

# Catalogue of Biotechnology Patents in the Mercosur

ARGENTINA – BRAZIL – PARAGUAY - URUGUAY



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# Catalogue of Biotechnology Patents in the MERCOSUR

## Introduction

With the aim of providing a clear description of technological development in the field of biotechnology in the MERCOSUR countries, a decision was made to obtain and analyse the documents granted, both in the national intellectual property offices of each country and in international databases, thus offering two differing standpoints.

In the former case, the registers in national intellectual property offices of each country in the bloc offer an account of the broadest range of inventions by agents in each country, but they also reveal the interest in their markets for non-residents who protect their inventions in each of the MERCOSUR countries.

Moreover, international databases provide a measure of the projection of the inventions from MERCOSUR countries in the world's most important markets. Although there are relatively few patent documents, they are the ones with greatest profit potential, thus justifying the costs involved in their presentation and maintenance. With this objective in mind, the patents registered by owners in countries of the bloc in three international sources have been studied. The three sources are: the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and the publications database of the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organisation (WIPO).

The USPTO database is one of the main sources used in constructing patent indicators. Given that the United States is one of the largest economies in the world, the commercialisation of products in the country is often a fundamental objective for those offering innovative products. It is for this reason that the patent registry in the US is a very important indicator of technological development worldwide. Over 180,000 patents are granted in the USA every year to owners from all over the world.

In the case of biotechnology, the USPTO data is of particular interest since genetically modified organisms, which are not accepted in patents offices in other developed countries, can be registered here.

The European Patent Office is a body of the European Patent Organisation, set up in 1977 on the basis of the European Patent Convention. It seeks to provide a uniform procedure for patent presentations in thirty-eight European countries.

The EPO database offers a valuable insight into technological development in the European Union, especially in cases of inventions whose economic potential means that their inventors wish to register them simultaneously in all the countries of the region. The EPO currently grants over 55,000 patents each year.

The other international source is the World Intellectual Property Organisation, a specialised agency of the United Nations system. It was founded in 1967 to foster the protection of intellectual property worldwide, by way of international cooperation. The WIPO has a database of the documents registered under the Patent Cooperation Treaty (PCT). This convention is in force in over a hundred countries, including Brazil and Mexico in Latin America.

The PCT permits a patent for an invention to be requested simultaneously in various member countries of the treaty, which the inventor may select on the basis of his own criteria. Although the decision to grant a patent lies with each of the countries, the mechanism facilitates enormously the registration procedure in many different offices since applications that are made under the PCT convention cannot be rejected in member countries due to questions of form. Similarly, before the application is sent to each country an "international search" is made similar to that carried out by examiners from each office. This document means that the owner can assess the patentability of his invention while easing the workload of national examiners.

The application and maintenance of international patents registered under the PCT are costly in both economic and management terms, so only inventions with certain economic or strategic potential are usually registered. The selection of this source was based on the criterion of quality, in an attempt to give an accurate assessment of progress in cutting-edge technology worldwide.

A statistical description of the characteristics of the catalogues obtained from each of the sources surveyed follows. The evolution over time in the numbers of patents granted in each source and the ownership of patents from each of the MERCOSUR countries is analysed. In analyzing the information from the patents offices in each country, patent documents of residents and non-residents alike are identified, along with the nationality of the non-residents.

The presence of inventors from MERCOSUR countries in relation to the number of patents they own is clear to see. The inventor, or inventors, appear in the patent documents, but in recognition of the intellectual work involved in the invention and this entails no rights over the exploitation of the patent. This information includes the nationality of the inventor, not his country of residence, and indicates the activity of a country's researchers and technology specialists, both locally and globally.

Similarly, in order to analyse the reach of the patents registered, the International Patent Classification (IPC) is used for each document. Since a great deal of information is contained in each document, the patents are organised according to classification systems designed to facilitate the identification of specific topics.

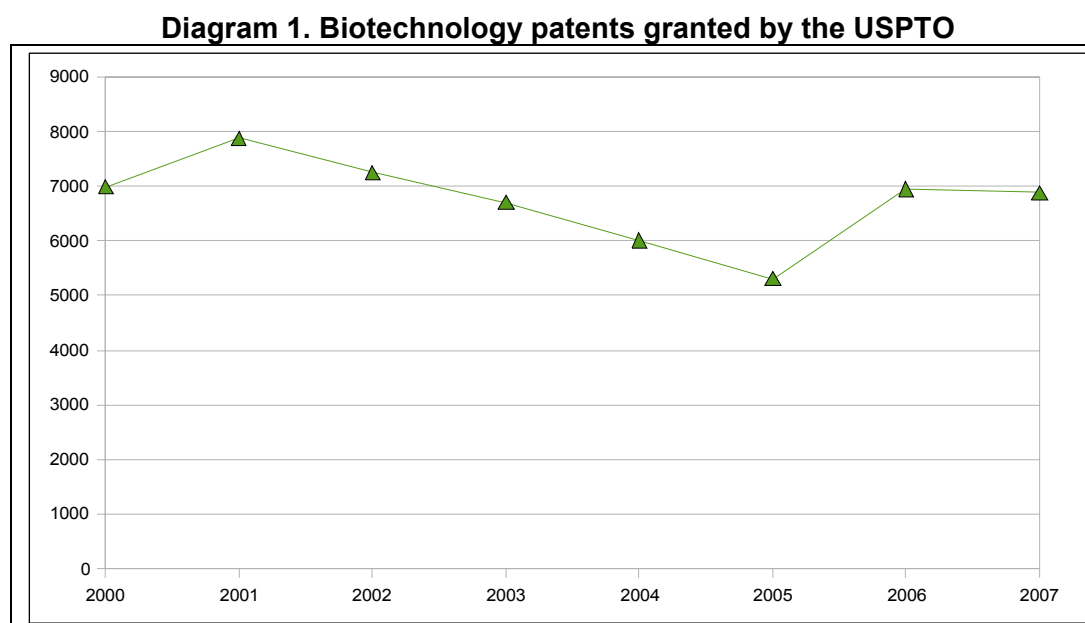
Given constant progress in the field of technology together with the appearance of new fields, the IPC classification, which in its current edition defines approximately 70,000 technological fields, is regularly updated. As part of the examination process for a patent, one or more of these classification codes are assigned to the document. Since these are hierarchical systems, each patent can be classified with a considerable degree of exactitude, although there may well be variations in criteria between examiners at the most detailed levels.

In fact, the OECD's definition of biotechnology patent, made as a result of the interaction of experts in analysing samples, is based on a set of IPC codes that attempt to account for the largest number of documents registered in areas included in the definitions of this conceptual framework. That same definition was used in selecting the documents referred to in this paper. The definition of the 30 IPC codes included in the OECD classification, with their respective descriptive names, appears in Annex 1 of this report.

# 1. International sources

## 1.1. United States Patent and Trademark Office (USPTO)

Between 2000 and 2007 the number of patents granted in the area of biotechnology varied (Diagram 1). The maximum was reached in 2001, with 7,871 patents granted. From then on until 2005, the series underwent a steady decline to a level of 5,302 documents. In 2006, however, the trend reversed and rose to 6,950 patents, a value which remained stable in 2007. The catalogue of biotechnology patents granted by the USPTO can be seen in Annex 2 of this report.



These variations, which are not replicated in other international sources (as will be seen later in this report), are related to changes both in the accepted criteria for patenting biotechnological developments and also in certain characteristics of US law.

Although the objective requirements for granting an invention patent (novelty, inventiveness and industrial application) are almost universally similar, the criteria used by each country to assess them differ in practice. Despite international agreements to define common guidelines for practical verification of the requirements for patentability of specific products and processes, there is still no homogeneous criterion for defining an invention and how it differs from a discovery. While the former is “any human creation that allows matter or energy to be transformed for use by man”, the second involves the finding of new knowledge in the world of nature.

For United States law the term invention is applied both to inventions in the strict sense of the word and to discoveries, and consequently, both categories can be legally protected. This

difference means that patent indices in the USA are considerably more extensive than elsewhere with broader and more flexible protection criteria as to the scope of the relevant subject matter. The flexibility of the US patents system lies mainly in the laxity with which the criterion of inventiveness is applied, i.e. in assessing the part played by human ingenuity in the result.

Therefore, in the 1980 *Diamond v. Chakrabarty* case, the Supreme Court of the United States authorised the *General Electric* company to protect by means of an invention patent a genetically modified microorganism which was able to break down crude oil for use in oil spills. The ruling set a precedent and was the first of a series of court rulings on the protection of biological matter, and even isolated elements of the human body, including genes and partial gene sequences and the instruments of genetic engineering in which a sequence is used. Likewise, for the United States Patent Office, “any person who discovers a gene is authorised to obtain a patent on that gene, as well as on several of its possible applications, even if their use is not proved, or only one is commonly used.”

These were the precedents that served as a basis for the *Patent Reform Act* of 2005 and the current American Biotechnology Patents Law of 2007, and mark a difference with other countries as regards what can be considered an invention, and on the type of inventions that can be the object of a patent. Given the weight of case law in the American legal system, the *Patent Reform Act* makes a very strong impact as its effects are clearly seen in a rise in the total number of biotechnology patents granted by the USPTO from that year on.

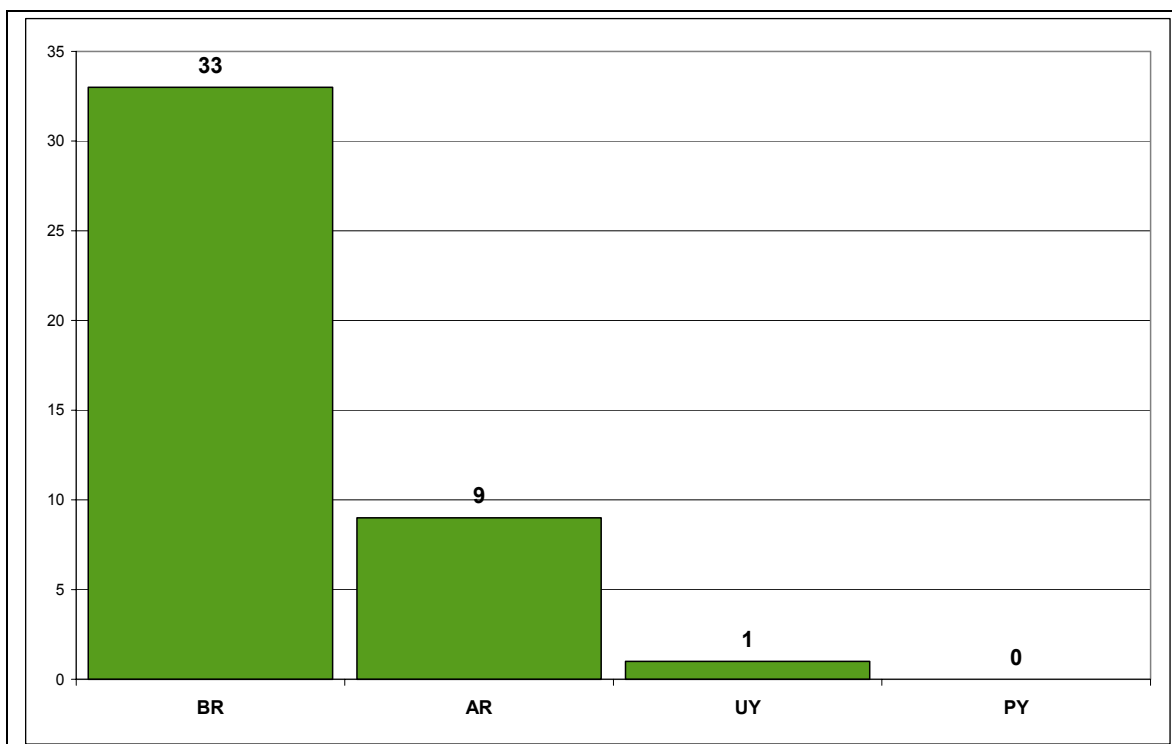
As regards the presence of MERCOSUR countries in this database, table 1 gives the number of patents registered in the area of biotechnology for each of the MERCOSUR countries in the period 2000-2007. The presence of owners based in the regional bloc in the patents granted by the USPTO, as in the remaining international offices, is low. Only Brazil was able to maintain a constant presence throughout the period.

**Table 1. Patents awarded by the USPTO in biotechnology. Total and MERCOSUR countries**

	2000	2001	2002	2003	2004	2005	2006	2007	Total
USPTO	6983	7871	7250	6698	6005	5302	6950	6880	53939
AR		1		1			3	4	9
BR	1	3	3	8	5	2	7	4	33
PY									0
UY								1	1

Diagram 2 is a comparison between the number of patents granted by the USPTO to owners from MERCOSUR countries, according to accumulated values in the 2000-2007 period. Brazil holds first place with 33 documents, followed by Argentina with 9. Uruguay has just one patent granted in 2007, and no register appears for Paraguay in the field of biotechnology in this period.

**Diagram 2. Patents granted by the USPTO to owners from MERCOSUR countries. Accumulated 2000-2007.**



The number of Brazilian patent owners registered in the US office reflects a strong presence of the public sector and, in particular, of higher education: approximately one third of the total number of documents registered corresponds to universities. Foundations also have a strong presence, including FAPESP in São Paulo (with the ownership of five documents) and FIOCRUZ (with four documents accumulated between 2000 and 2007).

Another important player is EMBRAPA, with a significant role in R+D in the farming sector, and which accumulated five patents in the United States during the period. Finally, the private sector, with a total of eight documents, has almost a quarter of the total number of patents owned by Brazilians. Table 2 is a list of Brazilian owners of biotechnology patents in the USPTO.

**Table 2. Brazilian owners of patents granted by the USPTO (accumulated 2000-2007)**

OWNER	NUMBER
Universidade Federal de Minas Gerais	6
Fundação de Amparo a Pesquisa do Estado de Sao Paulo	5
EMBRAPA-Empresa Brasileira de Pesquisa Agropecuaria	5
Fundação Oswaldo Cruz - FIOCRUZ	4
Ludwig Institute For Cancer Research	2
Universidad de Brasilia	3
BIOMM	2
Petroleo Brasileiro S.A.-Petrobras	2
Usina da Barra S/A	2
Universidade Federal Do Para	1
Suzano Bahia Sul Papel e Celulose	1
Biobras	1
CNPQ	1

Fundação Hemocentro de Ribeirao Preto	1
Fundação Antonio Prudente	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

The case of Argentina is rather different. On the one hand the volume of patenting is significantly lower, with only nine documents between 2000 and 2007, but the public sector has no direct participation in the ownership of US patents. A third of the patents belong to the Nidera company, dedicated to the seed trade, followed by companies engaged in the production of input products for biotechnological activities, such as Biodynamics and Immunotech.

On the other, there are two companies from the pharmaceutical sector and the Fundación Instituto Leloir, which own one patent each. A particularity of the Argentine case is the appearance of two natural persons as owners of patents, which does not occur in the cases of Brazil and Uruguay. Table 3 presents the list of Argentine owners of biotechnology patents in the USPTO.

**Table 3. Argentine owners of patents granted by the USPTO (accumulated 2000-2007)**

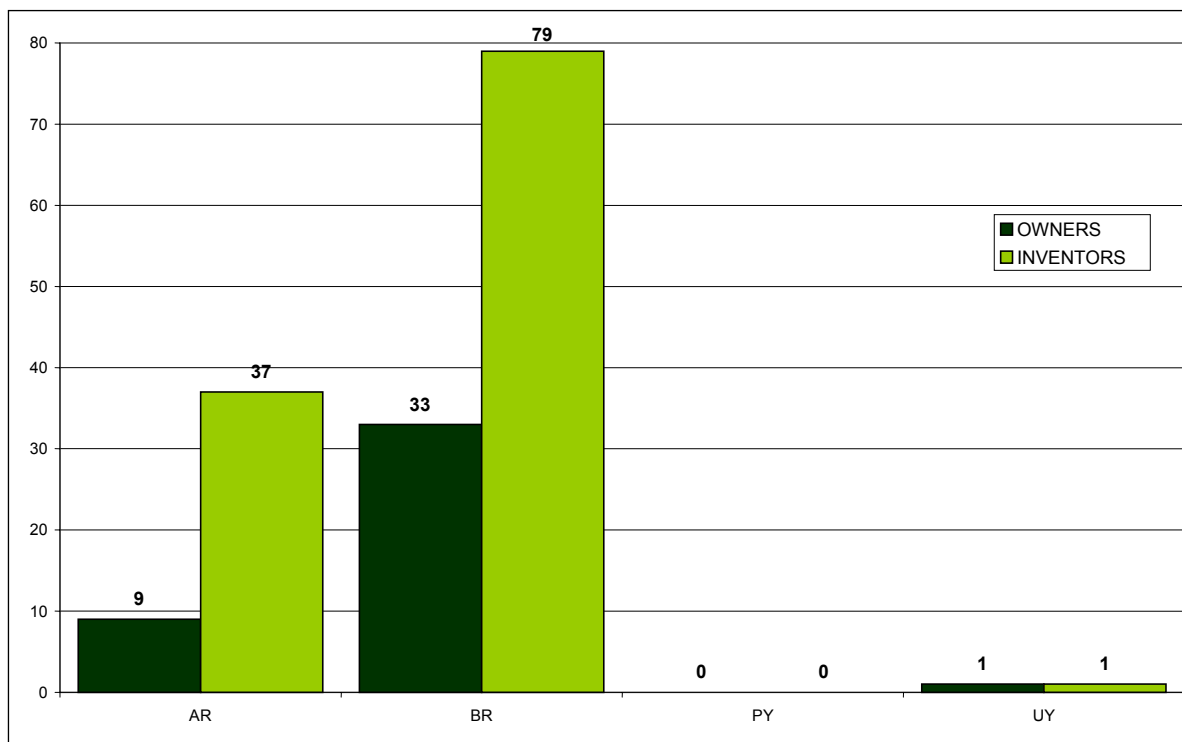
OWNER	NUMBER
Nidera Semillas	3
Biodynamics	1
Fundación Instituto Leloir	1
Gador	1
Immunotech	1
Laboratorios Beta	1
Depaoli, Tomas	1
Hager, Alfredo Adolfo	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

In the case of Uruguay, only one patent with an owner from that country has been registered. It is a document granted in 2007 to Widnes Company Inc, a firm of British origin with headquarters in Montevideo. Finally, no patents were registered under Paraguayan owners in the USPTO between 2000 and 2007.

An interesting approach made possible by the international patent sources is a parallel measure of the participation of MERCOSUR countries as patent owners and as inventors in those patents owned by compatriots or foreigners. Diagram 3 shows the accumulated values for both indicators for each of the MERCOSUR countries between 2000 and 2007.

