Biosciences and their development: an introduction

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Biosciences have been identified in numerous contexts as one of the keys to economic development in the years to come[2]. With Infosciences and Nanosciences, Biosciences constitute the real framework of the "New economy".

Three principle features are common to these three scientific and technological areas:

- The capacity to integrate with one another.
- The capacity to be a development key for other industrial sectors and therefore to "enable technologies".
- The fact of being "world-wide" and "global".

However, along with these similarities, the three scientific areas show great differences in the way they grow and develop, and in their impact on local economies.

I will try to outline the Biosciences case, in the light of development problems at local level, focussing mainly on qualitative structural aspects, rather than looking at economic, financial and quantitative data. A basic definition of Biosciences, will help to understand the main players in the sector and the way they and their different technologies converge and interact, and will also serve as a key to understanding the problems of development in this sector.

1. Defining life sciences and biotechnologies.

The difficulty of defining biotechnologies lies in their diversity. In fact, life sciences and particularly biotechnologies comprise a range of multidisciplinary technological platforms and scientific discoveries that can be combined in different and innovative ways as and when required..

To this regard, biotechnologies can be defined as "every technology that uses live organisms (such as bacteria, yeasts, vegetable cells, simple or complex organism animal cells) to obtain commercial quantities of useful products, or to improve animal and plant characteristics or to develop useful micro-organisms for specific use". This general definition also includes production technologies used long ago, such as agriculture, zootechnology and the exploitation of fermentation activities of microorganisms. The latter can therefore be distinguished by grouping them under the term *traditional biotechnologies*, to differentiate them from the truly *innovative biotechnologies*.[3]

From this point of view, innovative Biotechnologies are clearly the result of basic and explorative research. In this field, what is clearly evident is the close relationship between basic research and applied research and

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[2] United Nation Division for Sustainable Development, Agenda 21, Section II, Chapter 16, Environmentally sound management of biotechnology, internet site: http://www.un.org/esa/sustdev/agenda21chapter16.htm, European Commission, "Life Science and Biotechnology – A strategy for Europe" COM(2002) 27 Final January 2002, Brussels.

[3] Giorgio Poli, Biotecnologie e applicazioni all'ingegneria genetica, UTET Periodici Scientifici, Milano, 1997,

production, in contrast to the traditional concept of basic research taking place uniquely in universities, and applied research and production taking place in industry.

In times of globalization of information, this unique feature is bound to influence the key factors of development, and explains why real "biodistricts" come into being in specific areas.

The same multidisciplinary origin of biotechnologies partly explains their applications in different industrial sectors. Some examples of biotechnological applications deriving from life sciences which have become innovative processes in industrial production are:

- Human health (Pharmaceutical, diagnostics)
- Agricultural
- Zootechnology
- Cosmetics
- Bioindustry and chemical
- Environmental and energy

The integration of these technologies with infosciences and nanosciences opens further, exciting and new development areas in synergic sectors, such as bioinformatics, biomedicine, etc. The biotechnologies system therefore, is particularly rich and complex.

However, these remarkable biotechnologies have brought with them moral, ethical and legal implications, (for instance, consider the problem of patents).

2. Biotechnology industry: a structural analysis of the sector

2.1 "Towards an economy founded on knowledge"

In industrially advanced societies, the creation of wealth deriving from knowledge and product quality becomes increasingly important, while at the same time the prominence of classical parameters, such as the cost of raw materials and labor costs, decreases.

The "society of knowledge" gives rise to a new economy, *capable* of creating high value added products.

The following three sectors are the most characteristic of this new trend: information technology, nanotechnologies & new materials and biosciences. All of them need particular conditions in order to develop and stimulate the financial world to reconsider its investment risk evaluation parameters, acquiring an unexplored capacity to estimate the intellectual property of entrepreneurial initiatives (start-up)[4].

Biotechnology, as we have seen, includes a wide range of technologies and procedures that foster the creation of highly competitive new products and processes in numerous industrial, agricultural and health sectors, leading to new opportunities in many sectors.

Biotech products in fact distinguish themselves as being easily incorporated in multidisciplinary "technological solutions" that can be applied in different fields.

