

## **CAFÉ WORKING PAPER NO.20**

Centre for Applied Finance and Economics (CAFÉ)

# The Internationalisation of the Large Brazilian Pharmaceutical Companies: Challenges, Competitive Advantages and Strategies

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June 2022

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## Abstract

This paper aims to analyse the characteristics of the Large Brazilian Pharmaceutical Companies' internationalisation. Internationalisation can be used as a strategy to overcome the challenges the companies are facing in the domestic market and an opportunity to catch up. We carried out a multiple case study with eight companies to identify their competitive advantages and strategies of going abroad. The results show the typical characteristics of companies and two distinct patterns: the exploration and the exploitation of assets and capabilities in the international market. The conclusions bring contributions to the International Business of emerging countries and evolutionary literature: i) the competitive advantages of companies are built before internationalisation concerning financial capacity and adaptation to the home institutional environment; ii) the companies follow strategies of technological catch-up in developed countries as a shortcut to overcome their innovative weaknesses; iii) the main obstacles to internationalisation refer to the vulnerability of the institutional, political, and regulatory domestic environment.

**Keywords:** emerging markets multinationals; innovation strategy; competitive advantage; pharmaceutical industry; Brazil.

JEL: F23; L65; O32.

#### **1** Introduction

The International Business literature shows that internationalisation can shorten the technological gap between companies from emerging countries and companies from developed countries. In this sense, emerging markets multinationals use the international market as a strategy to acquire innovation capabilities absent in the home market (Li, 2003; Luo & Tung, 2007; Mathews, 2006). We can see this trajectory in the examples of Indian and Korean pharmaceutical companies, which adopted internationalisation strategies as a technological catch-up mechanism (Kothari et al., 2013; Lee, 2016). For this purpose, companies build competitive advantages in the home country before internationalisation (Aguilera et al., 2017; Bonaglia et al., 2007; Martin & Javalgi, 2016). But, on the other hand, the vulnerability of the home institutional environment and the lack of experience and knowledge about the internationalisation strategies (Cuervo-Cazurra, 2008; Teece, 2014).

This work provides pioneering research on the challenges, competitive advantages, and strategies of the Large Brazilian Pharmaceutical Companies' internationalisation. The research methodology is a multiple case study with eight Large Brazilian Pharmaceutical Companies through fieldwork to get first-hand evidence. The paper intends to contribute to the International Business and evolutionary literature regarding the internationalisation process of high technology-intensive and science-based firms from emerging countries.

The pharmaceutical sector is responsible for providing the health products necessary for the population's quality of life. Medicines (essential goods) are imported by countries when they are not manufactured domestically, increasing economies' external vulnerability. During the COVID-19 pandemic, countries with a well-developed pharmaceutical industry demonstrated a rapid and sustainable recovery. Furthermore, the pharmaceutical industry generates technological spillovers to other productive activities, as it is an activity of high technological intensity and science-based (Lichtenberg, 2006; Mazzucato, 2013). Due to these characteristics, the pharmaceutical sector is constantly the target of public policies, especially in developed countries, which see the importance of investing in strategic sectors, whether offering manufacturing, innovation, or internationalisation supports.

So far, studies on the internationalisation of Brazilian firms focus on competitive advantages and strategies of firms based on natural resources (Aguilera et al., 2017; Finchelstein, 2017; Gonzalez, 2019; Lopez-Morales et al., 2017), or on the internationalisation performance in aggregate firms (no sector differentiation) (Arbix & Caseiro, 2011; Esteban-

Jardim & Urraca-Ruiz, 2018; Fleury et al., 2013; Fleury & Fleury, 2011). The internationalisation of the high technology-intensive sectors is rarely analysed in the literature as a possibility of catching up and facing domestic challenges.

## 1.1 The challenges faced by the Brazilian pharmaceutical firms

The international organisation of the pharmaceutical industry illustrates the differences between countries with well-developed pharmaceutical sector and those that do not. The pharmaceutical industry is composed of transnational centenary companies from developed countries (TNCs) and smaller companies from emerging countries. The TNCs operate in the most innovative segment of the pharmaceutical industry, spending high R&D resources<sup>1</sup> for new drugs development and employing innovative strategies aligned with internationalisation strategies to access globally dispersed knowledge (McKelvey & Orsenigo, 2001; Radaelli, 2008). In this sense, the development of new products faces significant entry barriers. The costs of innovative activities for developing a new drug increased from 1.6 billion in 2000 (in 2013 dollars) to 3.9 billion dollars in 2013<sup>2</sup> (DiMasi et al., 2016). However, Asian pharmaceutical companies are increasing their share in the world market. For example, the non-patent Active Pharmaceutical Ingredient (API) produced by Chinese companies expanded the world's supply of inputs at lower prices, and the Indian generic drug companies increased the share of emerging companies in the world market (Chittoor & Ray, 2007; Stafford, 2006).

The Brazilian pharmaceutical market comprises national pharmaceutical companies, TNCs, and national public laboratories<sup>3</sup>. The creation of the Brazilian pharmaceutical industry did not focus on developing home technology, so the sector was dependent on foreign technology (Strucker & Cytrynowicz, 2007). Recent events have contributed to modifying the Brazilian pharmaceutical scenario. First, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in 1994, established sectoral non-discrimination of patents and patent recognition in the pharmaceutical area, which culminated in the Industrial Property Law (No. 9,279/1996). Second, the creation of the Brazilian Health Regulatory

<sup>&</sup>lt;sup>1</sup> The world's largest pharmaceutical companies spend about 20.9% of revenues on R&D (EvaluatePharma, 2019).