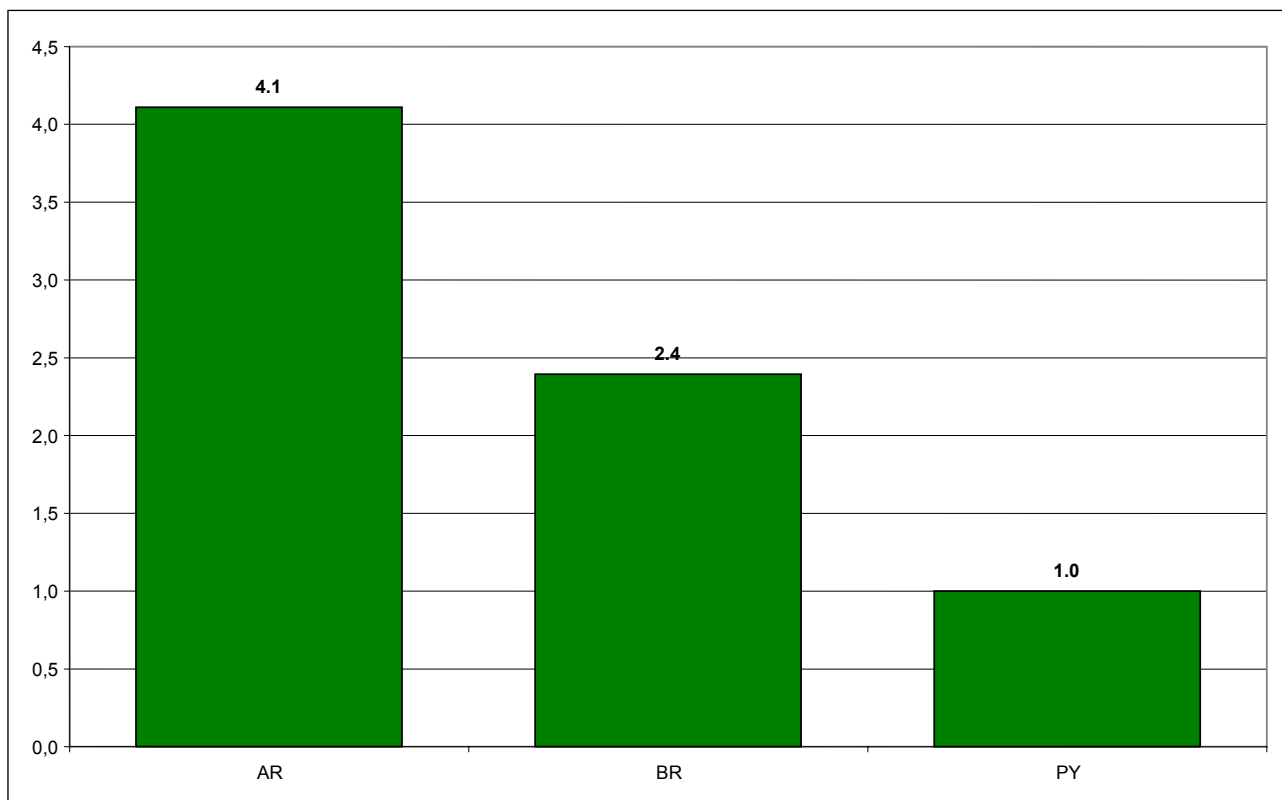
**Diagram 3. Participation of owners and inventors from MERCOSUR in patents granted by the USPTO (accumulated 2000-2007)**



While Argentina participates in the ownership of nine documents, the country's inventors participate in thirty-seven. In the case of Brazil, 79 inventors were recorded as participating in the biotechnology patents granted by the USPTO between 2000 and 2007. In the case of Uruguay, the participation of inventors from that country was detected only in the one patent registered under Uruguayan ownership.

Another form of expressing that proportion is by means of an index of the number of patents with participation of inventors from a country in relation to the number of documents in which that same country participates as an owner. That information appears in diagram 4. The highest value is obtained by Argentina with 4.1 patents with participation by local inventors for each patent of Argentine ownership. Brazil obtains a value of 2.4 and Uruguay 1.0.

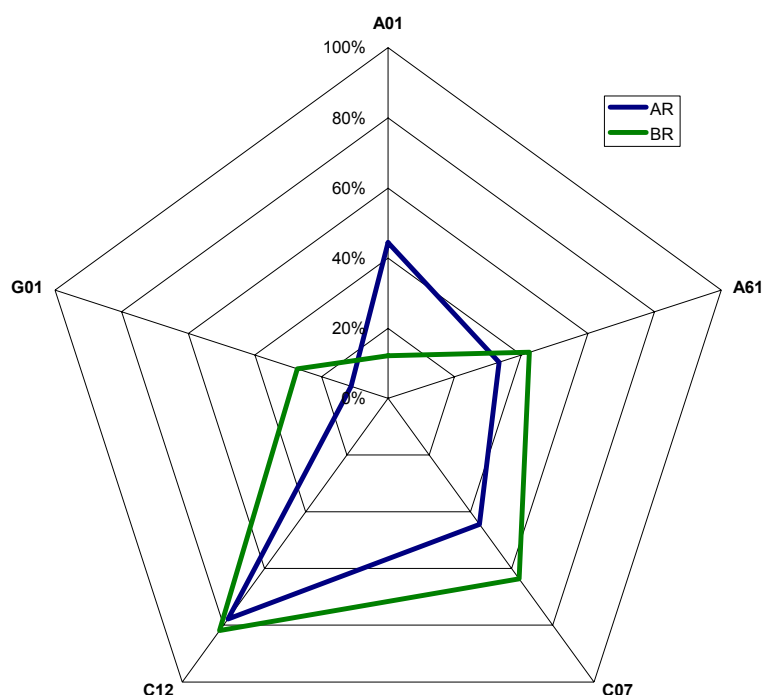
**Diagram 4. Relation between the participation of MERCOSUR countries as owners and inventors in biotechnology patents granted by the USPTO (accumulated 2000-2007)**



The disaggregation of fields of application of those biotechnology patents granted to owners from MERCOSUR countries by the USPTO shows differentiated trends. However, as a result of the number of documents registered it was only possible to analyse the cases of Argentina and Brazil. As shown in diagram 5, in both cases the most frequent three-digit category of the IPC classification is C12 (Biochemistry...), which appears in 78% of Argentine patents and 82% of Brazilian ones.

The main difference appears in the strong presence of Argentine patents in categories A01 (Agriculture...) with 44%, while only 12% of patent documents of Brazilian ownership come under this category. By contrast, in code C07 (Organic chemistry...) Brazil has 64% of documents, while Argentina has only 44%.

**Diagram 5. Distribution by IPC codes of the biotechnology patents of MERCOSUR countries granted by the USPTO (accumulated 2000-2007)**



Code	Description	AR	BR
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	44%	12%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	33%	42%
C07	ORGANIC CHEMISTRY	44%	64%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	78%	82%
G01	MEASURING; TESTING	11%	27%

Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

## 1.2. European Patent Office (EPO)

Unlike in USPTO registers, the number of European biotechnology patents grew steadily throughout the period, doubling in volume between 2000 and 2005, when they reached a total of 2,568 documents. The most remarkable year was 2006 which had very strong growth compared to the previous year, with a total of 3,489 patents. Although the figure fell in 2007, compared to the series total it is clearly very high. The catalogue of biotechnology patents granted by the EPO is in Annex 3 of this report.

**Diagram 6. Biotechnology patents granted by the EPO**

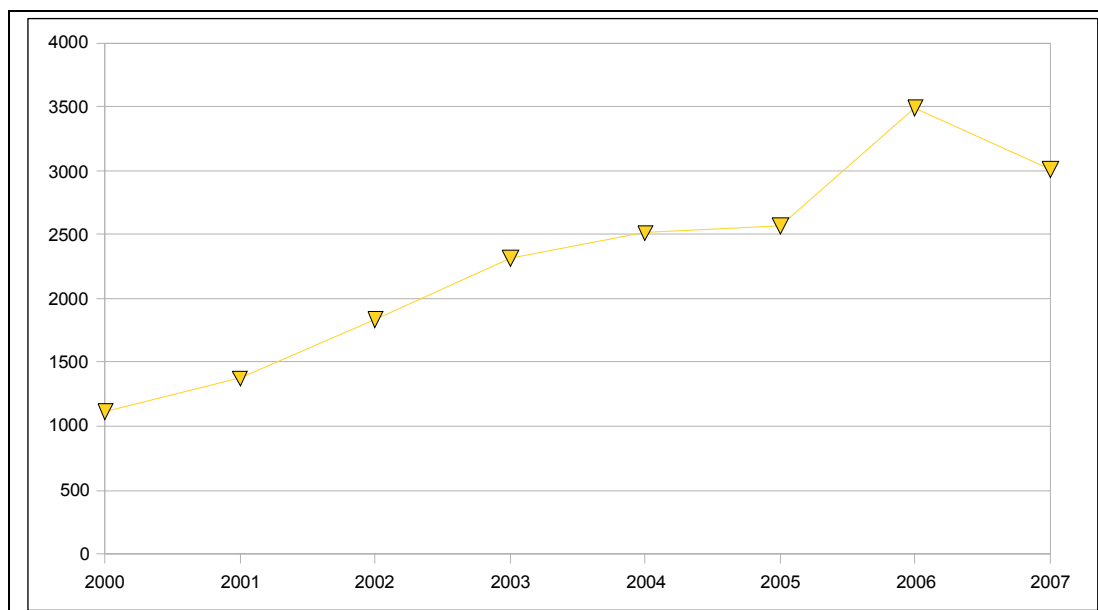


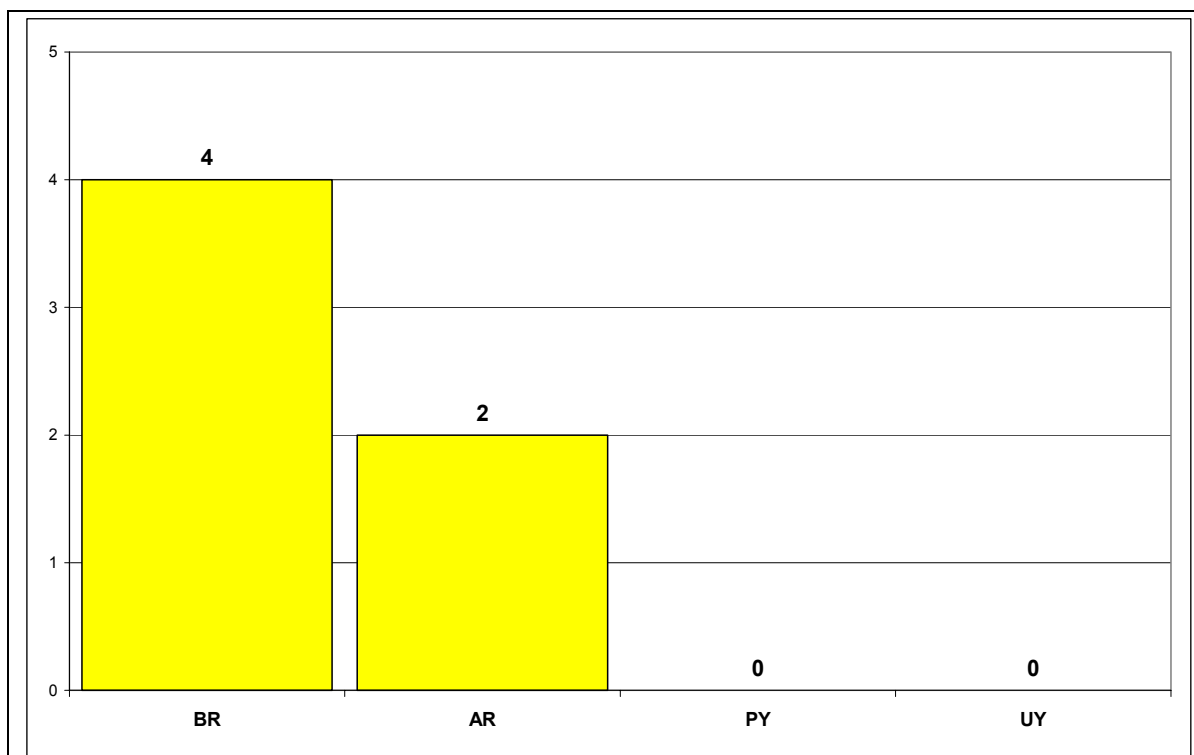
Table 4 shows the disaggregation of the patents granted by the EPO to owners based in MERCOSUR countries. In this case, the presence of the regional bloc is even lower than in the US patents, although MERCOSUR biotechnology patents have mostly appeared in recent years. Although it is a smaller database than the USPTO, the presence of the MERCOSUR is also lower in proportion to the difference in volume between biotechnology patents.

**Table 4. Biotechnology patents granted by the EPO. Total and MERCOSUR countries**

	2000	2001	2002	2003	2004	2005	2006	2007	Total
EPO	1114	1376	1833	2316	2514	2568	3489	3009	18219
AR								2	2
BR						1	1	2	4
PY									0
UY									0

Diagram 7 shows the total number of patents accumulated by MERCOSUR countries in the period 2000-2007. Brazil has four, granted as of 2005, while owners in Argentina have two, both obtained in 2007. Paraguay and Uruguay obtained no European patents in this period.

**Diagram 7. Patents granted by the EPO to owners from MERCOSUR countries. Accumulated 2000-2007**



Among Brazilian owners, the distribution of owners by sector appears more balanced in this source than in the USPTO. The FIOCRUZ Foundation has two patents in the health field, while the public sector is present with one patent for EMBRAPA, the government body which also has the greatest presence in the other international sources.

The higher education sector is represented by a patent of the University of Brasilia for the production of peptide antibiotics. The only presence of the private sector in the EPO between 2000 and 2007 is a patent belonging to PETROBRAS, the oil company.

**Table 5. Brazilian owners of patents granted by the EPO (accumulated 2000-2007)**

OWNER	NUMBER
Fundação Oswaldo Cruz - Fiocruz	2
Empresa Brasileira de Pesquisa Agropecuaria-EMBRAPA	1
Fundação Universidade de Brasilia - UNB	1
Petroleo Brasileiro S.A. - PETROBRAS	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

In the case of Argentina, two patents were granted in the EPO, one of them to a company in the pharmaceutical sector in connection with the production of certain compounds. However, none of the patents of Argentine owners registered in the USPTO between 2000 and 2007 was registered in the EPO in the same period.

In this source the presence of private individuals is also registered in the ownership of patents. The other patent registered was granted to three owners together and not to a company or institution. It is a patent for a method of generating carcinogenic cells for hormone testing.

**Table 6. Argentine owners of patents granted by the EPO (accumulated 2000-2007)**

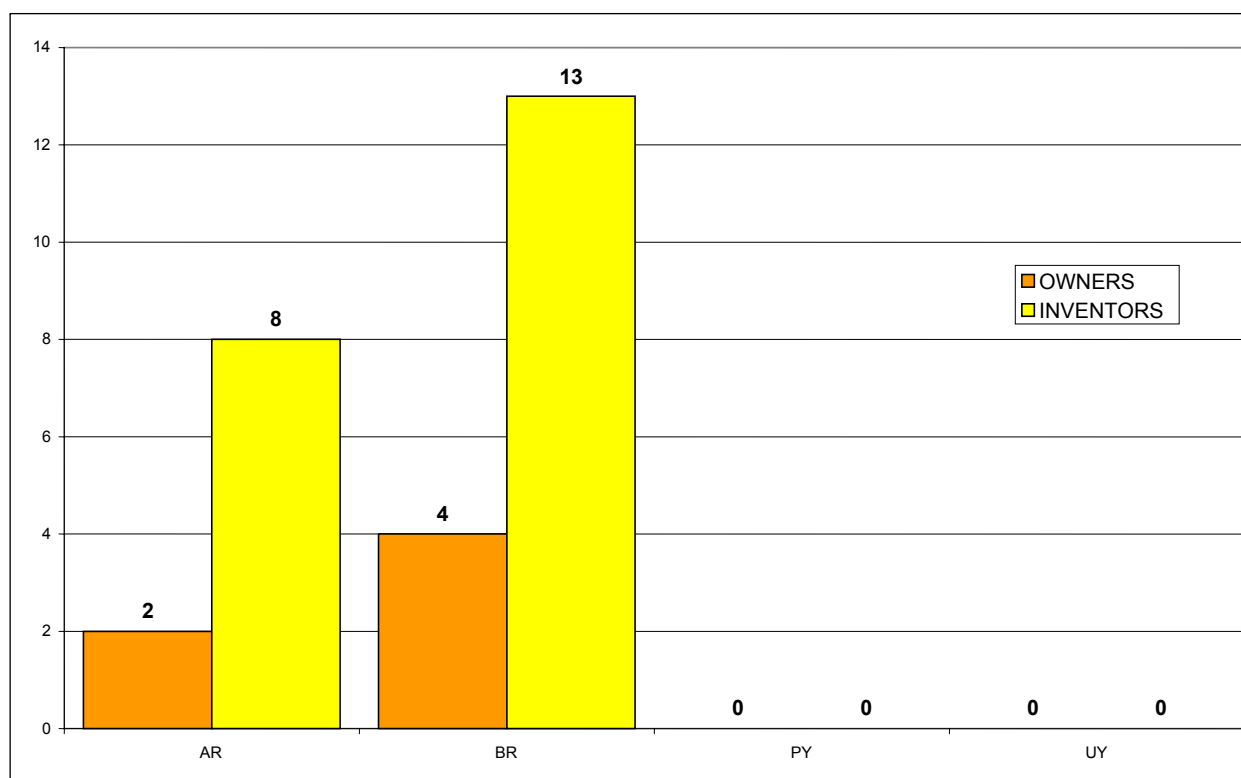
OWNER	NUMBER
Instituto Massone	1
Lanari, Claudia	1
Luthy, Isabel	1
Molinolo, Alfredo	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

No EPO patents were granted to owners from Paraguay or Uruguay between 2000 and 2007; nor was the presence registered of inventors from those countries in the total of biotechnology patents granted by the EPO in that period. That information can be seen in diagram 8.

In the period studied Argentine inventors were registered as participating in eight biotechnology patents of the EPO, only two of which were under the ownership of the same country. The presence of Brazilian inventors was detected in thirteen documents.

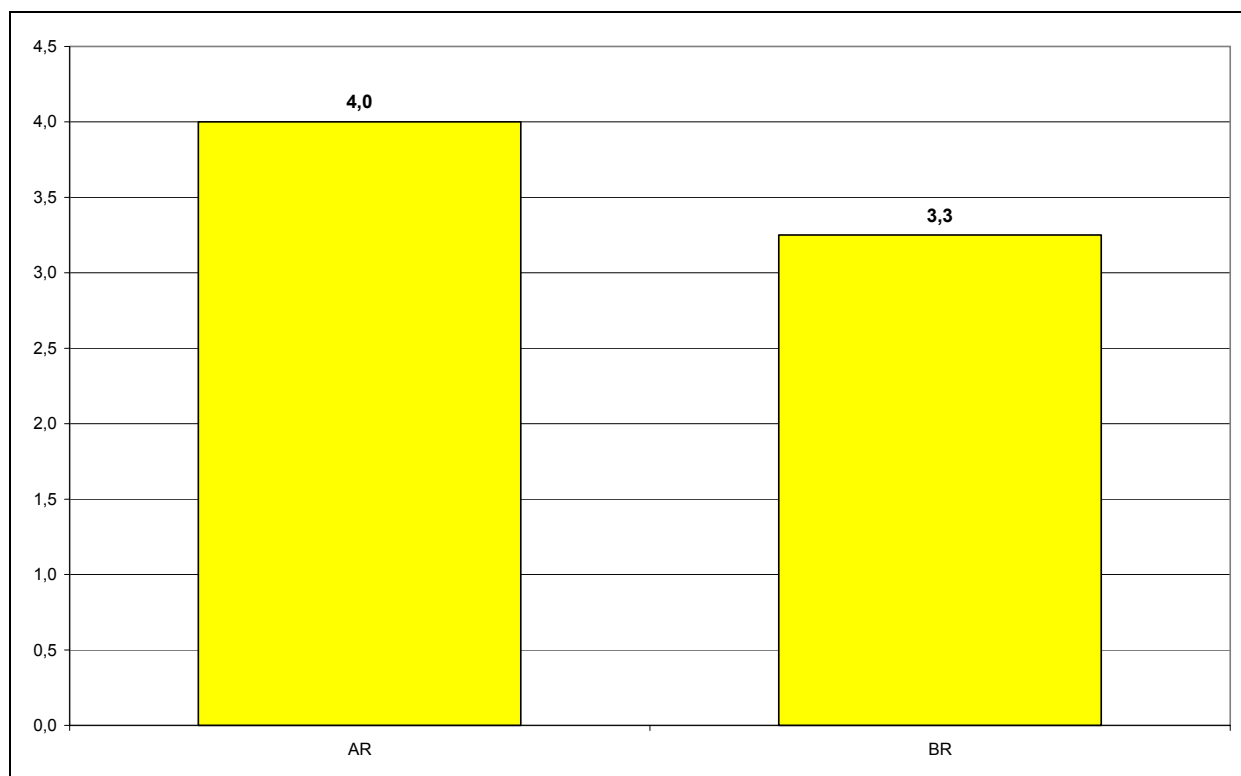
**Diagram 8. Participation of owners and inventors from the MERCOSUR in patents granted by the EPO (accumulated 2000-2007)**



The comparison between the participation of MERCOSUR inventors compared to owners in EPO patents can be seen in diagram 9, with the values accumulated between 2000 and 2007.

