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**Science and Society in Biotech
Enterprises: New Organisational
Frameworks and Knowledge-Sharing
Processes**

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**Science and Society in Biotech Enterprises:
New Organisational Frameworks and Knowledge-Sharing Processes**

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Abstract

During recent decades we have witnessed a transformation in science that has stimulated new organisational forms of knowledge production; the boundaries between science and market are becoming increasingly blurred. Essentially, science and society are moving towards an “integrated system”: choice of problems, conflict resolution, and negotiation of solutions no longer develop in a “closed environment” occupied only by scientists, but in a public space that includes various social actors.

In the field of biotechnologies, this transformation has led to the emergence of firms that adopt new organisational forms based on a network structure linking universities, research institutions, non-profit organisations and other firms, by means of stable relationships.

The logics that regulate creation and development of these networks are not only based on criteria of efficiency and performance improvement, but depend, rather, on a process of institutionalisation, which leads to their becoming consistent with the beliefs and values of the actors involved.

Our research in this field has focused on the processes of transformation and management of knowledge. In Italy, in particular, where biotechnology has only recently spread, it is of utmost importance to pay attention to knowledge transformation that involves regulatory subjects, and the gaining of know-how by researchers. This development progresses step by step throughout the “de facto” networks constructed around biotech enterprises. In this context, our field research has relied on a case study, based on a qualitative approach, of a university spin-off in the field of biotechnology.

In the first part of this field research, we focused on the figure of the researcher. He or she changes his or her traditional role by shifting his or her competences from a pure researcher’s standpoint to a more market-oriented position. Knowledge is transformed, from time to time, according to the qualification of those involved (patent releaser, researcher, holding and subsidiaries, authorities, consumers, etc.). This is a functional shift, the aim of which is to make knowledge useful and fruitful for specific purposes, whilst ensuring “knowledge givers” that their property rights will not be violated.

Keywords: Biotech, case study, sociology of organisation, knowledge transfer, public-private partnerships.

Introduction

In recent decades, we have witnessed a transformation in the field of science that has increasingly blurred the boundaries between science and technology, and between public and private. According to the perspective of Etzkowitz's "triple helix" (2005), innovation is no longer a prescription from government, but the result of a complex network of relationships between industry, government and universities, wherein the key element is the creation of an entrepreneurial university. This transformation puts an end to the apparent stability that has long characterised the field of science.

The reasons underlying this change are manifold. First, there is a problem of financing: public funds cannot grow at the same rate as the development of science, and the traditional academic system is no longer able to absorb all the PhD graduates. Therefore, we need a solid social machine to allocate resources, and to ensure that they are put to good use (Ziman, 2004). Secondly, expectations regarding the problem-solving potential of science have increased substantially. Science has contributed to the economic and technical development of the world, and scientists are now expected to continue to pursue the social objective of achieving ever-increasing wealth, thereby affirming the public "utility" of science. Finally, relativist thinking has eroded the concept of *scientific objectivity*, and even of *reliable knowledge*, and has contributed to the decline of the authority of science, which is no longer able to establish unequivocally and permanently which discoveries are reliable. We therefore need to introduce new parameters to determine the acceptability of scientific discoveries.

This transformation process, which develops around the relationships between industry, government and universities, stimulates new ways of organising knowledge production. Substantially, science and society are moving towards an integrated system. Scientists now need to interact not only with other scientists, but also with members of other communities or institutions. The choice of problems, the resolution of conflicts, and the negotiation of solutions, no longer take place in a closed environment populated only by scientists, but in a public space including various social actors (Ziman, 2004, Etzkowitz, 2005; Nowotny *et al.*, 2001). The concept of "extension of knowledge" has to be redefined so that it becomes compatible with the concept of "capitalisation of knowledge". This causes a transition towards an entrepreneurial science that generates a network of new cognitive opportunities, institutional rearrangements and regulatory changes (Etzkowitz, 1998). Researchers should not be limited to producing new knowledge, but should be able to confer commercial value upon their discoveries – or at least upon a part of them – thus making them "usable": "future scientists should be able to manage different and distant conceptual frames and see both the theoretical and practical implications of their research" (Viale and Etzkowitz, 2005, 11). Powell and Colyvas maintain that "there is also a widespread neo-liberal belief that market discipline is healthy, and [that] entrepreneurial

activities generate autonomy and build capabilities” (Powell and Colyvas, 2008, 289).