<sup>&</sup>lt;sup>2</sup> In many cases, the investment to develop a new drug are financed not only by companies, but also by public resources supporting basic research in universities and institutes of science and technology (Mazzucato, 2013).

<sup>&</sup>lt;sup>3</sup> The public laboratories produce drugs, serums and vaccines to meet Brazilian Unified Health System (SUS) demands, specially. They were created to provide pharmaceutical assistance and fill gaps in national vaccine and drug production resulting from the lack of interest of large pharmaceutical companies in certain therapeutic classes, such as neglected diseases (e.g., malaria, schistosomiasis, and dengue/zika) that mainly affect developing countries.

Agency (Anvisa) (Law No. 9,782) in 1999, enlarging the regulatory requirements for the marketing of pharmaceutical products in Brazil. Third, implementing the Generics Law (No. 9,787) in 1999 set bioequivalence and bioavailability requirements for drugs and established a new business segment for companies. Fourth, in 2003, the industrial and innovation policies took place in the government's agenda and set the pharmaceutical sector as a priority, encouraging innovative activities by providing incentives for the internationalisation of companies. Industrial and STI policies have played an essential role in strengthening national pharmaceutical companies (Hasenclever et al., 2018).

These events affected Brazil's pharmaceutical industrial structure. So, the Brazilian pharmaceutical companies created capabilities that made it stand out in the current Brazilian market. In 2017, among the 20 largest Brazilian pharmaceutical companies, eight are Large Brazilian Pharmaceutical Companies in terms of retail and public sector revenues.

Despite the growth of Large Brazilian Pharmaceutical Companies, they still have many challenges, in particular:

- (i) Maintain the market share in Brazil: the competition with world-leading TNCs in the local market is increasingly fierce. Since the economic opening of the 1990s, the participation of TNCs in the Brazilian market has grown significantly. The TNCs offer innovative drugs in the Brazilian market but focus on technological efforts on their headquarters (Carlsson, 2006). In their turn, The Large Brazilian Pharmaceutical Companies manufacture low-value and low-innovation drugs (generic and branded generic drugs).
- (ii) Access to good quality APIs: the Brazilian pharmaceutical industry has not developed the downstream chain to supply the drugs' manufacture raw materials. Then the companies import about 90% of APIs used in domestic production (Mitidieri et al., 2015). These products come from China (non-patent APIs) and developed countries – the USA, Germany, and Switzerland – (more innovative APIs). The survival of Large Brazilian pharmaceutical companies depends on international trade<sup>4</sup>, which is extremely worrying, especially in situations such as the COVID-19 pandemic and more protectionist relations between countries.
- (iii) Enter into higher value-added segments of the pharmaceutical industry: The manufacture of drugs by the biological route, the current technological trajectory of the

<sup>&</sup>lt;sup>4</sup> The Brazilian pharmaceutical trade deficit reached \$5.7 billion dollars in 2019 – concerning \$ 1.9 billion to drugs in bulk packages (e.g., API) and \$ 3.8 billion to drugs products (finished dosage form) (Brasil, 2019).

pharmaceutical industry (Malerba & Orsenigo, 2015), could be an alternative for the Large Brazilian Pharmaceutical Companies to the paradigm of the chemical route dominated by TNCs<sup>5</sup> (Gomes et al., n.d.). In this sense, other opportunities in emerging technologies can be seized, such as big data, precision medicine and artificial intelligence. For this purpose, companies must build technological capabilities to develop innovative drugs. The number of innovative Large Brazilian Pharmaceutical Companies had a slight growth between 2008 and 2014 (20 to 24), but the expenditure in innovative activities on their net sales revenue (NSR) decreased from 10.1% to 7.0%. The amount invested in R&D has increased (3.7% to 4.9% in internal activities and 0.5% to 0.9% in external activities between 2008 and 2014), but it is still relatively low compared with TNCs (Paranhos et al., 2020).

Considering that internationalisation could be a possible way for the Large Brazilian Pharmaceutical Companies to face these challenges and reach the technological catch-up, a question arises: How does the internationalisation process evolve?

## 2 Methodology

The research design is based on exploratory objectives, deductive method, qualitative approach and a multiple case study procedure (Marconi & Lakatos, 2016). We investigate and analyse the characteristic of the Large Brazilian Pharmaceutical Companies' internationalisation as a whole; we do not analyse companies individually. The advantage of having multiple cases reinforces the evidence and leads to more robust findings. Furthermore, the multiple case study makes it possible to carry out more complex analysis and observe broader issues than a single case study (Yin, 2017).

The data collection consisted of three stages. First, we created a list of concepts presented in the international business and evolutionary literature on the main characteristics of firms' internationalisation to guide the fieldwork (Table 1).

#### Table 1: Concepts used for data collection

Categories	Concepts	Reference

<sup>&</sup>lt;sup>5</sup> The lack of experience of Brazilian pharmaceutical companies in the API manufacture and innovation imposes difficulties in incorporating the production of drugs by the biological route. The nature of the biopharmaceuticals production process involves living cells, that are difficult to dissociate from the final formulation of the drug and require skills of greater technological complexity (Torres, 2016).