Argentine inventors participate in four biotechnology patents granted by the EPO for each one of Argentine ownership. This value is very similar to the one obtained in the same analysis of data from the USPTO. Brazilian inventors, on the other hand, participate in 3.3 biotechnology patents for each one with owners from Brazil. This proportion is a little higher than in the USPTO (2.4) and it is important to emphasise that the Brazilian presence in this base is clearly lower than in the US office.

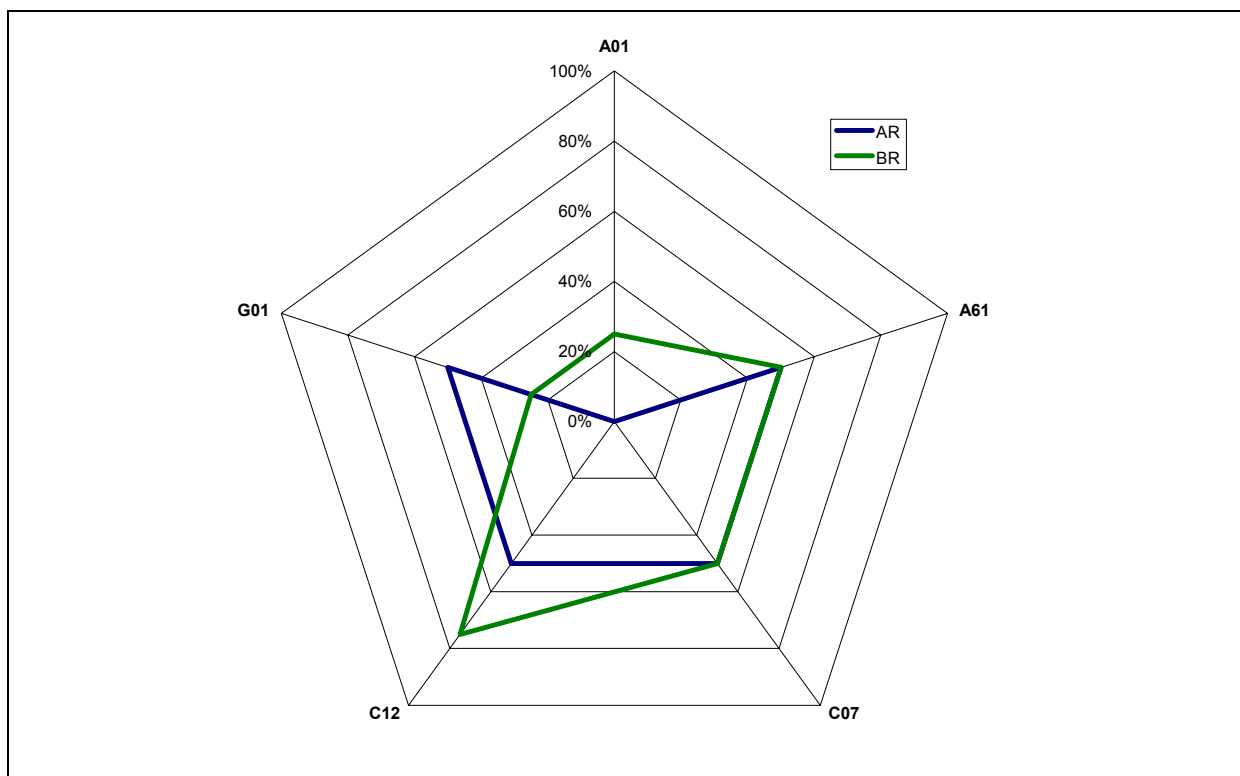
**Diagram 9. Relation between the participation of MERCOSUR countries as owners and inventors in biotechnology patents granted by the EPO (accumulated 2000-2007)**



The disaggregation of fields of application of biotechnology patents granted to owners of MERCOSUR countries by the EPO reveals little of note since the number of patents is very low. The results of the disaggregation of three-digit IPC codes can be seen in diagram 10.

Codes A61 (Medical or veterinary science...), C07 (Organic chemistry...), C12 (Biochemistry...) and G01 (Measuring...) are present in the two Argentine patents. It should be pointed out that although there are only two documents, there are no patents in the group A01 (Agriculture...) which has a strong presence in the documents of Argentine ownership granted in the United States.

**Diagram 10. Distribution by IPC codes of biotechnology patents from MERCOSUR countries granted by the EPO (accumulated 2000-2007)**



Code	Description	AR	BR
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	0%	25%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	50%	50%
C07	ORGANIC CHEMISTRY	50%	50%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	50%	75%
G01	MEASURING; TESTING	50%	25%

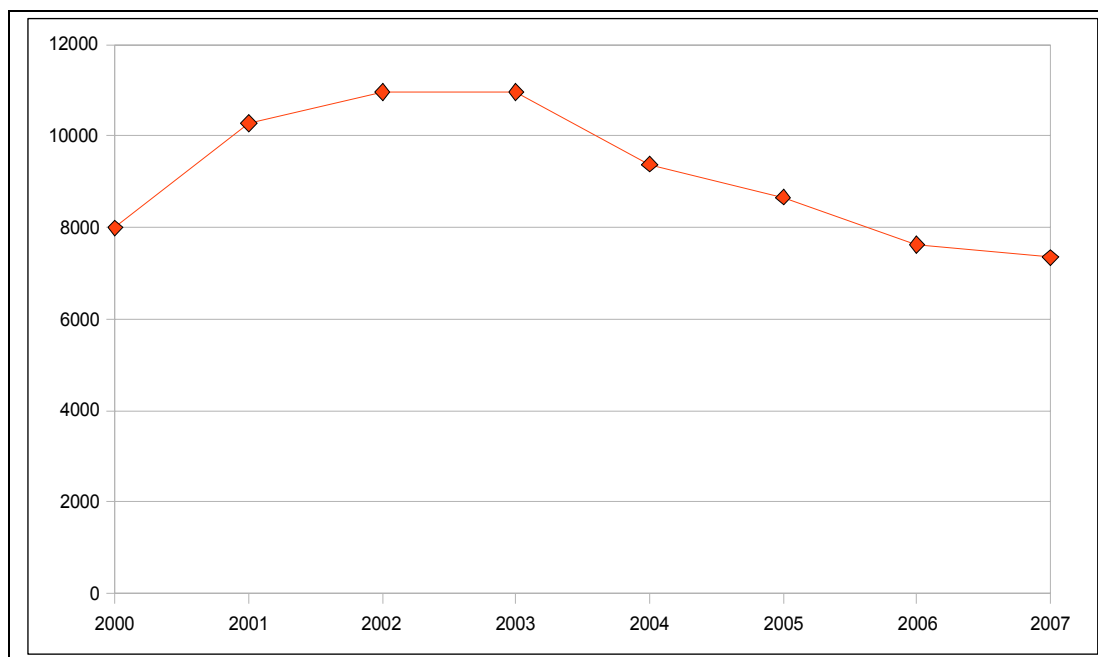
Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

The disaggregation of European patents of Brazilian ownership presents similar characteristics to that obtained in the American base, with a lesser presence in classification A01 (Agriculture...) and a greater concentration in code C12 (Biochemistry...), which covers 75% of the total number of patents obtained between 2000 and 2007.

### 1.3. World Intellectual Property Organisation (WIPO)

Biotechnology patents published by the WIPO followed an upwards path between 2000 and 2003, as can be seen in diagram 11, reaching a total of 10,963 documents that year. From then on there was a steady fall to a total of 7349 patents, a level even lower than that reached in the year 2000. The catalogue of biotechnology patents published by the WIPO is found in Annex 4 of this report.

**Diagram 11. Biotechnology patents published by the WIPO**



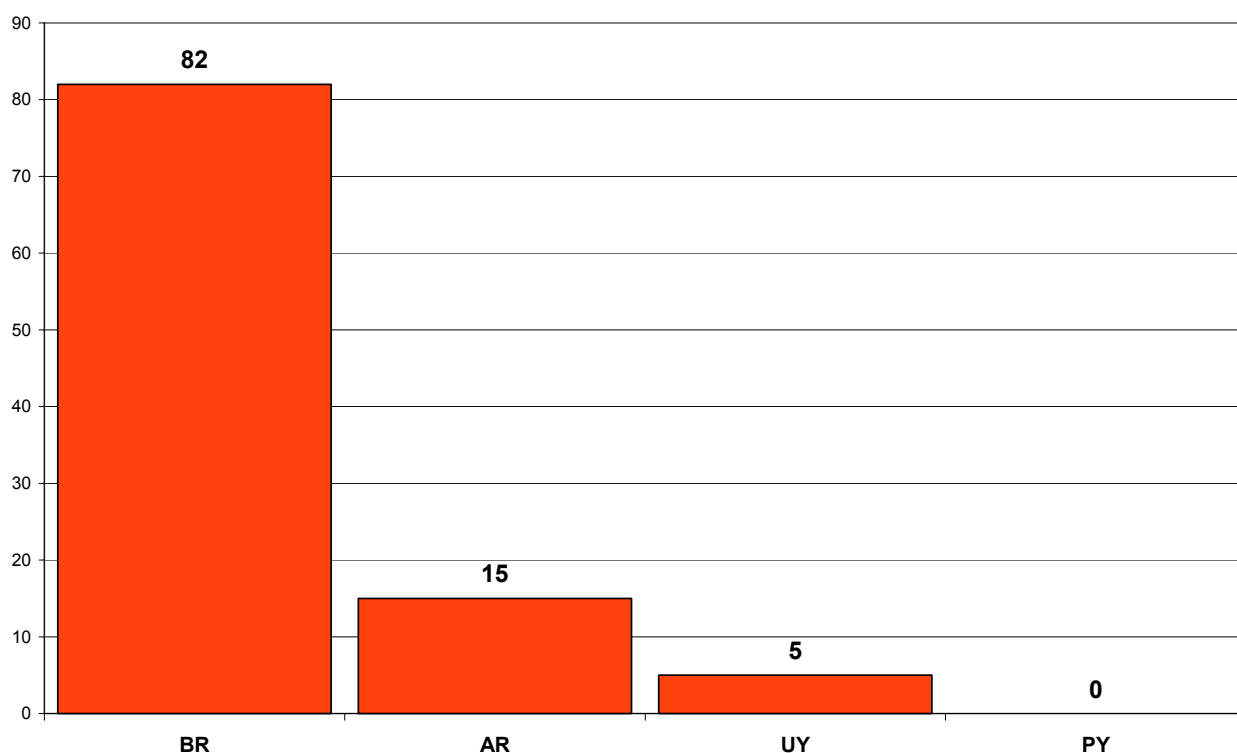
The greater presence of MERCOSUR countries in the three international databases selected for this study can be seen in this source. Brazil is the only country in the bloc which has biotechnology patents published in each year of the period 2000-2007, with the highest value of 16 reached in 2004. It is important to note that Brazil is an active member of the PCT, so it can present international patents through the Brazilian National Institute of Industrial Property, which does not occur in the other countries in the bloc.

**Table 7. Patents published by the WIPO in biotechnology. Total and MERCOSUR countries**

	2000	2001	2002	2003	2004	2005	2006	2007	Total
WIPO	7989	10287	10960	10963	9381	8668	7634	7349	73231
AR	1		2	1	2	1	4	4	15
BR	1	8	14	10	16	7	12	14	82
PY									0
UY			1		1	1	1	1	5

Diagram 12 gives the total of WIPO publications accumulated by the owners from each of the four MERCOSUR countries in the period 2000-2007. Brazil has a much higher volume than the rest, with 82 patents. Argentina, in second place, has 15 while Uruguay has five patents registered and owners based in Paraguay have none.

**Diagram 12. Patents published by the WIPO for owners from MERCOSUR countries. Accumulated 2000-2007**



The list of Brazilian owners of biotechnology patents shows that the first places are once more taken by foundations such as FAPESP, with 17 patents registered between 2000 and 2007, and FIOCRUZ, with 15. In third place is a company dedicated to the filed of genomics applied to plants and which was not present in the other sources. Within the public sector, CNPQ and EMBRAPA participate in ownership of six and five documents, respectively.

Emphasis should also be given to the strong presence of universities. Between 2000 and 2007 eight universities from the various states of Brazil participated in the ownership of around 20% of the patents published by the WIPO. The complete list of Brazilian owners of biotechnology patents published by the WIPO may be seen in table 8.

**Table 8. Brazilian owners of patents published by the WIPO (accumulated 2000-2007)**

OWNER	NUMBER
FUNDACAO DE AMPARO A PESQUISA DO ESTADO DE SAO PAULO	17
FUNDACAO OSWALDO CRUZ - FIOCRUZ	15
ALELLYX	7
CNPQ	6
EMBRAPA	5
UNIVERSIDADE FEDERAL DO RIO DE JANEIRO	5
BIOLAB SANUS FARMACEUTICA LTDA.	4
COGNIS BRASIL	3
PHB INDUSTRIAL	3
UNIVERSIDADE FEDERAL DE MINAS GERAIS-UFMG	3
CRISTALIA PRODUTOS QUIMICOS FARMACEUTICOS LTDA.	2

FUNDACAO DE AMPARO PESQUISA DO ESTADO DE MINAS GERAIS - FAPEMIG	2
HIGUCHI, Maria de Lourdes	2
UNIVERSIDADE DE SAO PAULO	2
UNIVERSIDADE FEDERAL DE SAO PAULO	2
BIOGENESIS BAGO	1
BIONEXT PRODUTOS BIOTECNOLOGICOS LTDA.	1
CAMARGO, Antonio	1
CENTRO DE PESQUISAS GONCALO MONIZ	1
CHUDZINSKI-TAVASSI, Ana	1
COMPANHIA SUZANO DE PAPEL E CELULOSE	1
CRISOGNO SIDNEY, Paulo	1
DE FIGUEIREDO, José Guilherme	1
FK BIOTECNOLOGIA	1
FUNDACAO UNIVERSIDADE FEDERAL DE SAO CARLOS	1
GETEC GUANABARA QUIMICA INDUSTRIAL	1
GHISALBERTI, Carlo	1
GM DOS REIS JR INDUSTRIA E COMERCIO DE EQUIPAMENTOS MEDICOS	1
HEMERLY, Adriana Silva	1
INDUSTRIA E COMERCIO DE COSMETICOS NATURA LTDA.	1
INSTITUTO DE PESQUISAS TECNOLOGICAS DO ESTADO DE SAO PAULO S.A. - IPT	1
LEVY, Nelson Luiz	1
LOPES SILVA, Claudio	1
NANOCORE BIOTECNOLOGIA LTDA	1
QUATRO G PESQUISA & DESENVOLVIMENTO	1
SANAB SANEAMENTO AMBIENTAL E BIOTECNOLOGIA LTDA.	1
SCHENKMAN, Sergio	1
UNIAO BRASILEIRA DE EDUCACAO E ASSISTENCIA - SPONSOR OF DA PUCRS	1
UNIVERSIDAD FEDERAL DO RIO DE JANEIRO-UFRJ	1
UNIVERSIDADE FEDERAL DE PELOTAS	1
UNIVERSIDADE FEDERAL DE VICOSA	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

In the case of Argentina, approximately 60% of documents are under the ownership of private companies, as shown in table 9. The largest of them has four biotechnology patents published between 2000 and 2007. They are companies in the biotechnological processes and input products sector and companies in the pharmaceutical area.

The National Institute of Farming Technology (Instituto Nacional de Tecnología Agropecuaria) obtained two documents in the period studied, and is the only representative of the public sector. It is important to point out that in this case a patent appears under the ownership of the Universidad Nacional del Litoral, the only Argentine university present as an owner in the international sources surveyed. The remaining documents are registered under the ownership of natural persons.

**Table 9. Argentine owners of patents published by the WIPO (accumulated 2000-2007)**

OWNER	NUMBER
IMMUNOTECH	4
INSTITUTO NACIONAL DE TECNOLOGIA AGROPECUARIA	2

FUNDACION UNIVERSITARIA DR RENE G. FAVALORO	1
GADOR	1
GOLDGENE LLC	1
ZELLTEK	1
NIDERA SEMILLAS	1
PROTECH PHARMA	1
UNIVERSIDAD NACIONAL DEL LITORAL	1
GONZALEZ, Daniel Hector	1
CHAN, Lia Raquel	1
DEZAR, Carlos Alberto	1
GAGO, Gabriela Marisa	1
IELMINI, María Verónica	1
IELPI, Luis	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

In the case of Uruguayan owners of patents published by the WIPO, only one company was identified with a patent for a fermentation process. Within the public sector there are two owners of WIPO patents: the Universidad de la República and the IIBCE, an institute dedicated to biology which belongs to the Ministry of Education and Culture.

Finally, two documents appear under the ownership of natural persons, one of which, a document concerning cryogenesis chambers, is shared by several individuals. The other is in the area of human health. The list of Uruguayan owners of patents published by the WIPO between 2000 and 2007 appears in table 10.

**Table 10. Uruguayan owners of patents published by the WIPO (accumulated 2000-2007)**

OWNER	NUMBER
INSTITUTO DE INVESTIGACIONES BIOLOGICAS CLEMENTE ESTABLE (I.I.B.C.E.)	1
SALINBAR	1
UNIVERSIDAD DE LE REPUBLICA	1
BATTHYANY DIGHIRO, Carlos Ignacio	1
CAYOTA GUZICOVSKY, Alfonso	1
PRITSCH ALBISU, Otto Franz	1
ROBELLO PORTO, Carlos Alberto	1
VERRI LIMA, Gaston Jeronimo	1

Note: Since patents can have more than one owner, the sum of the numbers may be more than the total number of patents registered.

The WIPO base is where the largest number of MERCOSUR inventors present in biotechnology patents can be observed. In the case of Argentina, 201 patents were identified with the presence of Argentine inventors, although only 15 patents were published under the ownership of Argentines. It is surprising that Brazil, which is far ahead of Argentina in all other indicators, is present in only seven other patents.

Paraguayan inventors did not appear in the WIPO database, while Uruguayan inventors participated in 25 biotechnology patents between 2000 and 2007, which is a very high number if compared with the two patents of Uruguayan ownership published. Figures for the presence of owners and inventors in biotechnology patents published by the WIPO can be seen in diagram 13.

