



Local context and firms creation: The case of biotechnology in Italy

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ABSTRACT

This paper explores Italy's biotech industry. This is the case of a new industry formation in a hostile institutional context. Our goal is two-fold. First, it is to extend our understanding of the role of institutions on firm formation and industry creation. Second, it is to offer prescriptive evidence for those regions that are trying to encourage entrepreneurship in innovative industries or increment existing systems of innovations. We adopt the interpretative lenses of the institutional theory. Our work aims to discuss the role that institutions (by the meaning of regulations, policies, and fiscal measures) provide to the development and change of industries around the world. We offer a comparison between Italy and other European countries in order to advise rules and suggestions to improve the competitiveness of the Italian biotech industry and firm formation. We recognize that the Italian institutional context is hostile to new industry creation because the rules and regulations do not support new firm formation. Moreover, Italy represents a context that shows a high level of risk aversion to radical innovation such as biotechnology.

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Introduction

The analysis and development of innovative industry creation is central to current thinking about industrial change and economic development. The formation of regional clusters of innovation grasps the attention at a regional and national level both from academic scholars and policy makers (Wong, Ho, Y& Autio, 2005). Commonly, it is agreed that entrepreneurship and new firm formation are the embodiment of innovation, especially for radical new technologies (Audrestsch, 1995). In fact, in recent decades, new technologies have largely supported the development of new industries in geographically defined clusters, and this captures the interest of the nation as a vehicle for economic development and industrial change (Fritsch & Wyrwich, 2019).

Moreover, we observed that new industries emerge from the collision of technological innovation and market opportunity in entrepreneurial areas that support new firm formation. In this direction, a crucial point for national institutions and political Governments is creating attributes that mimic the characteristics of successful locations (Feldman, 2001) and a critical question is how institutions and Governments can support these innovation and entrepreneurial processes. For instance, Government policy can: leverage the presence of local universities, design funds for academic research in the new technology, increase the availability of venture capital, encourage a culture of risk taking, and create strong local informational and business development networks (Feldman, 2001).

Conservative understanding about the factors that promote entrepreneurship formation is drawn from analysis of magnanimous environments (Dubini, 1989). In keeping with others' point of view, this paper considers the importance of economic agents (Kay, 2000), the co-evolution of technology and institutions (Nelson, 1998), and the way in which entrepreneurs are supported by the local context and actively interact with it. More specifically, according to what Shaper (1984) described as the influence of the regional context in entrepreneurship (i.e. decision to engage in the formation of a company), our perspective is compatible with frameworks that depict industry creation and evolution as a process that involves the co-development of technology and institutions via repeated interactions among a range of industry participants (Ruttan, 2001; Van de Ven, 1993).

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Thus, in order to explain how local contexts matter to radical innovative industry creation and firm formation, we adopt an institutional perspective (Weber, 1978). According to Commons (1936), institutional establishments convey collective action that constrains, guides, and liberates individual action. Institutional arrangements remain relatively stable within countries over time, but vary considerably across countries (Murtha and Lenway, 1994). Thus, in our opinion, this is a factor that should make a difference between the industrial change and development across countries.

In this direction, we first explore the case of biotech development in Italy, and then we compare this case to other European countries. In Horizon 2020, biotechnology was introduced as a Key Enabling Technology (KET), together with three other KETs (i.e. nanotechnologies, advanced materials, and advanced manufacturing and processing). KETs are investments and technologies that will allow European industries to retain competitiveness and capitalise on new markets. For such reasons, research in biotechnology is supported under Horizon 2020 to exploit the current and future know-how and to boost technological innovation and industrial leadership in those sectors. The economic impact of KETs is considerable. The global market for KETs is estimated to be more than EUR 1 trillion and KETs have huge potential for growth (growth potentials of 10 – 20% per year can be expected over the coming years) and employment. Countries and regions that fully exploit KETs will be at the forefront of advanced and sustainable economies.

With applications in a broad variety of sectors, biotechnology is one of the main innovation drivers in the European Union, and in Italy in particular. It leads to new growth and competitiveness in traditional sectors, such as paper and pulp and chemical, textile and many other industries. Biotechnology applies scientific and engineering principles on living organisms. On one hand, it serves to improve industrial processes and on the other hand, it allows the competitive, sustainable and innovative production of materials, chemicals and fuels.

We recognise that the Italian institutional context is hostile to new industry creation, because the rules and regulations do not support new firm formation. Moreover, Italy represents a context that shows a high level of risk aversion to radical innovation such as biotechnology. More specifically, aversion is explained through a cultural mood. For all such reasons, we decided to use biotech in Italy as case study.

Our analysis departs from the discussion of the conditions that would characterise the contest as munificent and pass to consider the role of institutions such as Government and political decisions as obstacles in the entrepreneurial action for the Italian context.

Our perspective is grounded in the framework of the system of innovation that depicts technological innovation as the evolutionary process of variation, selection, and retention. It is characterised by incremental advances in which institutions should play a key role and that the Government should support by implementing policies relevant to industrial development. Considering the role that innovation plays in industrial development, during the last two decades the system of innovation has emerged as a new topic on the research agenda of innovation studies (Geels, 2004) in which the scope of analysis has been increased from individual organisations (often firms) to systems of organisations (networks).

Searching for the reasons that should explain the success of a system of innovation to support firm formation, we adopt the lens of institutional theory. We consider that institutions are the key element to interpret the path of evolution of a system of innovation and firm formation. To sustain our point of view, we offer a cross-regional comparison with the European countries that present better conditions compared to Italy. In fact, institutional theory, which attends to the hidden and more resistant parts of social structure, considers how elements such as rules, norms, and routines are created, diffused, adopted, and adapted over space and time and how they fall into decline and disuse (Scott, 2004). Considering that institutions posit different bases of order, mechanisms, and logics, our paper reflects on the processes by which structure, including rules, norms, and routines established (maybe indirectly) the guidelines for Italian biotech industrial creation and firms' formation. We introduce the new metaphor of the seed-ground in order to explain the interaction among new idea, entrepreneurial context and firm formation.

