and academia. The diversity of the situations represented by the countries in the region provides a rich background of players and resources. The countries discussed in this paper are working to boost their competitive standing on the global front by capturing the benefits of biotechnology applications as they affect their established industries in agriculture, food processing, healthcare and others.

Because the region is still in relatively early stages of development, it offers

accessible options for the promotion of technology innovation and related activities. With the increase of global outsourcing trends in product development, manufacturing and product finishing, Latin American countries are preparing to help their businesses compete for contractual arrangements with companies in Europe, Canada, the USA and other regions. With regard to cultivating European links, a group of stakeholders from Latin America and Europe were convened in Barcelona in April 2005 to explore the current needs and areas of interest for collaborative endeavours. Under the title of BioEuroLatina this group worked to reach a consensus on a declaration which outlined the market arguments and mechanisms for supporting increased interaction. In the case of the USA, there are both new and existing trade agreements (Central American Free Trade Agreement, North American Free Trade Agreement, and Chile-US Free Trade Agreement) which include provisions of relevance to biotechnology-related commerce.

It will be of critical importance for the interested countries of Latin America to continue with the preparation of human resources in areas ranging from basic science to biosafety capacity-building to downstream processing. Evidence shows that selected countries in Latin America have increased their commitment to public funding of science and technology research and education. Among these countries, Brazil has the most researchers with doctoral and masters degrees. Mexico also has increased its number of PhD level graduates. Over the last decade, Mexico has experienced a growth of nearly 20 per cent in the number of PhDs. In Chile, the total number of scientists has increased 56.9 per cent from 1990. Professionals working in biotechnology-related jobs in Chile showed a steady annual growth of 17 per cent since 1995.

In the area of industrial biotechnology, there is an opportunity for Latin America

Opportunities are gaining visible momentum

to take advantage of growing interest in specialty enzymes. According to Dr Marco A. Baez, International Project Manager of Industrial Enzymes at Dyadic International in Jupiter, Florida, Latin America shares the world challenge of maintaining access to affordable energy and a clean environment for its population. In the case of energy, there is strong pressure within Latin America to find new alternative and renewable energy sources in order to reduce dependence on foreign oil. Latin America has an opportunity to shift from an oil-based economy to a 'bio-economy'. Dr Baez points out that this will require a fostering of industrial biotechnology platforms which integrate emerging and rapidly evolving knowledge about the megadiverse regions of Latin America with the implementation of cutting-edge technology. In this regard there is an important role for studies in functional genomics, protein evolution and metabolic control systems to engineer microbial strains and industrial enzymes.²¹

The challenges ahead for Latin America are as diverse as the growth of commercial biotechnology applications. There is a growing need to address a variety of issues and problems associated with the adaptation of public and private institutions. On the governmental side, adaptations are required in regulatory agencies as well as in economic development agencies. As agricultural applications have had the most dominant focus so far, the dialogue will need to be broadened as local development and production of biopharmaceutical products increase in the region.

Intellectual property rights issues will also continue to influence the institutional adaptation of universities and government agencies. Technology licensing offices are becoming more common at Latin American universities along with patent policies for university researchers. Both the public and private sectors are playing an active initial role to jump-start incubator systems and financing mechanisms. As government agencies and

universities increase their participation in the incubation efforts, there will be a greater need to create simple mechanisms for transparency and avoidance of conflict of interest situations. Continued funding for scientific research in the region will need to be increased and maintained along with private sector commitment to providing the investment capital for new biotechnology ventures.

In the area of public perception, new approaches must be adopted to respond to concerns about biosafety, ethical issues and the ways in which the general public views the overall risks and benefits of biotechnology applications. A key challenge will be to continue engaging certain interested segments of the public in objective dialogue on biotechnology applications for health, agriculture and food products.

The commercial biotechnology development activities discussed in this paper reflect only a small part of Latin America's new and exciting initiatives in this area. It is argued here that the substantive part of this development has been generated from within the region. The market dynamics of the coming years promises additional growth along with a continuing rotation of biotech leadership among the countries of the region and among the industrial sectors themselves. Now more than ever, Latin America is in a strong position to advance its commercial biotechnology efforts to create a business climate that will sustain the development of its local economies. Opportunities for international collaborations with biotechnology firms and research institutions in Europe, the USA, Asia and other regions will also continue to increase. Indeed, the added value from such collaborations can build upon the national initiatives and become an integral part of Latin America's future in commercial biotechnology.

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