**Diagram 13. Participation of MERCOSUR owners and inventors in patents published by the WIPO (accumulated 2000-2007)**

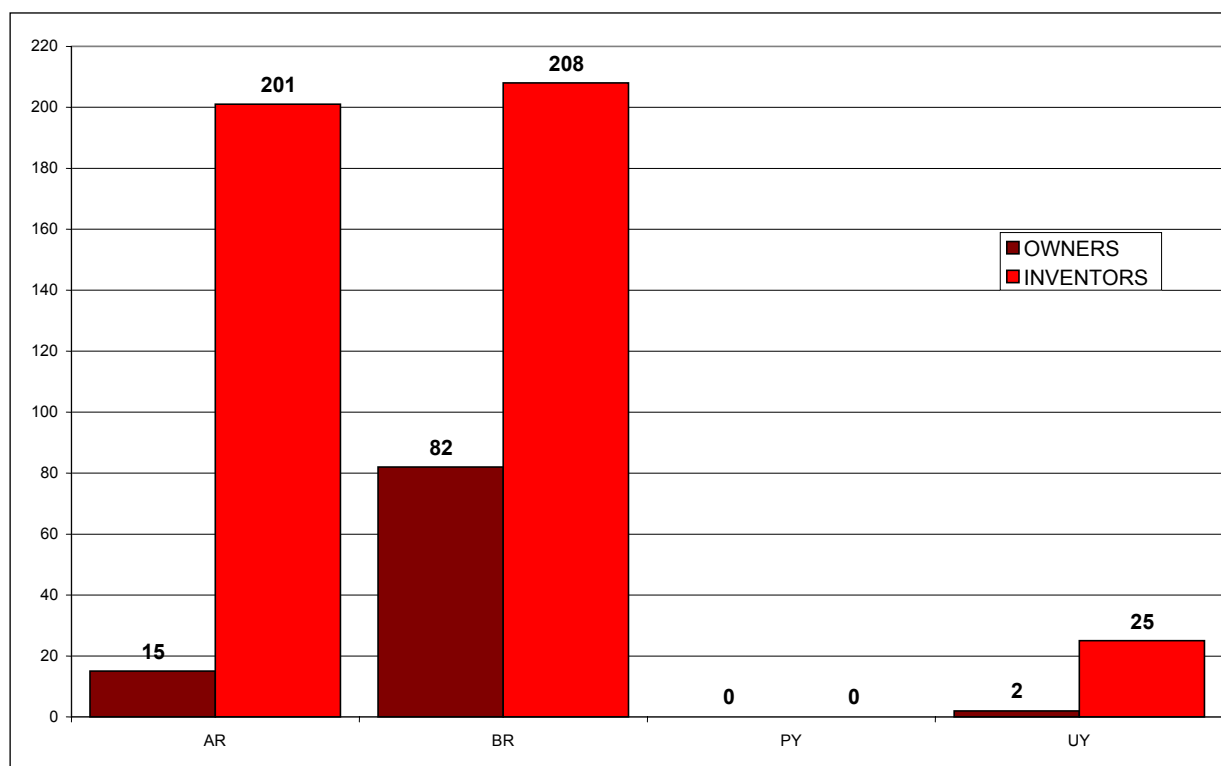
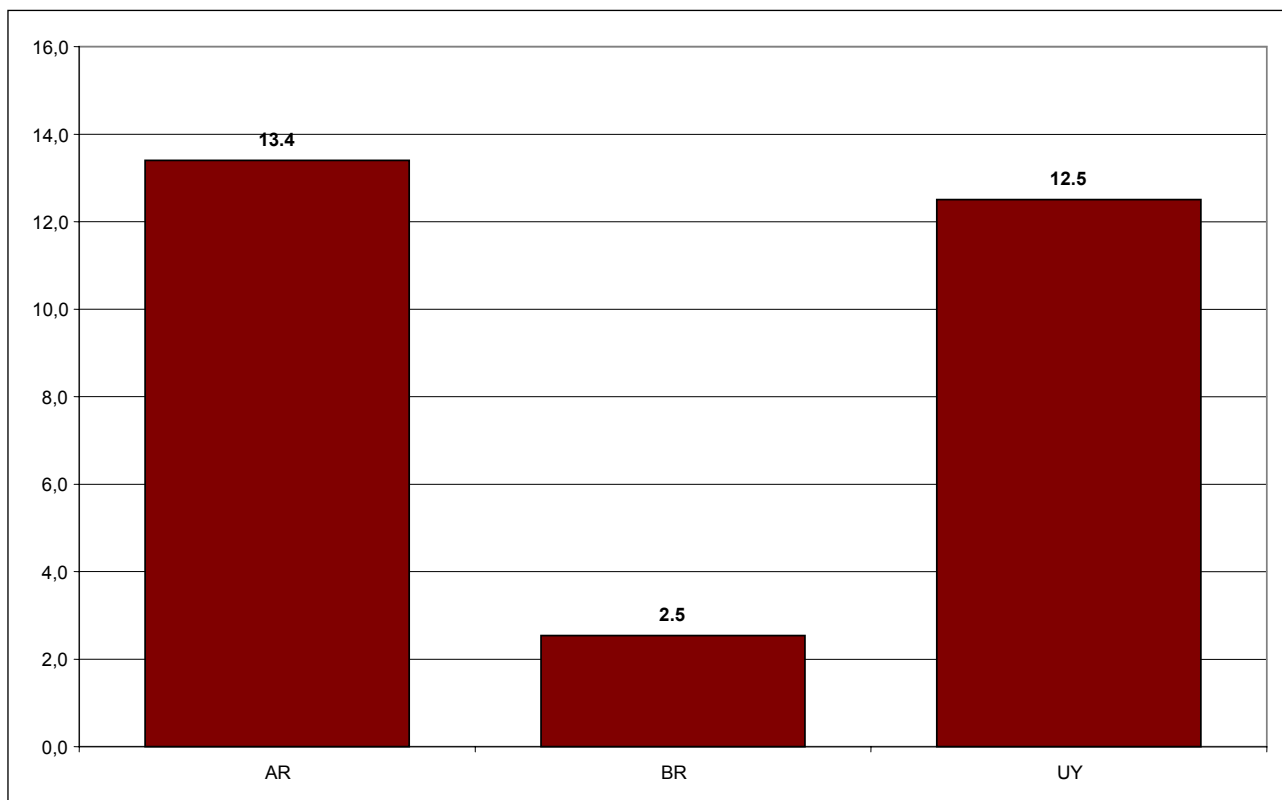


Diagram 14 compares the participation of MERCOSUR countries as owners and inventors in patents published by the WIPO. Considering the total number of sources surveyed, Argentina has the highest value for this indicator with the participation of Argentine inventors in over 13 patents for each one owned. Uruguay has a similar value, with the participation of inventors in 12.5 documents for each one published with the presence of Uruguayan owners.

Brazil, on the other hand, presents a similar value to that which it has in the USPTO, with the presence of Brazilian inventors in 2.5 patents for each of the patents with owners.

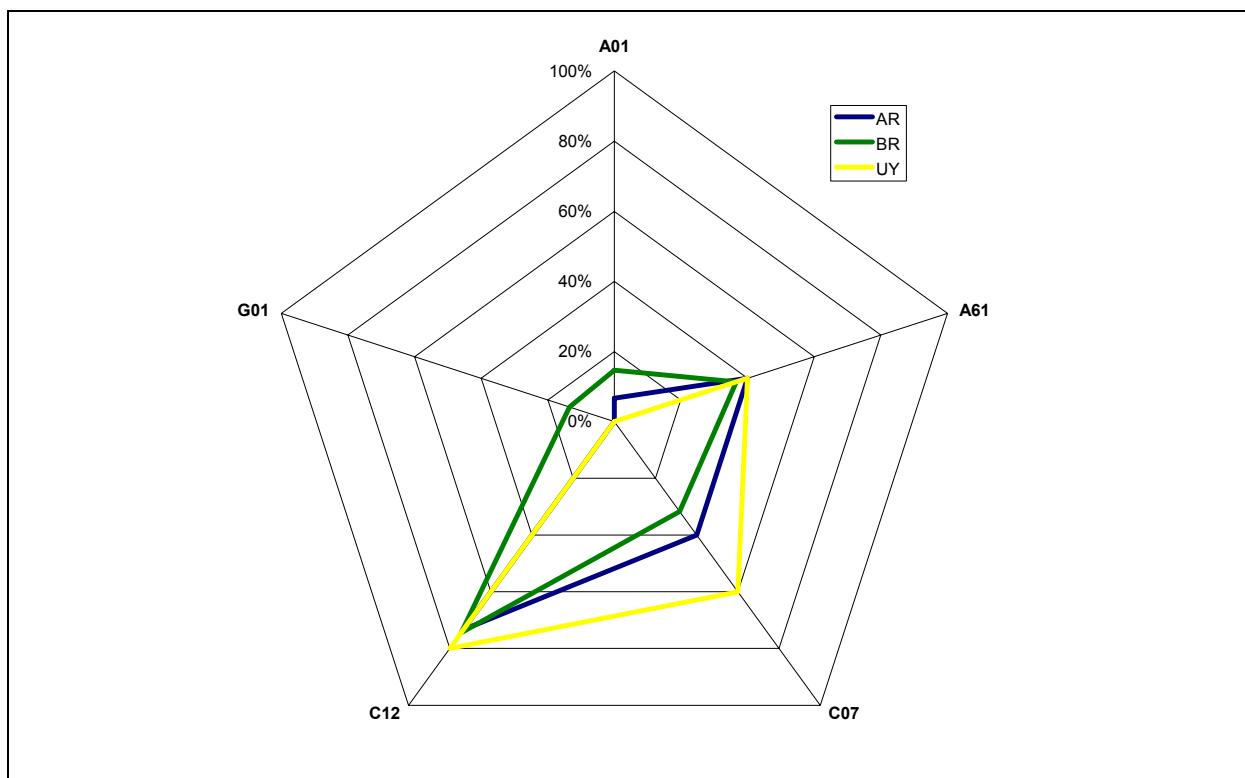
**Diagram 14. Relation between the participation of MERCOSUR countries as owners and inventors in biotechnology patents published by the WIPO (accumulated 2000-2007)**



The disaggregation of fields of application of biotechnology patents published under the ownership of MERCOSUR countries by the WIPO shows similar distributions for the three countries for which patents have been identified. The details of that distribution, based on the three-digit IPC classification, can be seen in diagram 15.

In the three countries, the highest concentration is in category C12 (Biochemistry...), with values close to 75% in each one. Uruguay has a higher concentration than the others in the group C07 (Organic chemistry...), which appears in 60% of its patents.

**Diagram 15. Distribution by IPC codes of biotechnology patents of MERCOSUR countries granted by the EPO (accumulated 2000-2007)**



Code	Description	AR	BR	UY
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	7%	15%	0%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	40%	37%	40%
C07	ORGANIC CHEMISTRY	40%	32%	60%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	73%	74%	80%
G01	MEASURING; TESTING	0%	13%	0%

Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

## **2. MERCOSUR sources**

There follows an analysis of the catalogues of biotechnology patents granted by the offices of Argentina, Brazil, Paraguay and Uruguay. It includes a brief description of the offices responsible for the registration of industrial property in each of the countries and a complete statistical description of the patents studied.

Unlike the study of the MERCOSUR patents granted in the main patent offices around the world, an analysis of data from local entities offers not only a vision of endogenous technological development capacities, but also of the vision held by foreign companies of the market potential of each of these countries, a factor of great weight in the decision to register an invention in that country or not. Details are included on the presence of residents and non-residents, specifying the origin of foreigners, the weight of biotechnology patents in the total and a description of the fields of application covered in the IPC classification of documents.

### **2.1 Argentina**

In Argentina, the body entrusted with the registration of industrial property is the National Institute of Industrial Property (Instituto Nacional de la Propiedad Industrial, INPI). As an office of the Argentine Finance Ministry, it is the enforcement body for laws on Utility Patents and Models (N° 24,481), Trademarks (22,362) and Technology Transfer (N° 22,426), as well as for the decree on Industrial Models and Designs (N° 6673/63).

The objectives pursued by the INPI are:

- To promote initiatives and develop activities conducive to enhancing knowledge and protection of industrial property at the national level.
- To participate in International Forums on Industrial Property, with particular interest in defending national interests (Cooperation Treaties and Conventions with Entities and Countries)
- To administer and resolve matters concerning the enforcement, concession, exploitation and transfer of Invention Patents and Utility Models.
- To register Trademarks, Industrial Models and/or Designs, and Technology Transfer Contracts.
- To provide the general public with information on the history of Industrial Property, nationally and internationally, and on applications for Patents, Trademarks and their respective concessions and transfers.

The INPI granted a total of 353 biotechnology patents between 2000 and 2007. As can be seen in diagram 16, the number of patents granted each year varies considerably, with a minimum of 6 in 2004 and a maximum of 107 in 2007. The catalogue of biotechnology patents granted by the INPI of Argentina is in Annex 5 of this report.

It is important to bear in mind, however, that these fluctuations are related to changes in the internal efficiency of the Institute in assessing and granting registrations. For example, the marked rise which began in 2005 is related to a productivity plan launched by the INPI which had strong repercussion in the number of patents granted per year in Argentina. This factor affected even more the patents granted to non-residents who, as they mostly had priority based on documents previously presented in other offices, saw a more efficient evaluation process of the invention presented.

**Diagram 16. Biotechnology patents granted in Argentina**



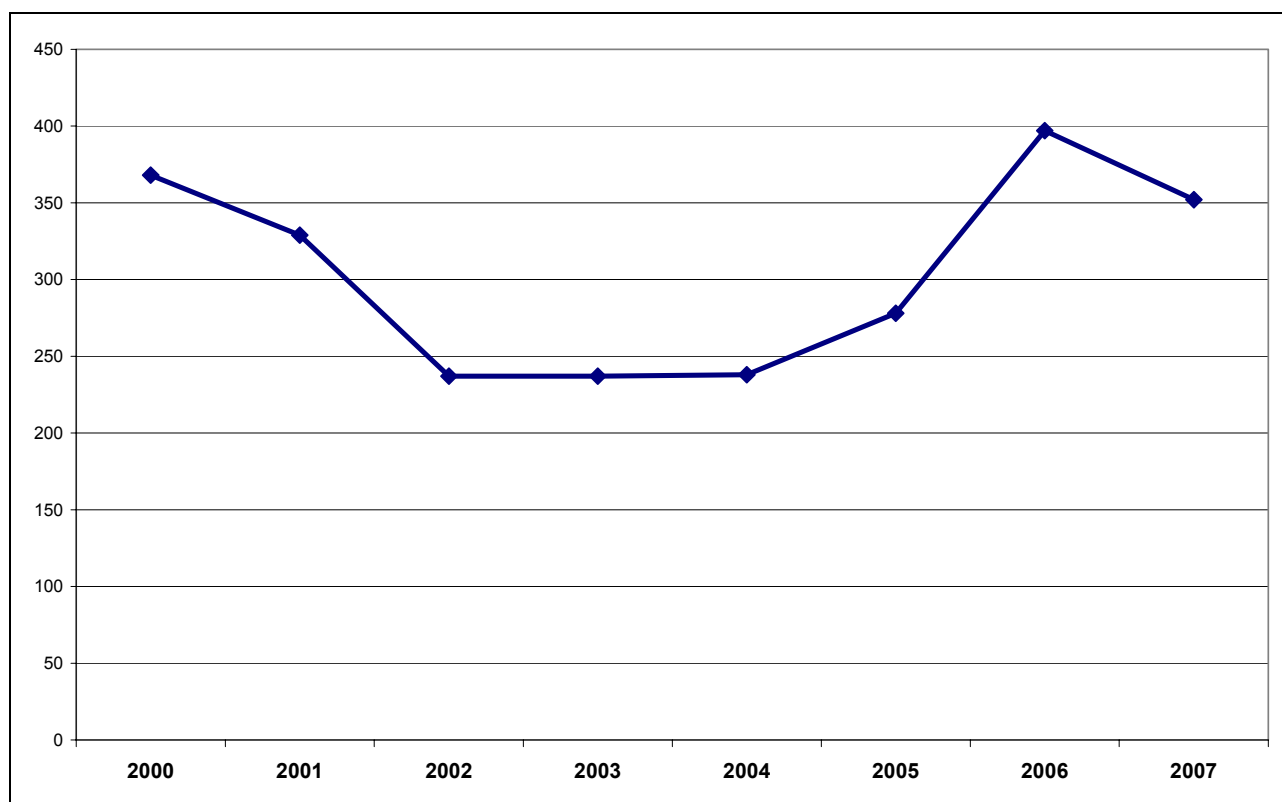
One way of abstracting the administrative factors from the intention to patent in a country is by analysing the change in applications for biotechnology patents. It should not be forgotten, however, that this data, although closer in time to the invention itself (because however rapid the process, it is rarely completed in under a year), does not provide such accurate information as an analysis of the patents granted, since many applications are turned down for a variety of reasons.

Similarly, a relation over time cannot be established between the applications and the patents granted, given that the evaluation and concession process can take a period of time which varies considerably, depending on factors such as the specific topic of the patent, its

complexity and the availability of experts in the matter at the registration body at any given time.

Diagram 17 shows the changes in biotechnology patent applications presented to the INPI between 2000 and 2007. A marked descent can be observed in the first two years, the causes of which are linked to the Argentine economic crisis of those years, which saw a fall in international interest in the local market and, therefore, the desire to protect inventions in the country in the hope of exploiting them commercially at a local level.

**Diagram 17. Biotechnology patent applications in Argentina**



Returning to the analysis of the biotechnology patents granted by the INPI in Argentina, the volume varied in relation to the total patents granted between 2000 and 2007. This information can be found in table 11, which shows that the titles in the field of biotechnology were on average 2.3%, with a maximum value of 4.2% in 2007 with 117 registrations granted, and a minimum of 0.7% in 2004 with just 6 patents.

**Table 11. Biotechnology patents granted in Argentina in relation to the total.**

	2000	2001	2002	2003	2004	2005	2006	2007
TOTAL GRANTED	1493	1232	914	1367	840	1798	2929	2769
BIOTECHNOLOGY	44	18	25	14	6	35	104	117
% BIOTECHNOLOGY	2.9%	1.5%	2.7%	1.0%	0.7%	1.9%	3.6%	4.2%

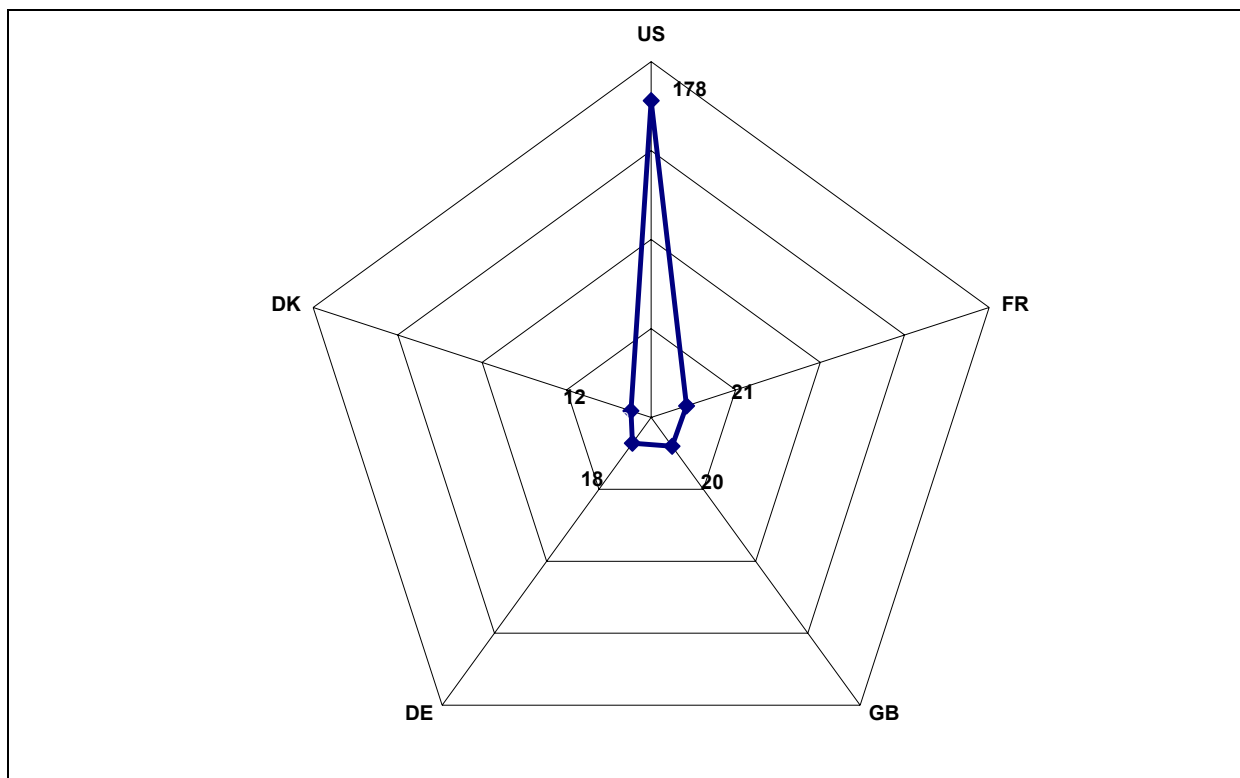
Among the owners of biotechnology patents granted in Argentina, the proportion of non-residents is much greater than that of residents, as can be seen in diagram 16 and table 12. On average, 89% of the owners of Argentine biotechnology patents between 2000 and 2007 were non-residents in the country.

**Table 12. Patents granted in Argentina to residents and non-residents in the country.**

	2000	2001	2002	2003	2004	2005	2006	2007	Total
RESIDENTS	2	0	4	2	1	5	12	18	44
NON-RESIDENTS	42	18	21	12	5	30	92	99	319
<b>TOTAL</b>	<b>44</b>	<b>18</b>	<b>25</b>	<b>14</b>	<b>6</b>	<b>35</b>	<b>104</b>	<b>107</b>	<b>353</b>

Looking in greater depth at the biotechnology patents granted to non-residents, diagram 8 gives the number of documents registered in Argentina under the ownership of each of the top five countries between 2000 and 2007. By a wide margin, the United States takes first place with 178 registrations, followed by France with 21 and Great Britain with 20. Then come Germany and Denmark, with 18 and 12 respectively.