At the international level, new scientific organisations can assume different configurations. In particular, in the United States in recent years, we can observe the creation of new firms that work in the field of scientific research and technological innovation, in which it is difficult to distinguish between public, private and non-profit organisations. In the field of biotechnologies, this transformation is quite evident. We have chosen to study the pure biotech firms, because they are the most representative of the intersection between scientific research and the business world. These firms, called Dedicated Biotechnology Firms (DBFs), have proliferated principally in recent years, making use of new types of organisation that allow them to mix new and traditional forms of logic. Generally, they use a network structure that links them to universities, research institutes, firms and non-profit associations, not by means of client/supplier contracts, or of a hierarchical structure whereby the various organisms are connected in a vertical manner, but rather by means of a stable network with external partners (Smith-Doerr, 2005). This network develops around research-and-development projects whose success depends precisely on their ability to maintain inter-organisational relationships, and to be flexible and open to new discoveries and technological inventions, in an environment in which little certainty exists regarding whether any given path will produce profits for the company. In these networks, different organisational and institutional logics survive and interact. The typical practices of the academic world, rather than being replaced by new practices, combine with the market logic of private companies.

According to Smith-Doerr (*ibidem*), working in a biotech firm is a viable alternative to an academic career. On the other hand, universities are no longer able to absorb the young PhD graduates. In fact, in biology, the percentage of PhD graduates pursuing an academic career has greatly diminished in recent years. Researchers no longer consider the jobs offered by these firms any less prestigious than those offered by academic institutions. Moreover, the new biotech enterprises operate within networks that include prestigious academic partners, such that scientists work side by side with university researchers on the same projects. Smith-Doerr (*ibidem*) argues that employment in the private biotech industry is gaining scientific prestige, but that, at the same time, does not de-legitimise traditional academic prestige; it adds, rather, another dimension to the scientific status.

Our research is based on a case study: a university spin-off working in the field of biotechnology. This choice depends on the fact that this particular type of firm can be considered the most visible consequence of a process that has led universities to become more entrepreneurial. Many universities no longer simply “do science”, but are becoming the engine of technological innovation. According to Viale and Etzkowitz (2005), the “centre of gravity” of the collaboration between science and technological innovation is just inside the academic world.

University spin-offs consist of PhD graduates, researchers and professors who remain strongly linked to their university of origin, whilst founding companies with the aim of commercialising some of their research results. These firms meet the need to create new knowledge-transfer mechanisms. In the United States, knowledge transfer from universities has been encouraged by governments since the 1990s. Since then, a lot of resources, both human and financial, have been dedicated to this purpose. Within universities, technology transfer offices (TTOs) with dedicated staff have been created. In addition, entrepreneurial academic initiatives are launched with the aid of incubators and investment funds. In general, all these efforts are aimed at producing new knowledge-transfer mechanisms, such as patents, agreements for using intellectual rights, and spin-off companies (Mathieu, 2011).

In Italy, entrepreneurial universities began to be promoted in the first years of the new millennium, when the first laws to support and regulate the creation of university spin-offs were enacted. So, universities began to issue regulations regarding the creation and management of spin-offs, and to found technology-transfer offices. Since 2012, Italian universities have also been evaluated in relation to the so-called “third mission”, which will probably encourage them to become more and more entrepreneurial.

With regard to the biotechnology sector in Italy, it can be observed that the first DBFs were born in the 1990s as spin offs of big pharmaceutical companies (Sorrentino, 2009), but in the last few years there has been a change of trend: a lot of DBFs are now being born as university spin-offs, and already in 2010, 50% of new firms were of this type (Ernst&Young, 2011).

Many social scientists have analysed the processes of institutionalisation and legitimisation associated with the birth and development of new organisational forms of DBFs. In particular, they: (1) study the partnership networks, focusing on the formal structures that emerge from inter-organisational relationships (Powell *et al.* 2005; Owen-Smith and Powell, 2008); (2) examine the processes and actions that involve actors that are often placed in different organisations (Bruni and Perrotta, 2007; Mieli, 2011; Smith-Doerr, 2005); and (3) analyse the norms regulating the interactions between actors (De Rond, 2003; Daniel and Dawson, 2008).