After analysing the phenomenon, we discuss implications for the industrial and firm development of biotech in Italy. The intent is to offer prescriptive evidence for those regions that are trying to incentive entrepreneurship in innovative industries.

Entrepreneurial contexts and innovative industry development: The seed-ground perspective

New industries emerge from collisions of technological innovation and market opportunity (Murtha, Lenway and Hart, 2002). Indeed, new firms' formation in a specific geographical area appears if firms reach across national borders for complementary assets, partners, suppliers, and customers necessary to create new business by assembling new knowledge (Doz, Santos and Willimanson, 2001). Porter's (1990) diamond of interrelated localised competition, demanding customers, linked supporting industries and supportive Government policy provides a set of factors that improve the functioning of firms. But, even if Porter's model considers the role of the context in order to support new firm creation in a specific area, he does not address the topic of how policies might influence entrepreneurship. Late, Feldman (2001) revisited Shapero models (1990) and provided a summary of environmental characteristics that conventional wisdom typically associated with locations strong in entrepreneurial initiative: availability of venture capital (Samila & Sorenson, 2011; Florida and Kenney, 1988; Sapienza, 1992); supportive social capital (Abetti, 1992; Flora, Sharp, Flora, & Newlon, 1997; Estrin, Mickiewicz & Stephan, 2013; Stephan & Uhlaner, 2010); entrepreneurial expertise and support service (Bruno and Tyebjee, 1982; Malecki, 1990) and research universities as growth engines (Bonander, Jakobsson, Podestà & Svensson, 2016; Etkowitz & Goktepe-Hulten, 2010; Stefanoni, Silvestri, & Piccarozzi, 2013).

Innovative context is defined as the context that produces ideas. Thus, there are necessarily two factors in the context: the entrepreneurial expertise and the research universities as growth engines. The entrepreneurial context, instead, is that context in which there is the availability of venture capital, support service for entrepreneurs, and supportive social capital (Cunningham, Menter, & Wirsching, 2019; Jones, Ratten, Klapper, & Fayolle, 2019). Indeed, the idea proposed in this work is that the context needs to be first innovative and then entrepreneurial. This is because the innovativeness of a context produces ideas, while the entrepreneurship of a context produces firms. The ideas are necessary to create firms, and then this turns into the creation of a context. This assumption becomes clearer when taking into consideration the relation that exists between a seed (idea) and the ground (entrepreneurial context). A good ground needs to be sowed to produce plants (firms). More specifically, a seed of high quality, even if planted in a challenging ground, adapts itself to that ground even if it takes longer. Certainly, the best solution is to have a good seed (ideas and innovative context) in a good ground (entrepreneurial context). Our discussion is based on this metaphor that became our interpretive lens, and we labeled it as seed-ground perspective.

National political institutional context: The role of the grower

The seed-ground perspective considers the key role exerted by the national political institutional context. It reflects that institutions are the major actors in the dynamic of industrial development and conceptualise the role of institutions in firm formation and innovation. From our literature review, we observed that sometimes institutions are a left-over category in this type of analysis. It also happens that institutions are wrongly equated with no market organisation (Reddy et al., 1991) and according to Geels (2004), there is a need to better conceptualise the role of institutions in firm formation and innovation.

In this direction, we consider that industry creation is an evolutionary process of variation in which the three main factors are: the seed (i.e. idea and the capacity to generate a new idea), the ground (i.e. the entrepreneurial environment in which we found availability of venture capital, supportive social capital, entrepreneurial expertise, support services, and research universities), and the grower (i.e. the Government enacting regulations, policies, and fiscal measures).

More specifically, the Governments, by enacting regulations, policies, and fiscal measures, shape the entrepreneurial environment by creating the national political institutional context. In fact, institutional arrangements embody collective action that constrains, guides, and liberates individual action (Commons, 1936). Institutional theory argues the processes by which structures, including schemas, rules, norms, and routines, become established as authoritative guidelines for social behaviour (Di Maggio and Powell, 1983). It inquires how these elements are created, diffused, adopted, and adapted over space and time, and how they fall into decline and disuse. Although the ostensible subject is stability and order in social life, scholars of institutions must attend not just to consensus and conformity but to conflict and change in social structures (Scott, 1987; 2004). As a consequence, we believe that previous institutions force and guide the development of that knowledge, specifically in the early stage of a new knowledge. Moreover, in the case of a disruptive innovation, such as biotechnologies, the point of view that the regulations and norms emanate from the Government sustain or hinder the diffusion of new technologies.

Additionally, from a managerial perspective, the environment in which firms take place (external or institutional environment) furnishes them the resources (capitals, input, knowledge, and workers) necessary to create and manage the inherent productive activity to undertake the entrepreneurial pattern (Oliver, 1991). Thus, the political logic promoted from the Government is the essential care that the *grower* does for the *ground* because it should favour (or cast-off) an entrepreneurial environment. Our framework poses and advances our understanding of industrial and corporate changes using the in-depth analysis of the case of the biotech system of innovation in Italy.

Theoretical model

Following our theoretical background, we define the biotech system of innovation as the set of actors that includes firms, universities, research centers, Government agencies, financial institutions, and buyers that operate under the influence of institutions (cultural frames, interaction rules, norms, and regulations). Thus, coherently with the definition of institutions we adopted above, we assume that the knowledge, preferences, and perceptions of the biotech actors (researchers, buyers, firms, and all actors in the biotech industry) together with their decisions and actions are driven by institutions.

