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The socio-economic landscape of biotechnology in Spain. A comparative study using the innovation system concept

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Abstract

Biotechnology is becoming a crucial factor for the innovation strategies of the industrialised countries. Thus, the analysis of the sector is gaining relevance for the identification of the technological strength and potential of a country (or region) in a context of globalisation. A specific national case study may serve for more general comparative analyses. We have selected the case of Spain as illustrative of the complexity and differences existing in Europe. By using the analytical framework of the "national systems of innovation" concept, we have performed a multistep analysis of the biotechnology sector in Spain, focussing first on regions of Madrid and Cataluña which together account for more than 50% of the sector in Spain. The firms in both regions have followed a common strategy based on diversification and investment in R&D and innovation, so as to be able to compete in an international and competitive environment. There are, however, some interesting differences between the two subsectors; the one from Cataluña being more based on industrial traditions, and the one from Madrid characterised by the emergence of more specialised firms. The study has been extended to the remainder of Spanish firms for comparative purposes. The case of Spain is illustrative of the divergences existing in the biotechnology sector in Europe. A comparison is made with the structural and organisational characteristics of the biotechnology sector in several European countries. It shows that there is diversity in the pattern of commercialisation between countries and within regions of countries. Understanding these differences may assist the design of appropriate policies to promote the development of biotechnology in Europe.

Keywords: Biotechnology sector; European comparison; Regional influences; Spin-off firms; Industrial diversification

1. Introduction

It is increasingly recognised that science and technology, as key elements in the process of knowledge production and transformation, are instruments of growing strategic value for the attainment of wealth in societies and for enabling them to compete in a global environment.

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During the second half of the 20th century, theories about the process of knowledge production and its transformation into, and/or its interactions with, technology have been changing (see as an example Rosenberg, 1991). The recognition of serious deficiencies in the "linear model of innovation" led to the development of a systems model of innovation. The purpose was to understand the production of scientific (and technical) knowledge in relation to the influence of networks of stakeholders and to link the process of innovation with social, political and economic factors.

There is now an important body of literature on national systems of innovation (Lundvall, 1992; Nelson, 1993) and the possible application of the system concept to regional (Braczyk et al., 1998) or sectoral scenarios (Malerba, 1999). The emergence of this systemic model has shown the limitations of the traditional input/output analysis—the use of microeconomic indicators, and bibliometric analysis—to provide fine-tuned information on the evolution and dynamics of innovative sectors. In all these models, the importance of the social and political environment was always implicit but was not made explicit. The relevance of the environment appears critical for understanding the development of the so-called emerging, new technologies.

Biotechnology is an enabling technology, which uses the properties of living things to produce and transform foods, to obtain substances with therapeutic activity, and to seek solutions to ameliorate environmental problems. In some cases it uses the properties of living things as they are found in nature; this is the case in traditional or classical biotechnology. In other cases organisms are genetically modified to produce specific substances or to improve processes.

Biotechnology applies science-based techniques that rely on the knowledge produced by a wide set of disciplines, ranging from microbiology to chemical engineering through other very basic and critical disciplines like molecular biology, immunology and genetics. Multidisciplinarity and interdisciplinarity are basic features of knowledge production in biotechnology.

Another important feature of the commercialisation of biotechnology stems from a specific form of industrial organisation (Saviotti, 1998). This is the launching of small- and medium-sized firms which are grounded in intensive knowledge and tight links with academia and public research centres. As Saviotti (1998) has pointed out, the behaviour of these dedicated biotechnology firms differs according to the sector in which they operate and on the role they adopt, i.e. as radical innovators, as specialists in a niche-market or as suppliers of knowledge services.

The characteristics of this technology—horizontality, rapid changes in evolutionary trends, combination of relatively old technologies with new ones—make this case particularly interesting for understanding the capability of old and new industries to evolve (co-evolution) and their adaptation to a strongly competitive environment.

Two projects funded by the European Commission considered the commercialisation of biotechnology in Spain as part of wider studies. The first, European Biotechnology Innovation System (EBIS) (SOE1-CT98-1117), aimed to identify whether the development of biotechnology in Europe is mainly influenced by national or sectoral factors. The second, Strategies and Policies for Systemic Interactions and Convergence in Europe (CONVERGE) (SOE2-CT98-2047), aimed to understand the economic and technological dynamics by identifying the main factors that account for the gaps between the "less-favoured" and the "more-advanced" regions of the European Union (EU) ("economic convergence"). Along the projects, several approaches and methodologies have been mobilised, including the selection of case studies. In the case of Spain, biotechnology was selected as an example of a sector requiring high technological intensity. The results of these studies provide the opportunity to present a detailed case study of biotechnology commercialisation in Spain and to set these findings in a wider European comparative framework. The comparison with the situation in several European countries allows us to draw lessons on the situation in Europe with respect to the possibilities and feasibility of biotechnology development and throw light on the challenge of convergence. The wider context of developments in the biotechnology sector in Europe is presented, before discussing the

Table 1
Structural and organisational characteristics of the biotechnology sector in several European countries

Country	Development[a]	Age[b]	Size[c]	Presence of subsidiaries	Spin-offs (%)	Predominant type
A	Low	Middle	Middle	High	<40	Mix CDB and diversified
D	High middle	Young	Low	Middle	~40	CDB based on opportunities and capacities
F	High middle	Young	Low	High	<10	CDB based on internal assets
GR	Low	Old	High	High	<15	Diversification
IRL	Low	Young	Low	Low	~40	CDB based on own capacities
NL	Middle	Middle	Low	Low	~25	CDB based on opportunities and capacities
UK	High	Young	Low	Low	≥50	CDB predominantly
SP	Low	Old	Middle	Middle	–	Diversification

Data gathered from the EBIS project. CDB, companies dedicated to biotechnology; commonly spin-off companies.
[a] Based on the number of firms and turnover figures.
[b] Average of year for establishment of firms: old, below 1975; middle, 1980–85; young, up to 1986.
[c] Median of the number of employees for firms: low, below 50; middle, below 100; high, up to 100.

methodology used for the Spanish case study and its results.