In order to understand the importance and impact of the biotechnology sector, one must start with a "economy based" definition.

[4] [4] L. Alberghina, Biotecnologia e finanza, Notiziario della Banca Popolare di Sondrio, n.82, aprile 2000, pag.16.

According to some analysts "Biotechnology is selling biology"[5]. This concept seems to be fully understood in many countries where by now biotechnologies represent an explicitly strategic[6] market, so much so that many leading international scientists and economists argue that the century which has just begun will be called "the biotechnology century"[7]. The revolutions in genetic and computer science have merged to form a "scientific, technological and commercial phalanx",[8] namely a new reality that promises to deeply influence both the individual and society.

2.2 Biotechnology sector

In the last few years in industrialised countries, the biotechnology sector has shown striking economic growth impacting directly on the quality of life and on socio-economic development.

This sector has been characterised by at least three relevant factors: a high technical-scientific content in rapid and continuous evolution, close links with basic research (therefore with University and other institutions) in which biotechnologies are deeply rooted, and the long time needed to introduce a new product on the market (which today varies between 5 to 10 years, for almost all sectors of application[9]).

Other fundamental aspects of this sector are the need for capital to be managed more effectively and for a more up to date and adequate system to patent products and processes.

Speaking of the biotechnological sector presupposes a knowledge of its industrial structure: in fact, it depends on the effective functioning of an innovative "system", that works by linking the three components, where the proper development of each component plays a crucial role.

Research

Research is the principal source of new ideas that, once developed, can lead to the commercial exploitation of new products or productive processes and/or their improvement.
It includes mainly research carried out in public and private research structures, although it can also involve industrial research partners. As a rule, companies use research results only if they are potentially marketable. In order to become a process and a product of innovation, research depends, above all, on the process of technology transfer and the creation of new enterprises.

Biotechnology specialized enterprises (ISB)

The "ISB" appear to be the most incisive in converting scientific discoveries into services and products with a commercial value. Essentially, there are three types:

a) developing enterprises: are proprietors of an idea engaged in converting it into a product or service of a precise commercial value. Many of them, in particular in the medical-healthcare sector, are

[5] L. Massotti, in Biotec, n.6, 1996.
[6] AA.VV., European Biotech 96. Volatility and Value", Ernst & Young 1996. AA.VV., European Biotech 97: a new economy, Ernst & Young 1997. AA.VV., New direction's 98, Ernst & Young 1998.
[7] J. Rifkin, The Biotech Century, J.P. Tarcher, 1999 pag. 23.
[8] J. Rifkin, The Biotech Century, J.P. Tarcher, 1999 pag. 23.
[9] S. Bucci, L'industria delle "nuove molecole", Il Sole 24 Ore, 10 maggio 2000, pag.17.

involved through investments and joint ventures with larger sized enterprises. This strategic approach is also adopted by large pharmaceutical industries, due to the opportunity it offers of making use of research and development activity results produced elsewhere;

b) "integrated activity" enterprises: are enterprises that have invested in research, development, production, marketing and sales. With the exception of new companies in the diagnostic sector, and Amgen, Genentech, Serono and Genzyme in the pharmaceutical sector, there are relatively few of them;

c) suppliers: are companies that supply equipment, materials and services either to companies which operate strictly in the biotechnology field or for end user companies. This type of firm is becoming increasingly more important because of the need for companies to use technologies and services which are not available in house.

All of the above companies can be regrouped in two other macro-categories[10]:

- Established Companies (ECs) or Large Diversified Firms (LDFs): organisations already operating in a traditional way in various market sectors, but which have adopted modern biological technologies, as an innovation product element and/or as an improvement of ongoing production;

- New Biotechnology Companies (NBCs) or Dedicated Biotechnology Firms (DBFs): enterprises created to perform research, or however to make use of biotechnology potential, characterised by high scientific content, close ties with basic research and distinct specialisation.

End user companies and synergistic sectors

This type of enterprise influences the market because it possesses numerous personnel and financial resources and considerable competencies.

They have the ability to influence regulations, as well as strong marketing and sales capacities.