In this perspective, the screening of the patterns of institutional context is the key variable to interpret and understand the formation of an industry, which in our case is the biotechnology industry in Italy. Moreover, directly from our theoretical assumptions, the results that biotech firms gain are strictly related to the researchers' and buyers' beliefs shaped by the institutions that depict and characterised the context under investigation. In fact, from our perspective we consider that human actors are embedded in the social group which shares certain characteristics (e.g., certain roles, responsibilities, norms, and perceptions). Considering their interactions, they share a specific knowledge, tell similar stories of their past and future, meet each other for different reasons, and often read the same journals. In short, there is a sharing of knowledge within groups that creates specific beliefs about a specific argument (Stankiewicz, 1992). Moreover, different groups also interact with each other and form networks with mutual knowledge. We assume that this behavior could influence the knowledge about a specific innovation and build the perception of it. Regarding biotechnology, Italian institutions and Government have been prudent, and, in our interpretation, this stopped and still stops the development of biotech in Italy.

Based on this assumption, institutions should support innovation when there is a diffusion of knowledge that reduces the perception of the risks in the buyer and researchers are supported to invest in the new technology. Moreover, institutions support new firms when regulations and policies plus fiscal measures reserve favourable conditions in terms, for instance, of tax reductions and bank accord to improve financial support. Otherwise, that context will suffer. The Italian context, compared to the European national contexts and also the other regions in the world, presents hostile conditions as we will describe in the next section. Instead, all the other key elements of the system of innovation are well represented. Thus, according to our definition, Italy is an innovative context but not entrepreneurial.

The patterns of national context in the formation of the biotechnology industry in Italy: An interpretative case

The Italian biotech industry is composed of 422 companies, mostly small, which employ less than 50 employees; 206 of these firms operate in the health-care field (Red Biotech). Thus, Red Biotech is the prevalent business (BioInItaly Report, 2016). Taking into consideration the geographical distribution, almost 80% of Italian biotech companies are concentrated in the following regions: Lombardy, Piedmont, Tuscany, Friuli Venezia Giulia, Lazio, Emilia, and Sardinia. Over 50% of the Small Medium Firms are located in Science Parks incubators established in the above-mentioned regions. Thus, we observed that the biotech industry is characterised by a strong geographical concentration. The total revenues of the industry amount to 7 billion Euros (+4%), and investments in R&D amount to 1.5 billion Euros. At the present, Italy is an alluring and competitive place for entrepreneurs and investors in the biotech pitch. Through a robust portfolio of potentialities, the country is hunting its own footpath in the direction of a level of maturity that will positively generate further innovation and economic growth, thus supporting the country's role as an international player.

Concurrently, even with current troubles in the economic situation, the Italian biotech industry showed a growth trend in 2014, reflecting a very surprising feature that essentially opposes the trend in the international setting. This development is a strong indicator of the Italian biotech industry's capacity of innovation, which, even in an international context characterised by little growth of investments and doubtful forecasts, has shown itself capable of forging ahead and confidently projecting itself towards the future. In this section, our framework is discussed. First, we describe our methodology and discuss some methodological issues related to our approach.

To scrutinise the development of the biotech industry, we used data on the Italian biotechnology industry for the period till 2016. We collected data by on-desk and on-field activities. For the on-desk research, we referred to the Report made for Assobiotech (Italian Association for Biotech Industry) and to KETs Observatory. Thus, we obtained a longitudinal analysis from on-desk data. The KETs Observatory is an online monitoring tool that provides the EU, national and regional policy makers and business stakeholders with quantitative and qualitative information on the deployment of KETs both within the EU-28 and in comparison with other world regions. In our analysis, we use the Observatory in order to provide a thorough analysis of how Italy covers the KETs deployment value chain from technology development to commercialization in comparison to other Countries.

There are some methodological issues to mention. First, it is important to note that this is a retrospective study made with the assumption of indirect data. We are limited by being able to identify the real decision processes made by the entrepreneurs in biotechnology, but we are sustained in our assumptions by the longitudinal analysis of the Assobiotech's Reports and KETs Observatory.

Moreover, the cross-regional comparison with other European countries reinforces our theoretical frameworks, posing the main differences among these areas exclusively to Government rules and regulations to the biotech sectors and its startups. Our approach allows us to consider the roots of successful entrepreneurship and the way in which Governments' activity took hold in other European areas.

Biotech industry in Italy: The entrepreneurial context

The seed-ground perspective will be related in this work to the creation of the biotech industry in Italy, considering how innovative ideas have adapted and survived in a hostile entrepreneurial context.

In order to describe the context, we refer to the Innovation Union Scoreboard that ranks Italy amongst the Moderate Innovator countries group (Table n. 1). This position reflects the score on the many input related indicators on science, technology and industry activity that constitute the scoreboard. In comparison to the EU average, Italy underperforms with respect to human capital available for research and, above all, public financial resources available for R&D. The public research system performs a large part of the R&D but in terms of public expenditure as a percentage of GDP, Italy is behind in comparison to the European counterparts. Also, collaboration of Higher Education and Public Research Institutions with industry seems limited, especially with regard to SMEs.

Another interesting aspect that can describe the entrepreneurial context in terms of entrepreneurial expertise and support services, is the dislocation of the KETs Technology Centers, in particular biotech ones. They help SMEs cross the 'Valley of Death' and go from lab to market to develop and produce new KETs-based products. These Centers are public or private organisations carrying out applied research and close-to-market innovation and typically provide the following services to SMEs: access to technology expertise and facilities for validation; demonstration; proof of concept and lab testing; prototype development and testing; pilot production and

demonstration, pilot lines and pre-series; product validation and certification. They also help companies reduce the time-to-market for innovation ideas. In order to characterize the Italian context, it's interesting to note the scarce availability of such institution in Italy (only two available, CETMA European Research Center for Technologies Design and Materials, Brindisi and MIST E-R S.C.R.L, Bologna) compared to other European Countries (Figure n. 1).

