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TECHNOLOGICAL, COMPETITIVE AND ORGANIZATIONAL COMPETENCIES IN PHARMACEUTICAL BIOTECHNOLOGY: THE CASE OF PHARMACEUTICAL COMPANY LIBBS FOR BIOSIMILARS

Cátia Favale*, Anapatricia Morales Vilha and Carlos Gamboa

1Universidade Federal do ABC–UFABC, Doutoranda no Programa de Biotecnociência, Brasil; Auditora e Consultora independente, Brasil; [2]Universidade Federal do ABC–UFABC, Profa. Dra. De Pós-Graduação de Economia, Biotecnociência e Ciências Humanas e Sociais, Brasil; [3]Universidade Federal do ABC–UFABC, Doutorando no Programa de Biotecnociência, Brasil

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Corresponding author:** ***Cátia Favale

ABSTRACT

Tecnologias cada vez mais Biosimilars drugs aim to change access to high-cost therapies, ensuing original biological drugs after their patent expiration. Every innovation movement requires from societies, economies, and enterprises to reshuffle to a new competition level. In the enterprise's perspective, the capabilities to manage complementary competencies (technical, organizational and competitive) and resources defines how they will succeed in the market. This paper aims to investigate the technological, organizational and competitive competencies developed by Libbs, a Brazilian pharmaceutical company, to create innovation in the field of biopharmaceutical drugs, especially biosimilars. The literature review is interdisciplinary, reaching several knowledge areas, like business management, technology economy, technological businesses, biology and biochemistry. Secondary data from sectorial reports and sector perspectives were reviewed too. The case study was supported by exploratory research, interviewing Libbs executives in 2019. The results show that the Brazilian pharmaceutical industry has virtuous cycles, linked to the strategical role of the State, its interest and the incentive policies. The case study enabled to evaluate the innovation practices which supported the approval of two biosimilars: Trastuzumabe (2018) e Rituximabe (2019). The Libbs organizational culture is compromised with innovation, but the innovation process management could be better structured, smoothing the reach of medium- and long-term targets.

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INTRODUCTION

The biopharmaceuticals and the biotechnological tracks to manufacture them are not new concepts. In the last years, monoclonal antibodies and immunotherapy drugs represent the biggest volume of approval to develop drugs. It is forecast that in 2026 50% of all drugs development will be biopharmaceuticals1 (JOZALA *et al*, 2016). They are heading the innovation in the sector and changing the value chain and target markets. This changing points to technological threats in R&D, production and marketing (REIS *et al*., 2017). In Brazil, the strategic and economic importance of pharmaceutical industry is magnified by the complexity and threats of the health sector. The local companies have no history of radical R&D and are recognized only by their manufacturing capacity (VARGAS, 2013; CGEE, 2017; DE NEGRI 2018). In this line, it is not observed biopharmaceuticals development. Hence, the transnational companies (mainly european and american) are responsible for the innovative effort, normally imported from their headquarters. (REIS *et al*., 2009). In this scenario, the skills to manage complementary competencies (technological, organizational and competitive) will define the success of a company in this market. The objective of this article is to investigate the competencies of Libbs to create innovation in the biopharmaceuticals market, especially biosimilars. The biosimilar drugs are similar versions of patented biological products (SALERNO; MATSUMOTO; FERRAZ, 2018) and shows as opportunity to Brazilian companies inserting biological drugs market, because it does not demand basic research. It is important to highlight those new capabilities need to be developed to this insertion succeeds. Libbs executives were interviewed in depth (2019) to understand how the company addressed the demands and made the way to launch

[1]Biopharmaceuticals are complex molecules of heavy molecular weight, obtained from biological fluids, animal tissues, or biotechnological procedures to manipulate or insert genetic material (recombinant DNA) or genetic change induced by irradiation, chemical products or forced selection. Brazilian law accepts seven categories: Allergenic, Monoclonal antibodies, Biodrugs, Hemoderivatives, Probiotics and Vaccines (ANVISA)

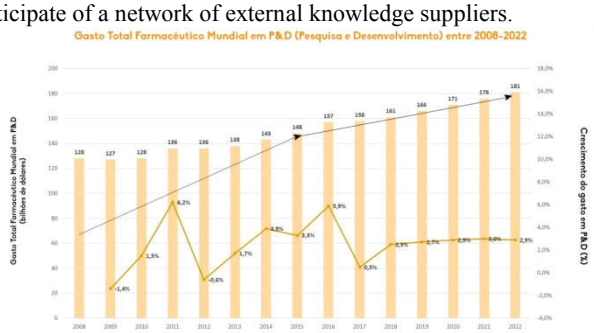
biosimilars in the Brazilian market. This paper makes a special contribution designing an analytical structure to address technological, organizational and competitive capabilities to help Brazilian pharmaceutical companies in new technological tracks.