Entry modes	<ul> <li>Exports (direct and indirect)</li> <li>Contractual relationships (licensing and collaborative agreements)</li> <li>Foreign Direct Investment (Greenfield, merger &amp; acquisition, and joint ventures)</li> <li>Gradual process</li> <li>Accelerated process</li> </ul>	(Dunning et al., 2008; Johanson & Vahlne, 1977, 2009; OECD, 2008; Root, 1998)	
Strategies	<ul> <li>Market-seeking</li> <li>Resource-seeking</li> <li>Efficiency-seeking</li> <li>Strategic-asset-seeking</li> <li>Strategic innovation-seeking</li> </ul>	(Bas & Patel, 2007; Dunning, 2000; Luo & Tung, 2007; Mathews, 2002, 2006; Vernon, 1966)	
Competitive advantages	<ul> <li>Ownership</li> <li>Location</li> <li>Internalisation Internationalisation knowledge</li> </ul>	(Dunning, 1988, 2006; Dunning & Lundan, 2008; Kogut & Zander, 1993; Narula & Zanfei, 2006; Teece, 2007)	
Obstacles	<ul> <li>Vulnerability of the home institutional environment</li> <li>Lack of experience and knowledge about the internationalisation</li> <li>Entry barriers</li> <li>Psychic distance</li> </ul>	(Cuervo-Cazurra, 2008; Cuervo-Cazurra et al., 2019; Dunning & Lundan, 2008; Johanson & Vahlne, 1977, 2009; Narula & Zanfei, 2006; Rugman & Brain, 2004; Teece, 2007)	

Source: Own elaboration.

In the second stage, we select the interviewed actors in the fieldwork. The criteria for companies' selection consist of (a) to belong to the pharmaceutical industry (classified in the National Classification of Economic Activity –  $CNAE^6$ , division 21); (b) to be a large size (at least 500 employees); (c) to be Brazilian controlling capital; and (d) to have internationalisation strategy, previously identified in the companies' report and news about them. We found thirteen companies that met these criteria. In the third stage, we interviewed eight of thirteen companies – Achè, Biolab, Blanver, Cristália, EMS, Eurofarma, Hebron, and Libbs – which represented more than 30%<sup>7</sup> of the Brazilian pharmaceutical market turnover in 2018. In addition, we conducted ten interviews during 2017 and 2018 with the companies' chairmen or heads of the companies' internationalisation/innovation department. The interview script addresses questions related to the entry mode of international insertion, strategies, competitive advantages, and obstacles to internationalisation.

The data analysis started with the transcription of the collected data (interviews, firms' reports, documents received from the interviewees, firms' interviews to the media) using Atlas.ti software. The coding process was conducted in three rounds – open, axial, and selective

<sup>&</sup>lt;sup>6</sup> The National Classification of Economic Activities (CNAE) have its structure based on the International Standard Industrial Classification of All Economic Activities (ISIC), from United Nations Industrial Development Organization (UNIDO). The manufacture of pharmaceuticals is classified in section C, division 21 of ISIC, Rev.4.

<sup>&</sup>lt;sup>7</sup> It does not comprise revenue from two of the sample companies because of confidentiality reasons.

coding (Gray, 2017). First, we conducted a top-down analysis, and then we worked on open coding on the data to reduce the amount of information. The codes names were based on the concepts derived from the literature. The data phenomena were named and categorised closely (Corbin & Strauss, 2015). During this process, the codes were constantly compared to categorise the phenomena with fitting names. Second, depending on their relatedness, the codes were connected into subcategories by axial coding (Gray, 2017). Third, the subcategories created during the axial coding were grouped into major categories using selective coding. Finally, to increase the reliability of the coding, several moments of discussion took place to revise the codes (Gray, 2017). When data saturation was reached to answer the research questions, the process was completed.

The analysis focuses on the relations of the characteristics, using techniques such as observation of patterns and trends, examining how the characteristics are related to each other, and the search for negative indications for the conclusions to be extracted from the data (Miles & Huberman, 1994). Them, we discuss the results according to the theoretical construct and the empirical context of the pharmaceutical industry; also, we compared them to other research results with a similar theme.

## 3 The foreign expansion of Large Brazilian Pharmaceutical Companies

The eight Large Brazilian Pharmaceutical Companies of this case study are 100% owned by Brazilian shareholders and family business owners. The Large Brazilian Pharmaceutical Companies have been in business for 21 to 60 years. The companies employ about 430 to 6,500 employees and have revenues of about 86 million to 1.4 billion<sup>8</sup> dollars<sup>9</sup>. The expenditures on R&D are 3.5% to 10% of the companies' revenue, a similar proportion to the share of employed people in R&D activities concerning the total employees, 3.2% to 11.1%. Together, the eight companies had more than 30% of the total pharmaceutical market turnover<sup>10</sup> in 2018.

<sup>&</sup>lt;sup>8</sup> Exchange rate (31/12/2018): 1.00 US dollar = 3.87 Brazilian Real.

<sup>&</sup>lt;sup>9</sup> According to the Brazilian Development Bank (BNDES) (2018), all eight companies are large in Brazilian market, because the revenues are exceeding US \$ 77.5 million.

<sup>&</sup>lt;sup>10</sup> It does not comprise revenue from two of the sample companies because of confidentiality reasons.

#### 3.1 Internationalisation strategies

The Large Brazilian Pharmaceutical Companies' international insertion started by indirect exports at least five of eight companies. The indirect exports were opportunists for these companies because they began not as a business strategy but as a random demand from a foreign customer. The international insertion started as a business strategy in the past 20 years, and it has developed since then. Some companies acting on the generic drugs market reported that this segment would not sustain their long-term growth in the home market because of the competition on prices and the extensive imports penetration. Due to this reason, companies have found the alternative to maintain their growth rate through internationalisation.

On the one hand, companies have adopted market-seeking strategies in locations where generic drugs are still competitive. On the other, the companies have followed strategies focused on developing innovative medicines. The characteristics of the Large Brazilian Pharmaceutical Companies' internationalisation concerning the entry modes and strategies are in Table 1.