Table 1: European environmental characteristics;

	EU27	Italy	Germany	France	United Kingdom	Finland
Availability of Venture Capital						
Venture capital (% of GDP)	0.09%	0.02%	0.06%	0.11%	0.24%	0.11%
Supportive social capital						
Population completed tertiary education (% of population aged 25-65)	34.6%	20.3%	30.7%	43.4%	45.8%	46.0%
Entrepreneurial expertise and support service						
KETs technology Center	252	16	31	39	11	13
Biotech technology Center	85	2	7	10	5	4
Research University as growth engines						
International scientific co-publications	300	500	715	683	989	1323
Scientific publications among top 10% most cited	10.90	10.11	11.64	10.33	13.28	11.48

Source: Innovation Union Scoreboard and KETs Tools.

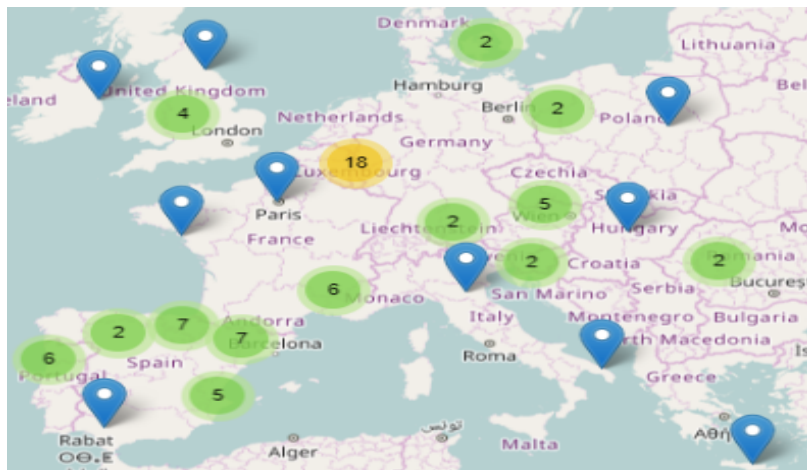


Figure 1: Dislocation of the KETs Technology Centers for Biotech in Europe; Source: KET Observatory.

Notwithstanding this picture, Italy does score relatively well on indicators reflecting the results revealing that innovation in Italy seems primarily knowledge driven, and not so much research driven. In fact, the number of firms involved in innovation in Italy is high in comparison to the EU average.

Summarizing, based on the reports of the sector (Assobiotech’s report, 2011, 2012, 2013, 2014, 2016) and on Innovation Union Scoreboard, Italy should be considered as a hostile entrepreneurial context for the biotech industry. This context can be described as lacking the presence of venture capital and unhelpful for social capital related in general to the biotech output. Instead, considering the context in its capacity to create innovation, Italy presents a good level of entrepreneurial expertise and virtuous and noble research universities as growth engines.

In this direction, the relationship between seed and ground is confirmed, and the pattern of the biotech industry in Italy should be discussed considering the seed-ground perspective presented above. We have a consistent development of the biotech industry in Italy, even though the context has been hostile. Moreover, following the seed-ground perspective, we consider how a “good grower” makes the difference between a good and a bad ground. Thus, if the quality of the seed (idea) is the same and the difference is related to the ground, to obtain good plants we need to hire a good grower that ploughs and waters the ground. But who is the good grower in our case? Who makes the difference in order to obtain an entrepreneurial context that supports and develops the innovative context? Spencer, Murtha and Lenway (2005) looked at the role of Governments in the new industry creation and adopted an institutionalist perspective. Similarly, we adopt the same perspective considering the role of the institutional context (i.e. Government’s regulations, policies, and fiscal measures) for the creation of an entrepreneurial context like the role of the grower for the ground.

Regulations, policies and fiscal measures: Italy vs. European countries

Italy accounts for numerous grants for R&D at national and regional levels; grants typically embrace costs such as employees' salaries, the acquisition of research instruments, and intellectual property rights. The biotech actors complain of the lateness to obtain the grants and the bureaucracy, often conflicting with the entry time advantages. Moreover, in Italy, Government grants are decreasing compared to other European countries, and this is disadvantageous for Italian biotech firms (Table n. 2).

Table 2: Public R&D expenditure; Source: Eurostat.

	EU27	Italy	Germany	France	United Kingdom	Finland
Public R&D expenditure (% of GDP)	0.75%	0.53%	0.94%	0.80%	0.64%	1.09%

As a common rule, benefits are provided in the form of investment grants, loans at reduced interest, or a state guarantee for exporters. Rarely, the benefit is established in the form of a combination of an investment grant and low interest loans, reliant on the geographical site of the investment and the size of the investing firm. In the zones struck by unemployment, predominantly in the southern area of the country, an indemnity is decided, subordinate to certain conditions, from corporation tax and local tax for a period of ten years.

Respecting the fiscal measures, different from other European countries, biotech firms in Italy are taxed as ordinary firms instead of being considered for the different level of risks and debts in the early stages of new ventures. This condition compromises competitiveness of Italian firms in terms of growth. A relevant exception is the fiscal measures for the R&D expenditure. The financial law adopted a specific fiscal reform which introduces a tax credit of 10% for in-house R&D expenditure. In this law, the tax credit for R&D expenditure was increased up to 90% for R&D investments in partnership with universities. Furthermore, it's important to note that KETs, and in particular Biotechnology, are included but not explicitly mentioned in thematic and structural programmes supporting the R&D and innovation policies addressing actors both at national and regional level. But they are included in the general target of improving the innovation system through funding and supporting cooperation between research and industry.