LITERATURE REVIEW

To understand the complexity to manage the R&D and innovation efforts to make Brazilian pharmaceutical industries competitive demands a multidisciplinary approach, gathering Management, Technology Economy, Biology and Biochemistry. It is also useful to use sectorial overviews and perspectives reports. Seminal studies that emphasize resources and competencies in companies' organizational and innovative processes are focused by authors like Prahalad e Hamel, 1997; Pisano e Teece, 1998; Dodgson, 2000; Tidd, Bessant e Pavitt, 2001; and Barney, 2002. They see resources and dynamic capabilities as key success elements to build innovation.

Resources and competencies approach: Innovation is a continuous process, triggered by dynamic and quick changes in the competitive environment, demanding ability to manage risk, instability and discontinuity in all sectors of activity (VILHA, 2010). The competencies approach originally was objecting the individual and the world of work (TAKAHASHI; BULGACOV, 2017, p. 26). More recently, the focus changed to organizations, as the companies' competencies are essential in the strategy building and operation and are recognized as differential for the market (PRAHALAD; HAMEL, 1997; PETTS, 1997; JAVIDAN, 1998). Teece (2017) says that value creation of the enterprises depends on generation of organizational, managerial and technological assets to innovate. Resources are everything owned and accessed by a company, physical and human (PENROSE, 1959, p. 7). Dodgson (2000) proposes that resources are all the assets and functions available to a company, including R&D, manufacturing facilities, financial assets, human resources, networks and processes and organizational practices. For Teece (2017), companies with weak dynamic capabilities[2], facing a new opportunity, will seek business models based on past investments and established organizational processes. It is critical to understand how effective the internal coordination and integration of processes and systems are to address the new scenario or problem. A deep knowledge of internal resources and external environment, especially intangibles like knowledge, competencies and capabilities drives are the bulk of "productive opportunities" (TAKAHASHI; BULGACOV, 2017). To create innovation, these assets need to be organized and managed, addressing the competitive scenario where the company is inserted and driving the strategy to succeed on it (VILHA, 2009). Hence, to embed the innovation concepts and culture to the enterprise strategy demand a continuous self-knowledge process, observing and reviewing practice, routines, and forms of action, turning difficult the replication of practices and products (PISANO; TEECE, 1998; TEECE 2017).

Technological, innovative and organizational landscape of Brazilian pharmaceutical industry and biosimilar drugs: The world pharmaceutical scenario has a differentiated oligopoly (REIS *et al*., 2009), known as Big Pharma, which are big transnational companies, mainly American and European. Merges and acquisitions in the past years leverage the competitive advantages of these companies, gathering competencies and assets, and the understanding that companies with high performance to generate innovations drive the competitive dynamics of the markets. These enterprises are strongly linked to universities, research institutions and startups, in the basic and applied dimensions of the research. Originally, the pharmaceutical industry concentrated whole R&D in house, but faced with the huge changes in the value chain of the sector, began to participate of a network of external knowledge suppliers.