2. Comparative characterisation of the biotechnology sector in European countries

The predominant role played by the United States in the development and evolution of biotechnology in the world has led to the adoption of those dynamics as the model for the development of this emerging technology. As is well known, the North American model is characterised by the establishment of many new firms based around the knowledge embodied in the key figure of the "entrepreneur–scientist". There is ready availability of risk capital to support these firms and a generally positive public attitude to their activities. But such a model is unlikely to occur in all countries.[2]

The information gathered from the EBIS project has served to confirm this statement. The basic characteristics of the biotechnology sector in several European countries are summarised in Table 1. This leads on to the identification of a series of models to represent differences in the sector between these countries (Table 2). Within this context, we have explored the case of biotechnology in Spain in depth in order to understand the specific situation of the biotechnology sector in a large European country whose model of

Table 2
Models for development of the biotechnology sector in European countries

1. Based on companies dedicated to biotechnology, established in the last decade, mainly as spin-offs of other firms, public research laboratories and universities. This is the typical model of development of biotechnology in USA. *European example*: United Kingdom
2. Relative importance of dedicated firms, established recently, based on the capacities and strategies of the countries, middle level of spin-offs companies. *European example*: Germany, The Netherlands, Ireland, Austria
3. Intermediate model with companies dedicated to biotechnology, created recently but based on the previous industrial assets, low culture in the establishment of spin-offs firms. *European example*: France
4. Sector based on diversification of industries already existing, low profile in the creation of spin-offs. *European example*: Spain, Greece

Based on the results recorded from Table 1 and previous work carried out under the EBIS project.

[2] The Ernst and Young report gives annual accounts of the biotechnology sector in Europe. It is based on the US model, and reveals deficiencies in this approach.

development appears to differ from that of the United States.

3. The case of Spain: the Cataluña and Madrid regions

The Spain case study focuses on the two main regions of Spain in terms of their contribution to gross domestic product. These regions, Madrid and Cataluña, also make a significant contribution to Spain's population and both have achieved 100% in convergence index with Europe. However, Cataluña has an established industrial tradition, while Madrid belongs to a location which is based on services but is rapidly evolving to use and develop new technologies. This in-depth study has been further extended to the rest of Spanish firms and landscape for a more definite characterisation.

3.1. Methodology

This research was carried out through a multi-step methodology.

1. The first step aimed to identify all the biotechnology firms operating in Spain. This was a necessary prerequisite in view of the lack of official statistics on the biotechnology industry in Spain. Several sources were used to carry out this identification such as the Directory "Spanish research groups & enterprises working in Biotechnology 1997" prepared under the support of the Interministerial Committee for Science and Technology (CICYT, acronym from the name in Spanish, Comisión Interministerial de Ciencia y Tecnología, 1997), a database on the subsidies allocated to biotechnology companies for the development of R&D and industrial projects by the Centre for Technological Development (CDTI from the Spanish name), as well as information resulting from the Innovation Survey and all reports and analyses published by June 1999.
2. In the second phase a quantitative approach was applied, based on collecting the opinions of the main industrial stakeholders. A questionnaire was used to gain information on the general objectives of firms' research programmes: identification of the main characteristics of the industrial sector of biotechnology in Spain, and its relationships with and attitudes towards the process of technological innovation. The selected population was that resulting from phase 1 and amounted to 148 firms from the whole of Spain. Two of these firms were withdrawn, because of the difficulty of making contact after a change of address. This led to a sample of 146 companies to which a questionnaire was mailed in the spring of 1999. After careful monitoring of the responses in relation to the degree of identification with the industrial sector and its relevance for innovation and business activities, 49 firms were identified as companies mainly involved in biotechnology (CMIB). In statistical terms, the selected sample represents 34% of the original sample, with a maximum sample error of 9.9% and a confidence level of 95.5%.
3. In the third phase, the results obtained through the surveys were validated by carrying out semi-structured interviews, based on interview guidelines about the following items: innovation activities performed, goals to be attained, collaborations and co-operations with the different stakeholders, problems hampering the evolution of the sector, and perception of the situation.

The following concepts were developed and adopted to carry out this study. *CMIB*: firms that have a consolidated activity in biotechnology, either as their main industrial activity or as an activity well incorporated into company strategy. The firms with such an involvement may use the techniques of both modern and classical biotechnology in the elaboration of products or processes.

These firms are evolving into biotechnology by a process of industrial diversification. This concept of CMIB complements the concept of companies dedicated to biotechnology (CDB), essentially start-up and spin-off companies.

Small and medium enterprise: Owing to the characteristics of the biotechnology sector in Spain, which emerged in the 1980s, two profiles of small- and medium-sized enterprises have been

considered: (a) the classical industries, with less than 250 employees, which began activities in biotechnology before the 1980s with no exclusivity; and (b) the more specialised firms with less than 50 employees whose activities have focussed on biotechnology since the 1990s.

3.2. Characteristics of the firms

3.2.1. Number, age and strategies

The number of companies is greater in Cataluña than Madrid. Of the companies (49) identified in our study, 18 are located in Cataluña (37%) and eight in Madrid (16%), with the two regions accounting for more than 50% of the national total.