Taking into consideration the results of our investigation, we formulate the follows proposition:

Proposition1: The Italian institutional context is less favourable to biotech startup in comparison to the other European countries due to the limits set at the Country level

Another aspect of the investigation about the political and legislative Italian context is the examination of the normative on the intellectual property rights for which it is possible to highlight some limits that set Italy, once more, in a position of weakness in comparison to the international context (see Figure n. 2 and Figure n. 3). According to the declaration of the operators of the sector, in order to achieve the intellectual property, it needs to face an elevated cost of the patents, often unbearable for the smallest firms, among which there are a lot of academic start-ups (Assobiotech, 2016).

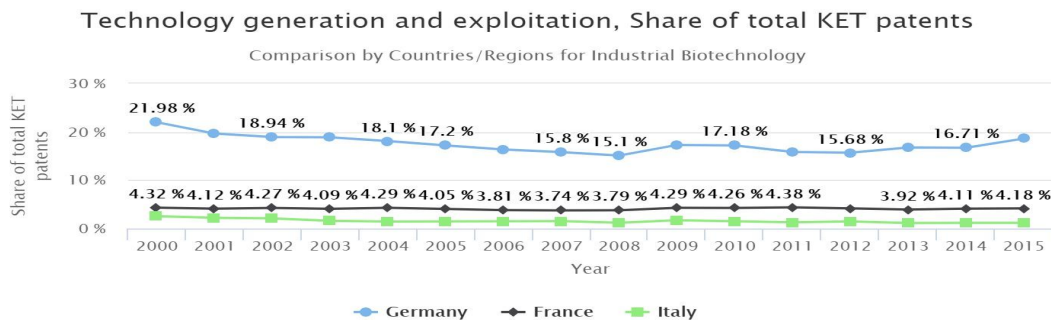


Figure 2: Share of total patents for Biotechnology, comparison by Countries in 2016; *Source:* KET Observatory.

Additionally, the patent has a territorial value, but only for the country (or countries) in which the application is presented. Thus, in this condition the firms are forced to ask for the European patent (valid only for a narrow number of countries) whose costs are particularly elevated since it is sustained for every country in which they make the patent application.

In order to illustrate the level of patent activities of biotech within the Italian innovation system, we compare its market share in the total production of patents for the biotech with that of other countries. Such measures indicate the relevance of a country in the respective technology market and compiled by dividing the number of patent applications of a certain country by the total number of patent applications in the respective Biotech area. Note that this indicator is strongly influenced by the size of a country as larger countries are more likely to produce more patents than small countries. Notwithstanding this, Figure 2 indicate that Italy has a constant

share of patents, and that it is trailing behind the major economies in the EU (i.e. France, Germany), as well as some of the smaller economies in Europe (e.g. the Netherlands, Austria)

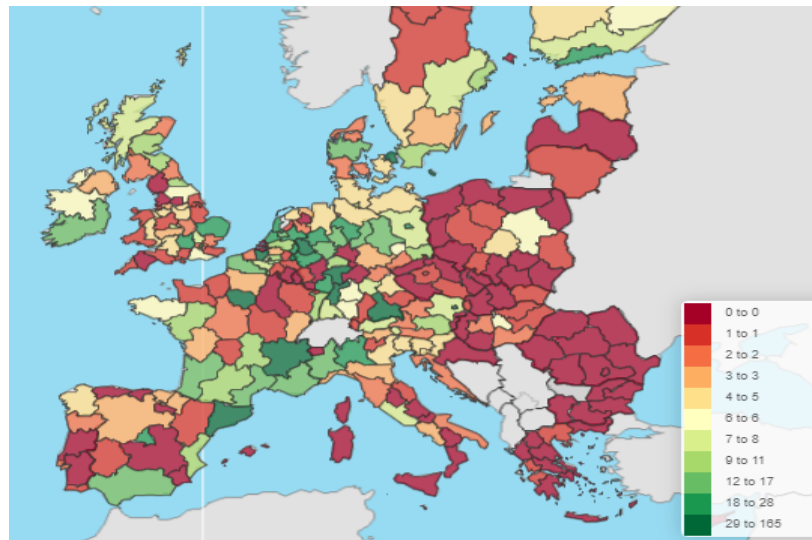


Figure 3: Number of patents for Biotechnology, by Countries and regions in 2016; *Source:* KET Observatory.

Furthermore, Italy is weak in comparison to the other European countries for fiscal incentives to the enterprises for patenting. To such intention, in the other nations it is contemplated a smaller or complete elimination of the taxation for those activities that originate for the concession of license. Based on these observations, we consider that:

Proposition2: The Italian institutional context is less favorable to biotech startup in comparison to the other European countries due to the limits set to the activity of patenting

The modest possibility to protect the inventions discourages the private initiative that would want, contrarily to take financial advantages from their investments done in R&S, as we noted happens in other countries. Besides, we believe that the guardianship of the public interest is more related to the public institution, since they hold the goal to behave with initiative free from economic and private purposes. Such a hypothesis could find return if at the institutional level financial support would be increased for the universities and for the Centers of Public Search, though modest funds if we compare the Italian context with the international.

Technology generation and exploitation: Italy vs. European countries

In this paragraph, we aim to show to what extent Italy can use the potential of biotechnology to improve its competitiveness by manufacturing KETs-based products and applying KETs in production processes. Our approach uses production and employment indicators.

About the composite's time series analysis in the field of production and employee, only limited dynamics during the past decade can be observed. Since 2006, almost all countries show a stable performance, same for Italy. One reason could be that many ongoing product developments in Biotechnology are still in an early stage, implying that increasing dynamics can be expected in the upcoming years. In 2016 Italy registered a percentage only around 0.11% in terms of production and 0.01% in terms of employee (Figure n. 4 and Figure n. 5).

