

# Value Creation Processes in the European Biotech Industry: The Role of Collaboration Strategies

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#### Keywords:

Biotech industry; Collaboration strategies; International business; Knowledge; Development; Sustainable competitive advantage

Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-Non-Commercial 4.0 License (https://creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission. **Abstract:** Global-scale competition is based on the ability to generate innovation, particularly in knowledge-intensive sectors such as healthcare, biotech, and pharmaceuticals. The purpose of this paper is to analyze the collaborative strategies pursued by European biotech firms, as preferential ways to promote the innovation processes necessary for value creation. The methodology followed consists of the strategic analysis of European biotech firms to highlight value creation pathways. The main result of the study is the observation that the pursuit of a position of sustainable competitive advantage derives from the ability of European biotech firms to establish different and articulated strategic relationships of a collaborative nature.

## 1. INTRODUCTION

lobal scale competition is based on the creation, acquisition, absorption, sharing, and trans-Green of new knowledge. Knowledge creation has significant effects on the speed, quality, and quantity of innovation, while knowledge integration has relevant effects on innovative performance. Firms exploit innovation in a strategic vision: i) to obtain a competitive advantage, both locally and globally; ii) to adapt their strategy to the changing needs of the external environment; and iii) to create value (Arsawan et al., 2022). The propensity for innovation is greatest in the socalled knowledge-intensive sectors (Bloem & Salimi, 2023), namely: pharmaceutical, chemical, biotechnological, electronics, telecommunications, and information technology. Sectors characterized by a higher degree of competition, such as the biotech one, have a greater number of cooperative interactions among firms. The coexistence of competition and collaboration depends on the combination of the characteristics of the sector and the specificities of the business areas. The relevant factors of the biotech sector are: i) the high degree of concentration of firms (dichotomous structure; geographical aggregation); ii) the threat of potential new entrants and the presence of high barriers to entry, such as the need for large financial investments, and investments for the production and the access to distribution channels (Fraterman et al., 2023); iii) the presence of strategic barriers. Furthermore, the ability of firms to establish collaborative relationships with other firms is one of the factors on which depends the survival and development capacity of the firm. From a strategic point of view, the proliferation of different collaboration strategies and strategic alliances for business governance is certainly one of the most interesting aspects of this sector. Numerous sub-sectors are active in the biotech industry (Iseppi & Rosa, 2022; Martin et

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al., 2021): i) healthcare and pharmaceutical applications; ii) agriculture, livestock, veterinary products, and aquaculture; iii) key enabling technologies; and iv) industrial and manufacturing processes. This study aims to analyze the collaborative strategies pursued by European Biotech Firms (EBFs), such as intra- and inter-sectoral alliances and collaborations, as preferential ways to promote the innovation processes necessary for the creation of value. In more detail, the paper intends to analyze the macro-environmental and sectoral dynamics that influence the strategic choices of EBFs and the strategies that allow EBFs to engage in the innovation processes necessary for the creation of value. The following methodology consists of the strategic analysis of EBFs from the macro-environmental and sectoral characteristics up to the analysis of the key activities, and sources of competitive advantage to highlight the main value creation trajectories. The structure of the paper can be summarized as follows: i) definition of the conceptual framework deriving from the analysis of the main theoretical contributions on Inter-Organizational Relationships (IORs); ii) analysis of the biotech industry and identification of the main active business areas; iii) on-desk analysis to explore the main strategic approach of IORs established by EBFs.