(a) The companies located in Cataluña were not set up during a specific time period as a response to market tendencies or to "industrial trends". None of the companies was created with the initial objective of full commitment to biotechnology activities, but rather they have incorporated the new technological developments into their original aims and primary activities as a response to society's new demands. Some companies were created during the mid-19th century, but the youngest companies were founded at the end of the 20th century. Biotechnology activity began for this last group during the 1970s, and rose to particular significance in the 1990s. There appears to be a clear difference between the dates of setting up a company and the introduction of biotechnology, providing evidence of the non-existence of companies created with the sole objective of carrying out activities linked to the sector under study.

(b) Half of the companies from Madrid were set up during the 1980s with varying aims, but these were already directed towards and linked to biotechnology. The principal activities of the companies created after 1980 are connected with biotechnology, making them what could be termed "biotechnology companies". Those companies founded before 1980 have incorporated the new techniques into their activities, processes and/or products as a method of adapting to the market and its new demands. The date of starting the biotechnology activity is similarly centred in the 1980s and, therefore, the setting up of companies at this time is intimately linked with this activity.

The adapting or acquiring of knowledge in biotechnology has also come about, as occurred in the companies in Cataluña, through innovative activities and R&D. The companies consider innovation as a mechanism by which they assimilate and put into practice changes in the design of processes, product manufacture, organisational changes, etc., and it is by this mechanism that they have incorporated the new technologies. In fact, all the companies have undertaken R&D in biotechnology in the period 1995–98, in products or processes or both: five companies have undertaken these activities in both products and processes (these are the companies most committed to the sector and which consider biotechnology to be their principal activity, having been set up with this objective), one solely in processes and two solely in products.

3.3. Property and commercial activities

All the companies are private both in Cataluña and Madrid, though with differing distributions, depending upon the nationality of capital: from the 18 Catalan companies, 12 are national and six multinational, whilst there is a 50:50 distribution (four national and four multinational) among the companies in Madrid.

The activities carried out by companies from Cataluña may be directly related to biotechnology or, on the other hand, show a diversified field of action in which biotechnology is just one activity amongst many. Grouped according to the sector in which they work, three companies are in human health, four in animal health, three in agriculture, three in agro-food, one in industrial processes, three state that they carry out activities in the sectors of human and animal health and one in animal health and agriculture. There is no significant concentration of these companies in any of the market segments in which they operate. Thus, seven companies state that they act in the segment "therapeutics: human and/or animal

healthcare''; eight in ''other healthcare''; seven in ''supply industries''; three in ''agro-food: plants''; two in ''agro-food: animals''; one in ''energy and environment'' and one in ''basic aspects''.

With respect to turnover, the data obtained are those for 1998, with a total turnover for the companies in Cataluña involved in biotechnology activities of 1647 million euros. There is a wide range of turnover figures in the interviewed companies from 0.63 to 589 million euros, showing the existence of two very different groups: the SMEs (small- and medium-sized companies), innovative companies entering the biotechnology market and making a great effort to adapt themselves to the new technologies; and the multinational companies, larger and with a high turnover derived from their multiple, current business interests, and which have seen an opportunity for business in biotechnology.

The mean percentage of turnover attributable to biotechnology activities in the year 1998 was 30%. However, there are companies already specialised in this sector in which sales are completely attributable to their activities in biotechnology (100% of sales), whilst another group is just beginning to enter the sector and its sales from this activity may be considered trivial compared to its principal activities. Sales are also influenced by exports, and 15 companies carry out business abroad. The volume of this business for 1998 was of 96 million euros, with a range of 0.02–17 million euros and a median of 4.3 million euros. Of the 15 exporting companies, 12 export to countries of the EU, six to other European countries (not members of the EU) and seven to other countries (excluding those countries mentioned in the previous categories).

Regarding the group of companies in Madrid, two are independent, six form part of a group, and five are subsidiaries and one is a joint venture. Of the companies which form part of a group, the group head office of two is in Spain, two in countries of the EU, one in another European country and one in a non-European country.

Five of the companies consider that biotechnology is their principal activity, but it is one of the various activities in three of the firms. These data present us with a clear difference in comparison to those companies found in Cataluña, whereas the ''biotechnology companies'' or ''companies fully committed to biotechnology'' in Madrid represent 62.5% of the total for the region; in Cataluña this group represents only 22.2%. Companies in Madrid appear to have committed themselves more fully to the sector and show a higher degree of specialisation, or at least the present distribution in percentage terms would suggest this.

Of the eight companies in Madrid, three operate in the sector of human health, one in animal health, two in agriculture, one in industrial processes and one works in three sectors—human health, animal health and agriculture. This industrial group does not concentrate on a specific area of work, rather the contrary that there is no significant concentration in any of them.

The companies from Madrid had a mean turnover of 46.1 million euros and a median of 43.8 million euros. The small difference between the median and the mean indicates a more homogeneous level of turnover than in the case of Cataluña. The range in turnover was from 1.3 million euros for the company with the lowest turnover to 113.8 million euros for the largest company; a figure quite different from the level of turnover of the largest company in Cataluña (589 million euros). The sales from activities specifically related to biotechnology represent 34% of the total for 1998. There are five exporting companies in Madrid, with a mean volume of exports of 11.3 million euros and a median of 6.1 million euros. Three companies export to EU countries, three to other European countries not belonging to the EU and a further three to other countries not included in the previous categories.

3.4. Human resources

3.4.1. Cataluña

The total number of employees in the 18 companies located in Cataluña is 7993, ranging from small companies with 14 employees to large multinationals with a total of 2800 workers. The mean number of employees per company is 444, a figure which is distorted by the presence of large companies. In comparison, the median, understood as

the middle value of all values found, gives us a figure of 149 employees per company, a value closer to the reality of Spanish industry in the biotechnology sector.

The proportion of graduates is just short of 30% of employees (28.8%), with a total of 2300. The difference between the small and large companies is also very wide, ranging from six graduates in the smallest company to 1000 in the largest. The mean is 128 graduates per company, and the median, and more representative figure, is 27.