Graphic 1. Total world pharmaceutical investment in R&D 2008-2022

Today, the actors of the pharma R&D are technological based startups, Center Research Organizations (CROs), universities, research centers *and* the big pharmaceutical industries (Centro De Gestão E Estudos Estratégicos, 2017). A study of Interfarma, a Brazilian Association of Pharmaceutical Research Industry) shows that the R&D investment of the pharmaceutical industries in the world is huge and is growing, at last until 2022, as presented in the Graphic 1, with source in *Evaluate Pharma, World Preview 2018.* In the Brazilian pharmaceutical industry, R&D mainly means D (development) than R (research) (SILVA, M.; SILVA, E; LEAL, 2018). Compared with the transnational companies, local enterprises are short of resources, technical and economic, to invest in research (TIGRE *et al*., 2016). In addition, there is an established culture to manufacturing products, instead of researching, and an unstable institutional scenario, with government policies and economics up and down across the years. The R&D processes of pharmaceuticals are long termed, risky, with many steps and, overall, capital intensive. This logic applies to biopharmaceuticals too, which have more complexity and specificities. There are good market perspectives to biosimilar drugs, although demanding more studies. To 2022 there is the forecast that 50% of the pharmaceuticals market will be fulfilled by biological products. This tendency is reinforced by some drugs whose patent are expiring. The biosimilars could allow more patients to be treated with biopharmaceuticals. But this situation demands a regulatory environment and clinical rules that improves a positive or neutral opinion to biosimilars compared to the biological drugs of origin, allowing the former to be economically sustainable (REIS *et al*., 2017).

Methods and procedures used on the research

The research was designed based on two analytical methods: the first looks at the industrial picture of the Brazilian pharmaceutical industry, using secondary data coming from sectorial reports, to study the local biosimilar drugs. The second method uses case study to understand how the Libbs Industry absorbs and manage resources and competencies to innovate and compete in the biosimilar market, combined with internal documents and institutional data. The research was made in 2019, in the company headquarters, and interviewed the CEO (founder heir and member of administration council) and three executives, strategic planning director (seven years in the job); institutional relations director (twenty years in the company) and the head of innovation (three years in the job). It was developed a semi-structured questionnaire, with open and closed questions, based in the approach of resources and competencies (Teece, 1986; Prahalad; Hamel, 1997; Pisano; Teece, 1998; Bell; Pavitt, 1993; Dodgson, 2000; Barney, 2002). Three investigation pillars were used: i) processes and organizational abilities; ii) technological opportunities and their track in the company; iii) enterprise assets (technology, location, finances and market interfaces)

The first pillar focused

- Coordination and integration of collaborative practices, like company structure, communication, tasks coordination,

[2] Dynamic Capabilities – Concept that represents a concrete proposal for the integration of internal aspects of the organization and external aspects of the environment. They represent the ability to restructure resources and reconfigure competencies through environmental changes. (TAKAHASHI; BULGACOV, 2019, p. 15). They are precursors of the theory of dynamic capabilities Teece, Pisano and Shuen (1997).

decision levels (internal dimension), integration with external actors targeting collaborative development of business and technologies
- Routinization of activities, from operational to strategic, in an organic and coherent shape, between functions and areas
- People and company learning by use, operation, interaction, research, search
- Reconfiguration, i.e., company reaction to monitoring markets and technologies
- Development of technological plan to address business priorities, evaluating internal R&D capabilities, immediate and strategic needs and technical and economic potential of several technologies

The second pillar addresses

- Technological opportunities detection, monitoring external and internal environments of the company
- Alignment of technological opportunities and company business strategy
- Use of cumulative experience and business history of company

The third pillar refers to

- Technological assets
  - Technologies development using R&D
  - Technologies acquisition by licensing, alliances and direct buying
  - Routines of R&D of pharmaceutical sector, addressing drug discovery; initial essays and chemical optimizing; pre-clinical studies; clinical studies - phases 1 and 2; formulation; genetic research; clinical studies phase 3
  - Intellectual property protection
  - Improvement of R&D policies
- Location Assets: presence in technological parks and districts and industrial clusters
- Financial assets: resources to leverage technologies and businesses – short, medium and long term
- Market interfaces: commercial, marketing, logistics structures, services, technical support

A fourth dimension was used, looking at: 1) How Libbs manage its productive processes – exploring abilities, equipment, systems and organizational methods to manufacture goods and services; and 2) Capabilities to adapt manufacturing, considering licensing of external technologies and coordinate of productive capabilities aiming multiple technology sources integration.