In the last few years they (especially pharmaceutical companies) have developed strong links with specialised companies in this sector through alliances, joint-ventures and take-overs with the aim of accessing new ideas and products. Many of the biggest end-user companies have developed internal research and development capacities in the biotechnological fields.

It is worth noticing how biotechnology "cross impacts" condition innovation and development even in distant market sectors: (Agriculture-Diagnostics; Energy-Environment-Food; Chemical-Equipment-Therapeutics, Biotechnologies-Informatics-Biomedical, etc.).

[10] G. Aglialoro, Il diritto delle biotecnologie, Giappichelli Editore, Torino, 2001, pag. 34.

This "multiplier" effect is also manifest in the analysis[11] of links existing between biological, medical research and equipment development in USA "biodistricts", as well as in the co-operation between industrial enterprises in different sectors. The intensity of research-research, research-enterprises and enterprises-enterprises interactions reinforces the capacity of biodistricts to attract more organisations.

For the purposes of "biodistricts/biovalleys" development, the presence of a nucleus of expert scientific skills is of central importance, as is the presence of the instrumentation sector which consists predominantly of micro-organisations.

The "Biotech System" which develops through links between the following components: Research-Enterprise-specialised Biotechnologies - End-user Enterprises, can be defined as a Virtual/Cluster District. This term describes the grouping of organisations, companies and research institutions who can provide and/or share their high technology resources and services. This concept will be taken up again in the last part.

Seen from this point of view, it would appear that there is a strong competitive advantage for organisations in this sector to exploit the on-site structures dedicated to technology transfer and the enterprise incubators where the links between the components are monitored in the start-up phase.

2.3 Sector evolution – notes

At the beginning of the 1980's, the main players in the *biotech* sector were highly specialised research laboratories investing in a few or single projects which presented an extremely high entrepreneurial risk rate. This risk was linked to the fact that these players focussed their efforts on the development of a single or few molecules. Thus, only a limited number of biotechnological enterprises succeeded in reaching the extremely high returns expected from the market, with the result that in the U.S., for example, more than 90% of them went bankrupt within the first five years of life[12].

During the early 1990s, many of the institutional investors distanced themselves from this environment, especially from start-up phase companies, becoming even more selective and reduced-risk oriented, because of the difficult financial period.

In this scenario, many of the biotechnological companies began to sell their most prominent projects to the large pharmaceutical companies, often through the transfer of their entire majority share-holding. In more recent times, biotechnological enterprises have benefited from a strong recovery both in terms of economic prospects and, consequently, of capital influx. This was also made possible thanks to the use of new, particularly sophisticated technologies and to the development of highly specialized know how. The rapid development of the convergence of biotechnology competencies and applied information technology during the early 1990s, contributed enormously to advances in analysis and calculation methods, enhancing new innovative technologies such as, genomics, proteomics, combinatorial chemistry and high throughput screening[13].

In the "health care" area, for example, this development has had the effect of accelerating target identification for the cure of even more specific diseases.

Innovative biotechnologies have opened completely new roads to pharmaceutical, agricultural and environmental research: from the identification of new pharmacological receptors and of their structure, to the targeted synthesis of active substances, from the development of new oncogenic and oncosuppressors to the identification and modification of the active sites structure of enzymes, to the utilisation of hormone

[11] The Dynamics of Industrial Clustering – International Comparisons in Computing and Biotechnology, ed. G.M. Peter Swann, Oxford, 1998, see Senker J. (edited by) "Biotechnology and competitive advantage. Europe's Firms and the US challenge", Edward Elgar Publishers, Cheltenham (UK), Northampton (MA-USA), 1998

[12] P. Bruschetta, R. Cinquegrani, Ieri, oggi e domani, in Ricerca Roche, n. 25, settembre 1999, pag.75. S. Bucci, Per le biotecnologie investimenti e ricerca, Il Sole 24 Ore, 31 maggio 2000.

[13] Ernst & Young "Beyond Borders: Ernst & Young's Global Biotechnology Report 2002", 2002

blocking monoclonal antibodies, and to the definition of molecular bases of the links between plants and their parasites.