Employee numbers over the past three years have experienced growth for 12 companies, a reduction for four and stability for two. These data indicate a sector in marked expansion and growth, aiming to consolidate its market position.

There has been a very significant change in the employee profile: graduates have been hired in significant numbers to work, particularly in the areas of R&D and innovation. In fact, in the above mentioned period, no company lost employees from their graduate staff; 15 companies have increased the number of graduates on their workforce and only three have shown stability of numbers (they have not increased the number of graduates but neither have they reduced the numbers).

3.4.2. Madrid

The total number of employees from Madrid is 957, with a mean of 120 employees per company. Correction of this value using the median gives a value of 80. The companies in Madrid are smaller than those from Cataluña, and the range in the number of employees is from 7 to 399. With respect to the number of graduates, eight companies have a total of 316, with a range of 4–120, a mean of 40 and a median of 19. The number of graduates employed is also lower than in firms of Cataluña in absolute values but higher in percentage terms with respect to the total number of employees, reaching 33%.

The level of qualification (using the percentage of graduates as an indicator) is higher in the companies in Madrid than in the companies from Cataluña.

In the last three years, six companies have shown growth in their human resources, one has lost employees and one has maintained stable levels. With respect to graduates, seven companies have added members to their staff and only one has shown no change. The incorporation of staff with university degrees has been a marked element of business strategy.

In this respect, the number of employees dedicated to R&D in biotechnology has increased in five companies over the period 1995–98 and has remained stable in three. The figures related to the numbers of graduates are even better than the above, with six companies increasing the number of graduate employees dedicated to this area, whilst two companies have maintained stable levels.

3.4.3. Common arguments in relation to human resources

The evolution, albeit positive, of the biotechnology sector in the two main regions of Spain is still insufficient to attract massive human resources to this sector. The hiring of graduates by the companies represents an additional cost which, in most cases, is not supported by the overall management of the firms, as there is still no real culture and commitment to hire graduates amongst their employees. A further important aspect, highlighted by the companies with respect to the hiring of graduates, is the mismatch between the academic training received and the tasks to be carried out thereafter in the companies. This lack of congruity with the real needs of the companies is a handicap which conditions and interferes with the entry of graduates into industrial employment. University graduates require a period of training and adaptation which is equal to or even greater than that demanded by workers with vocational training, while the latter asks for lower wages. In the case of similar skills, the firms tend to prefer hiring those with lower salaries. Nevertheless, the strategic importance of research, innovation and technological development in high technology sectors like biotechnology may modulate the policies for hiring personnel. These tasks emerge as the determining ones for delineating the profile of employees.

3.5. R&D and innovation activities

3.5.1. Cataluña

The companies in Cataluña recognised the importance of these activities, and the companies which carried out innovation (15 out of the 18 companies studied) have financed these activities with their own funds, showing a direct involvement in the change produced.

The total cost for the group (15 companies) for R&D in 1998 was 61.7 million euros, around 5% of the total turnover, with a mean of 4.1 million euros per company and a median of 1.32 million euros. These figures have shown an increase over time.

The percentage of the R&D expenditure corresponding to biotechnology amounted to 37.7% in 1997 and to 39.4% in 1998, representing an increase of 1.7%.

The companies also raise funds from other organisations, as they consider the expenditure which has to be committed in order to undertake innovation with some degree of success to be excessive. The securing of external funds, therefore, becomes a concern itself and one of the objectives for management. All the companies in this group find that the cost of innovation is very high and consider this to be a factor which, to a great extent, limits these activities.

Furthermore, the return from these investments is considered to lie in the long-term, whereas their annual results are really important for successful management. For this reason, one of the deficits of this part of the system is the lack of continuing economic support for business projects designed to promote technological development and innovation. There is a clear need for public funding for the research undertaken in private companies and there is a demand for it.

The companies from Cataluña allocate funds for R&D and innovation to both internal and external spending (purchase of equipment, training related to new products and processes, marketing of new products, industrial design and engineering and, a minor percentage, to buy intellectual property).

Innovations are both of a technological character and an organisational nature. Among the first, about 50% of the companies said that they had introduced new products; the same percentage has made significant achievements in traditional products and about one-third have only made slight modifications. Among the organisational innovations, new strategic orientations, advanced management techniques and the acquisition of new equipment for long-run activities were most often mentioned by firms.

The factors which, in the opinion of the companies, contribute to the success of innovative activities are, in first place, the commitment of the high level management and the innovative culture of the company and, in second place, co-operation with research centres and universities.

3.5.2. Madrid

The companies in Madrid, for their part, also consider innovation and research as fundamental to the building of companies and making them competitive. All of them (eight companies) have undertaken biotechnological activities during the period 1995–98. Furthermore, they confirm their commitment to innovation when they declare that these activities are undertaken systematically and not as temporary activities, forming part of the routine tasks in the different processes in which they work.

The funds which they use to cover the costs of research are mainly provided internally by the company. They also state that it is only through this line of action that they can consolidate their position in the market and that the future of the companies depends on continuous innovation and a rapid adaptation to the needs of the market. Despite covering the costs of innovation themselves, some companies do look for public money to supplement the funds which they have provided. The investments made by the Madrid companies amount to 4–5% of the total turnover, a figure similar to that recorded for firms from Cataluña. Funds invested in innovation increased by 34.4% from 1997 to 1998.

On comparison of the medians, the middle value found for Madrid in the distribution of R&D and innovation expenditure is higher than in the case of Cataluña and so is the percentage devoted to innovation in biotechnology

(around 4–5%), a fact which serves to confirm the greater degree of specialisation of the companies located in Madrid: this is a group whose principal activity is more closely linked to biotechnology and which, thus, makes a greater economic effort towards its development.