	Market-seeking	Resource- seeking	Strategic asset-seeking	Strategic innovation- seeking
Number of companies	8	7	6	3
Entry mode	Exports; licensing agreement; FDI	Exports; licensing agreement; FDI	Licensing agreement; FDI	FDI
Process start	2005	2008	2012	2015
Host country/region	Latin America; Africa	Europe; Latin America; North America; China	Latin America; North America; Europe	USA; China
Strategic goals	<ul> <li>To maintain business growth</li> <li>To approach customers.</li> <li>To marketing and product recognition.</li> <li>To aggregate distribution channels.</li> <li>To diversify the portfolio and extend the product cycle</li> <li>To leverage home productive capacity.</li> </ul>	<ul> <li>To complement other strategies</li> <li>To seek inputs</li> <li>To get foreign currency flow</li> </ul>	<ul> <li>To seek technological expertise</li> <li>To improve production capacity</li> </ul>	• To seek market niches with radical innovation

 Table 2: Internationalisation entry modes and strategies of the Large Brazilian

 Pharmaceutical Companies

Source: Own elaboration.

All Large Brazilian Pharmaceutical Companies adopted the market-seeking strategy, often being the primary goal of international insertion, others as a complementary strategy. Although companies have been acting in international activities for years, they only designed their market-seeking strategy in 2005 (two companies), in 2010 (one company), or 2015 (two companies). Large Brazilian Pharmaceutical Companies used exports, licensing agreements, and FDI as entry modes to access Latin American and African markets.

The market-seeking strategy is part of the business growth strategy for five Large Brazilian Pharmaceutical Companies. These companies intend to extend the life cycle of products to less developed countries, as set by Vernon's theory (1966). For this purpose, Large Brazilian Pharmaceutical Companies acquired smaller firms to add recognised brands of generic drugs or distribution channels in the host market. Other times, Large Brazilian Pharmaceutical Companies invested in building distribution channels in host markets for exports. The establish of distribution channels is a critical factor for the commercialisation of pharmaceutical products and for licensing products of developed countries TNCs, which seek to insert their products in developing countries.

Six Large Brazilian Pharmaceutical Companies have the internationalisation based on strategic assets-seeking to pursue technological expertise (four companies) or improve production capacity (two companies), looking to upgrade their competitive advantages in the home country. The Large Brazilian Pharmaceutical Companies sought to improve production capacities combined with the market-seeking strategy, acquiring whole companies or shareholding to access the portfolio and start operating in a new segment. In turn, Large Brazilian Pharmaceutical Companies sought technological expertise to support drug development through licensing agreements, buying a shareholding in R&D companies, or establishing their R&D centres in developed countries.

Three Large Brazilian Pharmaceutical Companies adopt strategic innovation-seeking to develop innovative drugs and gain market competitiveness in Brazil and abroad. This kind of internationalisation strategy is emerging market companies attribute, which instead of adopting a strategy asset-seeking or market-seeking, companies identify gaps – such as new segments, new customers needs or new ways of producing – in some industries and seek to fill them to become leaders of a new market (Cuervo-Cazurra, 2008; Luo & Tung, 2007; Mathews, 2006). The goal of Large Brazilian Pharmaceutical Companies' strategic innovation-seeking is to step up radical innovation efforts to fit into innovative opportunities segments, which small players could compete in terms of size, financial and technological capabilities. The internationalisation by strategic innovation-seeking was the alternative found by Large Brazilian Pharmaceutical

Companies to enter into more profitable segments of the pharmaceutical industry since they would not be able to develop an innovative drug alone, such as the transnational centenary companies from developed countries. For this purpose, the target niche markets are disease-specific drugs that are not the target by the world's largest pharmaceutical companies. The entry mode in the international market was through investment in small and medium-sized companies in countries recognised by the technological structure in the pharmaceutical industry, such as the USA and China.

The way of one Large Brazilian Pharmaceutical Company set strategic innovation was creating a company that acts as a venture capital to raise shareholder resources and invest in biotechnology companies with radical innovation projects under development. This company has made FDI in 10 biotechnology companies with radical innovation in complex diseases, thus obtaining equity interest and the right to market their products. In addition, the foreign subsidiary has the role of registering, in the Food and Drug Administration (FDA), generic drugs with incremental innovation made in Brazil to sell in the USA. The other two Large Brazilian Pharmaceutical Companies with strategic innovation-seeking set up technological foresight units for new research and innovative products to pioneer in licensing these drugs in the Brazilian market.

Seven Large Brazilian Pharmaceutical Companies has resource-seeking as an internationalisation strategy. The common resource for such companies is API, most available in developed countries, China and India. All eight Large Brazilian Pharmaceutical Companies are large API importers, two of which produce about 50% of API used in drug manufacturing. Overall, companies have sought to build closer relationships with international suppliers to have an exclusive supply of API. However, resource-seeking was not the primary strategy for none of the eight cases. Instead, it was complementary to another international strategy.

## 3.2 Competitive advantages for internationalisation

The Large Brazilian Pharmaceutical Companies' competitive advantages that allowed their internationalisation show up in five types: specific ownership advantage, location advantage, internalisation advantage, knowledge about internationalisation, and the political, institutional, and regulatory environment of Brazil. The lack of these advantages reflects the existence of obstacles to the internationalisation of the same nature. Thus, there are four sets of obstacles experienced by Large Brazilian Pharmaceutical Companies in the internationalisation process: the vulnerabilities of the political, institutional, and regulatory environment of Brazil, entry barriers, psychic distance, and lack of experience and knowledge. The characteristics of the Large Brazilian Pharmaceutical Companies' internationalisation concerning the competitive advantages and obstacles are in Table 2.