The human genome sequence constitutes the basis for the preparation of new drugs and diagnostic systems[14]. It is therefore fundamental for biotechnological companies to invest in research, aiming at growth and balancing of their project portfolio, at the expansion of their technological platform, and at increasing their intellectual capital.

2.4 Biotechnological industry convergence

Biotechnology has had the opportunity to become one of the most dynamic phenomena of this century, thanks to the convergence of numerous forces from different sectors.

Biotechnology is in fact creating extensive platforms for new products and markets on various fronts (from agriculture to chemical and industrial processes, from medicine to informatics) with many companies that relocate and integrate their scientific approaches and financial objectives.

The convergence between previously distinct industries is taking place rapidly, and this could eventually lead to a more stable and sustainable biotechnological market. If this trend continues, the dividing line between biotechnological and industries of other sectors will be less evident, increasing the number of new hybrid products.
The biotechnological industry, apart from giving rise to the production of many new drugs for man, is increasingly interacting with non-traditional sectors, such as chemical products, semiconductors, information technology, and agriculture. Many of these industries have begun to take advantage of the power of biotechnologies, and numerous companies operate contemporaneously in many different sectors.

We can identify two different main elements of the convergence phenomena:

- A ***market convergence***, due to the fact that many companies that were previously focussed on a single market are now expanding into other sectors;
- A ***technological convergence***, led to the choice of many enterprises that, having a technological platform or a product dedicated previously to a single market, are now applying their technologies in other areas, too. In this way, creativity and innovation that support the single markets can impact the growth of many other sectors[15] like informatics/ICT (Bioinformatics), nanotechnologies, etc. .

A direct consequence of the convergence of activities in this sector is the continuous growth of mergers and takeover phenomena, both for Dedicated Biotechnology Firms and for the "traditional" Biotech and Pharmaceutical enterprises, in order to reach the size necessary to "survive" in a highly competitive environment.

3. Keys to local development in the Biotechnological sector

All these factors help us understand how development in the biotech sector is subject to a high number of variables. The European Commission[16] has identified numerous factors that come into play when the

[14] A. Massarenti, Senza dogmi la biologia vola più alto e C. Venter, Il codice segreto della diversità, Il Sole 24 Ore, 16 aprile 2000; C Di Giorgio, Completata la sequenza del genoma umano, La Repubblica, 6 aprile 2000; G. Vattimo, Genoma per tutti e L. Silver, Biotecnologie, per un pugno di geni, La Stampa, 18 aprile 2000; M.C. Ferri, Biotecnologie, SEI, Torino, 1997, pag. 152.
[15] Ernst & Young, "Convergence. The Biotecnology Industry Report", 2000, pag 2, 12 e 26.
[16] European Commission, "Life Science and Biotechnology – A strategy for Europe" COM(2002) 27 Final January 2002, Brussels

problem of how to encourage growth in this sector is encountered. Briefly, the key elements identified are the following:

- the presence of a strong scientific base;
- the capacity to transform scientific research results into innovations;
- social impact;
- alignment with social values;
- adoption of demand oriented solutions through an informed choice;
- reliability of scientific instruments on which regulatory boards base their criteria;
- shared and transparent regulatory principles;
- belonging to international networks.

It is easy to see that these key elements actually concern many aspects – economic, financial, ethical, political and communicative aspects – and can be dealt with exclusively at a macro-economic or continental level.

Little, however, is said of the local dynamics that must be activated to help sector development. Many experts have come to the conclusion that the biotechnology sector can grow following the logic imposed by its surrounding territory and by the particular groupings of activity, based on the cluster concept or on the concepts of growth connected in part to the evolution of Biovalleys. The aspects of these phenomena, illustrated above, can be understood and dealt with using apposite and synergistic policies and means.