At present, the companies consider that adapting their infrastructure to the new technology is a priority, and the purchase of new machinery to cope with the technological advances is essential for this purpose. All companies consider this a business strategy priority and a first step towards undertaking truly innovative activities and technological research and development in the future. The greatest number of technological innovations has been in new products, introduced and manufactured by the company itself, followed by significantly improved products, and, finally, slightly modified or unmodified products.

The organisational changes which have occurred have been put into practice as a new strategic orientation required by the introduction of new technologies which, without doubt, necessitated a change in current practices.

As a first step, the companies were only acquiring the equipment necessary to adapt their technologies to the new era, without redefining business objectives and the new tools required. Innovation was only considered from the point of view of the technology itself, without taking into account the consequent need for a change in the organisational culture with new, more dynamic and flexible management techniques. This group now appears to have achieved this second stage.

These companies, as mentioned above, base the success of innovation primarily on the R&D department, and the presence of this department can be considered as an example of the organisational change which has occurred: in the mid-1980s there were almost no companies carrying out R&D and, naturally, not one of them had a specific department for this. They all now have a well-defined department which concentrates all its efforts on finding effective solutions for manufacturing processes, on the improvement of existing products and the creation of new ones.

In most cases general management is considered to be a fundamental element not in the provision of usable ideas for technological research and development but rather in the adaptation of the organisational structure to modern times. The redefinition of the personnel department (which used to be concerned only with salaries and social security) to the human resources department (which decides training policy, career planning, remuneration, etc.), and of the research group (when there was one) to the R&D department, etc., are some of the benefits which the companies attribute to management.

The new technologies must be accompanied by new methods of management, and these must be implemented by upper management. Furthermore, the companies also state that these ''executives'' participate actively in innovation by their commitment and by the study of global processes. As a test of the importance given to general management, the innovation culture of the company and the dedication of upper management are considered by all companies as factors which contribute to the success of innovative activities.

The marketing and production departments are, in their opinion, the most distant from innovation. These departments, presently, only undertake activities related to production and do not participate in any practical way at this level: their involvement is intermittent and always linked to an improvement in the production chain, either in the process or in the product itself.

3.6. Linkages and interactions: co-operation

In general, the companies studied have a positive opinion of co-operation, particularly with regard to undertaking work related to innovation. The appreciation of innovation-linked competitiveness, conditioned by the search for ''partners'' to jointly finance the high cost of the research, favours relationships with various institutions.

The situation seen up to the 1980s, when no company carried out innovation or research and development, placed each company (or business group) within defined limits, working in isolation, distanced from its competitive environment and with no need for input from external organisations. Now, the search for solutions to specific problems demanded by the market, for sufficient

financing for the costs of R&D and, in general, for integral solutions for new processes and products, encourages companies to sign agreements and enter partnerships with both public and private institutions.

In *Cataluña*, the companies are even beginning to participate in various national and international research programmes related to biotechnology research projects: 13 companies have undertaken projects financed by funds from the "Spanish National Plan of R&D", five with funds from the "Autonomous Community Plans" and nine with support from the EU framework. This participation in projects began in the 1990s.

Furthermore, as mentioned above, the companies have begun a strategy of co-operation with other institutions to carry out innovation or R&D which, on many occasions, has resulted in the development of new products.

The relationships with public institutions appear more formalised, and these contacts already form part of business culture. Co-operation with Spanish universities has been established by all the companies which are undertaking or have undertaken innovation of products or processes in recent years, and almost half of these companies have had contact with universities in other countries of the EU. It is also very significant that two-thirds of the companies undertaking R&D have co-operated with public research organisations (the "Consejo Superior de Investigaciones Científicas" (CSIC) {The Spanish Research Council}, for example) in Spain and in almost equal number with EU organisations. However, this type of co-operation only occurs in a small group of companies dedicated to research which make use of public resources, both human and economic, to assure the quality of their projects. It is clear that there is still a long way to go in this matter as the relations between the private sector companies and the public sector are still far from ideal and the potential of public research organisations is not optimised or "exploited" by the Spanish industry.

Co-operation with other companies of the same group and with other companies of the sector is at a secondary level. The mergers now commonplace throughout the EU are also seen in the biotechnology sector in Spain. Companies come together to form business groups which are able to take on research in an integral manner, producing total solutions to specific problems. For this reason, the companies within a group keenly maintain co-operation between the various members. Even more important is the finding of co-operation with other companies in the sector (those which could be called competitors), easier to understand in terms of the different levels in a production chain. As well as intermittent contact with the competitors as such, companies in the sector (particularly those concerned with agro-foods) are stratified according to their proximity to the final product. For this reason, most of the co-operation takes place through the production chain itself, when intermediate solutions are required for specific problems as they occur.

One of the indicators when assessing the results of research and innovation is the development of new biotechnology products. In the period 1995–98, 13 out of the 15 companies in Cataluña which carried out innovation developed new products, showing the success of the action undertaken. Investigation into the manner in which these products have been developed reveals that eight companies achieved this internally, within the company, and in 10 it was thanks to co-operation established for this purpose. The Spanish universities and public research centres are the principal institutions collaborating in the development of new products. Once again, these institutions appear in first place when the companies speak about products obtained in collaboration with other organisations, giving these institutions a very high assessment with respect to their active participation in attaining the objectives. All the companies confirmed they have been able to find within the universities and public research organisations those aspects which they cannot cover in their own organisations. Furthermore, the opinion of this industrial group on the scientific qualification of the professionals in the two mentioned organisations is very high.

There has been a favourable trend in co-operation with the various organisations in carrying out innovation and R&D in the field of biotechnology over the period 1995–98, with 13 companies

showing growth of this aspect (five intense and eight moderate) in this period. Only one company said that it has had fewer professional contacts in recent years. In general, however, the companies state that they do not maintain the levels of co-operation which they would like because of the continuing low investment in R&D and innovation as compared with the average of EU.