RESULTS

Libbshistory: Libbs is the eighth pharmaceutical company in Brazil, in terms of revenue (IQVIA, 2017; LIBBS, 2019). Founded more than sixty years ago, with Brazilian capital, has 2.7 thousand employees and has its products in 84% of point of sales of Brazil - 60.300 drugstores (LIBBS 2019). Its innovation investment reaches 10% of revenues - R$ 1.5 billion in 2018 (GRUPO FARMA BRASIL). The first plant to the production of biosimilars has an investment of R$ 500 million (Entrevistas, LIBBS 2019). In March, 2018, the laboratory starts to sell the first biosimilar, based on monoclonal antibodies (trastuzumabe, used in breast cancer therapy), with the brand Zedora®. The development model is classified as a Productive Development Partnership (PDP). Following the initial plan, the drug will be totally manufactured in Brazil in five years. Until there, Libbs will transfer technology of the biosimilar to Instituto Butantan -a Brazilian research institute (LIBBS 2019). In the historic records about Libbs – in public and private sources – the company is a pioneer in the pharmaceutical segment, daring and innovating across its entrepreneurship path. Its original name was Libbs, meaning Brazilian Laboratory of Biology and Synthesis, born in the sixties of last century. It was bought by Alcebíades de MendonçaAthayde, a pharmaceutical distributor in Recife, Pernambuco, a Brazil's northeastern state. Athayde gather some critical competencies to manage a pharmaceutical business. Of special relevance to grow were the government incentives (tax reduction) and public policies developed in the 50s, as a strategic project of president JuscelinoKubitschek, to "make 50 years in 5", added to personal investment. From the pharmaceutical distributor came the point of sales network. As Mazzucato (2014) points, the government role to lever innovation is evident. But it is not exclusive. Innovation needs a pack of capabilities and competencies, acting in all the steps of creation and development of a product or process, combined with a friendly institutional environment and financial incentives and funding structure. It is a set of internal and external factors relating the company and its context (FUCK; VILHA, 2012). The original portfolio had quite simple products, like royal jellyNectargel®, feet powder Diaperol®, positioned like "miracle products", common at that time. A new partner, bringing funds, gave the opportunity to start a strategic differentiation model, with products like Fructocistein®, a formula to act over hepatic dysfunctions. The revenue increase drove the built of a new manufacturing plant in middle of the seventies of last century. Another opportunity came in 1969. The military government aimed self-sufficiency in pharmaceuticals and edited a decree ending intellectual property protection – patents and processes – to make drugs. Libbs took the opportunity and marketed a copy of the anxiolyticDiazepan, named Ansilive®, promoting it with medical doctors and selling to government health departments. More sophistication and network were brought by a consultant with technical skills who worked for the São Paulo Clinical Hospital, the biggest Brazilian public hospital. Following the path, Libbs launches Ancoron® - anti arrhythmic Amiodarona, a product which contribute with 40% of total revenues in last 1980s. This product had some problems with raw material quality, which provoked a strategic redefinition, starting the production of active pharmaceutical ingredient, like Amiodarone. In the end of the 1990s Libbs had in its portfolio 70 active pharmaceutical ingredients (active drugs to produce medicines).

The decision of invest in a pharmaceutical synthesis operation can be considered an innovative strategic redirecting. This new technological path complements the main business, which is manufacturing active pharmaceutical ingredients. The core products were cardiological and gynecological drugs. This strategic vision is confirmed by the records and interviews and is pursued until nowadays. Empirically, Libbs noted, in the end of 1990s, the need to improve its competencies in R&D, implementing a verticalization process in Embu das Artes facility and a R&D center. In addition, Libbs starts to prospect new clients abroad, beginning in 1995 to conclusion in 2003. The creation of ANVISA (National Agency of Sanitary Surveillance – 1999) represents a huge challenge to Brazilian pharmaceuticals, due to the technical-regulatory competencies demanded by new laws. To comply, Libbs reviewed and adapted its portfolio and processes, aborting some new products and ending sales of others. It was a turmoil period, unsettling the company structures. It was viewed by the company top managers as the worst crisis Libbs experienced (Porque se trata da Vida page. 90). The good news was that the company invested largely in R&D, buying HPLC (High Performance Liquid Chromatographers) used in stability studies and pharmaceutical equivalence and improving quality control, aligned with R&D demands. This movement can be considered incremental innovation and drove a new strategic path. As Libbs gathered new competencies and resources, it decided not to invest in the generic drugs market, which could represent a loss of its structural characteristics. Strategically, enlarged the contraceptive and gynecological line, investing in marketing and promotion, establishing a competitive fortress in the segment. The first decade of new century is marked by strategicendeavor, and Biotechnology was one of main bets. Seizing the opportunity created by promotion and incentive policies, Libbs made an agreement with Fiocruz, a Productive Development Partnership (PDP) to produce, exclusively for five years, Tacrolimo (immunosuppressant for transplanted patients), leveraging thebiological drugs facility. Libbs bought a stake