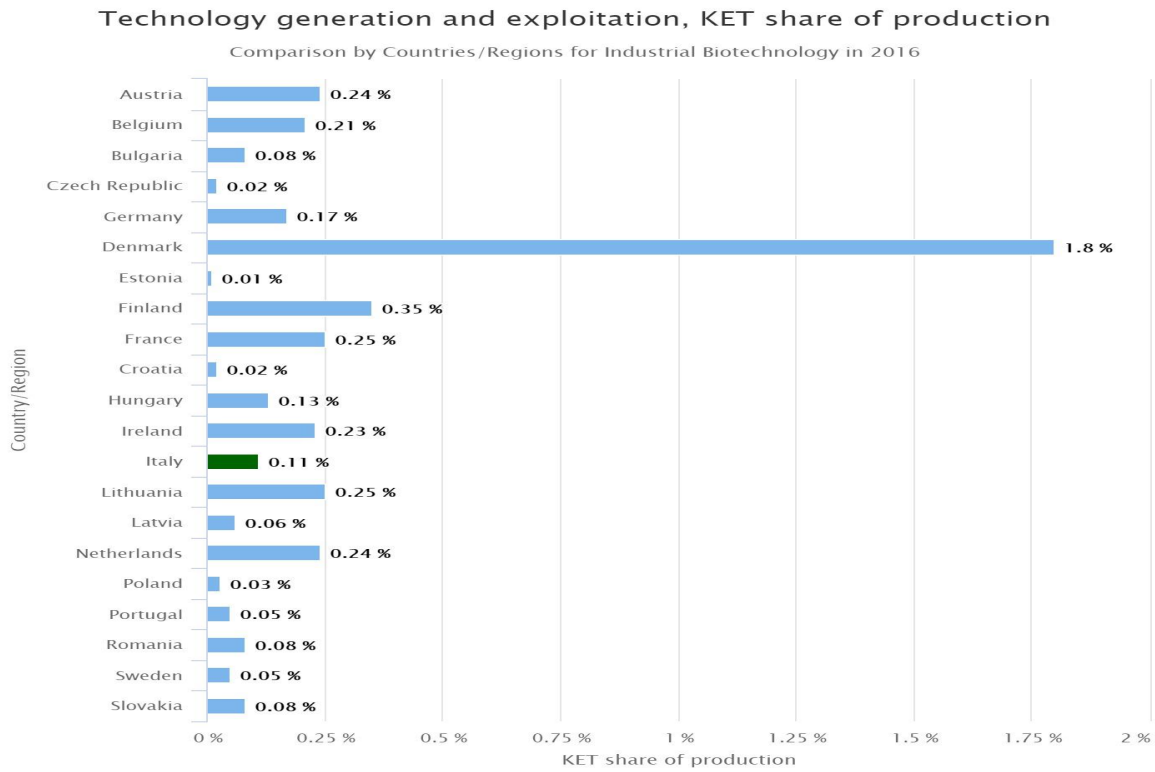


Figure 4: Biotech share of production, comparison by Countries in 2016; *Source:* KET Observatory.

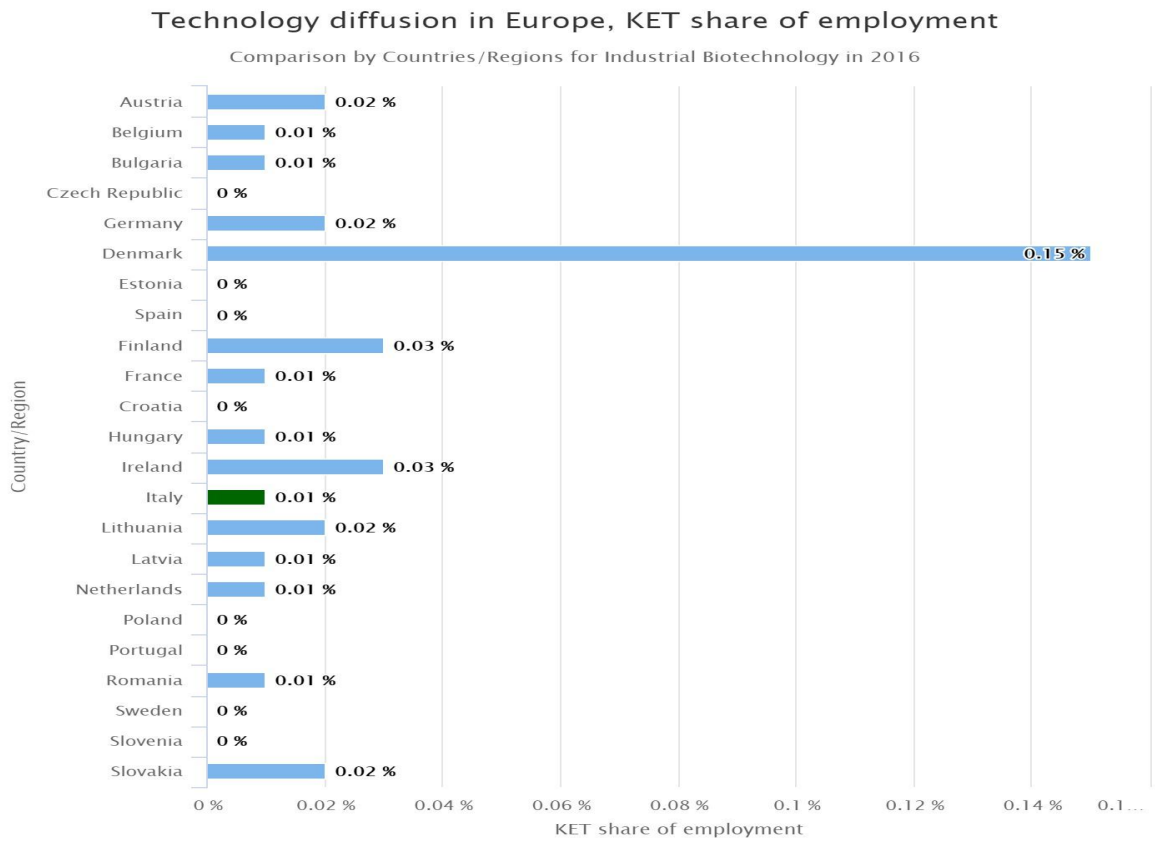


Figure 5: Biotech share of employment, comparison by Countries in 2016; *Source:* KET Observatory.