Co-operation with the various available institutions (from suppliers, clients and other companies to research centres and universities) is one of the factors which the 15 companies highlight as a key to success in innovative processes. The importance given to research centres and universities continues to be higher than that given to other organisations.

In *Madrid*, the profile of the companies with respect to co-operation with other institutions follows the same lines as those mentioned for Cataluña: the companies are beginning to participate in the National Plans for research and are increasing their co-operation with the public research centres and universities.

Entering into greater detail, four of the companies in Madrid have participated in the National Plans related to biotechnology research projects, four have participated in EU programmes and three in the Autonomous Community Plans running in the different autonomous communities. However, the companies continue to feel that the public financial programmes do not take the industry's opinion into account, so as to adapt their policies to the real needs of the sector and that, therefore, the public research funds are not efficiently used.

It is true that the basic research carried out in public research centres has always been out of touch with industry and motivated, in part, by the industry's lack of interest in any significant advance. The companies, due to the small size which has always been one of their characteristics, and apart from the truly innovative companies, have not considered R&D as one of their strategies up to now. This has led to a clear difference of interests between industry and the public research system. Despite this traditional culture, the companies studied have begun to change this situation and have started to set up co-operation in a systematic manner. The Spanish public research organisations and universities are the preferred organisations with which the companies maintain contact, as can be appreciated from Table 3. Both Spanish and the EU universities and public research organisations have seen an increase in requests for work from these companies, but contact and co-operation with these organisations in other countries are negligible.

Other organisations with which co-operation has increased are other companies in the sector and the companies of the same group, also at a national level. Companies in Madrid have a very noticeable lack of contact with international organisations, though present trends suggest an increase in these contacts: the companies first establish contact with national institutions; from there, they look for partners in the EU and finally they attempt to set up contacts with other companies or organisations at an international level. The leap to establishing co-operation with American organisations "frightens" general management, and a first level of co-operation with European organisations is preferred.

This co-operation has resulted in the development of new biotechnology products on many occasions. In the period 1995–98, seven companies (of a total of eight) have achieved this objective and all of them in collaboration with other centres or companies. Five companies have been able to achieve new products internally, without co-operation with any other external organisation. In this manner, it appears that the companies interviewed find greatest support within the group to which they belong, as the largest number of products is developed in collaboration with these companies. These groups have companies in various countries, and this favours international contacts, increasing the number of these contacts with respect to contacts with public research centres and universities.

In general, these eight companies state that they have increased the number of contacts in the development of innovative activities between 1995 and 1998, achieving an increase in the number of occasions on which co-operation was undertaken. All the companies are anxious to achieve a significant increase in co-operation with public organi-

Table 3
Number of companies in Cataluña and Madrid which have bought and/or sold technologies

New technologies	Spain				EU countries				Other European countries				Other countries			
	Bought		Sold		Bought		Sold		Bought		Sold		Bought		Sold	
	C	M	C	M	C	M	C	M	C	M	C	M	C	M	C	M
Equipment	6	2	1		4	2			1				4	1		
Subcontracted R&D	9	3	3	1	4	1	2		1		1		3	1	1	
Consultancy services	4	2	1		2	1							1	1		
Personnel contracts	6	4	1		2		1		1				2		1	
Communications and training	4	2	2		3		2		2		2		5		2	

C = Cataluña; M = Madrid.

sations, though they also considered that the public research system is an obstacle in relationships: a change in the outlook of public sector scientists is believed to be necessary in order for them to better understand the problems of industry. The companies also criticise the established career system of public sector research for not according merit to contracts with companies in the curricula vitae of the investigators.

3.7. Technology transfer

With reference to the processes of acquiring, transforming and transmitting technology, it should be mentioned that the Spanish industry involved in the tasks of technological innovation, research and development is still in an early phase, based, fundamentally, on the acquisition of technology and equipment from abroad. Innovation, therefore, has been practically limited to the purchase of the "latest generation technology" which provides them with an up-to-now unknown potential.

The companies in *Cataluña* find themselves within the framework described above, and the greatest activity insofar as concerns new technology is the acquisition of equipment and externally subcontracted R&D. The results of the interviews on this issue are summarised in Table 3.

The results show a clear negative balance between the companies which buy in new technology and those which sell. The group of the 15 companies in Cataluña is modernising its production systems by the incorporation of new equipment, though there is already a small group (three companies) which is beginning to sell their innovations to other companies in the sector.

The companies face a series of factors which make this expansion difficult and which are classified as: internal—economic and business—and external. With respect to the first, the economic factors most frequently cited as a restraint on innovation are the high cost of these activities and the risk of this investment. All quality innovation requires the medium term allocation of funds which is not always positively viewed and accepted by general management, particularly when the results of these investments do not assure tangible benefits in a reasonably short period of time.

The prime business factors are precisely the low spending on R&D and the inability to count on sufficient innovative potential. Although the mentality of management is changing towards a more long-term view, they are looking for investments to be made based on the success of the proposals, but an association between investment and later economic benefit cannot always be assured.

Finally, the external factors which have a bearing on innovation are current regulations, legislation and norms and the uncertainty which is a characteristic of innovation. We must not forget that the sector at which we are looking, the biotechnology sector, works under totally new legislation and that it gives rise to certain doubts in all sectors of society: the companies, the scien-

tists, the consumers, the associations, environmental groups, etc. The companies interviewed insist on their request for a single, unified, community legislation for all countries of the EU so that they can work under equality of conditions and competition.

The situation for the companies interviewed in *Madrid* is similar to that in Cataluña, with all of them consolidating their position as potential purchasers of new technology. This is despite the fact the group in Madrid is being considered as more "biotechnological" than the Catalan group.