**Diagram 18. Biotechnology patents granted in Argentina to non-residents, according to nationality of the owner**



The remaining MERCOSUR countries are practically absent among non-residents in Argentina. Only four patents were requested from owners from the other countries in the bloc between 2000 and 2007, representing 0.4% of the total applications presented by non-residents in the country. Of those patents, three were presented under Brazilian ownership and one under Uruguayan ownership. However, none of them has been granted to date.

The list of owners with the highest number of patents obtained in Argentina between 2000 and 2007 is shown in table 13. These are all international companies, with a pronounced bias towards the pharmaceutical industry, among which Eli Lilly and Pfizer stand out. There are also companies dedicated to manufacturing biotechnological products, such as Novozymes and Genentech. The list also includes the specialised agrochemicals division of French company Rhone-Poulenc.

**Table 13. First ten owners of biotechnology patents granted by the INPI (accumulated 2000-2007)**

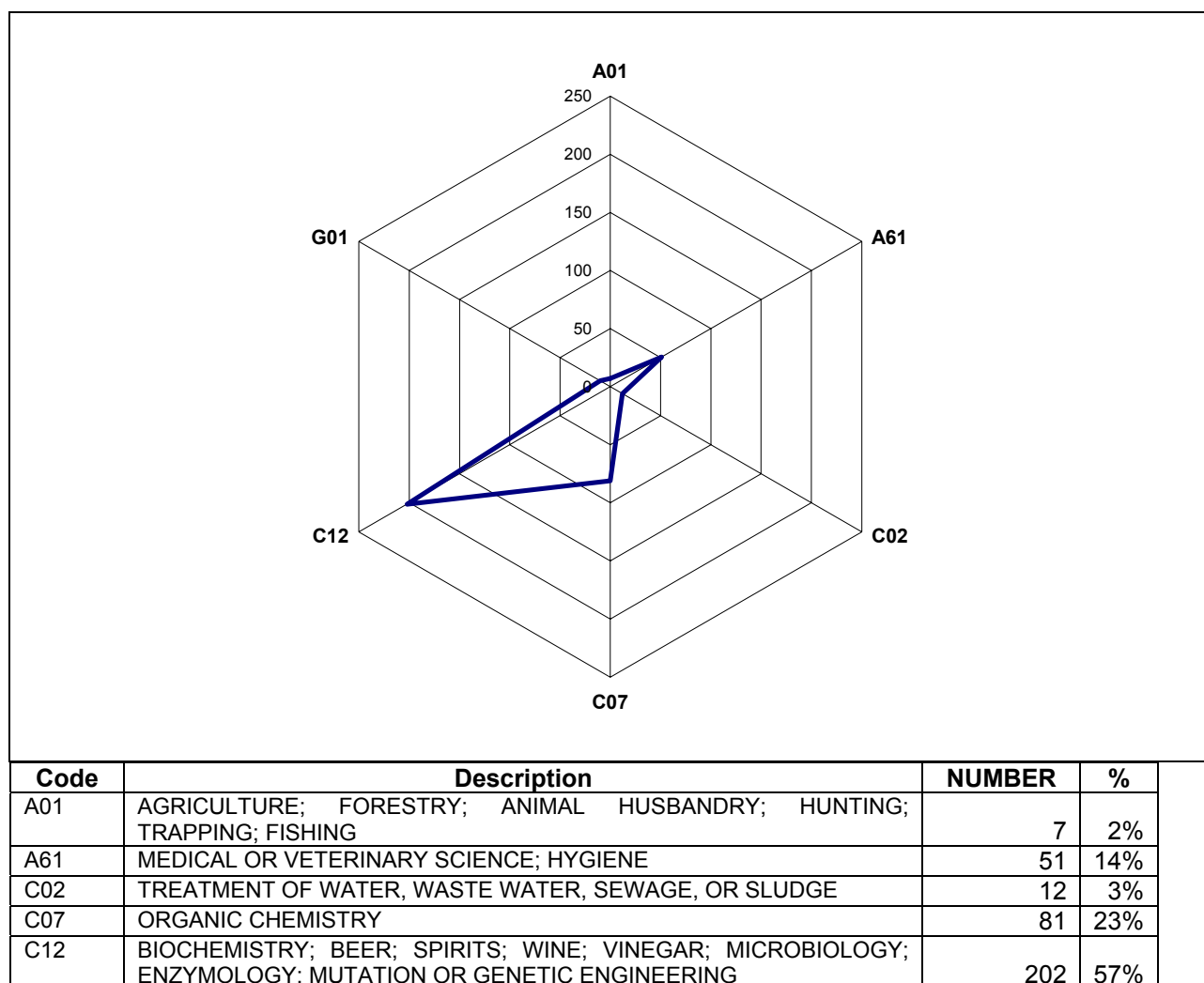
OWNER	NUMBER
ELI LILLY AND COMPANY	10
NOVOZYMES	10
GENENTECH, INC.	8
PFIZER PRODUCTS INC.	7
WYETH	7

BAYER CORPORATION	6
F. HOFFMANN-LA ROCHE AG.	6
RHONE-POULENC AGROCHIMIE	6
MERCK & CO., INC.	5
ROCHE DIAGNOSTICS GMBH	5

As an approximation to the fields of application of the total number of patents granted by the Argentine INPI in the area of biotechnology between 2000 and 2007, diagram 19 gives the distribution of documents according to their three-digit IPC classification, considering the six relevant fields in defining a biotechnology patent used in this report.

The classification with the greatest volume is C12 (Biochemistry...), which has a total of 202 documents granted throughout the period 2000-2007. In second place is position C07 (Organic chemistry...), with 81 documents equivalent to 23% of the total. Classification A61 (Medical or veterinary science...) has a volume of 14% of the total of patents granted, while the remaining classifications do not exceed 3% of the total.

**Diagram 19. Distribution by IPC codes of the biotechnology patents granted in Argentina (accumulated 2000-2007)**



G01	MEASURING; TESTING	10	3%
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Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

## 2.2 Brazil

In Brazil, the body entrusted with the registration of industrial property is the National Institute of Industrial property (INPI), an office of the Ministry of Development, Industry and Foreign Trade. It was set up in 1970, under Law N° 5,648, in the midst of Brazil's industrialisation process.

Its responsibilities include the registration of trademarks, the granting of patents, the validation of technology transfer contracts and company franchises, as well as the registration of software, industrial designs and geographical information. Its actions are endorsed by the industrial property laws (N° 9,279/96) and software law (N° 9,609/98).

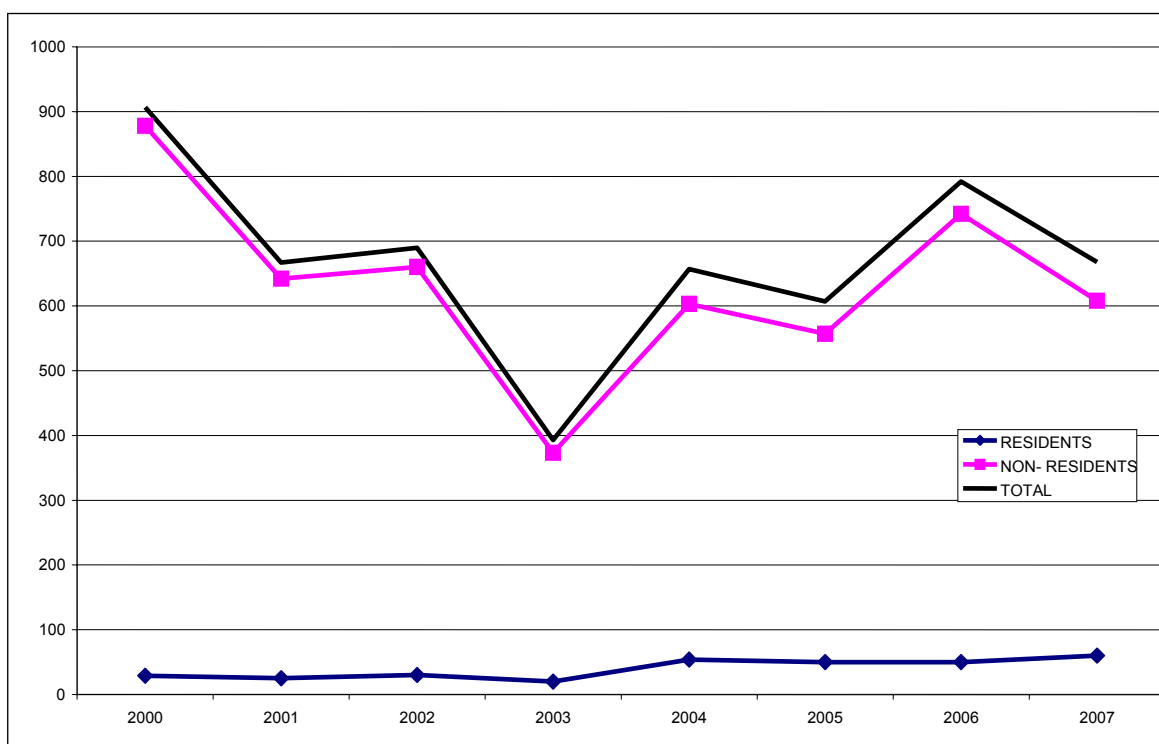
Within the INPI, the Directorate of Patents is responsible for assessing and granting industrial property rights. Its main functions are:

- To coordinate, supervise, accompany and promote the enforcement of projects, agreements and treaties on patents.
- To analyse, decide on and grant patent rights on the basis of the legislation in force.
- To participate in activities with other organisations, companies or entities with the aim of giving Brazil greater participation in the protection of intellectual property systems.

In the area of biotechnology, a total of 5381 patents were granted in Brazil between 2000 and 2007. As in Argentina, the volume of patents granted per year fluctuates in relation to the average time taken by the INPI between the presentation and granting of the patents. The catalogue of biotechnology patents granted by the INPI of Brazil is in Annex 6 of this report.

Diagram 20 shows the total evolution in the number of biotechnology patents granted in Brazil, with the disaggregation of those granted to residents and non-residents. Although the fluctuations mentioned are clearly visible, the general trend is downwards, given that the year of greatest volume recorded is the first in the series, with 907 patents granted.

**Diagram 20. Biotechnology patents granted in Brazil**



In comparison with the number of patents granted yearly, the total number of biotechnological registers reached an average of 8.4%. The highest point of the series with 11.2% was in 2006, while the lowest relative volume, with just 3.9%, was in 2003. This information is found in table 14.

**Table 14. Biotechnology patents granted in Brazil in relation to the total.**

	2000	2001	2002	2003	2004	2005	2006
TOTALS GRANTED	9259	7576	8864	10184	7047	7720	7096
BIOTECHNOLOGY	907	667	690	393	657	607	792
% BIOTECHNOLOGY	9.8%	8.8%	7.8%	3.9%	9.3%	7.9%	11.2%

These values are much lower, both in volume and in their relation with the total patents granted, which in the case of Argentina, where the average of biotechnology patents was just over 2% of the total, reached a maximum value of 4.2%.

Table 15 and diagram 20 give a breakdown of the number of registrations granted to residents and non-residents in Brazil. The total average gives 94% of ownership for non-residents,

although the percentage has tended to decline, since it was equivalent to 97% in 2000, while in 2007 the patents granted to non-residents was 91%.

**Table 15. Patents granted in Brazil to residents and non-residents in the country.**

	2000	2001	2002	2003	2004	2005	2006	2007	TOTAL
RESIDENTS	29	25	30	20	54	50	50	60	318
NON-RESIDENTS	878	642	660	373	603	557	742	608	5063
TOTAL	907	667	690	393	657	607	792	668	5381

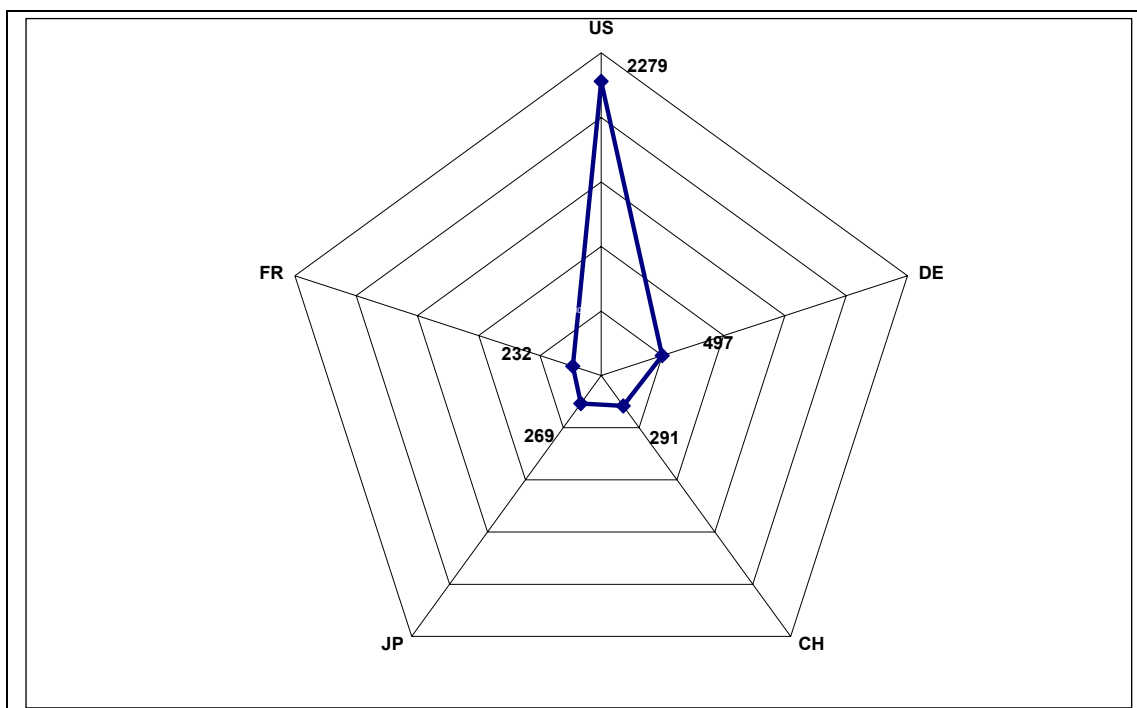
As in Argentina (see diagram 21), the main owner of Brazilian biotechnology patents is the United States, with a total of 2,279 registrations accumulated between 2000 and 2007. Germany takes second place with 497, third place goes to Switzerland, with 291, and fourth to Japan, with 269. In fifth place is France with a total of 232 patents obtained.

As regards the presence of the other MERCOSUR countries, Brazilian patents have only been granted to owners from Argentina and Uruguay. Argentine owners have a total of 17 patents, among which the CONICET, the Universidad Nacional del Litoral and the BIOCERES company stand out, with two patents each. In the case of Uruguay, owners have four patents, i.e. the SALINBAR company has one while the others were assigned to natural persons.

**Table 16. Patents granted in Brazil to owners of MERCOSUR countries.**

	2000	2001	2002	2003	2004	2005	2006	2007	TOTAL
ARGENTINA	3	2	3	0	4	1	2	2	17
URUGUAY	0	0	2	0	2	0	0	0	4

**Diagram 21. Biotechnology patents granted in Brazil to non-residents, according to the nationality of the owner**



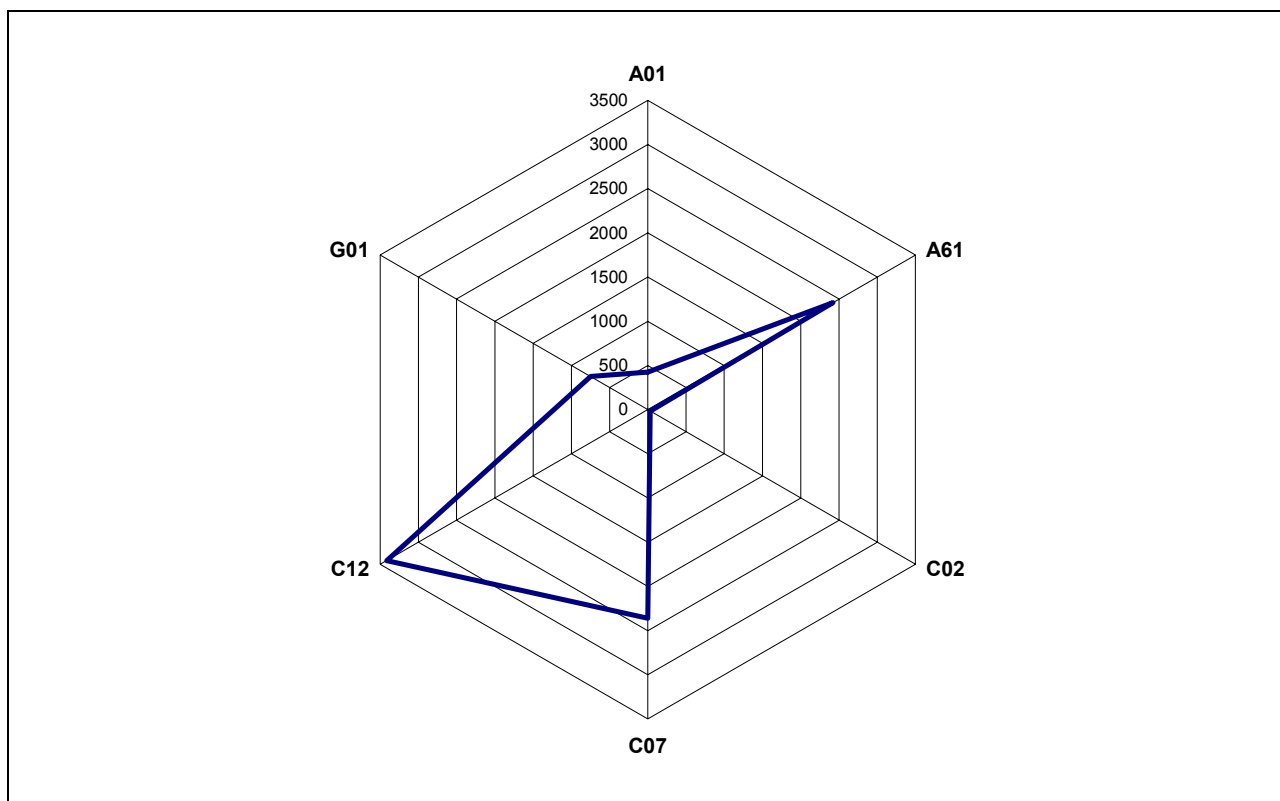
In the case of Brazil, the list of the ten owners with the highest number of patents is less biased towards the pharmaceutical industry than in Argentina. The company which boasts the highest number of patents granted is AJINOMOTO, a company of Japanese origin whose principal activity is the food industry. The second in volume, with 48 documents accumulated between 2000 and 2007, is the agricultural biotechnology firm MONSANTO, followed by Du Pont, with 47.

**Table 17. First ten owners of biotechnology patents granted by the INPI (accumulated 2000-2007)**

OWNER	NUMBER
AJINOMOTO CO.	80
MONSANTO TECHNOLOGY LLC	48
E.I. DU PONT DE NEMOURS AND COMPANY	47
F. HOFFMANN-LA ROCHE AG	46
NOVARTIS AG	45
WYETH	45
BASF AKTIENGESELLSCHAFT	40
THE PROCTER & GAMBLE COMPANY	34
ELI LILLY AND COMPANY	33
NOVO NORDISK	31

As regards the distribution of patents granted in the area of biotechnology in Brazil according to the three-digit IPC classification, the accumulated total between 2000 and 2007 shows a strong concentration in the group C12 (Biochemistry...), with 3415 patents, equivalent to 63%. The detail of that information, considering the six relevant fields in defining a biotechnology patent, is in diagram 22.

**Diagram 22. Distribution by IPC codes of the biotechnology patents granted in Brazil (accumulated 2000-2007)**



Code	Description	NUMBER	%
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	426	8%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	2421	45%
C02	TREATMENT OF WATER, WASTE WATER, SEWAGE, OR SLUDGE	31	1%
C07	ORGANIC CHEMISTRY	2358	44%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	3415	63%
G01	MEASURING; TESTING	747	14%

Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

With similar accumulated volumes, the patents grouped together under the classifications A61 (Medical or veterinary science...) and C07 (Organic chemistry...) account for nearly 45% of the total each. It is important to bear in mind that the multiple classifications assigned to each patent have been considered, so the sum of the three-digit disaggregations is greater than the total.