## 2. CONCEPTUAL FRAMEWORK

The cooperative strategic behavior of any firm is remarkably widespread and consequently generates a growing interest of researchers in the field of IORs. IORs enable firms to bridge internal weaknesses and cope with the complexities of the external environment. It is possible to study IORs from multiple perspectives including i) the Resource Based View (Helfat et al., 2023); ii) the Transaction Cost Theory (Rindfleisch, 2020); iii) the Institutional Theory (Di Maggio, 1988); iv) the Knowledge-Based View (Grant, 1996); and v) the Stakeholder Theory (Savage et al., 2010). To date, IOR has become a strategic factor for many firms (Berends & Sydow, 2019). In some sectors, such as biotech, healthcare, and pharmaceutical, competition and cooperation may co-exist, so it is possible to refer to this situation as a co-opetition (Brandenburger & Nalebuff, 2011). Co-opetition depends on the specificity of the context and the activities involved. It is significant in the case of innovation (Corbo et al., 2022) and research and development (R&D). Compared to the traditional vision in which collaboration was seen as an umbrella including cooperation and coordination, recent studies (Kretschmer & Vanneste, 2017) underline the need for further insights, recognizing the distinction between the two concepts. In the field of IORs, some aspects assume particular importance, such as motivations, shapes, characteristics of the partners, and the key contents of the collaboration. These aspects assume different weight and importance in relation to the phase of the life cycle of the alliance (Russo & Cesarani, 2017). It is possible to individuate five fundamental reasons at the basis of IORs, which can coexist: i) development of the asset of resources and skills; ii) improvement of effectiveness and efficiency; iii) expansion of production and distribution capacity; iv) management of competition in the sector; and v) emerging strategies (Caroli, 2021). Firms collaborate, for example, to develop innovations, face major challenges, make supply chains sustainable (Sharma et al., 2022), set standards, carry out creative projects, respond to emergencies, to create value (Le Pennec & Raufflet, 2018). Over time, specialized literature has been developed on specific forms of IOR such as strategic alliances (Russo & Cesarani, 2017), consortia (Yang, 2022), international joint ventures (Nippa & Reuer, 2019), industry-university collaborations (Rybnicek & Königsgruber, 2019), networks and ecosystems (Shipilov & Gawer, 2020), regional clusters (Mitze & Strotebeck, 2019) and meta-organizations. In the context of IORs, the objective/s represent the primary unit of analysis and they can be of a private and/or collective nature, sometimes even opportunistic towards the other partners (Castañer & Oliveira, 2020). Defining the purpose of the collaboration, however, is not the only relevant aspect. In this context, the firm should evaluate: i) the actual potential impact that the collaboration has on the strategic objectives of the individual partners; ii) the balance between costs and benefits deriving from the agreement; iii) the relationship governance system; and iv) the determination of a correct balance between autonomy and integration of the alliance management of the actors involved. In the context of collaborative relationships, time assumes strategic importance. Indeed, time is a key resource both for the internal dynamics of the collaboration and for relations with the context external to the alliance. Other critical elements for the success of the IOR that should be considered include: i) knowledge sharing and selection of strategic partners (strategic factors), ii) intellectual property rights, economies of scale, spillover effects, market size and volatility, and costs (impacts); and iii) trust, commitment, and opportunism (conditions) and the evaluation of the impact of the overall collaboration strategy. The ability of the firm to collaborate is the basis of the potential success of the IOR. It can be influenced by the relational capital of the firm, the managerial style adopted, the clarity of its strategic objectives, its organizational skills, and its reputation.