Our research in this field has focused on the processes of transformation and management of knowledge. This development progresses step by step inside the “de facto” networks constructed around biotech enterprises. For this first phase of our research project, we selected a case study: a company born as a spin-off of the University of Urbino. The aim has been to study in depth the processes of change in the careers of Italian researchers in the field of biotechnology, and, at the same time, to understand how the networks of relationships form within this sector.

Case Study Results

Our research is based on the study of an Italian academic spin-off biotech company, founded in 2002 by a professor of the University of Urbino. Its aim is to bring research into industrial products in the biomedical field. It works on development, production and marketing of new and innovative products, such as antibodies, recombinant proteins, immunoassays and SNP detection kits, for research and therapeutic applications in the fields of Cancer, Microbial Infection and Pharmacogenetics.

The spin-off has participated in various projects funded by the EU and the Marche Region, collaborating with different universities and research institutes. It owns national patents, and has published many scientific papers.

Initially, the largest shareholder of the company was the University of Urbino, but in 2012, a multinational company, which produces and distributes technical gases and drugs, acquired 51% of the shares. The professor who founded the company is now the scientific director and a member of the board of directors.

The founder's main concern in building the spin-off was that researchers should not limit themselves to knowledge acquisition, but should concretely develop the possibilities that emerge from the study of the biological world:

One must be able to imagine how this knowledge could become a utility, for instance, to cure a disease, to diagnose it, or to develop products more economically and ecologically, and with simpler manufacturing. It is the acquisition of a more international way of thinking. The predominant culture that we have in Italy is a humanistic one, in which study and research are in some way directed towards comprehension and knowing, and to communicating and transmitting. In other countries these things instead aimed at knowing for the purpose of applying the knowledge to solving problems. This doesn't mean that basic research is excluded, but this research is use instrumentally to understand complex phenomena. In short, it gives us some explanations, and on the basis of these we can seek to construct some applications to resolve contingent, concrete problems. There is a vision that goes beyond mere comprehension.

With this spirit, the spin-off research is managed by young researchers (all of them in their 30's). From the interviews it emerges that the spin-off constitutes a new job opportunity for young PhD graduates. In Italy during the last decade, the highest level of university education (PhD) in biotechnologies (but also in other disciplines) has often not been matched by an adequate capacity of absorption into the academic context (Moscati, 2011; ISTAT, 2010). The researchers involved in this study underline the difficulties in pursuing an academic career. The precarious aspect of this career entails many years of temporary work, which is not easily accepted. Therefore, when a

private company offers a job, few will consider refusing it. In our case study, the typical career of the researcher starts with a collaboration during the degree, and a period of project work during the PhD, followed by a stable work position.

I really like research work in academia, but you don't have a real chance to access that career. Maybe if you go abroad you can still find meritocracy, but salaries in firms are higher even there. The situation is not so different. But here you don't have the opportunity to choose. After a PhD, you can be involved in some university part-time project, or apply for some temporary research fellow position, but ten years later you have to go home! In the commercial world things are different: if you have the required capabilities, you can find a job. Academia is a different world with different career rules. In other countries, to attempt this career is a conscious step. Here in Italy it is not like that: it is a question of being able to survive, and not of choosing the career you like best. I like pure research. I also like to follow more complex projects. Now, after the first few years [of the spin-off], we have the resources to do these projects, and I really enjoy working here. And now I'm even in a stable job position as a full-time researcher.

In this setting, job satisfaction is positively influenced by the presence of intrinsic motivation, certain job characteristics, such as a certain degree of autonomy, and the quality, as perceived by the researchers, of relationships with colleagues, customers and partners (considered as “relational goods”, consumables at work). The firm's research team comprises five full-time researchers, each of whom is leader of a specific area with specific tasks that are followed personally: from research and development right up to the final marketing of the product. This implies the need for an integrated vision by researchers with respect to their area of responsibility. In fact, apart from performing the research-and-development activities, once the process of industrialisation of the product has begun, the researcher also has the role of product specialist. This means that he or she has to provide assistance to customers interested in buying the developed product, or to those who already use it.