## 2.3. Paraguay

In Paraguay, intellectual property management is the responsibility of the Ministry of Industry and Commerce (MIC), and specifically the General Directorate of Intellectual Property (Dirección General de Propiedad Intelectual, DGPI). This is reflected in the mission of the ministry:

*“To lead the sustainable development process; to establish clear policies, designed to strengthen the industrial, commercial and service sector, to foster the economic reconversion of the country with a view to harmonising the interests of the various production sectors, facilitating the distribution, circulation and consumption of goods of national origin and to promote domestic and foreign trade in a framework of free competition, fostering fair trading practices and protecting the rights of the consumer and intellectual property”.*

Specifically, the General Directorate of Intellectual Property (DGPI) is responsible for issues of industrial property. Its objectives are:

- To guarantee the correct administration of the national copyright and related rights systems, as well as of industrial property system.
- To promote and foster intellectual creation, both in its literary, artistic or scientific form, and in the field of industrial application, as well as disseminating technological knowledge within the cultural and productive sectors.
- To advise and participate in the formulation of national policies in all those matters which have to do with the protection of intellectual property and in other related areas.
- To promote initiatives and develop activities conducive to a better knowledge and improved protection of industrial property nationally.

The legal intellectual property framework in force in Paraguay is based mainly on three laws:

- Law N° 1294 of Trademarks of 6 August 1998 and Decree N° 22,365 of 14 August 1998 by which the Law of Trademarks is regulated;
- Law N° 1328 of Copyright and Similar Rights of 15 October 1998 and Decree 5159, of 13 September 1999, by which the law is regulated;
- Law N° 1630 of Invention Patents of 29 November 2000 and Law 2047/02 of 19 December 2002, modifying the transitory provisions of art.90 (“Concerning the entry into force for pharmaceutical products”), of said Law 1630 /00.

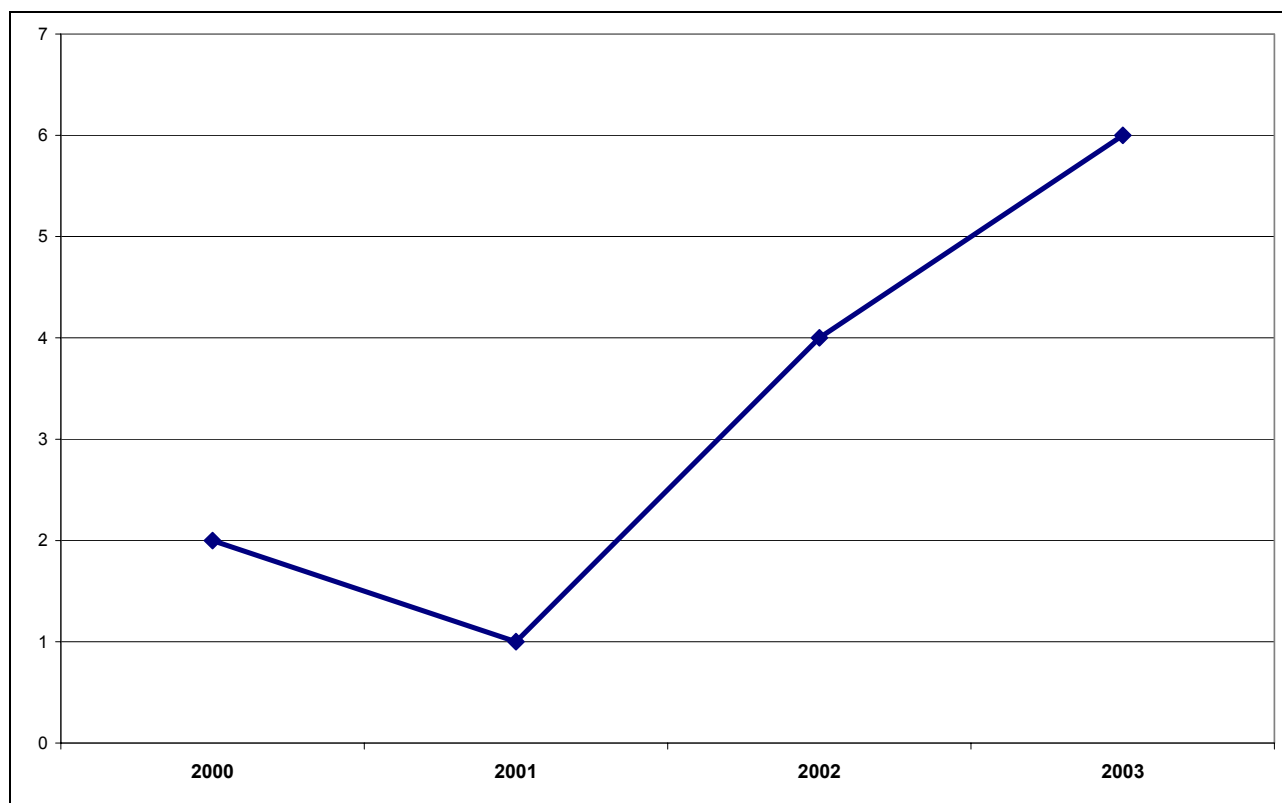
As for international agreements, Paraguay ratified the Uruguay Round agreements, including TRIPS, in 1994, under Law 444/94. The new legislation in matters of patents, trademarks and copyright seeks to comply with this regulation. In August 2000, it also ratified the World Intellectual Property Organisation (WIPO) Copyright Treaty (Law 1582), and the World Intellectual Property Organisation (WIPO) Performances and Phonograms Treaty.

The Law of Investments and Patents, N° 1630, was specifically enacted on 28 November 2000, and came into force on 29 January 2001. The object of the new law is to grant rights and obligations to authors of invention patents and utility model patents. These rights are granted through the industrial property document granted by the Directorate of Industrial Property.

The new legislation covers all aspects related to invention patents and utility models, having as a source comparative law and the most modern legislations and conventions on the matter, especially the Trade-Related Aspects of Intellectual Property Rights (TRIPS), included in the Final Act of the GATT Uruguay Round, ratified by Paraguay under Law N° 444/94 mentioned above.

It is important to note that the volume of patents granted in Paraguay is very low, as seen in table 18. However, in recent years the number of patents granted annually has been even lower. Only thirteen biotechnology patents were granted between 2000 and 2007, all of them before 2004. The catalogue of the biotechnology patents granted by the DGPI is in Annex 7 of this report. That information appears in diagram 23.

**Diagram 23. Biotechnology patents granted in Paraguay**



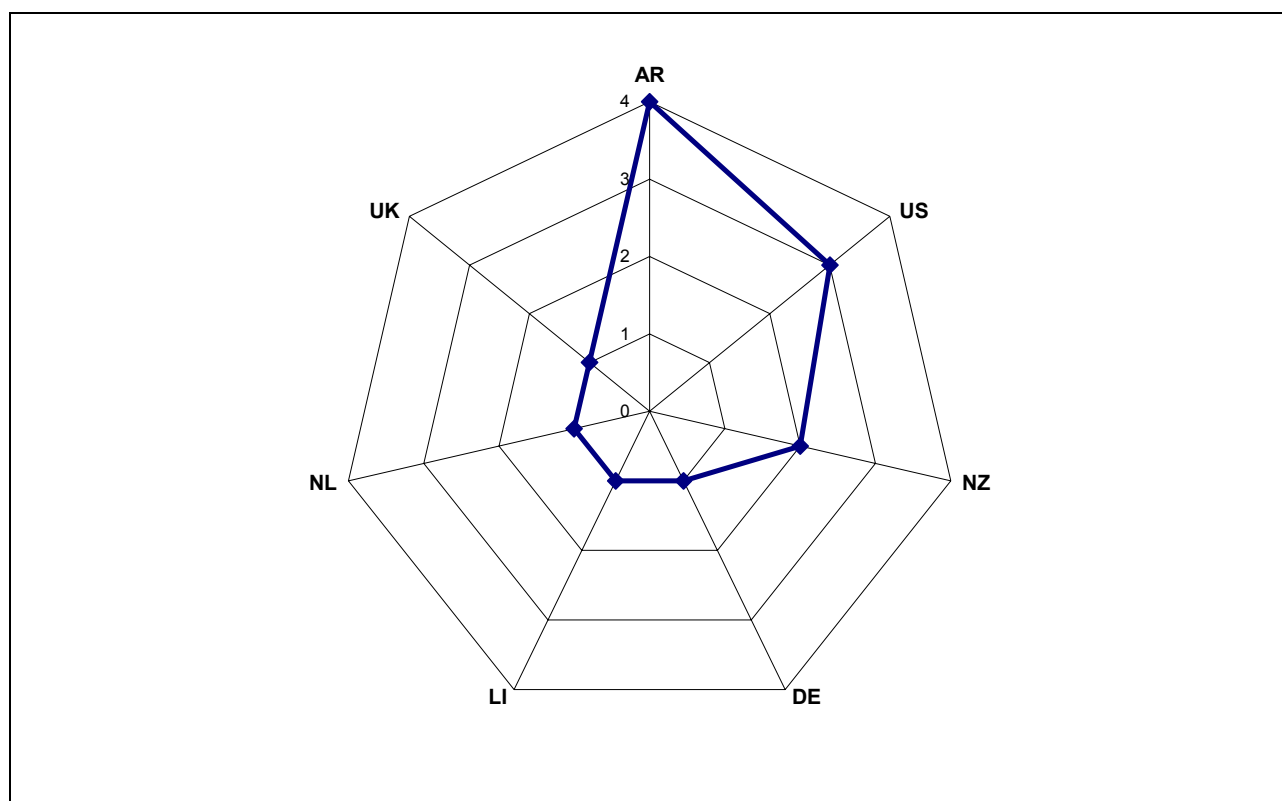
Moreover, as this is such a low number, the percentage of biotechnology patents is very variable. It reaches a maximum in 2003, when six biotechnology patents accounted for 10% of the total number of patents.

**Table 18. Biotechnology patents granted in Paraguay in relation to the total.**

	2000	2001	2002	2003	2004
GRANTED TOTALS	83	90	92	60	11
BIOTECHNOLOGY	2	1	4	6	0
% BIOTECHNOLOGY	2.4%	1.1%	4.3%	10.0%	0.0%

Similarly, all the patents granted in Paraguay in the area of biotechnology have non-residents as owners. A disaggregation of the patents granted by country of owner appears in diagram 24.

**Diagram 24. Biotechnology patents granted in Paraguay to non-residents, by nationality of owner**



Unlike the situation in the remaining MERCOSUR countries, the principal owner of patents is a country from the same economic bloc: Argentina. They are four patents, three of which belong to the BIOSIDUS company. The remaining one, granted in 2003, is under the ownership of the Instituto Nacional de Tecnología Agropecuaria (INTA). It should be remarked however that no patents appear with participation by owners from any of the other countries in the bloc.

Patents of US owners appear in second place, with a total of three. New Zealand has two patents, while Germany, Liechtenstein, the Netherlands and the United Kingdom complete the list with one each.

In addition to the Argentine BIOSIDUS company, the New Zealand company Genesis Research also appears in the list of owners of biotechnology patents granted in Paraguay with the ownership of two documents, one of them granted in the year 2000 and the other in 2003. The remaining owners have only one register obtained under their ownership. The complete list of owners of biotechnology patents granted in Paraguay can be seen in table 19.

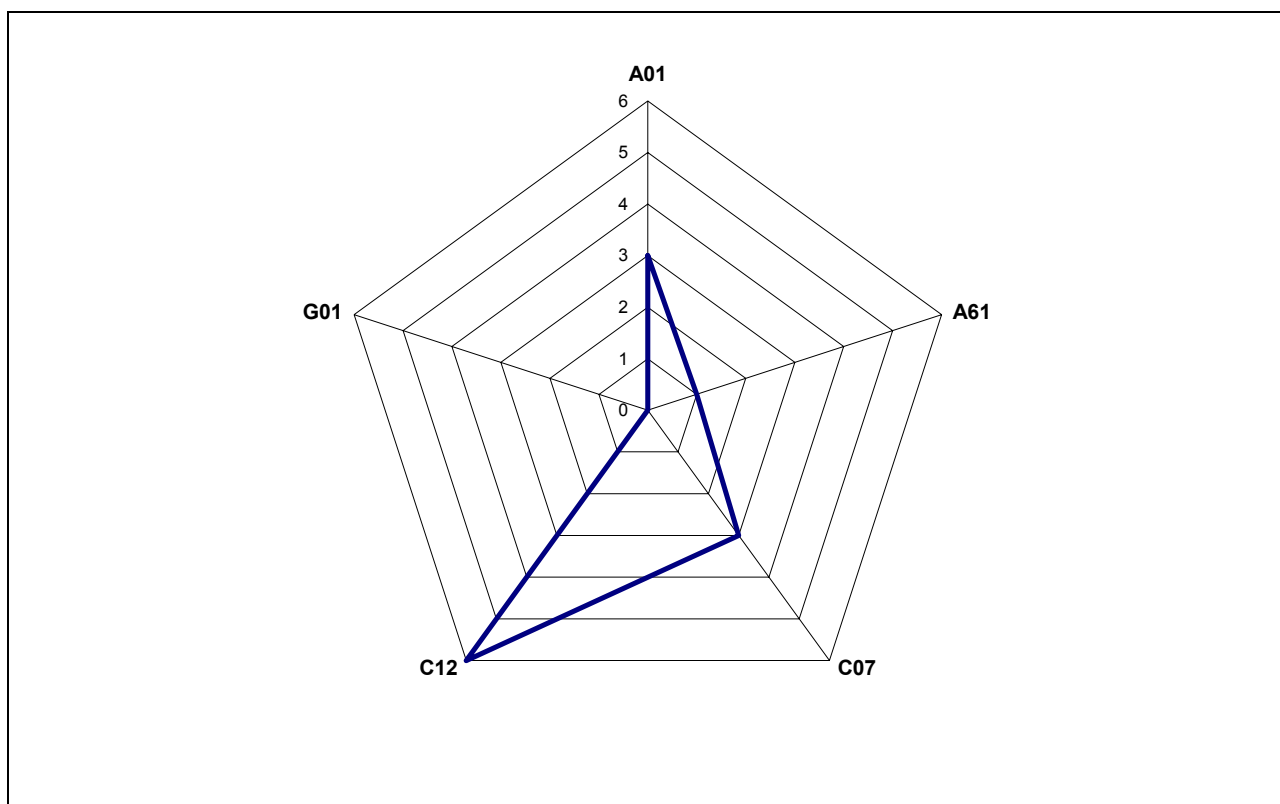
**Table 19. Owners of biotechnology patents granted by the DGPI (accumulated 2000-2007)**

Owner	Number
Bio Sidus S.A	3
Genesis Research & Development Corporation Limited	2
Midwest Oilseeds INC.	1
Ecogen INC.	1
Nika Health Products Limited	1
Instituto Nacional de Tecnología Agrícola	1
Immunex Corporation	1
Grunenthal GMBH	1
Zeneca Limited	1
Mogen International N.V.	1

As an approximation to the fields of application of the total number of biotechnology patents granted by the Paraguayan DGPI between 2000 and 2007, diagram 25 gives the distribution of the documents according to their three-digit IPC classification.

The classification of greatest volume is C12 (Biochemistry...), with a total of 6 of the patents granted, representing 46% of the documents accumulated throughout the period 2000-2007. With three patents each, the equivalent to 23% of the total, come categories A01 (Agriculture...) and C07 (Organic chemistry...). Only one of the documents is classified under category A61 (Medical or veterinary science...).

**Diagram 25. Distribution by IPC codes of biotechnology patents granted in Paraguay (accumulated 2000-2007)**



Code	Description	NUMBER	%
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	3	23%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	1	8%
C07	ORGANIC CHEMISTRY	3	23%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	6	46%
G01	MEASURING; TESTING	0	0%

Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

## 2.4. Uruguay

In Uruguay, all activity concerning industrial property is the responsibility of the National Directorate of Industrial Property (Dirección Nacional de la Propiedad Industrial, DNPI), an office of the Ministry of Industry, Energy and Mining. The legal framework that regulates its activity includes:

- The Law of Trademarks N° 17,011, sanctioned in 1998, which includes the figures of licensing of trademarks, pledge on industrial trademarks, attachments, advertising slogans, collective brands and certification brands or guarantee.
- The Law of Patents N° 17,164, sanctioned in 1999, which substituted the former regulation on patents, adapting it to the international obligations contracted as of the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

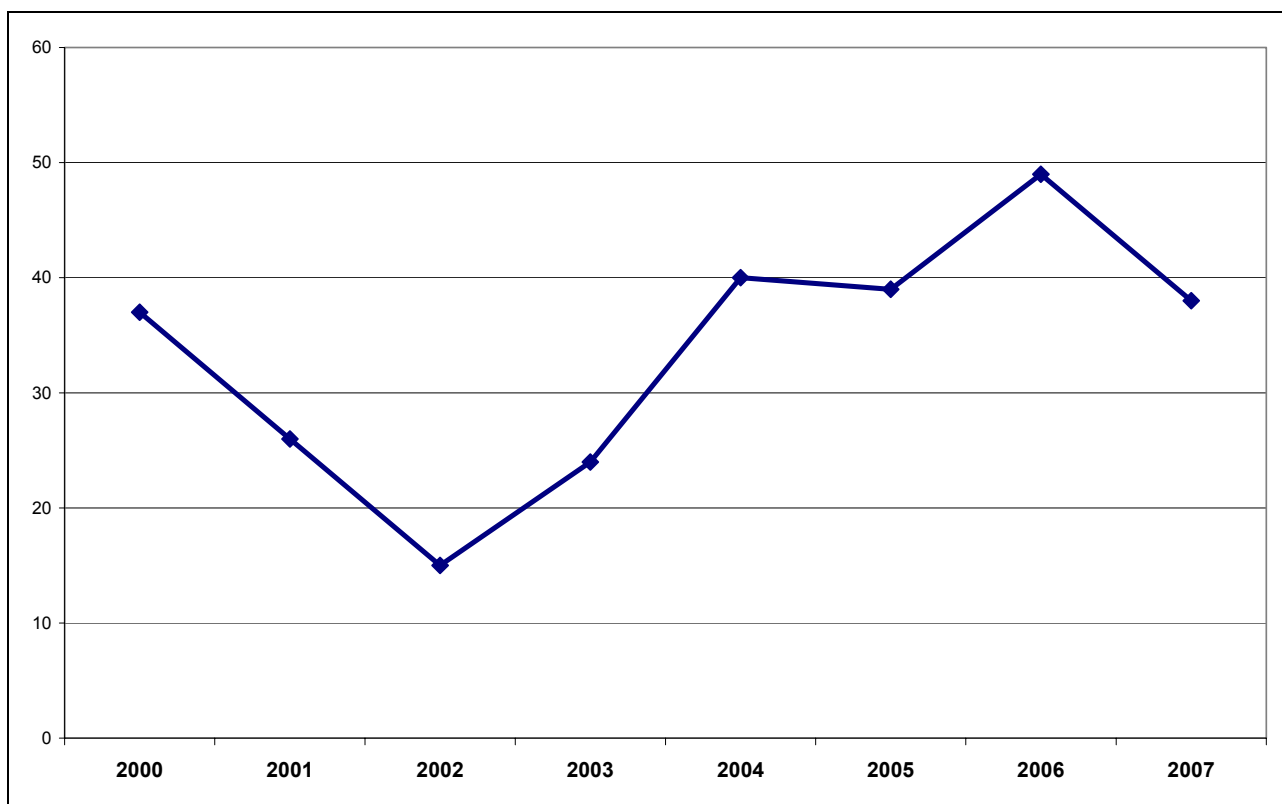
The total volume of patents granted by the DNPI has been falling since the year 2000 and, on average, 74 patents were granted per year between 2000 and 2005. In that context, only four biotechnology patents granted between 2000 and 2007 were detected, two of them in 2001 and two more in 2002. The catalogue of biotechnology patents granted by the DNPI can be seen in Annex 8 of this report. That information is summarised in table 20.