#### 3. EUROPEAN BIOTECH INDUSTRY: COMPETITIVE DYNAMICS

Demographic changes, increasing life expectancy, changes in disease patterns, social globalization, and significantly increasing access to health services (OECD, 2022), are playing a crucial role in the growth of the biotech industry worldwide, stimulating greater investment in R&D. The European strategy has highlighted, since 2002, as life sciences and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades. Life sciences and biotechnology are enabling technologies - like information technology, they may be applied for a wide range of purposes for private and public benefits. Based on scientific breakthroughs in recent years, the explosion in the knowledge of living systems is set to deliver a continuous stream of new applications (European Commission, 2002). To date, several factors indicate that the biotech industry is characterized by a strong competitive dynamism. The relevant factors, i.e. those most capable of influencing the strategic behaviors of EBFs, are summarized below (Ho, 2014). The expenditure on R&D as a share of GDP (14.5 trillion euros) (European Union, 2023), in Europe, increased between 2000 and 2021. In 2021, approximately 2.15 % of GDP was spent on R&D in the biotech industry (Statista, 2023). The global growth rate of biotech between 2015 and 2020 was 1.3% (Martin et al., 2021). The biotech industry is characterized by the presence of numerous product and process innovations, which, according to a forecast analysis, will stimulate a fundamental expansion of the sector in the coming years (Global Market Insight Report, 2021). In Europe, as of 2020, there were about 2,820 biotech patents, recording a growth of 23% since 2005 (Statista, 2023). Process innovations are characterized by a high degree of interdependence with the technology sector, the healthcare sector, and the pharmaceutical one. For example, R&D activities have promoted the development of innovative medical technologies such as 3D bioprinting or biosensors, used for personal health monitoring. Another process innovation that has important interdependencies with the healthcare sector is personalized medicine. Personalized medicine is based on the concept that the genome of everyone, interacting with the environment, gives unique characteristics to complex pathologies that can thus be diagnosed and treated more effectively. Finally, new concepts such as cell therapy used for the treatment of oncological pathologies, have the potential to provide regenerative medicine until the pathology is remitted. Regarding product innovations, instead, biopharmacy will register a growth rate, globally, of 9.2% by 2027. The growing use of new ways of developing basic research, such as the use of proteins bio-recombinant, will favor the creation of innovative therapeutic solutions e.g. in the treatment of many chronic diseases. The growing attention to sustainable development is creating challenges for firms in the biotech industry. Indeed, biotech firms can offer a significant contribution in terms of creating solutions, in harmony and balance with the persistence of living systems. In addition to what has been observed so far, it cannot be neglected that changes occurred as a consequence of the COVID-19 pandemic (Tabish, 2020). Indeed, the pandemic emergency served to underline the strategic importance of the biotech industry for global health and safety, highlighting the key role played by biotech firms in the phases of prevention, treatment and management of the effects generated by pandemics. As an example, it can be cited the capacity to develop valid COVID-19 vaccines in a very short time, producing them on a large scale, and introducing mass vaccines around the world. As of 2022, the global biotech industry has a market size of 414 billion dollars, in which 12,203 firms are active, generating employment equal to 950,250 human resources (IBISWorld, 2023). A biotech firm is defined as a firm engaged in key biotech activities such as the application of at least one biotech technique to produce goods or services and/or the performance of biotech R&D (OECD, 2005). The differentiated and diversified nature of biotech firms does not allow for their clear classification and categorization. Therefore, it can be convenient to recur to the color criterion (DaSilva, 2004), which allows distinguishing the biotech companies according to their belonging to the main sub-sector of activity. Four colors are used: red (health, medical, diagnostics), green (agricultural, environmental biotechnology-biofuels, biofertilizers, bioremediation, geomicrobiology), white (gene-based bioindustries), blue (aquaculture, coastal and marine biotech). It is possible to distinguish biotech firms in relation to their core business. OECD identifies two types of firms i) dedicated biotech firm (DBF)- defined as a biotech active firm whose predominant activity involves the application of biotechnology techniques to produce goods or services and/or the performance of biotechnology R&D; ii) innovative biotech firm (IBF)- defined as a biotech active firm that applies biotechnology techniques to implement new or significantly improved products or processes. The European biotech landscape is multifaceted and mainly consists of i) thousands of firms, ii) hundreds of world-class research institutes, ii) universities, iii) medical centers, and iv) integrated hospitals. The various actors are integrated through shared paths of innovation and financing created within clusters spread across Europe. A study conducted by McKinsey & Company identified 8 clusters that represent half of EBFs. They are mainly located in France, Germany, and the UK (Le Deu & da Silva, 2020). The three largest clusters focus on providing services, immunotherapies, and brain and neuronal therapies. The UK has not only played a disproportionate part in multiple technologies and disease areas but has also been home to 35% of all biotech start-ups in Europe since 2012. Europe represents a favorable context for the development and commercialization of biotech products, being second only to the United States. Approximately 70% of the European market is in five countries: Germany, France, Italy, Spain, and the UK (Fraterman et al., 2023). An analysis conducted by LabiotechEurope has highlighted the relevant characteristics, from a strategic point of view, of the European biotech sector (Labiotech.eu, 2021a). The sector is expected to reach a value of €2 trillion by 2028. EBFs also performed well in 2020. At the end of November, Euronext-listed biotechs reached a total market capitalization of 29.1 billion euros, an increase of around 5 billion euros compared to 2019. Out of 62 biotech firms listed on Euronext, 16 saw their market capitalization grow by at least 100 million euros in 2020. The average market capitalization of biotech firms on Euronext increased by 20 billion euros from the beginning to the end of 2020. This massive industry growth is driven by numerous factors, including favorable government policies, increased launch of new and advanced biopharmaceutical products, continued robust investment, growing demand for synthetic biology, and increasing funding for biotech start-ups. Table 1 shows the European countries that have contributed most significantly to the growth of the sector in terms of the number of public companies present, turnover, market capitalization, and investments in R&D. The market capitalization is the market value of a firm's outstanding shares and represents a relevant factor to consider in choosing investment strategies.