in Orygen – one of Brazilian "super pharmaceutics"- but backed it down, preferring to pursue a solo path and launched two new drugs, Trastuzumabe (2018) and Rituximabe (2019), interesting examples of biosimilars market performance. Looking at radical technological innovations, Libbs is investing in a regenerative cell therapy. Biotechnology turns stem cells in heart cells, to regenerate cardiac tissue. The startup PluriCell, founded in 2013, was incubated in USP/IPEN-Cietec developed the technology and Libbs is investing angel capital, about US$ one million.

Processes and organizational and managerial abilities to innovate: The historical path of Libbs and its consistent strategic positioning focusing efforts to develop business and capture opportunities in cardiology and gynecology specialties highlights that, even without systematization efforts, the company built a learned lessons pack which improve substantially its essential competencies. Hamel e Hene (1994) teach that there is a buildup of learning that makes the core of competencies acquisition process. Libbs practices, like purpose, aspirations, creed, are foundations to structure new management models. To Libbs CEO, the understanding of the purpose superimposes the understanding of the mission. Company substitutes the concepts of mission and vision by purpose and aspiration, transmitted to the team in the motto: "Our purpose is to contribute to people reach a complete life". To the interviewed, the routines systematization and perfectioning of management practices is a permanent goal, supported by acknowledged methodologies and management models. An example is the implementation of the cells management model, based on horizontal organization of tasks aligned to projects, instead of vertically hierarchic leadership. In this model, a project commands the activities organization. Libbs has a team focused on innovation prospecting and management, supported by a proprietary platform named PortasAbertas (opened doors) disposed in the company website. Its objective is to contact startups with convergence with Libbs interests, to start association projects, not only in the health segment, with tailor made cooperation models. Over 300 leads came from this initiative. The innovation team searches projects through associations and innovation programs. In addition, the company's employees are stimulated to search innovation, through activities and challenges. As a success case, it was proposed a new method to build shows and fairs stands, reducing the lead times. Another is a tracking system to monitoring expiration date of drugs, being developed. The manufacturing plant reconfiguration and adapting to biosimilars is considered a big innovative effort by the interviewed, due to the complexity of the productive process, the regulatory exigencies and technology transfer.

Technologicalopportunities: The interviewed people said Libbs drives and organizes its technological efforts according to the markets, being proactive in searching and capturing opportunities to generate products or therapies to sicknesses out of the strategic main areas of the portfolio but could complement it. It is important to highlight that this is not a structured process. It lacks a database of records to feed marketing intelligence and record lessons learned. This is a gap acknowledged by the managers. The decision between to buy a technological transfer pack or to buy the active principle and develop formulation internally depends on time to implement. Market conditions are relevant to decision making. Libbs prefer to work in new projects with partners with history in the company. Regarding to biosimilars, the technology suppliers were Libbs partners in other projects.It is not relevant to Libbs to buy a third part technology or to prospect licensing to produce in Brazil. What really matters is to work with someone reliable. The R&D does not have a structured activities protocol to research new drugs. It is busy to adjust formulae or develop new methods of analysis and validation, coming from regulatory area or not. Some scientific studies can be conducted inside company, in collaboration with medical team). Asked about the ponder of R – high technological density research or new products development - or D – incremental innovation - in R&D, the interviewed answer the second group is the main track of the company. About difficulties to scale up, e.g. transform innovations in products to sale, the role of universities is secondary front to startups, due to red tape in the universities relationship. Using the example of Pluricell, the startup is agile, but lacks structured processes (DRSKA 2019). Looking at intellectual property, Libbs do not recognize patents as a competitive tool, although it has a team focused on check competitors' patents as a tool to evaluate a project's viability, although it is not considered a performance measurement. In some cases, a project is started to benefit of a patent expiration to launch a new product. Regarding the interviewees, Libbs continually monitor fiscal incentives and policies and public funding lines to leverage its profits or develop a project. It was not observed innovative cases in marketing, services, technical support, sales or distribution.