Competitive advantages		Obstacles			
	Types	Description	Types	Description	
1. 5	Specific ownership advantages	<ul> <li>Portfolio (diversity and good quality)</li> <li>Increase in size: economies of scale and own financial resources</li> <li>Capabilities created to comply with Brazilian regulatory and legislative requirements</li> </ul>			
2. 1	Location advantages	<ul> <li>Demand from customer</li> <li>Low psychic distance</li> <li>Market growth potential</li> <li>Regulatory quality</li> <li>Innovative, entrepreneurship, and competitive environment</li> <li>Industrial Property Rights</li> </ul>	1. Entry barriers	<ul> <li>Regulatory and industrial property differences</li> </ul>	
3. 1 8	Internalisation advantages	To avoid transaction costs     To appropriate intangible     assets			
4. ] i	Knowledge about nternationalisation	<ul> <li>Recognition of the importance of internationalisation</li> <li>Role of the entrepreneur</li> <li>Foreign sources of information</li> </ul>	2. Lack of experience /knowledge enough 3. Psychic distance	<ul> <li>Lack of international culture</li> <li>Cultural differences</li> </ul>	
5.	The institutional, political, and regulatory environment of Brazil	• Non-financial instruments	4. Vulnerabilities in the institutional, political, and regulatory environment of Brazil	<ul> <li>Ignorance of supporting policies/instruments</li> <li>Regulatory issues</li> </ul>	

 Table 3: Internationalisation competitive advantages and obstacles of the Large

 Brazilian Pharmaceutical Companies

Source: Own elaboration.

The specific ownership advantages include the attributes that a company may create or purchase from other institutions and therefore have ownership rights over these resources. In addition, they can derive from the institutional, political and regulatory environment of the firms' country (Dunning, 1988; 2006). Most of the Large Brazilian Pharmaceutical Companies (five) reported that increasing their sizes strengthened their internationalisation strategies. All eight companies said that the business growth by creating the generic drugs segment was essential to making available financial resources to afford the international insertion. Besides, the economies of scale obtained by producing for the sizeable Brazilian consumer market have led to competitive prices in the international market.

The portfolio with good quality and diverse products was a competitive advantage by five Large Brazilian Pharmaceutical Companies in their market-seeking strategies. Furthermore, the production capacity and technological capabilities created from the companies' adaptation to meet Anvisa's institutional changes and the Generics Law are expressed as competitive advantages for internationalisation. According to companies interviewed, Anvisa's regulatory requirements are comparable to developed country agencies, such as the FDA and the European Medicines Agency (EMA). In addition, many countries in Latin America and Africa do not require testing to certify generic drugs, so Brazilian drugs have better quality than companies in these countries.

The regulatory and industrial property rights divergences, which are specific entry barriers to the pharmaceutical sector, were indicated by five Large Brazilian Pharmaceutical Companies as obstacles to internationalisation. One of the regulatory barriers concerns the dossiers required in the drug registration process, which vary widely across countries. This process takes time and investment for companies that want to access the foreign markets, and many countries require clinical trials on the local population. The regulatory divergences between countries generally were the obstacle that blocked the export process, as reported by one Large Brazilian Pharmaceutical Company that stopped selling to the USA due to restrictions on product marketing. In the last years, Anvisa has been trying to match its requirements with the world's most significant regulatory agencies<sup>11</sup>.

The location advantages refer to the attractiveness of the h for firms, and it depends on the type of strategy the company adopts. Large Brazilian Pharmaceutical Companies with more sophisticated strategies (strategic asset-seeking and strategic innovation-seeking) have chosen the host country because of the innovative environment that encourages entrepreneurship and networking. Furthermore, the Large Brazilian Pharmaceutical Companies have pursued to fit into national systems of innovation that offer advantages, such as physical infrastructure, qualified personnel, prompt regulatory systems, and the availability of financial resources and investors. In turn, for Large Brazilian Pharmaceutical Companies with a market-seeking strategy, the most crucial location advantages are related to the market growth potential and the low psychic distance found in Latin American and African countries. The mitigation of a

<sup>&</sup>lt;sup>11</sup> In 2016, Anvisa became a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH is formed by the world's leading regulatory authorities, such as the FDA, EMA, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). As a participant in the ICH working groups, Anvisa has five years (2016 to 2021) to adapt within ICH five guides to Pharmacovigilance, Clinical Research, implementation of the Common Technical Document (CTD), and the Medical Terminology Dictionary (MedDRA) vocabulary. Consequently, Anvisa needs to standardize its manuals according to the regulatory agencies of those countries (ANVISA, 2016).

psychic distance obstacle can occur through the company's access to information and knowledge.

The knowledge about internationalisation is a critical element in the international insertion process since the organisational ability to create, absorb and store knowledge is an essential source of the companies' competitive advantage (Teece, 2014). One of the most critical factors of knowledge about internationalisation is the recognition of its value (Cohen & Levinthal, 1990). The Large Brazilian Pharmaceutical Companies have recognised internationalisation as necessary to gain growth rates, primarily through innovation. The role of the entrepreneur was prominent in the decision-make to include internationalisation in business strategies, often being the creators of the process. In contrast, the Large Brazilian Pharmaceutical Companies also pointed out the lack of international culture in the companies' boards, which are family business ownership, as an obstacle to internationalisation.

Brazil's political, institutional, and regulatory environment has shown, in some cases, competitive advantages for the companies' internationalisation. The non-financial policy instruments to encourage international insertion, represented by the Brazilian Pharma Solutions Program, coordinated by Apex-Brasil and Abiquifi<sup>12</sup>, were the most crucial support for the Large Brazilian Pharmaceutical Companies' internationalisation. The measures offered by the Brazilian Pharma Solutions Program include: (i) buyer projects, bringing potential buyers to know the Brazilian factories; (ii) business roundtables with Brazilian companies to seek international partnerships; (iii) promotion of Brazil's sanitary image abroad; (iv) assistance for technology transfer; (v) training from partnerships with foreign companies for product co-development, and (vi) business intelligence, identifying target countries for insertion. The Large Brazilian Pharmaceutical Companies did not show interest in the financial policy instruments of export supports and the financing of international production offered by the Brazilian Development Bank (BNDES) because the companies reported having their resources available to carry out the international insertion.