State	Public Companies	Market Capitalization*	Revenue*	R&D*
Sweden	79	22.098	2.704	764 (28%)
UK	56	25.779	969	2.663 (274%)
France	41	16.51	4.636	1.401 (30%)
Germany	23	83.725	23.076	2.172 (9%)
Switzerland	17	13.647	1.207	1.497 (125%)
Denmark	16	61.529	3.937	1.569 (40%)
Norway	15	7.4	215	125 (58%)
Ireland	9	41.461	8.381	2.371 (28%)
Netherlands	7	34.744	3.56	1.1168 (33%)

 Table 1. European biotech areas

\*values are in millions of \$

Source: Own elaboration based on Ernest & Young, 2023

In 2021, the largest number of public companies was active in Sweden. UK had the highest levels of investment in R&D. Indeed, the UK has always had a reputation for scientific excellence. The country produces 29% of European scientific journals and ranks fourth on the Global Innovation Index with 116.815 jobs created and R&D spending supposed to rise to 2.4% by 2027. Germany, instead, ranks better in terms of total revenue and market capitalization, a performance determined almost entirely by BioNTech in 2021. In 2020, the European Medicine Agency (EMA) issued 97 approvals, including 39 new active ingredients (Figure 1), i.e. 83% more than those approved by the Food and Drug Administration (FDA) in the same year.



Figure 1. Positive opinions issued by the EMA over 10 years Source: Own elaboration based on Labiotech.eu, 2021a

Year 2020 was characterized by an increased interest in EBFs from investors. Euronext indicated a 30% increase in the number of institutional investors. Globally, 170 mergers and acquisitions were carried out with EBFs in 2020 (+ 4.7% compared to 2019). Start-ups represent the dynamism factor of the European biotech industry, the trends of recent years highlight their priority commitment to R&D activity, contributing to the construction of solid foundations for growth and innovation. For example, there are currently 823 active biotech firms in Italy alone, of which 29.6% are innovative start-ups (ENEA, 2023). The importance of small biotech firms and their essential role in the development of innovative therapies in Europe is reflected in the EMA market approval rate for small biotech firms, which has increased by more than 100% since 2016. In 2020, the EMA approved about 90% of applications for marketing authorization for new drugs from micro, small or medium-sized biotech firms (Labiotech.eu, 2021b). The strategic peculiarities that characterize the sector mainly derive from its high growth rate. Indeed, the latter determines the need to: i) develop the ability to access funding sources and attract investors; ii) promote collaborative relationships with other operators in the sector and not; iii) favor the development of innovative 9<sup>th</sup> International Scientific Conference ERAZ 2023 Selected Papers

solutions, which at the same time favor digitalization; and iv) access distribution channels. In addition, it is necessary to locate firms in strategic areas (clusters) in which a multitude of actors/firms coexist and share the value-creation processes. To date, EBFs are looking for new sources of value, based on a wide range of diversification models and choices, including the development of potential blockbuster drugs and the research of next-generation therapies (Levy, 2023).