Assets to position the company in markets: Innovation and technology are deeply linkedconcepts, and the type of activity developed in the R&D department is an important indicator of the innovative effort. As theorized by Nelson (1998), the type of professional (engineers, scientists) that make up the R&D department may indicate a promotion of technological advances in production. At LIBBS, when asked about the type of activity prevalent in R&D, if they are type P activities, referring to research with technological density and / or the development of new products or D for incremental activities, the answer is that D (development) has is more relevant in the context of departmental activities. Most professionals in R&D are pharmacists and chemists. The difficulties of carrying out the scale-up, in the other words, transforming innovations into products for the markets, is a statement in the interviews and converges with what is discussed before when the role of the University in the generation of critical knowledge and technological innovation is addressed. In this regard, when asked about the role of universities, respondents mention that establishing partnerships with a startup is easier than with a university from the point of view of agility and bureaucracy. The analysis of competitors' patents is a strategic tool for positioning in the markets. Some patents, relating to processes, have already been filed by the company. There is no defined policy and they do not rule out filing new patents, for example, in the case of success with Pluricell. There is a view in the company that the patent for the patent does not offer benefits, nor can it be seen as a performance indicator as practiced by some competitors. According to the president of LIBBS, there are many parallel processes related to the patent, such as compensation by the holder to postpone the launch of the "copy" of the product on the market. Also discussed before, the market dynamics involving patents has been the subject of intense debates. This scenario is expected to worsen in a few years when around 50% of patents on original biological medicines are expected to expire (Evaluate, 2018). The company's commercialization, distribution, marketing, services, technical support structures do not have an innovation case to be highlighted. However, the use of a specific methodology purchased from third parties for the commercial area is considered a successful innovative initiative that can be adapted by other areas.

Production processes: Libbs has one manufacturing facility in Embu das Artes, São Paulo state, with budget to update or invest in new manufacturing technologies to this plant. According to interviewed, a critical element to trigger or scale up a new project is the possibility to optimize this plant resources. There are frequent investments to suit new projects. Libbs has no conceptual problems to license technologies to make feasible new projects. It is relevant to the decision the alignment with market demands and strategic convenience of the project. To buy a technology to take an opportunity is a common practice. ANVISA inspections are periodic, reaching all the production lines. Libbs is certified by the agency in terms of manufacturing best practices. New projects are fully inspected by the agency, even before the sanitary registration publishing.

FINAL CONSIDERATIONS

It is estimated that, until 2026, 50% of drugs being developed will be biopharmaceuticals (JOZALA *et al*, 2016). This information incentives research about the perspectives of biosimilars drugs. The question which drove this study was the motives to the Brazilian

pharmaceutical industry to organize itself and to manage resources and competencies to be inserted in value chains and to face the challenges of this innovative market. Literature review, sector and secondary data confirm that Brazilian pharmaceutical industry has periodic virtuous cycles strongly dependent of government policies, interests and incentives. A strategic and critical challenge is to build a solid tripod between State, companies and technological research projects to reduce the dependence of transnational companies' technologies. There is a strategic need to improve strategic and innovation management, as well as to optimize the use of public resources. The low confidence and interest level in the relationship with universities – which are an essential innovation vector – is an important challenge to insert the national pharmaceuticals in the country's innovation and technological scenario. The case study of Libbs allows evaluating, in a differentiated dimension, considering different analysis axis, the innovation practices which supported the approving of two biosimilars drugs, Trastuzumabe (2018) and Rituximabe (2019). Data show that Libbs organize its resources in a way to reinforce its essential competences and build new competencies, adapting its dynamic capabilities aligned with the strategy. In other words, observing the business environment dynamics and configuring internal resources and capabilities to optimize the capturing of opportunities in this environment (TEECE; PISANO; SHUEN, 1997). Libbs organizational culture is compromised with innovation and learning, which, along its history are being incorporated, helping the decision-making process. However, the innovation management needs to be better structured, to facilitate the reaching of medium- and long-term targets.

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