<sup>&</sup>lt;sup>12</sup> Apex-Brasil is an entity governed by private law and has a council formed by public bodies, created in 2003. The Agency promotes the promotion of Brazilian products and services abroad through prospective and commercial missions, business roundtables, support for the participation of Brazilian companies in international fairs, and develops sector specific programs, among other functions. Abiquifi, founded in 1983, is a class association of the pharmaceutical sector that brings together pharmaceutical companies and producers of pharmaceutical raw materials (e.g. API). The Association undertakes actions aimed to developing the Brazilian pharmaceutical sector, such as the internationalisation project "Brazilian Pharma Solutions", renamed in 2018 to "Brazilian Pharma & Health" – in partnership with Apex-Brasil.

None of the Large Brazilian Pharmaceutical Companies considered that there are sufficient instruments of policies supporting the internationalisation of Brazilian pharmaceutical companies. Nevertheless, none of them<sup>13</sup> also reported knows the industrial policy agenda concerning the internationalisation of Brazilian companies and are unaware of some instruments available. Therefore, the lack of knowledge about the policies and instruments supporting internationalisation is the main obstacle to international insertion regarding the vulnerabilities of Brazil's political, institutional, and regulatory environment. In addition, the regulatory issues regarding the standardisation of Anvisa rules to the international model are a concern of the Large Brazilian Pharmaceutical Companies because they can influence sales to countries with low regulatory rigour.

## 4 The patterns of Large Brazilian Pharmaceutical Companies' internationalisation

Considering the internationalisation characteristics of the Large Brazilian Pharmaceutical Companies described above, we found that there are idiosyncrasies in the process of international expansion and two different internationalisation patterns, each one comprising specific attributes of the international expansion process adopted by the companies of the study.

The first common characteristic of all eight Large Brazilian Pharmaceutical Companies was the accelerated international insertion, a pattern found in the internationalisation of emerging market companies (Bonaglia et al., 2007; Li, 2010; Luo & Tung, 2007). As latecomers companies, the increasing commitment and learning that would gradually develop in the host countries have been replaced, at least in part, by the evolution of the information and communication technologies (ICTs) and the liberalisation of investment flows and trade. These facts have made it possible to accelerate obtaining knowledge and reduce barriers between countries; they also influenced the internationalisation of emerging market companies before they were mature in the home countries (Dunning et al., 2008). However, as evidenced in the fieldwork, the Large Brazilian Pharmaceutical Companies have been operating for at least 20 years in the home market and have been leaders in revenues in Brazil.

Therefore, the explanation for the accelerated international expansion of Large Brazilian Pharmaceutical Companies has two reasons. The first one is the impact of economic liberalisation, which has influenced the Large Brazilian Pharmaceutical Companies

<sup>&</sup>lt;sup>13</sup> One company did not answer the question about the policies and instruments to support the internationalisation of the companies.

internationalisation to react to international competition in the local market and maintain their growth rates. The other one refers to the competitive advantages that Large Brazilian Pharmaceutical Companies built over Brazilian industrial development. The Large Brazilian Pharmaceutical Companies have always been dependent on foreign technology, developed over a long period of the market reserve, suffered from the abrupt economic opening, and underwent swiftly imposed regulatory, sanitary and industrial property rights reforms (Carneiro, 2002; Hasenclever et al., 2010; Pinheiro & Almeida, 1994; Strucker & Cytrynowicz, 2007). The truculence of the Brazilian competitive environment has forced Large Brazilian Pharmaceutical Companies to develop capabilities supported by sector-oriented policies, to survive and succeed in the local market. The companies had to satisfy a rigorous and price-sensitive demand, overcome institutional uncertainties, and face competition with the TNCs. Measurably, these capabilities have been converted into competitive advantages in international expansion. Kothari et al. (2013) identified the same pattern in the internationalisation process of Chinese and Indian companies, which managed to transform the non-market resource disadvantages of the home environment into internationalisation advantages.

The home market characteristics (regulations and protectionism through tariffs and subsidies) allowed the rapid growth and accumulation of financial resources by Large Brazilian Pharmaceutical Companies to invest in internationalisation, especially for those started by FDI. These results were also identified in other research on emerging market companies' internationalisation (Aguilera et al., 2017; Bonaglia et al., 2007; Luo & Tung, 2007; Martin & Javalgi, 2016). For that reason, the availability of financial resources was a competitive advantage highlighted by all eight Large Brazilian Pharmaceutical Companies.

The institutional environment is one of the factors that can be a promoter or an obstacle to internationalisation; because of this, many countries have policies to support the companies' internationalisation (Aguilera et al., 2017; Dunning, 2006). The vulnerabilities of the Brazilian political, institutional, and regulatory environment affected all Large Brazilian Pharmaceutical Companies' internationalisation in this study. Regarding the Brazilian regulatory system, Anvisa acts the internationalisation of companies dually. On the one hand, the creation of Anvisa and the setting up of the Good Manufacturing Practice (GMP) contributed to improving the Large Brazilian Pharmaceutical Companies' competitive advantages, which built capabilities to adapt their manufacturing processes. On the other hand, the slowness to the approval of new drugs, the lack of deadlines for approval, and the lack of openness for the companies' requirements have affected the internationalisation and innovation strategies of the Large Brazilian Pharmaceutical Companies. The slowness also partly interferes with the

decision to undertake drug development by TNCs located in the Brazilian market. Paranhos (2012) have also pointed out the same obstacle in her study of 2010, and there have been few changes since then. It is also noteworthy that Anvisa standards are still far from ICH standards. The regulatory standardisation process seems to be moving slowly, so companies will have little time to adjust to international standards until the deadline in 2021.