**Table 20. Biotechnology patents granted in Uruguay in relation to the total.**

	2000	2001	2002	2003	2004	2005
TOTAL GRANTED	134	80	51	72	83	24
BIOTECHNOLOGY	0	2	2	0	0	0
% BIOTECHNOLOGY	0.00%	2.50%	3.92%	0.00%	0.00%	0.00%

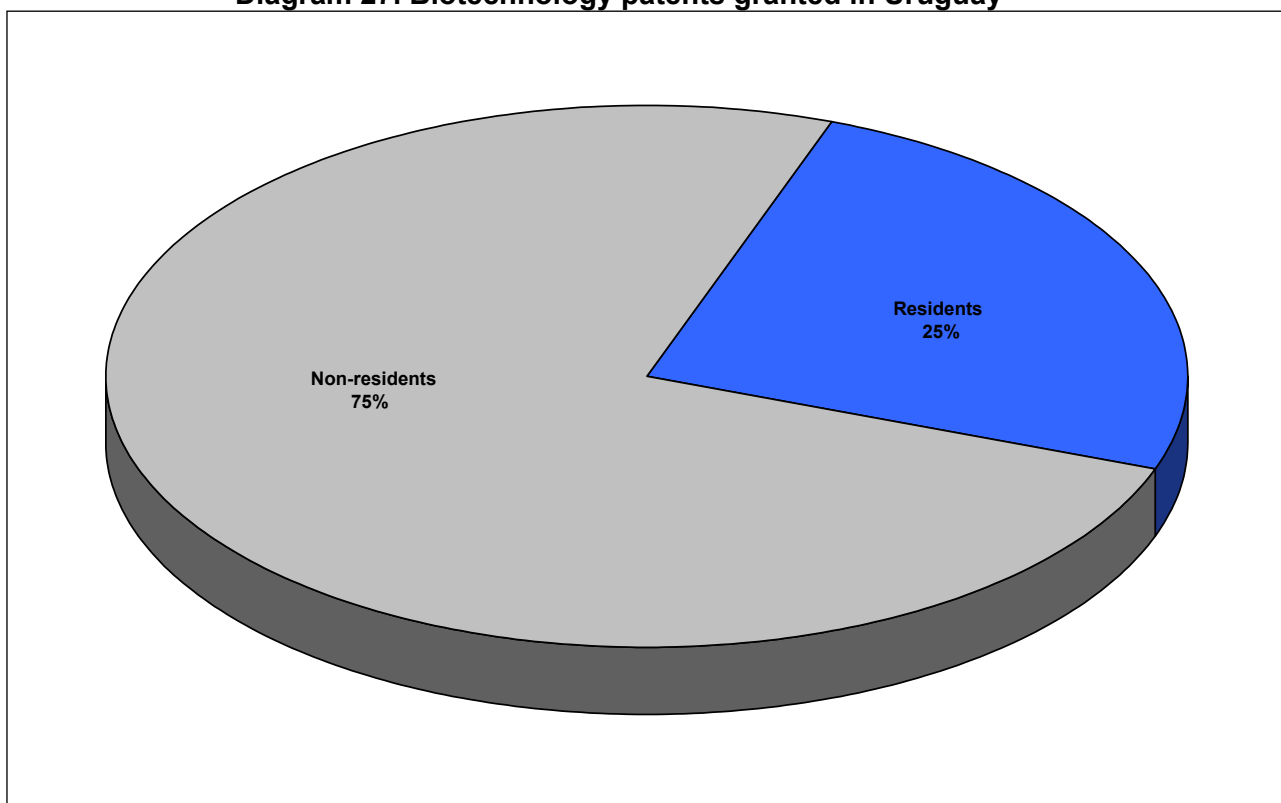
There were also few applications for biotechnology patents between 2000 and 2007, with an average close to thirty a year. As shown in diagram 26, the number of applications fell until 2002, when they reached their lowest point with 15 patent applications. Then a recovery in the series took place until 2006, when the highest number of applications was made, with 49 documents. However, the rhythm at which patents are granted is extremely slow, even outside the field of biotechnology.

**Diagram 26. Biotechnology patent applications in Uruguay**



Of the four biotechnology patents granted by the Uruguayan DNPI between 2000 and 2007, only one belongs to Uruguayan owners. It is a document related to organic chemistry and granted under the ownership of three natural persons: Alfonso Cayota Guzikovsky, Carlos Alberto Robello Porto and Otto Franz Pritsch Albisu. As can be observed in diagram 27, the remaining patents, equivalent to 75% of the total, were granted under the ownership of non-residents in Uruguay.

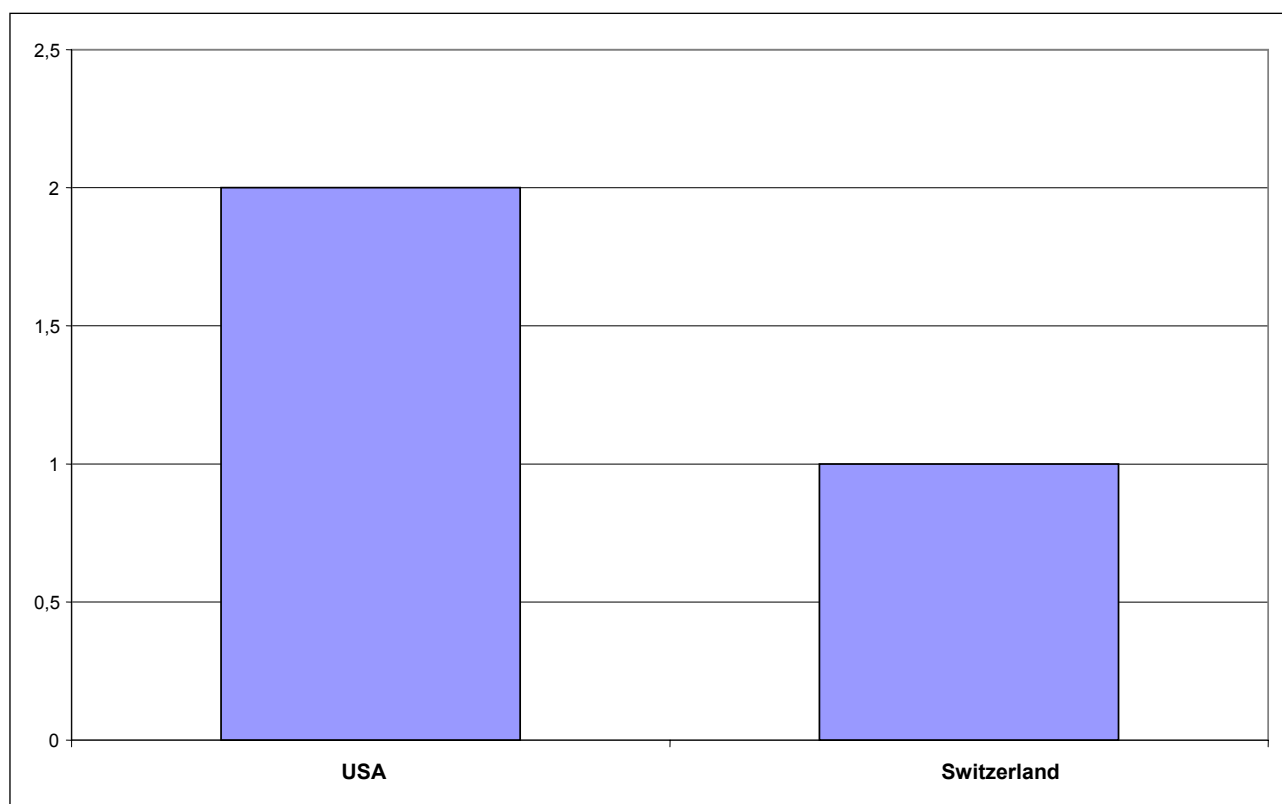
**Diagram 27. Biotechnology patents granted in Uruguay**



Of the three patents granted to non-residents, two are under the ownership of US companies. One of them, granted in 2001, belongs to the IMMUNEX company, dedicated to the production of pharmaceutical products and whose main activity concerns cancer treatment. The other patent under US ownership was granted in 2002 to GENETICS INSTITUTE, a company which is also active in the pharmaceutical industry.

The remaining title was granted under Swiss ownership, in 2001. It is a patent for the NOVARTIS company, which is also active in drug production. This information is summarised in diagram 28.

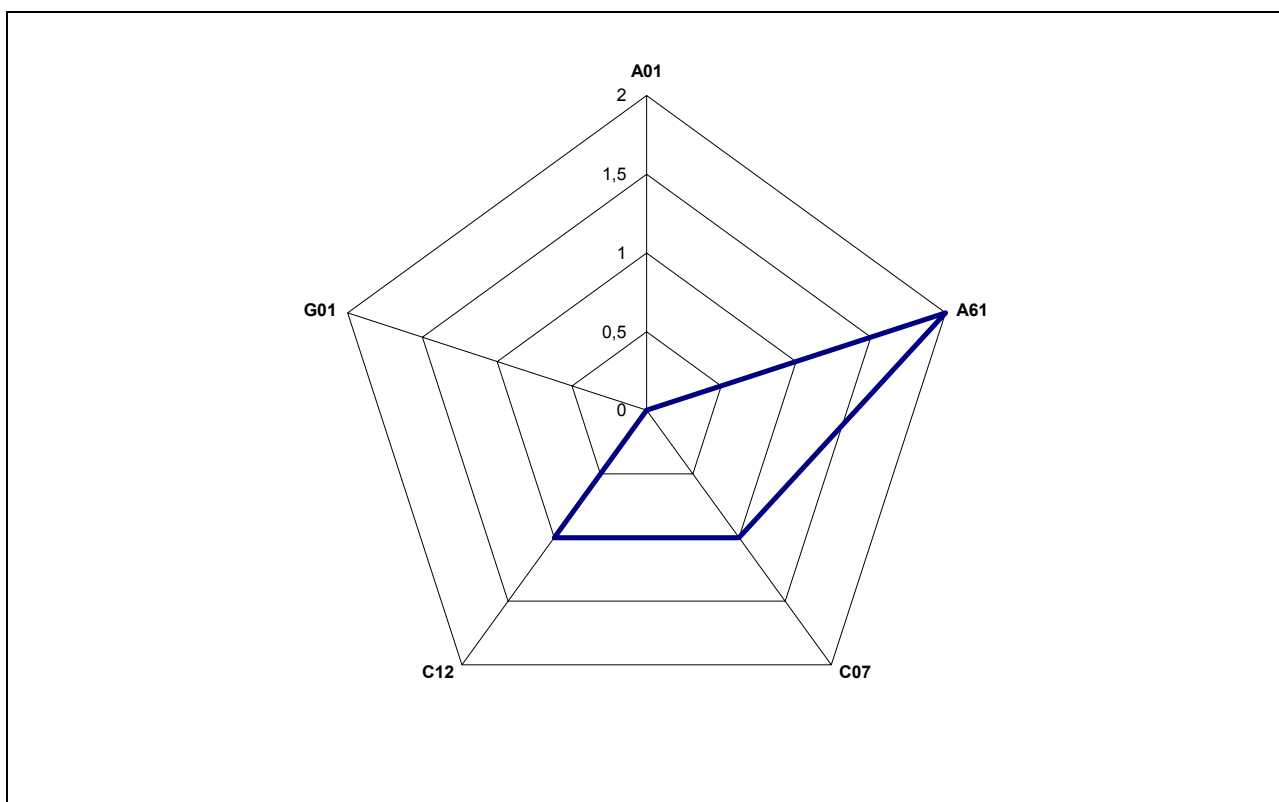
**Diagram 28. Biotechnology patents granted in Uruguay to non-residents, by nationality of owner**



By making an analysis similar to that made in the other sources, diagram 29 shows the distribution of the biotechnology patents granted in Uruguay between 2000 and 2007, according to the three-digit IPC classification.

Corresponding with the above description of the company which own the patents granted by the DNPI, two were classified under category A61 (Medical or veterinary science...), and the other two were in category C07 (Organic chemistry...) and C12 (Biochemistry...).

**Diagram 29. Distribution by IPC codes of biotechnology patents granted in Uruguay (accumulated 2000-2007)**



Code	Description	NUMBER	%
A01	AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING	0	0%
A61	MEDICAL OR VETERINARY SCIENCE; HYGIENE	2	50%
C07	ORGANIC CHEMISTRY	1	25%
C12	BIOCHEMISTRY; BEER; SPIRITS; WINE; VINEGAR; MICROBIOLOGY; ENZYMOLOGY; MUTATION OR GENETIC ENGINEERING	1	25%
G01	MEASURING; TESTING	0	0%

Note: Since patents can have more than one IPC code, the sum of the percentages is greater than 100%.

### **3. Final comments**

This analysis offers a detailed overview of the growth in patenting in the field of biotechnology internationally and in particular in the MERCOSUR countries. The results reveal that this is a field which is strongly consolidated around the world and in which a great number of patents are granted with the most diverse fields of application. For a true dimension of the phenomenon, it should be noted that in 2007 WIPO published almost eight thousand patents processed under the PCT convention.

However, although the patents offer a privileged approximation to the dynamics of technological development, it is important to bear in mind that bureaucratic, legislative and regulatory factors have a strong direct impact on the results obtained. By way of example, mention can be made of the recovery in biotechnology patents in the USPTO over recent years, linked to a change in what an invention for potential patenting is considered to be. Although this may have an effect on future decisions on R+D activities, in view of the possibility of commercially exploiting the inventions, the initial growth is not related to changes in the dynamic of knowledge production. Another example within the MERCOSUR is the growth in the number of patents granted in Argentina as a consequence of an increase in the efficiency of the INPI.

It is therefore very important to be clear as to the characteristics of each source in order to interpret the results obtained. An initial review of the biotechnology patents in the main international databases (USPTO, EPO and WIPO) can thus offer an overview of cutting-edge developments in MERCOSUR countries. Given that the presentation and maintenance of patents in these offices is costly in economic and management terms, only those inventions with a certain economic potential are registered there.

MERCOSUR presence in all these sources is very limited, especially in the European office, where only six patents were granted with the participation of owners from the South American bloc between 2000 and 2007. Even among the four member countries there are very varied levels of development, which is reflected in the number of patents obtained.

To illustrate this phenomenon, if the 93 countries that participate in the ownership of biotechnology patents published by the WIPO between 2000 and 2007 are placed in order, Brazil appears in position 27, Argentina in 44 and Uruguay in 61, while no documents of Paraguayan ownership were published. Similarly, although the level of participation of MERCOSUR countries varies, it cannot be ignored that the ownership of biotechnology patents is heavily concentrated: in the catalogue of WIPO patents, the first ten countries concentrate over 90% of total patents.

The characteristics of the patents registered in each of the industrial property offices of the MERCOSUR countries have also been analysed. This approach is very useful in observing inventions with economic expectations at a local level and, principally, the interest of large international biotechnological companies in the markets of member countries.

Here the comparative panoramas of the MERCOSUR countries diverge. Principally in Brazil, but also to a certain extent in Argentina, a considerable volume of biotechnology patents may have an impact in the production of biotechnological goods and services, as well as in the market for them. In both cases the presence of foreign owners is overwhelming, exceeding 90% of patents, and the specific fields that these documents cover, measured by means of the IPC classification, are comparable. The patents registered in the property offices bear witness

to the protection of knowledge which is the property of international companies for its commercialisation in markets with certain potential. In all cases, the role of the pharmaceutical industry in these processes is very important.

In Paraguay and Uruguay, in contrast, the number of biotechnology patents granted is so low that the critical mass needed for their impact in innovation and the market to become significant does not exist. Likewise, the patterns observed in those documents vary when compared to the largest countries in the bloc, both in the countries of origin of the owners and in their fields of application.

Finally, indications can be obtained on the characteristics of the industrial systems and those of innovation in these countries through the development of their industrial property offices, since they are a very important tool for the development of innovative industry based on the application of knowledge.

The bodies responsible for industrial property in the MERCOSUR have very different levels of development. That becomes apparent when considering the availability of the information they produce. Brazil is the only country of the bloc to offer public access to its patents database, which contains very valuable information for companies, inventors and researchers. Argentina is in a similar process, although its level of progress is much lower. In contrast, Paraguay and Uruguay have no digitalised databases, which not only restricts public access to information but it even makes access to data within the offices themselves less dynamic.

This level of development of industrial property systems which go beyond the characteristics of the legislation in force may also have a strong impact on the development possibilities and the incentives to innovation in the MERCOSUR countries.

# Characteristics of seed certification systems in MERCOSUR countries

## Introduction

Together with patents, the intellectual property regarding plant varieties is a very important variable in the development and application of biotechnology. Below is a description of the characteristics of the various seed certification systems in MERCOSUR countries and the particularities of genetically modified seeds in each one of them.

Before beginning with an analysis of each particular country, we believe it appropriate to make several general explanations as to the characteristics of seed certification systems. The seed sector is one of the strategic elements in the development of the biotechnology sector and its applications in agriculture. After all, the research work undertaken in incorporating new characteristics into a country's germplasm base serves for nothing if the appropriate instruments to ensure that those improvements effectively reach producers and are incorporated into production processes are then not available. The very nature of the innovative process in biotechnology –whether in terms of the creation of a useful living modified organism (LMO), or, perhaps, the improvement process assisted by molecular markers– brings with it the combination of two very different scientific tasks: a biotechnological phase and a phyto-improvement phase.

The biotechnological phase includes the development of the marker itself or the identification of the gene of interest and its insertion in a “prototype” plant. This should produce a tool (the marker and its methodology of application) for either a genetic event or the transformation of a gene that is useful in solving a serious agricultural problem from an economic point of view. The next step is the introgression of the gene in those crop varieties which have the commercial characteristics demanded by the market of interest. Once the biotechnological phase is successfully completed, an adapted cultivar is developed by using conventional phyto-improvement techniques. Farmers will not accept an LMO unless it is included in a genetic environment with acceptable yields. Winning the acceptance of farmers and access to improved, conventional or LMO varieties continues to be a relevant challenge in any crop and production situation. All this requires development in local phyto-improvement and an efficient competitive seed industry that has an appropriate institutional and legal framework for its development.

So the state system that certifies the quality and origin of seeds<sup>1</sup>, reliability in the enforcement mechanisms on intellectual property rights (plant breeder's rights in the case of seeds), etc. plays a strategic role.

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<sup>1</sup> In general terms, seed certification involves a direct official control process, by means of agreements with other public or private institutions. In seed production this process entails checking the origin of the seed to be sown; inspecting the production, harvesting, storing, packing and labelling. This proves that the content of the seed package matches the characteristics indicated on it. The quality control mechanism in seed production ensures the best expression of the qualities of the varieties developed and commercialised nationally.

Besides the institutional aspects, the seed markets are also strongly influenced by a series of aspects of a biological nature which fundamentally influence its functioning and which it is vital should be reflected in the regulatory frameworks adopted for them, since they affect very significantly the investment strategies of companies.<sup>2</sup> So for example, protection systems are not fundamentally important in crops such as maize, where the bulk of seeds are hybrids and the production obtained from previous harvests cannot be used as seed in future without seriously affecting yield levels, germination, vigour and production quality. In such cases, protection may in practice be effective, even in the absence of regulatory systems, through the industrial secrecy mechanism.

The opposite happens with soya or wheat varieties in which the production of previous years can be used as an input in future sowing of the species almost without affecting quality, at least in the first sowing exercises. These aspects have always been important for how markets function and have influenced the format of the regulatory frameworks –the need for a stronger protection framework for self-pollinating varieties (including wheat and soya) *vis-à-vis* the species in which hybrids are important, such as maize and sunflower– but they have become much more significant now in the face of the high costs of investment required by innovations based on biotechnological applications and the fact that in many cases some basic components are themselves subject to protection by patent.