When you're also product specialist you are in closer contact with the outside world. When a product you have created or managed is released, you are placed in contact with the outside world, with the end users, which could be research centres, universities, private laboratories, etc. – in short, any type of institution which is placed in contact with you as product specialist for the resolution of any problem or questions.

The company relationships include contacts with various private and institutional partners closely regulated by Confidential Disclosure Agreements. These formal contracts, protecting any data or information belonging to the disclosing Party, are not generally known to the public, whether in tangible or intangible form, whenever and however disclosed. This kind of formalisation is a critical step for the functioning of the economic system of the company. It produces a strong awareness, on the part of researchers, regarding the need for protection of the scientific work within the company.

The knowledge that we develop here is not transferred in any way, because it is company property. There are non-disclosure agreements if you need to share this business information with other researchers. These are signed agreements according to which any of the parties may disclose certain information. Or, if there is a partnership, there is always a contract that complies with an agreement allowing you to transfer information only in an official manner, having signed the appropriate agreements.

This network of relationships has been functionally configured, over time, as a result of the projects developed by the spin-off. In this sense, the researchers are also responsible for coordinating the parts of the project that are developed by local partners. The logic of these operations also involves university partnerships with regard to the testing of specific products developed by the firm.

We are engaged in various projects for which we are in contact with universities. I, for example, have several projects for which I am in contact with people from the University of Urbino, who collaborate on various parts of these projects. There are also experimental projects of our products with the University of Modena, and so on.

In addition to activities related to the development of knowledge and products, in order to meet visibility requirements researchers should devote themselves to the construction of specific contacts with opinion leaders of the areas where products will have to be inserted. In the field of dissemination of the results obtained from the activity of the firm on the development and industrialisation of products, the ability to build up validation partnerships that can positively influence the consideration about the product becomes central. Forcing a parallelism with the academic world, the company partnered with an opinion leader for the testing of a product corresponds to a publication in a high-ranking scientific journal.

For example, you have a kit for detecting a pathogen in water, and you put it on the market. For us it is important that an opinion leader test this product, hopefully on real samples in a study of hospital water monitoring. He or she uses your product in its final form, and

does not need to know what research underlies the product, because it can simply be used in the field, to assess its performance and validity. This is what happens quite frequently. If an opinion leader in this sector tests the product with good results, and together you decide to publish it in a journal, then the appearance of the opinion leader's name and yours in the experimental paper will increase the credibility of the product. In this sense, when you set out to propose a product, you already have references. And in this field, to have some references from opinion leaders is the most important thing.

This networking operation is also important from the point of view of disseminating results throughout the scientific community. This strategy, therefore, takes value both at commercial and scientific levels.

Given the high scientific specialisation of the company, people that find a placement here are highly trained persons from academic contexts. They need to be able to research and perfect new processes and products. In this new context, which differs from that of the purely academic world, new capabilities have had to be created within the company, or, as pointed out by the firm's founder, gained from outside by means of some co-operative agreement. The new skills that have to be developed in the transition from academia to industry deeply involve the researchers. In their interviews there often emerged the need to reorganise the individual work and research objectives within the company according to a market-oriented logic.

This firm is borderline because we are a spin-off. At the beginning, we were less characterised as a company, because we all had academic backgrounds. And then we became more aware of many things. For example, one can't publish before patenting. Perhaps there is less awareness of this in universities. But it is also true that if you find the cure for a disease, and you hasten to publish, maybe it will never cure any patients, because no company will ever invest in something that anybody could repeat because you have not protected your results. So, probably no one will develop that cure! We have also made use of several consultancies to protect our products. We now have more awareness of the rules of the market and business.

Development, industrialisation, protection and diffusion of scientific knowledge: this diachronic sequence represents the standard of knowledge-based business practice. The researchers point out that this sequence is not taken for granted by those from the academic world. During a company career, it becomes clear that, in this area, there are logics that differ from those of the academic world. There is no longer a separation between science and technology in biotechnology, nor a path that distinguishes between theory and applications. Researchers need to follow the development of the scientific products permanently, in an integrated process that moves from research and development to commercialisation. Compared to an equivalent job in

academia, the rules are different. The characteristics change because when you design a project and arrive at a result, it needs to be extremely stable and reproducible. It must also have all the characteristics that make it of interest to the market.