In this paragraph, we also want to explore the ability of Italy to generate and commercialize new knowledge in Biotechnology. Like previous results, we can see the trade performance's time series (Figure n. 6). The dynamics are characterised by punctual ups and downs instead of middle to long term trends making them difficult to interpret. Only Belgium and Spain were able to significantly increase their trade performance, Italy is stable at 0.25%.

Technology generation and exploitation, Country significance of total exports

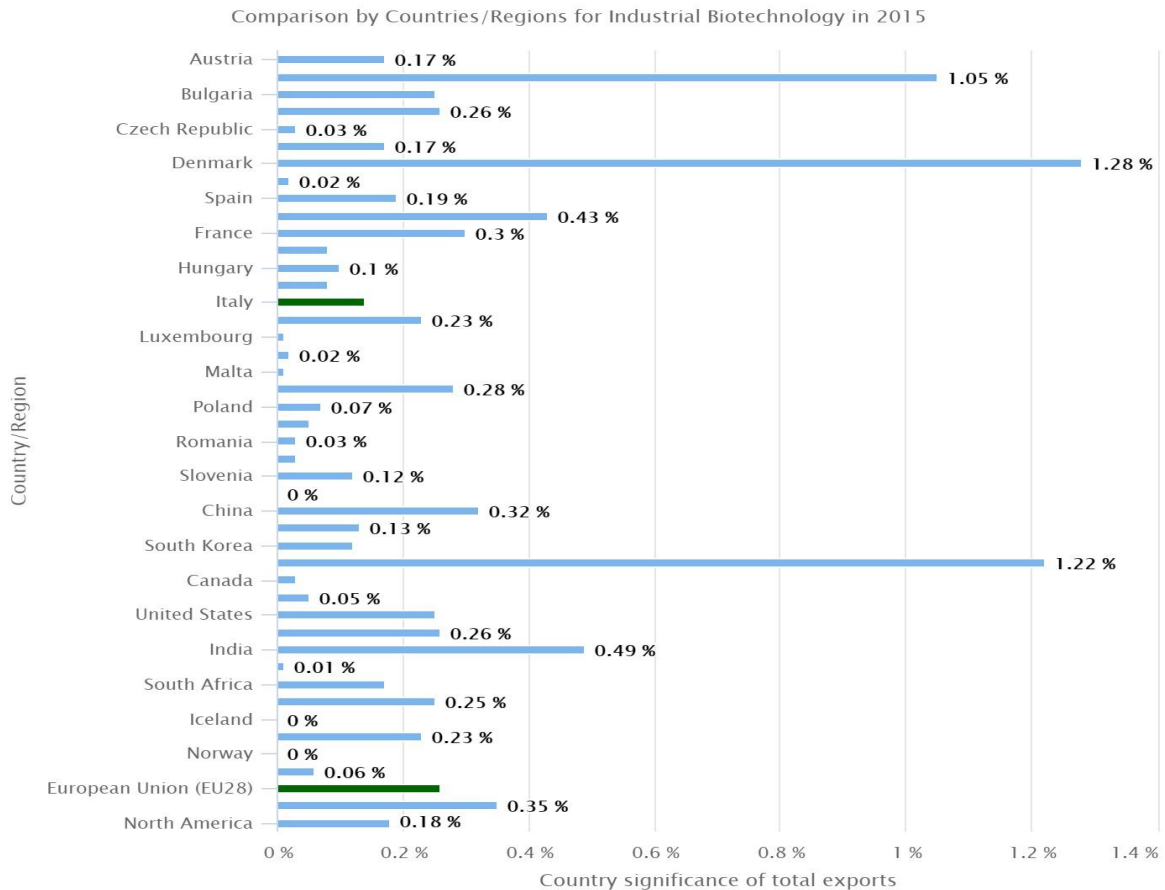


Figure 6: Country significance of total export in Biotechnology in 2016; Source: KET Observatory.

Supportive conditions for the development of the biotech industry in Italy

Our discussion turns now to the evaluation of the Italian context. At the end of our analysis, according to our theoretical model, we confirmed that the Italian institutional context presents opposite conditions compared to the international one: modest investments for the scientific research, poorly support at the institutional level, scarce utilisation of the capital of risk from the biotech enterprises, a culture and legislation that have hindered genetic experimentation, and the existence of an ample and effective system of protection of intellectual property

Hence, the research commitment is growing, and in this picture settlements between Italian companies and international partners are increasing. Another key factor about the Italian institutional context is the good academic and research backgrounds present in Italy, with a strong commitment towards education and training of biotech scientists and technicians. Italy is one of the top three countries worldwide in the number of publications per researcher, and among the top 10 countries in terms of citations per scientific article, presenting a distinguished skill of improving the research value through patents (Assobiotech, 2016).

Explicitly, the progress of the emergent life sciences industry in recent times has been enhanced by incentives for foreign investors that are addressed with a selection of measures and deprived of limitations on foreign ownership. Furthermore, regional authorities are energetically involved in promoting biotechnology through funding technology transfer agencies, incubators, and seed funds. Thus, according to our theoretical model, we pose that the Italian biotech system of innovation, in order to develop the biotech industry, asks for a meaningful investment that aims to review the regulations, policies, and fiscal measures in order to support, first of all, the biotech entrepreneurship.