Regarding Large Brazilian Pharmaceutical Companies' lack of knowledge about policies and instruments to support internationalisation, policymakers and companies have a substantial misalignment. Since the Large Brazilian Pharmaceutical Companies are seeking international expansion to improve their productive and innovative capabilities, public policies need to keep up and ahead of the internationalisation process to plan how this movement can bring positive returns to the Brazilian industry. Furthermore, it is up to the public policies to identify what the home market wants to gain from international insertion and build paths for that purpose (Perez, 2008).

## 4.1 The exploitation of the companies' assets and capabilities in the international market

The exploitation of assets and capabilities was the internationalisation motivation for Large Brazilian Pharmaceutical Companies with market-seeking strategy, strategic-assetseeking (related to production capacities strategies), and resource-seeking strategy (as a complementary strategy). These companies are large Brazilian producers of generic drugs and have entered developing markets, where their products are still in the mature phase (Vernon, 1966), enabling the maintenance of profit growth.

The main attribute exploited in the international market is the drug portfolio. The portfolio diversity and the quality of drugs, attested by Brazil's regulatory and legislative rigour, are different from competitors in developing countries (Latin Americans and Africans). This advantage made it possible to enter into countries with an unsophisticated regulatory process, which allows selling Brazilian products without on-site registration. The case of Indian pharmaceutical companies is noteworthy, which followed a different internationalisation path. First, Indian pharmaceutical companies sought to qualify internationally with the FDA and the World Health Organization, and after, they created strategies to enter developed countries. Thus, today, these companies have greater prominence in the global pharmaceutical market (Chittoor & Ray, 2007), especially in the USA.

As reported by Large Brazilian Pharmaceutical Companies that exploited their assets and capabilities, the destination of most of their international operations was to Latin American and African countries. However, when compared to official trade data from the Ministry of Economy of Brazil (Brasil, 2019), the destination of half of Brazil's exports of pharmaceutical products are Latin American countries, and the other half are European countries, the USA, and Canada. Moreover, a small proportion of exports went to African countries (less than 2% on average from 2015 to 2018). The result corroborates other studies in different sectors (Cuervo-Cazurra, 2008; Perin & Cario, 2020), which showed Brazilian companies have internationalised to access the primarily Latin American markets.

The exploitation of Large Brazilian Pharmaceutical Companies assets and capabilities in the international market is affected by regulatory divergences between agencies. Thus, the ICH standardisation can benefit Large Brazilian Pharmaceutical Companies with internationalisation strategies to enter developed countries. However, the obstacle will remain in the insertions into developing countries, where the focus of this group of companies' strategies does not follow the standardisation of ICH rules. Likewise, in the home market, Large Brazilian Pharmaceutical Companies may also have difficulty adapting to ICH rules, and, probably, they will have market share lost to TNCs that are already following these rules.

## 4.2 The exploration of the companies' assets and capabilities in the international market

Exploring assets and capabilities was the internationalisation motivation for Large Brazilian Pharmaceutical Companies with strategic innovation-seeking and strategic-assetseeking related to technological expertise. This international expansion's main objective is to seek niche markets with radical innovation. Most of the companies have generic drug portfolios, and they entered the global market to access the higher value-added segments of the pharmaceutical industry.

The companies interviewed in the study reported that international insertion is a way to accelerate the development of their capabilities and resource to increase competitiveness. This idea of the springboard perspective set by Luo & Tung (2007) is also present in many studies (Athreye & Kapur, 2009; Guillén & García-Canal, 2009). Emerging market transnational companies tend to enter in developed countries to access intangible knowledge and resources and benefit from possible market synergies. Likewise, their rapid internationalisation is a characteristic of emerging country companies with strategies to access technologies and knowledge from developed countries (Buckley et al., 2014; Kothari et al., 2013).

The Large Brazilian Pharmaceutical Companies driven by the exploration of capabilities and assets were the ones that most valued competitive advantages concerning the knowledge about internationalisation. Therefore, the Large Brazilian Pharmaceutical Companies has changed organisational structure – hiring staff, setting up specific departments for radical innovation and internationalisation, and formal mechanisms for internal sharing the knowledge created in the internationalisation process – to enhance learning capabilities on their external expansion paths.

Despite the efforts made by Large Brazilian Pharmaceutical Companies to learn from international activities to influence innovative performance, the companies need to increase their absorption capacity to capture existing technological spillovers (Filippetti et al., 2017). Regarding Large Brazilian Pharmaceutical Companies' innovative efforts<sup>14</sup>, 81.5% made product innovations on their own, 49% acquired external R&D, and 30% acquired other external knowledge between 2012 and 2014. These companies invested 0.9% of their net sales revenue (NSR) in the acquisition of external R&D and 4.9% of NSR in acquiring internal R&D between 2012 and 2014 (Paranhos et al., 2020). Paranhos et al. (2019) also found that the same Large Brazilian Pharmaceutical Companies of this study are expanding efforts on more sophisticated innovation strategies by setting up radical innovation departments, holding scientific committees, and technology internationalisation strategies.