This leads you to work in a different way. When you design a system and arrive at an outcome, you don't immediately publish your work. Once you get a result, you have to confirm it and reconfirm it; you must ensure that it is stable and reproducible, and that it works for the eventual customers. Everything changes, from the design to – everything! You design and industrialise. To do this, if there is a law, you have to be fully compliant, because every one of your customers, be it a certified laboratory or institution dealing with the quality and safety of foods rather than other aspects, is very attentive to these regulations. You design and industrialise. When you do that, you must have, in your hands, a compliant product. Moreover, we can't publish before patenting, but we publish later. Here, if we obtain information or an important result, the first thing we do is protect it. Then maybe we'll produce a detection kit, a publication and so on.

Concluding Remarks

In this work, we tried to understand how Italian biotechnological researchers change their traditional role by shifting their competences from a purely research-oriented standpoint to a more market-oriented position, and how partnership networks are formed.

The subject of our case study is a university spin-off born in 2002, when, in Italy, the legal and institutional rules that stimulate the universities to become entrepreneurial, had not yet been activated. The spirit that stimulated the founder of this company was the desire to make science “useful”. According to him, researchers should be responsible towards society with regard to their work. Their aim should be not only to discover or create new knowledge, but to ensure that science is at the service of humanity, progress and well-being, by means of the development of concrete products resulting from the newly acquired knowledge.

Before entering in this spin-off, some of the researchers had obtained a PhD, while others had taken part in research projects at the university. According to the researchers interviewed, working in this spin-off has become an unavoidable choice for those who wish to continue scientific research, because academic careers, in Italy, have become very uncertain for new graduates. The spin-off offers an alternative that allows them to use their high level of competence, and to continue to do research with greater economic stability.

However, the role and activities of researchers differ from those of academic scientists, particularly in the various stages of the management of

knowledge transfer. We can identify three important elements in this difference.

1. Researchers must reorganise their work and their individual research objectives according to a market-oriented logic. In addition to being scientists, they must also be product managers, and must identify the areas of research that can generate something “usable”. So, the links between science and business are not made by inserting, in the firm, people with different professional roles –such as researchers, marketing experts, accounting and legal experts – but by choosing specific profiles of scientists interested in developing products rather than exclusively developing new knowledge. In addition, researchers follow all the phases of production, from the choice of research topics and the development of collaboration with other researchers, to marketing and customer support. They collaborate with research centres and institutions dedicated solely to scientific research, but, at the same time, they interact both with potential customers, by showing them the characteristics of the product, and with already-acquired customers, by providing customer support. In addition, they try to establish collaborations with opinion leaders of specific sectors, to ensure widespread awareness of the products of their research. In this new organisational framework, researchers become the link between various stakeholders. They manage their products and knowledge, and all interfaces with both the academic world and the world of business.

2. It is important to protect the knowledge developed within the company before spreading it. For this reason, all interactions with partners are regulated by specific agreements aimed at protecting intellectual property. However, this is not inconsistent with the idea that science should be at the service of individuals and society. In fact, the publication of scientific findings that are not protected by patent would result in a probable lack of interest by investors. Consequently, the product would not be distributed and put to the service of humanity.

3. The link with opinion leaders is crucial for the company, as they are the bridge between the world of scientific research and the rest of society. Through them, the audience extends beyond the specialised community of scientists. Identifying them and building partnership networks with them is relevant from a commercial point of view, and also for disseminating scientific results within the scientific community.

Obviously, our case study represents a particular situation within a broader and far more varied framework that characterises the context of new entrepreneurial firms in the field of biotechnology. However, it already allows us to identify some factors that characterise the transition towards a new entrepreneurial science in Italy. We plan, in the future phases of our work, to analyse other case studies – in particular, non-academic start-ups and university research groups – in order to compare the different types of logic and practice of research in various areas. We suppose that this comparison can highlight more precisely the characteristics and the specific roles that should be played by young Italian researchers.

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