There is an important gap between rules and regulations for biotech entrepreneurship in Italy and the rest of Europe that constrains Italian biotech firms to sustain major costs for their innovative and risk activities and productions.

First, it needs to move to an expansion of the system of financing and fiscal measures for the enterprises that present distinct necessity in comparison to those working in sectors in which innovation and the research and development assume a different value. In this direction, it is necessary that the Government makes some national provisions to manage the access to funds for biotech firms. A good solution that we posit to support those firms is the strengthening of the interdisciplinary character of the research and the conditions of diffusion of the knowledge through the European financial appointment. Coherently to such purpose both the Sixth and the Seventh European Programmes designate biotech as a priority sector in the destination of the funds of research. Thus, Italy, as all the states of the European community, is invited to increase its ability in the development of biotech projects that involve more countries in order to develop European leadership in the biotech industry. The weak point of such potential is the ability for private and public investment. Italy expiates, as for other sectors, the difficulty of cooperation at the territorial level in order to build poles of excellence able to support scientific research in this field. There are also similar problems at the infrastructure level.

From our theoretical perspective, we consider that the competitiveness and the development of the biotechnological sector are slowed down by the deficiencies at the political level. There is a dearth in regulations for supporting biotech scientists by financing their activities and supporting their collaboration by creating infrastructure to cooperate at the national and international levels. These aspects limit the cognitive potential and abilities of Italian researchers that are at risk for being discouraged in comparison to their colleagues in the international arena that, contrarily, can count on more consistent investments and support.

Thus, taking into consideration the institutional theory insight and our data, we propose that the development of the biotechnological sector should have three fundamentals aspects.

1. Legal context: to create the conditions to support the private initiative of innovations. So far, the sharing of acquired knowledge represents, for the firms, the risk not to re-enter in the costs of investment sustained. A suggestion in this direction is to create the conditions to sustain the firm to become a supplier of knowledge for public actors, or to increase the support of the research through public funds. Only in this way is there an advantage for private initiatives.
2. Public financing for biotech research and biotech firms; to increase the financing of research based on the collaboration of private and public actors. More specifically, our suggestions are directed to institutional actors in order to hold their role of coordination of the private initiatives in the territory with the purpose to program the activities toward a plan for the development of the area under their control.
3. Diffusion of knowledge about biotechnology: to invest in communications in order to promote the diffusion of biotechnological products in a clear way and to create events on biotechnologies such as fairs, shows, and workshops with the purpose to widen the knowledge of the opportunities and the risks that this field offers to individuals. So far, we observed a bad management of this aspect, which has generated a lot of confusion and false beliefs about biotech products during recent decades.

Conclusions

Scholars have the task of understanding the institutional and social dynamics that underlie economic development. In this paper, we have investigated the case of the Italian biotech industry. The reason was two-fold. The biotech sector is an evolving field that provides ample opportunities for growth and development. Italy is considered to be the vanguard for the quality of research and researchers; however, Italy is not a leading country in the biotech industry with respect to other European countries and the global context. We are in the presence of an innovative context that does not get results from the economic point of view equal to other contexts. Specifically, the analysis has been developed on a path that has combined two streams of research, the innovation system's research and the institutional theory in order to understand the role of institutions in the development of a given context. The perspective of the seed-ground brings together the two streams of research. In fact, it considers on one hand the fact that the success of a system of innovation requires more actors who must coordinate with each other with a common purpose. On the other hand, it reveals the central role that institutions and, in particular, local Governments have to create the conditions to develop an entrepreneurial context.

The literature on innovation systems raises the question of what the key elements for success in a specific area are. The purpose of previous studies was to provide guidance to verify the key actors of the process of innovation. However, the study of the role that Governments have in orchestrating these actors has often been omitted. Instead, the present research is especially concentrated on this aspect because we believe that local Governments are crucial for the success of a system of innovation and firm formation. The institutional theory provides a valid support to this hypothesis, and the analysis of the biotech industry in Italy has supported the fundamental idea of our theoretical perspective. Governments seek solutions to create conditions favorable to the creation and development of firms in an innovative industry.

This approach explains, according to our theoretical lens, the development of the biotech industry in Italy. We observed that rules and regulations have been noticed and restrictive about biotech. Following our theoretical model, Italy is an innovative context, but not an entrepreneurial one. Another inspiration for this paper was to understand how to act on an innovative context in order to make it an entrepreneurial one. From a public policy point of view, appropriate subsidies to support the innovativeness of national firms

could speed up the process. In most cases, these subsidies depend on the size of the firm and do not take into account the governance structure and the features of the firm itself. This is one of the weaknesses of these policies.

Our discussion opens the way to a different approach to regional policies that should move from direct actions (e.g. incentives or actions aimed at promoting markets) to the idea of promoting stronger links through which knowledge can spread. A strong industrial system is a means to learn about markets that is at least as important as actions directed at promoting innovation. Whether and how to help build a strong industrial system and an intense network of knowledge are matters of discussion. Entrepreneurial associations can play an important role. We suspect, however, that the major sources of knowledge contagion are relationships with buyers and suppliers, management inter-firm mobility, and shared platforms for business information and business-to-business management.

In conclusion, we believe that our understanding of firm formation in innovative industry should be directed towards the study of the quality of the laws and regulations enacted by Governments over time, because they can explain the results at the industrial and national levels. The case of the Italian biotech industry has allowed us to move in this direction. It was a case that made it possible to theorise about the seed-ground perspective. Future research could advance knowledge in this same direction.

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