However, the needs of the industry do not stop there: there is also a need to train the workforce, adapting it to the technological advances, as well as to take on R&D projects in a systematic manner to assure competitiveness.

As may be seen from Table 3, the greatest efforts are being put towards taking on personnel and carrying out R&D projects. The most ambitious companies with the most commitment to innovation make great efforts towards these two objectives as the means to assure their success in the market. The sale of new technology is considered to be the next step, though it is still far from being within current possibilities. First the companies must get themselves "up-to-date" in current biotechnology developments and, from there, consolidate their position and achieve a balance between purchases and sales.

Accepting these deficits as reality and of primary necessity, the means for their solution must be sought; the companies are aware that the cost which this represents is very high and to undertake them they demand encouragement in the form of innovation programmes supported by government (both at a central and regional level) and the promotion of co-operation with public research centres.

A change in the innovative culture (considered a key factor in competitiveness) already appears to be taking shape in all the companies, favoured in large measure by the commitment of high-level management. Both factors are closely linked to a greater predisposition of the workforce towards this type of work and the search for better alternatives.

3.8. Convergence trends and factors of development

The main aim of the sector in *Cataluña* is to increase the range of currently available products in order to increase or maintain their market share. To achieve this, a product of higher quality must be offered. Other objectives of great importance, such as the entry into markets in other EU countries or in the rest of the world, appear to take second place, though they are given consideration when future business strategy is being drawn up.

The very close agreement in the objectives established by the companies as a whole is remarkable. Above all, they appear to be looking for a leading position in the national market before taking on activities which would allow them to broaden their horizons to foreign countries.

For their part, the companies in Madrid have established as priorities the improvement in the quality of the products and an increase in the range of products. This group considers that a leading position with respect to competition is gained by offering the best possible product on the market. Having achieved a truly competitive product, with its niche in the market, the means are sought to introduce further new products to consolidate their position.

Furthermore, their aims also include the opening of new markets in Spain. It has already been mentioned that this sector is considered to be "a new creation", and the companies have still not been able to penetrate all the available markets at a national level. This is how the companies perceive the situation and express it in the interviews; their intention is to dominate the largest possible number of sectors.

Concern for the environment is another factor labelled as a priority in the strategy for the future. The companies require full awareness of and commitment to sustaining the environment, and they already express this concern.

3.9. Main factors that may be affecting those expected trends

In the same line, there is also consensus in

considering innovation and R&D to be the mechanism by which existing products and processes may be adapted to real needs, though the prospects of their economic impact on turnover and the volume of exports are still not considered to have been fulfilled.

In *Cataluña*, at present, these activities, which up to now have been considered as giving ''added value'', have not yet compensated for investment in the form of consolidated economic benefits. Despite this, five of the companies have already correlated the increase both in turnover and in exports with the R&D activities in biotechnology. This increase has been estimated at slightly over 10% at a global level (for all five companies), with an increase of 13% in sales and of 16% in exports.

In *Madrid*, with regard to the economic impact of innovative activities and R&D on company profits, the figures made available in the interviews are not particularly encouraging: one company has only increased sales and two have increased sales and exports. Three companies which have increased sales have done so with a mean of 25.3% and the two which have increased exports have shown a mean increase of 57.5%. The forecasts made by all of them are of experiencing growth in the short- and medium-term, conditioning the results to more mature markets which are open to the continuous changes being introduced.

3.10. Expectation about reduction of the gap

The perspectives defined by all the companies for the immediate future are, in a first phase, to make the investments in R&D profitable by making their products or processes more suited to the demands of society, thus achieving a better position in the market. From that moment, the increase both in turnover and in exports becomes an objective which must be fulfilled.

The problem in both regions, *Cataluña* and *Madrid*, is two-fold: public policies and consumer acceptance for the newly created products (or already known products using new, more modern procedures based on biotechnology). It is clear that Spanish society has been able to accept products derived using these new techniques in the area of therapeutics and healthcare and that this is not a problem when they become potential consumers of these products. All those drugs which contribute to an improvement in the quality and length of life, even if openly called ''biotechnological'', with all its implications, are accepted without condition.

However, the advances made in the agro-food sector have led to considerable social controversy concerning the problems caused by the consumption of food from genetically modified organisms. Despite the safety of these products (they have to pass a series of strict controls which, to date, have raised no doubts about their suitability for marketing), the public is negatively disposed to them without having received sufficient information to be able to form a qualified opinion. For this reason, the success of companies working in this sector seems to be conditioned by consumer acceptance, both in the production chain (food manufacturers, for example) and the final consumers of the newly developed products.

4. The biotechnology sector in the rest of Spain

The rest of the firms in Spain (23 firms, 47% of the total firms identified in the study) are distributed throughout the country, though three regions (Andalucia, six firms; Galicia, four firms; and Comunidad Valenciana with four firms) still show a certain degree of concentration (28.6% of the total). The nine remaining firms are scattered in other regions with the following distribution: Aragón, Castilla-La Mancha and Basque Country (País Vasco) with two each, and Canary Islands, Castilla-León and La Rioja, with one firm each.

There is a degree of specialisation in the area of agro-food and environment for the region of Valencia (Comunidad Valenciana), whereas in the other two regions with the higher share (Andalucia and Galicia) there is an even distribution of the firms into the three classical subsectors: agro-food, health and bioprocesses.

Three firms out of 23 are of public ownership. The other 20 are private, 15 of national property and five multinationals.

The great majority of the firms (19) were created before the 1990s, with their activities not specifically addressed to the development of biotechnology. However, the incorporation of this technology has opened new business opportunities, thus leading to an important strategic orientation in the market and new entrepreneurial organisation. Two-thirds of the firms undertook their activities on biotechnology during the 1990s, with the remaining firms beginning their activities in biotechnology earlier; five firms in the 1980s and the other four well before that decade.