We can state that the Large Brazilian Pharmaceutical Companies employ innovation and absorption of knowledge efforts. However, these efforts are still nascent and grow concomitantly with international expansion. According to Cohen and Levinthal (1990), the absorption capacity of new knowledge generated by companies in the international market depends on its absorption capacity built before the internationalisation process. This was the case with the internationalisation of Chinese and Indian companies, which developed technologically in home environments with low technological supply. To overcome technological backwardness, companies strategically collaborated in home markets with TNCs from developed countries to develop specific skills or leverage niche markets while shifting a significant portion of technology development abroad. Later, these companies adopted the strategy of finding new market niches while simultaneously investing in innovation, thus making them a competitive advantage in developed countries (Kothari et al., 2013). The interaction between TNCs and local firms could influence the course of the country's international investments (Narula & Dunning, 2010). However, this trajectory was not possible for Large Brazilian Pharmaceutical Companies, which had an environment marked by perverse competition, where pharmaceutical TNCs operate on the most sophisticated products, but

<sup>&</sup>lt;sup>14</sup> The sample of large innovative national pharmaceutical companies from the 2014 Brazilian Innovation Survey (Pintec) is comprised of 24 companies, representing 85.3% of the total large pharmaceutical companies in the survey.

without developing the innovative activities in Brazil – such as local R&D, supplier training, interactions with Brazilian Science and Technological Institutions – thereby disabling national pharmaceutical companies from receiving significant technology spillovers.

## 5 Conclusion

Operating in international markets can improve the companies' competitiveness and innovative capabilities. Therefore, internationalisation can be an opportunity for Large Brazilian Pharmaceutical Companies to overcome the challenges – maintain the market share in the home market, access to good quality APIs, and enter into higher value-added segments of the pharmaceutical industry – that threaten their survival in the Brazilian market. However, some concerns regarding the characteristics of internationalisation remain.

Large Brazilian Pharmaceutical Companies driven by exploiting their assets and capabilities in internationalisation follow strategies in developing countries. These companies exploit their competitive advantages built into the home market while acquiring knowledge in dealing with different markets, consumers, laws, and regulations. However, as Patel and Pavitt (1984) warned, the internationalisation made to exploit the company's capabilities is only interested in increasing the company's profitability in the short-term, without improving its technological capital through long-term investments. For these companies, internationalisation is an alternative to maintain their growth rate, but their competitive advantages in the international market may undermine, as are related to generic drugs.

On the side of Large Brazilian Pharmaceutical Companies driven by assets and capabilities exploration in international markets, their strategies will not be effective if there is no absorptive capacity of external knowledge. Hence, these companies articulate their competitive advantages, growth and innovative strategies in the internationalisation process. However, adopting these strategies is not a guarantee that companies will enter the competition for innovative drugs. Although the implementation of R&D activities and marketing operations in developed countries increases the absorptive capacity (Zahra & George, 2002), the in-house R&D further enhances local absorptive capacities (Cohen & Levinthal, 1990), enabling the development of the essential knowledge and know-how for new product development and innovation (Kogut & Zander, 1993). Therefore, internationalisation driven by technological improvement is essential to insert Large Brazilian Pharmaceutical Companies in the international pharmaceutical market, which is only possible if companies build absorptive capacity to learn what is being done at the center of innovations in the global pharmaceutical

industry. Therefore, they can seize a future window of opportunity for catching-up, as South Korea's biotechnology industries (Lee & Malerba, 2017).

The results found in this research contribute to international business literature, especially on the companies in technology-intensive industries, science-based and from emerging countries. The results reinforce the finding that companies build their competitive advantages before the internationalisation in the home market. The Large Brazilian Pharmaceutical Companies developed competitive advantages ex-ante to internationalisation related to financial capacity and adaptation to the home environment, where it has always been a place of significant instability. It corroborates with studies' finding that companies from emerging countries seek to explore their assets and capabilities in developed countries, often as a shortcut to overcome technological backwardness and, in some cases, as a strategy of being worldleading in the market niches. The international business literature has shown this behaviour by companies in emerging Asian countries. This paper shows that there are also cases in Latin America.

As in other emerging countries, the main obstacle to the companies' internationalisation comes from the vulnerability of the institutional, political, and regulatory environment. This factor dramatically impacts the build of competitive advantages and the design of companies' strategies. In the case of Large Brazilian Pharmaceutical Companies, regulatory divergences between countries are the main obstacle to internationalisation. Therefore, it is the role of industrial and STI policies to promote internationalisation to overcome the challenges that appear and prevent the emergence of new ones.

The methodology used in this paper allows a deepener and broader understanding of a complex and contemporary social phenomenon. Still, there are limitations regarding the possibility of generalisations and statistical coverage. However, as it is a recent phenomenon with a small number of companies, the results found in this research are relevant and contribute to understanding the pharmaceutical industry dynamics in Brazil and to the literature of internationalisation of companies from emerging countries. It is the first step, and future research should deepen the subject's knowledge. We suggest an exhaustive investigation of one of the characteristics, such as strategic innovation-seeking, the application of a case study with only one company, and the comparison between companies of technology-intensive sectors from emerging countries. It is also interesting to follow up on the Large Brazilian Pharmaceutical Companies performances after the internationalisation consolidation.

### **Compliance with Ethical Standards**

Funding: this work was supported by the Coordination for the Improvement of Higher Education Personnel (CAPES) (grant number 001); and the Ministry of Health through the National Council for Scientific and Technological Development (CNPq), as a partial result of the Project "Reflection of Brazilian Health Industrial and Technological Policies for Local Production and Supply of the Unified Health System (SUS)" (grant number 41/2013).

Conflict of interest: the authors have no relevant financial or non-financial interests to disclose.

Ethical conduct: participants interviewed for this research consented to use the information and publish it anonymously.

Data availability statements: the data generated during the current study is not publicly available as it was obtained through interviews with the CEOs and managers of companies under an anonymity agreement. Information on how to obtain it and reproduce the analysis is available from the corresponding author on request.

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