# 4. VALUE CREATION PROCESSES OF EBFS

The analysis of value creation processes in biotech firms requires a broader strategic vision, which extends beyond firm boundaries. Therefore, it is appropriate to consider all the value relationships established by the value constellation firm. In an extended strategic context, such as one of the biotech firms, the firm tends to specialize in certain core activities by activating numerous collaborations of a different nature to achieve adequate supervision over the others. It is possible to identify two macro-areas of activity, mostly but not exclusively involved in the value generation process: production and R&D. These two macro-areas may represent a source of competitive advantage for DBFs engaged in the production of goods and services and for DBFs and IBFs carrying out R&D activities. The large-scale use of IORs in the biotech industry is strategically relevant for access to knowledge. Recently, EBFs have shown a preference for developing innovative paths through IORs rather than through acquisitions of other firms. In 2022 biotech firms signed alliance agreements for a potential value of 132 billion dollars (Ernest & Young, 2023). IORs that are considered worthy of attention for this paper are i) innovative ecosystems; ii) consortia; iii) regional clusters; iv) strategic alliances; v) research joint ventures; and vi) university-industry collaborations.

According to (Granstrand & Holgersson, 2020), "an innovative ecosystem is the evolving set of actors, activities, and artifacts, and the institutions and relations, including complementary and substitute relations, that are important for the innovative performance of an actor or a population of actors" (p. 1). A European representative example is IBISBA, a pan-European research infrastructure dedicated to gene-based bioindustries (white). IBISBA brings together the main European public research structures (from 10 European Countries) to provide low carbon and low environmental footprint. The considered ecosystem accelerates the production and translation of cutting-edge knowledge into innovation, sharing expertise and R&D facilities. Firms participating in R&D consortia not only can obtain the usual benefits of cooperation but can also further promote communication and mutual learning, because of the common knowledge with other actors of the consortium (Yang, 2022). A representative example is represented, in this case, by the Biobased Industries Consortium (BIC), which includes over 240 firms, covering all the activities of the value chain. The strategic aim of the Consortium is the creation of a sustainable bioeconomy in Europe. The firms participating in the BIC operate both in green and blue biotechnologies and in other complementary sectors. The BIC is also a private partner in the Circular Bio-based Europe Joint Undertaking (CBE JU) - a Public-Private Partnership (PPP), worth €2 billion, with the European Commission. Regional Clusters profit from the positive competitive effects deriving from IORs, in addition to more favorable access to funding sources (Olk & West, 2020). Moreover, in the case of Regional Clusters, according to Delgado et al. (2014), "there are multiple types of externalities occurring, including knowledge, skills and input-output linkages" (p. 1785). An interesting example of Regional Clusters can be found in Emilia-Romagna Region (central Italy). In this Region, seven so-called Clust-ERs are active to support the competitiveness of firms operating in the following sectors: healthcare, building and construction, culture and creativity, energy and sustainability, innovation in services, mechatronics and engines. The Clust-ER attaches to the regional network coordinated by ART-ER Attractiveness Research Territory. The Clust-ER Health is an association made of large and small firms,