The total of human resources for the 22 firms that provided information on this topic amounted to 9537 employees, with an average per firm of 433.5 and a median of 50–60. The strong differences between the average and the median rest on the effect of two big firms: one in Andalucia with 7500 and another in Castilla-León with 700 employees. The influence of these two big companies does not mask the profile of the biotechnology firms in these regions of Spain as that of an industry which is nationally owned and of small-to-medium size.

The turnover figures amounted in 1998 to 700 million euros (average, 34 million euros, and median, 3 million euros). The average of the sales which are a result of the activities of the firms in biotechnology amounted to 41% (though some firms were unable to provide such data), a percentage that matches well with the percentage of the R&D spends which was devoted to developing biotechnology (41.7%, with the following figures: 1.15 million euros as average and 0.54 million euros as median). In spite of this good match, it is perhaps worth to note that the relatively small differences between these values as compared with the larger ones existing in other parameters like human resources and turnover figures, may point out that the small and medium firms are those carrying out the highest effort in the R&D spent.

Most of the firms have been involved in performing innovation in processes, though their main innovative strategy is driven by improving their organisational structure. Their goals are to be able to compete in the market by increasing the number of competitive products and their market share. The reduction of the environmental impact is also recognised as an aim of the firms' goals. About 50% of the firms are able to export, namely to the EU, with smaller percentages to other European and non-European countries.

The firms recognise the high cost of R&D and innovation, together with their limited resources, the lack of the trust of consumers in new biotechnology products as well as the constraints imposed by *regulations* as the main factors hampering the development of the biotechnology sectors. On the other hand, the existence of an intra-firm innovative culture, supported by the will of the general management of the firms and the ability and opportunity to co-operate with public research centres are applauded as the main drivers for a satisfactory development of that sector.

In summary, this data confirms the argument that the landscape of the biotechnology sector in Spain is shaped by the intervention of industries from the agro-food, bioprocesses and someone in the health subsectors, which have been able to diversify their activities, processes and products, to cope with the introduction and development of modern biotechnology.

5. Conclusions and comparative framework

1. In carrying out comparative studies on biotechnology industry in Europe, there is a risk to follow the North American pattern—the Ernst & Young approach. This model does not apply to all Europe, although it is relevant to United Kingdom, and partially to the new developments in Germany and other central European countries. But it scarcely fits into the development of biotechnology in France and in other less developed countries of Europe. The case study of Spain adds support to this argument. As a consequence, the comparative analysis based on that approach might be either incomplete and/or biased in terms of information for taking decisions and designing policies at European level. The case study of Spain, for example, identifies deficiencies in the development of public sector research pro-

grammes and the attitudes of public sector scientists. Adapting policies to remedy these problems could be of great importance to further developing the commercialisation of biotechnology in Spain.

2. The analysis of the Spanish case on biotechnology, carried out within a European frame, has served to illustrate the complexity and diversity underscoring the comparative studies on this technology. Several models have emerged.
3. There are evident similarities and differences in the landscape of industrial biotechnology between Cataluña and Madrid. The differences seem to stem from culture and socio-economic values and traditions, as well as from their respective organisations to tackle with these issues. There is a primary state of biotechnology development in both regions, Cataluña and Madrid, and they already have a regional capacity for innovation in biotechnology, relying on the specific characteristics of each of these regions: an industrial tradition in Cataluña, and the strength of the services sector and new technologies in Madrid.
4. The evolution of biotechnology in Madrid is showing a trend towards the Anglo-Saxon model with the creation of several spin-offs from universities and public research centres. The evolution in Cataluña appears to be based on institutional initiatives bound to the concept of technological (and scientific) parks and the corresponding infrastructures. The quantitative weight of the Cataluña region in the case of Spain biases the model of the Spanish biotechnology sector towards type 4 (Table 2). However, the subsystem of Madrid matches better with a mix of models 1 and 4.
5. The lack of statistical data on biotechnology in Europe, due to the complexity and transversality of the sector, hampers the feasibility and validity of European comparative studies. Studies as those carried out in the frame of European projects such as the one reported here may help to increase the knowledge on the situation of biotechnology in Europe.
6. Some previous works have shown differences in the role being played in the making of biotechnology policy in Europe by public administrations at supranational, national and regional level (see for details European Commission, 1999).
7. It is evident that biotechnology is operating at a global level, but in this operational situation, the importance of the national and regional levels is emerging as critical environments for the appropriate evolution of the technology.

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References

Braczyk, H.-J., Cooke, P., Heidenreich, M. (Eds.), 1998. Regional Innovations Systems. University College London (UCL Press), London.

Comisión Interministerial de Ciencia y Tecnología, 1997. In: Albert, A. (Ed.), Spanish Research Groups & Enterprises Working in Biotechnology. CINDOC, Madrid.

European Commission, 1999. Inventory of Public Biotechnology R&D Programmes In Europe, (multiauthored work), Office for Publications of the European Communities, Luxembourg (3 volumes).

Lundvall, B.A. (Ed.), 1992. National Systems of Innovation. F. Pinter, London.

Malerba, F., 1999. Sectoral Systems of Innovation and Production. TSER ESSY Project, Milan (mimeo).

Nelson, R., 1993. National Innovation Systems: a Comparative Study. Oxford University Press, New York.

Rosenberg, N., 1991. Critical Issues in Science Policy Research. In: Science and Public Policy, vol. 18, pp. 335–346 (number 6).

Saviotti, P.P., 1998. Industrial structure and the dynamics of knowledge generation in biotechnology. In: Senker, J. (Ed.), Biotechnology and Competitive Advantage. E. Elgar, Cheltenham, UK and Northampton, MA.