Although many of the aspects covered by the relevant legislation reveal varying levels of updating in accordance with the conditions of society in general and of the market in particular, the drafting of regulations and their functioning in practice have generated great debate, particularly concerning their effectiveness as a mechanism for the recovery of investment in technological innovation. In fact, today core aspects of debate in the world in general, and in the MERCOSUR countries in particular, revolve around plant breeder's rights due to their great importance in the development of the seed market. Unlike remaining intellectual property rights, plant breeder's rights have been especially developed to protect plant varieties, particularly germplasm (or genetic information) and the plant variety resulting from the expression of all the genetic information contained in the seed. Due to its intrinsic and productive particularities, the enforcement and development of regulations require that specific aspects be addressed which in other kinds of patents are not necessary (Rapela, 2006: 136). Although important, this takes on an even more strategic sense with the appearance on the scene of genetically modified (transgenic) varieties, since they require coordination between legislation on patents and legislation on seeds, which does not seem easy to achieve in practice, particularly in the case of self-pollinating species.

Below is a summary of the main characteristics of the seed systems in the MERCOSUR countries, emphasizing in each case legal and organisational aspects (related to certification and control of the seed market) of the relevant government offices.

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<sup>2</sup> Las especies vegetales que tienen reproducción sexual (es decir, tienen órganos femeninos y masculinos de reproducción) pueden ser clasificadas en dos grandes grupos de acuerdo con su tipo de fecundación. Así, aquellas especies que se autofecundan se las conoce como **autógamas** y las que requieren de otro individuo (porque no pueden autofecundarse) se las denomina **alógamas**. Debido a que las variedades autógamas no intercambian información genética con otros individuos, su producción (granos) puede ser utilizada como simiente, pues la planta que se obtenga de su cultivo mantendrá casi intactas las características del cultivo inicial, tal es el caso del trigo y la soja. Por el contrario, la producción obtenida de especies alógamas, como el maíz o el girasol, presenta una mayor variabilidad genética al ser utilizada como semillas debido a que la planta que se obtiene de este simiente presenta, en general, características distintas a las del cultivo original por la variabilidad genética resultante de la fecundación entre distintos individuos. Estas características se manifiestan con mayor intensidad cuando el cultivo es de una variedad híbrida.

# 1. Argentina

Internationally, Argentina as a member of the WTO, has agreed to abide by the agreement known as TRIPS, which establishes that for innovations in plant and animal species it recognises the possibility of protection either through the general patents system or by a specific system for the sector, which is called a *sui generis* system. Although different from the general patents system, it offers the basic protection conditions agreed in the treaty. Argentina has a system of this kind, but many aspects of the legal framework are currently subject to debate since their enforcement does not appear to have been as effective as required to ensure transparent functioning of the market, particularly as regards the innovations resulting from biotechnology applications.

The *sui generis* system posed by the by the TRIPS agreement is fundamentally regulated by the Law of Seeds and Phylogenetic Creations -N° 20247, of 1973- and its respective regulatory decree 2183/91. Both regulations, in accordance with the provisions of article 1 of the Law, have as their object “to promote an efficient activity of seed production and commercialisation, to guarantee farm producers the identity and quality of seed and to protect the property of phylogenetic creations”. This law regulates:

- the institutional structure for enforcement, as is the case with the creation of the National Seed Commission (Comisión Nacional de Semillas, CONASE), the National Seed Institute (Instituto Nacional de Semillas, INASE), the National Cultivar Register (Registro Nacional de Cultivares) and the National Register of Cultivar Ownership ( Registro Nacional de la Propiedad de Cultivares)<sup>3</sup>
- the categories seeds will have for their circulation on the national market;
- the intellectual property rights to phylogenetic creations;
- tariffs and subsidies in carrying out the activity, and;
- sanctions for lack of compliance.

As regards enforcing legislation on plant breeder’s rights, for some time now in Argentina there have been discussions on core questions arising out of the Law which have significant impact on the development of the seed market. More exactly, incorporated genes may be patented locally and are governed by the legislation on patents (Law of Invention Patents and Utility Models N° 24,481 and their modifying law 24,572, both of 1995), while the variety developed is governed by the plant breeder’s right (Seed Law) but the object of application of the right (the seed) is the same in both cases. As this situation was not contemplated when both laws were drafted, at present, there are overlaps and contradictions which are difficult to resolve and which considerably complicate the context. In this regard, Witthaus (2006: 244)

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<sup>3</sup> The functioning of the National Cultivar Register (Registro Nacional de Cultivares, RNC) is the responsibility of the Directorate of Registration of Varieties (Dirección de Registro de Variedades), an office of the National Seed Institute (Instituto Nacional de Semillas, INASE). The objective of this institution is to register all the varieties **commercialised** nationally given the fact that those natural persons or corporate entities that commercialise varieties which have not been entered into the registers must be sanctioned (Art. 36 of Law 20,247). The National Register of Cultivar Ownership (Registro Nacional de la Propiedad de Cultivares, RNPC) also known as the Directorate of Registration of Varieties (Dirección de Registro de Variedades) unlike the RNC, grants the plant breeder who registers his creation **ownership rights over the plant variety**<sup>3</sup>. Similarly, the fact that a cultivar is registered in the RNPC does not imply authorisation for its commercialisation nationally, since in order to achieve that right, as mentioned above, it must be registered in the RNC.

mentions the main problems that arise when both legislations are applied to the same objective:

- Scope and regulation of the right to take a variety as the starting point for another plant-improver to obtain a new variety (plant-improver's exception).
- The farmer's exception.
- Different validity periods for the plant breeder's rights over a variety and patent rights over a gene incorporated into it.
- Differences in regulating restricted public use of the Law of Plant Varieties and of the exceptions to the rights of the patent holder set forth in the Law of Patents.

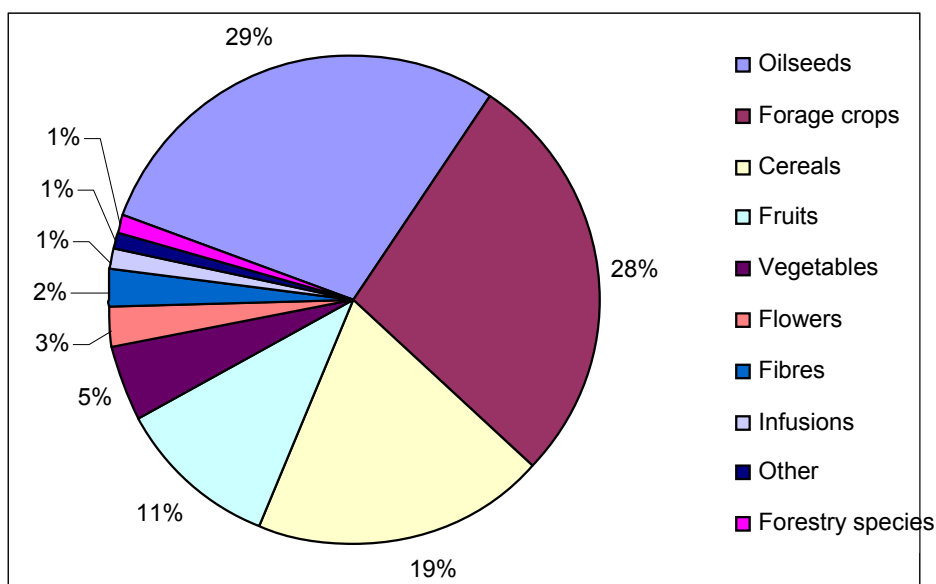
From the words of Witthaus (ibid.), the farmer's and the plant improver's exceptions are at the heart of the debate in Argentina (and in most other countries) since they involve conflicting interests, both economic and political and social, which so far have not been effectively conciliated and which have a negative impact in the development of the seed market. Massot (2006: 64) sums up situation very well when he says: *"So far, initiatives taken on a specific seed regime have been considered to be mistaken or insufficient from the point of view of law, economics and science, or rather, they have not been effective in striking reasonable multisectoral agreements."*

The registration of varieties in the National Register of Cultivar Ownership (RNPC) only becomes important in the second half of the 1990's. In fact, the proportion of varieties with requests made for plant breeder's rights registered for commercial release has increased considerably, and in 2006 exceeded 30% of all the varieties registered annually. Among the factors contributing to this are:

- the development of a greater number of varieties with possible commercial importance, so enjoying the plant breeder's rights requested would allow the benefits of research to be guaranteed if the variety is accepted on the market,
- the generalisation by seed companies, public institutions, and plant improvers in particular, to recognise and request the benefits originating from the work and the originality taking material form in the varieties developed; and
- greater confidence in the legal framework on local plant breeder's rights.

Regarding the varieties that enjoy plant breeder's rights, the group of oilseeds (almost exclusively varieties of soya) takes first place, due to the importance of self-pollinating species in this group, followed by forage varieties of alfalfa, ryegrass and rescuegrass, among others; and by varieties of cereals, fundamentally wheat (See diagram and table 1).

**Diagram 1. Participation of the varieties registered according to species group in the RNPC between 1987 and 2006.**



Source: own data based on RNC figures.

**Table 1. Varieties registered in the RNC and in the RNPC according to species group/year, for the period 1987-2006**

Species group	'87	'89	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	Total
Oilseeds				2			7	3	7	10	15	11	23	16	10	33	42	33	51	263
Forage crops				2	5	12	8	6	3	30	27	18	19	14	8	12	23	32	26	245
Cereals				1		3	7	7	8	10	15	8	18	12	14	7	24	21	17	172
Fruits			2		2	1	3	3	5	7	16	8	3	3	3	3	20	13	7	99
Vegetables	1	1			4	2	2	2	3	6	5	1	1	2	3	1	3	7	2	46
Flowers										2	7	4					2	8		23
Fibres						1		1	1		1		3	2		3	7	1	2	22
Infusions																		2	10	12
Others					1		1	1				1					4		3	11
Forestry species																	9	1		10
<b>Total</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>12</b>	<b>19</b>	<b>28</b>	<b>23</b>	<b>27</b>	<b>65</b>	<b>86</b>	<b>51</b>	<b>67</b>	<b>49</b>	<b>38</b>	<b>59</b>	<b>134</b>	<b>118</b>	<b>118</b>	<b>903</b>

Source: own data based on RNC figures, January 2007



## 2. Brazil

While the enforcement of legislation on industrial property has yet to meet the expectations of some experts in Brazil, the internalisation of the concepts of protection for improved cultivars of different plant species took off with the approval of Law 9456 in 1997. At present the market coexists with the sowing of protected and unprotected varieties and there is no lack of seeds for small farmers who still use unprotected varieties. The Ministry of Agriculture and Provision (MAA) runs government seed distribution programmes, principally in the poorest regions of the country. Embrapa is active in the production of such material.

According to the National Cultivar Protection Service (SNPC), linked to the MAPA, users today can protect 68 genuses/species and the Service team is in a position to start the protection process for any other species for which there is market demand. Between public and private companies, the list of users of the system includes 255 registered users. Between 1997 and 2006, the SNPC received 1149 applications and granted 908 protections, 112 applications are being analysed and 129 were filed.

Although the cultivar protection law is relatively recent, it already requires urgent review according to comments made by users. Some of the modifications suggested for harmonising it with the version of the 1991 UPOV Act are: to include all species; restrict the privilege of the farmer to those who really need it; exclude private use for groups of the most vulnerable species (plant propagation); extend the protection period from 20 to 25 years; optimise administrative procedures (reduce bureaucracy and costs, make periods more flexible); extend possibilities of use of molecular techniques; modernise procedures with living samples; define prohibitions; improve mechanisms for legal action over undue use; rethink the distinguishability, homogeneity and stability tests to increase the credibility of the system <sup>4</sup>.

## 3. Paraguay

In terms of intellectual property protection Paraguay has a fairly well defined formal scheme, and most of the relevant forms of protection for biotechnological innovations are enforced in the country. In fact, in the field of property rights, any shortcomings would appear not to be so much in the letter of the laws and regulations but in the implementation capacities, both concerning human resources and the administrative procedures for the enforcement of existing bodies of legal regulations.

In Paraguay, there have been significant modifications in the public institutions in the seed sector in recent years. The Directorate of Seeds (Dirección de Semillas, DISE) has been integrated into the Directorate of Plant Protection (Dirección de Defensa Vegetal) of the National Service of Plant Quality and Health and of Seeds (Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas, SENAVE). In designing this process, concepts of administrative efficiency and functions directly linked to seed management were the priority – registration and protection of varieties, test laboratory, control of production and commerce,

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<sup>4</sup> Daniela Aviani – Paper presented at the 20th Pan-American Seed Seminar – 2006, [www.abrasem.com.br](http://www.abrasem.com.br)

and certification – have been integrated into the functional departments of the SENAVE (the seed laboratory is part of the Directorate of Laboratories, the issuing of labels is the responsibility of the central administrative sector and trade inspection of the Directorate of Operations) and therefore the “single window” nature of the DISE has been lost and with it the chance to establish an effective relationship with the private sector in the field. This dispersal of functions and loss of identity has meant the problems of migration of the most qualified staff and of the five officials with master’s degrees in the field of seeds that belonged to the plant in 2004 have become more serious. Currently, only two officials with the technical level required to fulfil their functions remain in the institution.

Because of its characteristics and impact, it is important to offer certain specifications on the case of GM soya in Paraguay. GM soya which is tolerant to herbicides (glyphosate) is the principal biotechnology product used in Paraguay, and its development is not based on local R+D, but it evolved out of the import of Argentine varieties, which are thought to have been used as of 1998. Moderate estimates claim that the area sown with herbicide-tolerant LMO soya is 80% or more of the total area for the crop. The original irregular nature of soya cultivation has gradually been organised by means of different legal measures and, finally, the definitive approval of the use of herbicide-tolerant varieties in 2004.

## **4. Uruguay**

The situation concerning intellectual property protection in matters related to biotechnology in Uruguay is governed by the provisions of a series of international agreements and conventions to which the country is party. These include the 1961 Paris Convention, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) (1986-1993), the 1978 UPOV Act, the Rose Garden Agreement (1991) and the Convention on Biological Diversity of Rio de Janeiro (1992).

In the specific area of seeds, the institutional framework for the development of the sector is ruled in its substantive aspects by the National Seed Law 16,811, which not only declares of national interest the obtaining, production, circulation and internal and external commercialisation of seeds and cytotenetic creations, but it also regulates everything concerning the production, certification and commercialisation, export and import of seeds, guaranteeing agricultural producers their identity and quality. From the point of view of operations the National Seed Institute (Instituto Nacional de Semillas, INASE), as a non-state public corporate entity, also created by Law 16,811, but linked to the Executive Power through the Ministry of Agriculture, Livestock and Fisheries (Ministerio de Ganadería, Agricultura y Pesca, MGAP) is the competent body in setting national seed policy. As regards plant breeder’s rights (an area over which the INASE also exerts functions in registering the property of cultivars and granting of property deeds) protection was established by Law 15,173/81 and Law 15,554/1984 and is granted for a period of between 15 and 20 years, depending on the species considered. As regards this last aspect, Uruguay signed the 1978 UPOV Act on 13 November 1994 and that Law 16,811 reflects the provisions of the international agreement.

Until May 2006 a total of 160 plant varieties had been registered under this institutional framework, of which 32.9 % were forage species, 26.3 % were soya, 10.1 % wheat, 5.7 % rice; the remainder includes varieties of malted barley, sunflower and other less important crops. These percentages are an approximate reflection of the relative importance of crops in

the country and, especially the great increase in soya cultivation with the approval of herbicide-tolerant varieties in 1996.

From the point of view of the functioning of the system in terms of fulfilling the regulatory functions of the seed trade and the protection of plant breeder's rights and, therefore, their use as a mechanism for technology transfer, the effectiveness of the system varies considerably from crop to crop. In the case of maize and rice –since Uruguay has signed UPOV 78, the proper use in this last case is legal– most of the seed used is of legal origin, although in the case of rice the level of proper use is fairly high. It is not the case with wheat and soya where an illegal seed trade has been identified (white bag), although the levels are no worse than in similar situations in other countries in the region.

## **5. Summary and conclusions**

Among the elements thought suitable for developing a formal seed market and in accordance with the expectations of participants are:

- the existence of a clear regulatory framework in accordance with the complexity of the system to cover possible loopholes;
- control bodies effective in the exercise of enforcing legislation and,
- legitimisation in society of the financial benefits arising out of compliance with the law (both as a result of the fines for lack of compliance and for considering the current regulations appropriate).

As regards the above comments, general regulations in the various countries are relatively well consolidated. However, in the MERCOSUR countries several issues remain to be defined and updated in order to achieve a clear legal framework in accordance with the complexity of the system. This is the case for all countries in the use of seeds by farmers and produces a situation in which, due to the lack of clarity, the institutions entrusted with controlling their compliance are “rather unclear” as to the strategies to follow (such is the case of Argentina), or the legislation is thought to be outdated (such is the case of Brazil), or there is institutional weakening (as is the case of Paraguay).

As a consequence of institutional weaknesses in the enforcement of legislation, this scenario, together with a price for self-pollinating seeds which is considerably lower in the informal market and notwithstanding participation, has made way for the development of a very large illegal market for seeds in the region. Although the subject was not the central focus of this paper, various studies reveal that the growth in this type of trade is an almost inevitable consequence of the scenario posed, and this has been happening for at least the last two decades, thus discouraging the private investment needed to foster (local and international) innovations in the development of (mainly genetically modified) seeds for the region.

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## Annex 1. Definition of biotechnology patents in the OECD

IPC Codes	Titles
<b>A01H 1/00</b>	Processes for modifying genotypes
<b>A01H 4/00</b>	Plant reproduction by tissue culture techniques
<b>A61K38/00</b>	Medicinal preparations containing peptides
<b>A61K 39/00</b>	Medicinal preparations containing antigens or antibodies
<b>A61K 48/00</b>	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
<b>C02F 3/34</b>	Biological treatment of water, waste water, or sewage: characterised by the micro-organisms used
<b>C07G 11/00</b>	Compounds of unknown constitution: antibiotics
<b>C07G 13/00</b>	Compounds of unknown constitution: vitamins
<b>C07G 15/00</b>	Compounds of unknown constitution: hormones
<b>C07K 4/00</b>	Peptides having up to 20 amino acids in an undefined or only partially defined sequence; Derivatives thereof
<b>C07K 14/00</b>	Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof
<b>C07K 16/00</b>	Immunoglobulins, e.g. monoclonal or polyclonal antibodies
<b>C07K 17/00</b>	Carrier-bound or immobilised peptides; Preparation thereof
<b>C07K 19/00</b>	Hybrid peptides
<b>C12M</b>	Apparatus for enzymology or microbiology
<b>C12N</b>	Micro-organisms or enzymes; compositions thereof
<b>C12P</b>	Fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture
<b>C12Q</b>	Measuring or testing processes involving enzymes or micro-organisms; compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes
<b>C12S</b>	Processes using enzymes or micro-organisms to liberate, separate or purify a pre-existing compound or composition processes using enzymes or micro-organisms to treat textiles or to clean solid surfaces of materials
<b>G01N 27/327</b>	Investigating or analysing materials by the use of electric, electrochemical, or magnetic means: biochemical electrodes
<b>G01N 33/53*</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: immunoassay; biospecific binding assay;

	materials therefore
<b>G01N 33/54*</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: double or second antibody: with steric inhibition or signal modification: with an insoluble carrier for immobilising immunochemicals: the carrier being organic: synthetic resin: as water suspendable particles: with antigen or antibody attached to the carrier via a bridging agent: Carbohydrates: with antigen or antibody entrapped within the carrier
<b>G01N 33/55*</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: the carrier being inorganic: Glass or silica: Metal or metal coated: the carrier being a biological cell or cell fragment: Red blood cell: Fixed or stabilised red blood cell: using kinetic measurement: using diffusion or migration of antigen or antibody: through a gel
<b>G01N 33/57*</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: for venereal disease: for enzymes or isoenzymes: for cancer: for hepatitis: involving monoclonal antibodies: involving limulus lysate
<b>G01N 33/68</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: involving proteins, peptides or amino acids
<b>G01N 33/74</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: involving hormones
<b>G01N 33/76</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: human chorionic gonadotropin
<b>G01N 33/78</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: thyroid gland hormones
<b>G01N 33/88</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: involving prostaglandins
<b>G01N 33/92</b>	Investigating or analysing materials by specific methods not covered by the preceding groups: involving lipids, e.g. cholesterol

Note: The IPC codes marked \* include sub-groups of above one digit (0 or 1 digit). For example, in addition to code G01N 33/53, codes G01N 33/531, G01N 33/532, etc., are included.