laboratories of the High Technology Network, research centers, healthcare facilities, and training institutions that share skills, ideas, and resources to support the competitiveness of the Regional Health System. The business areas pertain to red biotechnologies. Clust-ER Health represents a key player in the regional innovation ecosystem, capable of multiplying the opportunities for territorial development through a collaborative approach. Referring to strategic alliances it is not possible to avoid referring to a worldwide major event, during which the biotech industry has played a key role, i.e., the COVID-19 pandemic. IORs, in the form of strategic alliances, have been the primary way to promote rapid vaccine development. As an example, it can be mentioned BioNTech (Biopharmaceutical New Technologies), a global firm, born in Germany in 2008, fully integrated, operating in red biotechnologies. Over time, BioNTech has established a variety of relationships with other global pharmaceutical firms, including Genmab, Sanofi, Genentech, Regeneron, Genevant, Fosun Pharma and Pfizer. The strategic alliance with Pfizer, as known, has allowed BioNTech to develop, produce, and market the first FDA-approved mRNA vaccine and the first COVID-19 vaccine. The vaccine development collaboration began in March 2020 and was built on a pre-existing partnership created in 2018, for the development of an mRNA influenza vaccine. Following the scientific success achieved with the first COVID-19 vaccine, the two firms signed a new collaboration which has facilitated the development and commercialization of the mRNA-based vaccine for the prevention of herpes zoster. Research Joint Ventures are, instead, a form of IOR that favors the overcoming of the possible gaps existing among R&D policies, the free diffusion of knowledge, private incentives to invest in R&D, and the appropriation of returns (Cassiman, 2018). Very interesting is the case of Xellbiogene, a firm aimed at the development and production of biological drugs and advanced therapies for the management of onco-haematological diseases for other research institutions, pharmaceutical firms, hospitals, and charities. The firm was born as a joint venture between two private Scientific Institutes for Research, Hospitalization and Healthcare operating in the Italian National Health System: Ospedale Pediatrico Bambino Gesù and Fondazione Universitario Policlinico Agostino Gemelli. Finally, University-Industry knowledge transfer can be seen as an important driver of innovation and economic growth, requiring two-way knowledge sharing to identify relevant issues, share and develop new insights, as well as the transfer and implementation of knowledge or technology (de Wit-de Vries et al., 2019). Referring to an Italian example, it can be cited the EryDel joint-stock company a spin-off of the University of Urbino. EryDel is active in red biotechnologies and operates in the business of developing innovative medical technologies. It attracted investments from venture capital funds and European loans for more than 30 million euros. The main objective is to commercialize the EryDex System medical device (phase III clinical development), to improve the management of Ataxia Telangiectasia, a rare genetic disease. It still boasts of the strategic collaboration with the University for the clinical industrial development of the results of the basic research conducted in the laboratories of the University.

The importance of the overmentioned relationships is because IORs favor the acceleration of the process of sharing resources and skills, especially in production and R&D activities. The proliferation of different ways of collaboration confirms the macro-environmental and sectoral characteristics, highlighting how innovative paths can be achieved through the activation of IORs. Cooperative contexts are potential platforms for the indirect and direct transmission of knowledge. A systematic analysis of the literature on the role of cooperation in innovative efforts confirmed that IORs have a positive effect on innovation performance (Freire & Gonçalves, 2022). Innovation can only occur in the presence of knowledge sharing (Kremer et al., 2019): a firm that encourages knowledge sharing stimulates innovative capabilities (Castaneda & Cuellar, 2020). The strategic role of IORs arises from the contribution that they make in the context of value creation. The on-desk analysis illustrates that biotech firms engaged in collaborative processes generate innovation by favoring the creation of value. 9<sup>th</sup> International Scientific Conference ERAZ 2023 Selected Papers

## 5. CONCLUSION

The European biotechnology industry is a complex and challenging environment. The study of macro-environmental and sectoral dynamics indicates intense competition determined by the high growth rate of the sector. This implies the need to develop the ability to access funding sources, attract investors, encourage product, and process innovation processes, promote digitization and finally, access distribution channels. Establishing IORs is a critical success factor that positive-ly influences the achievement of a position of competitive advantage. The analysis of the strategic action of the EBFs, conducted in this study, underlined the strategic significance of the IORs. EBFs that activate IORs, favor the sharing of knowledge to support innovative processes by activating virtuous circles of value creation. The paper represents a starting point for more in-depth research, to be conducted through semi-structured and structured interviews, and the administration of questionnaires, aimed at supporting the validation and impacts of the identified strategies.

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