It is worth, therefore, dwelling for a moment on these two concepts in order to define the reference model for development. If Biovalleys can be defined as a circumscribed territorial area, clusters, on the contrary, are "..a local concentration of enterprises which are inter-linked, i.e. specialised suppliers, service distributors, enterprises belonging to allied sectors and institutions (for example university, regulation boards, category associations) that compete and co-operate in particular fields "[17]. We have therefore a definition that on the one hand reminds us of an industrial district[18] and of a technological district[19] and, on the other, it is differentiated by its geographical valence. Speaking of clusters, the territorial variable that is the identification of "where" - partially loses its importance. A cluster is a "flexible" concept that depends on the perception of the players' proximity to one another. This perception varies depending on territories and cultures. One parameter that can be used is the opportunity for workers/researchers' mobility within the territory without having to move home. This parameter is particularly high in a country such as the USA. In Europe, and particularly in Italy where mobility is low, the same parameter has a much lower value and is usually associated with regional or extra-regional boundaries.

Clustering as a model of sector development at territorial level enables us to identify in advance the dynamics which, if functioning properly, guarantee its sustainability and self-generation. The exchange of knowledge, the sharing of common resources, the presence of research institutes and training are only some of the essential factors. Clustering, however, must strictly follow the rules of the game which are demand oriented and are difficult to impose adopting a top-down type of approach. Consequently, the role of public authorities is perceived as simply guaranteeing the conditions and the pre-requisites in the shaping and growth of a cluster.

[17] Porter M "The competitive advantage of nations", The Free Press, 1998

[18] Marshall A. "Principles of Economics", MacMillan, 1920, Beccattini G. "Mercato e forze locali-. il Distretto Industriale", Il Mulino, Bologna, 1987, Brusco S. "The Emilian Model: Productive Decentralization and Social Integration", Cambridge Journal of Economics, 1982, p. 167-184, Onida F. - Viesti G. - Flazoni A. "I Distretti industriali: crisi o evoluzione?", EGEA, Milan, 1992, AA.VV. "Innovazione, piccole imprese e distretti industriali - 3° rapporto CNEL/CERIS-CNR" Documenti CNEL n° 7, Roma 1997

[19] Antonelli C. "L'attività innovativa in un distretto tecnologico", Fondazione Giovani Agnelli, Turin, 1986, Ciciotti E. "Natalità delle imprese e diffusione delle innovazioni di processo in un distretto tecnologico", Fondazione Giovani Agnelli, Turin, 1986, Storper M. "Technological District and International Trade: the limits to globalization in an age of flexible production", Working Paper UCLA, 1991

These pre-conditions, however, are configured as an essential element for every type of "private" and entrepreneurial initiative. What we have, therefore, are key variables that exist before the cluster comes into being, and which support its growth[20] :

- A significant scientific base and local universities, research and clinical centres together with a "critical mass" of researchers
- A dynamic and innovative entrepreneurial culture
- A growing entrepreneurial base especially in high technology sectors with spin-off and start-up
- Environmental conditions that can attract qualified personnel from other territorial areas
- Infrastructures and international links
- The possibility to access venture capital in order to support the activities
- Availability of specialised service distributors and enterprises in correlated sectors
- Availability of qualified manpower
- Availability of support networks and technology transfer
- The existence of public authority, international, national and regional policies and relative financial support structures

Having analysed the biotechnology sector in terms of type of enterprise and the importance of convergence/integration phenomena, the variables identified can be interpreted in the light of the future prospects they represent, as a range of strategies and as industrial policy, starting with the assumption that "in spite of the tendency towards broad internationalisation of research, high technological performance tends to be tied to "home-based"[21] research capacity.

[20]. Allansdottir A., Bonaccorsi A., Gambardella A., Mariani M., Orsenigo L., Pamolli F., Riccaboni M. "Innovation & competitiveness in European biotechnology", European Commission, Enterprise Papers No. 7, 2002 p. 47 - 59
[20] AA.VV "Biotechnology cluster" Departement of Trade and Industry - UK, 1999, pag. 18, Pammolli F.,R M. "Geographical cluster in the biotechnology industry" EPRIS working paper, University of Siena, 2001
[21] Allansdottir A., Bonaccorsi A., Gambardella A., Mariani M., Orsenigo L., Pamolli F., Riccaboni M. "Innovation & competitiveness in European biotechnology", European Commission, Enterprise Papers No. 7, 2002, p. 2. Oxford Intelligence (edited by) "Investment Strategies & European Benchmarkink survey – The MedTech report", Oxford Intelligence, January 2002