The home country institutional environment as an internationalisation driver for the Large Brazilian Pharmaceutical Companies

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Abstract

This study analyses the internationalisation characteristics of Large Brazilian Pharmaceutical Companies. It contributes to the international business and evolutionary literature by showing how the home country institutional environment affects the firms' internationalisation at a country- and industry-level. The methodology is a multiple case study with eight companies, exploring their competitive advantages, strategies and obstacles to international expansion. findings reveal that home country institutional environment constraints pushed companies to build capabilities to survive and compete in the domestic market, which served as advantages when going international. Companies' internationalisation is driven by the exploitation and exploration of assets and capabilities.

Keywords: emerging markets multinational enterprise; home country institutional environment; internationalisation drivers; pharmaceutical industry; Brazil.

JEL: F23; L65; O32.

1 Introduction

The increasing participation of emerging markets multinational enterprises (EMNEs) in the global market has attracted substantial research concerning their internationalisation process, motivations and performance (Meyer 2004; Luo and Rui 2009; Cuervo-Cazurra 2012; Verbeke and Kano 2015). In particular, the role of the home country institutional environment (HCIE) in shaping organisational behaviour and internationalisation strategies of EMNEs has been recently addressed by International Business (IB) scholars (Cuervo-Cazurra et al. 2019; Chidlow et al. 2021). In this literature, studies have found that the HCIE has different influences on the internationalisation of EMNEs, including two branches.

The first branch defines the emerging economies context as one of greater volatility, uncertainty, complexity, and ambiguity in the firm's economic, political, social, and innovation-related institutional environments (Tulder et al. 2019). So that EMNEs go international to exploit their capabilities created to deal with the HCIE constraints. For example, EMNEs build management capabilities in a challenging HCIE, improving their international competitiveness to enter less developing economies (Cuervo-Cazurra and Genc 2008). The skills created for survival in an unfavourable institutional environment were tested in the case of Chinese multinational enterprises (MNEs) that managed to build capabilities at home, which became their unique advantage of being more resilient to the vulnerabilities of the host countries (Yang 2018).

There is also analysis of Latin American MNEs showing that the routines based on their accumulated organisational knowledge to deal with corruption and political risk at home has prepared them to manage abrupt changes in the internationalisation process and host countries, regardless of developed or developing economies (Cuervo-Cazurra et al. 2018a). In addition, some theoretical studies argue that EMNEs see the weaknesses of the HCIE as an opportunity for innovating at home. Such products/services/managerial innovations could be used in other emerging economies facing similar institutional challenges or even adapted for use in specific segments in developed economies where the same conditions may not exist (Cuervo-Cazurra and Ramamurti 2017). The studies of Kothari et al. (2013) and Kotabe and Kothari (2016) verified this argument for Chinese and Indian MNEs, whose foreign expansions were based on their capability to acquire and absorb resources in the hostile HCIE and then build their advantages to compete in market niches in developed countries.

In the second branch of literature, authors argue that the volatility, uncertainty, complexity, and ambiguity of the HCIE is a comparative disadvantage that motivates

internationalisation (Cuervo-Cazurra and Ramamurti 2017). In this sense, MNEs escape to the international market to avoid misalignment between their strategic needs and their home country's institutional constraints (Witt and Lewin 2007). Analyses of this argument to Latin American MNEs were provided by Cuervo-Cazurra (2016) in hypothetical terms. The proposition is that the characteristics of Latin American countries (political uncertainty, violence, pro-market reforms and reversals, and geographic isolation) have impacted the EMNEs' capabilities, resulting in their foreign expansion, either because organisational learning of the home country conditions facilitates internationalisation, or because such conditions induce internationalisation to escape them (Cuervo-Cazurra 2016).

In sum, the literature on the influence of the HCIE on EMNEs' motivations to invest abroad is either exploitation of their capabilities or escaping institutional conditions at home country. Although much improvement has been made in identifying these patterns, it is still an under-explored topic. In this sense, another EMNEs driver to internationalise that has been identified in recent literature is the exploration of assets and capabilities (Almahendra and Ambos 2015; Faroque et al. 2021), i.e., the EMNEs' seek to explore the international market in order to develop completely new capabilities (March 1991). This driver goes beyond escaping from the HCIE vulnerabilities, as the firm also intends to create new value by going international. Therefore, the relationship between the effect of the HCIE on the exploration driver of EMNEs should be investigated further. Moreover, the studies on the influence of HCIE have focused mainly on the internationalisation strategies of Chinese MNEs (Chidlow et al. 2021). Only a few studies were conducted about the Latin American context and based on a theoretical approach; even fewer studies applied an empirical approach.

This study aims at analysing the internationalisation characteristics of the Large Brazilian Pharmaceutical Companies (LBPCs). It contributes to the international business and evolutionary literatures by providing evidence on how the HCIE affects the firms' internationalisation at a country- and industry-level. The research methodology is a multiple case study with eight LBPCs[1], and concerns their competitive advantages, strategies and obstacles in the international expansion.

The social and economic relevance of the pharmaceutical sector justifies its selection. The pharmaceutical industry provides essential goods to meet health needs. Autonomy in the supply of domestic medicines is a health security issue, as the COVID-19 pandemic showed

[1] It only includes Brazilian residents-owned companies. It does not include foreign-owned companies based in Brazil.

when countries with a well-developed domestic pharmaceutical industry demonstrated a more rapid response to health needs than countries more dependent on imports (Paranhos and Perin 2021). Furthermore, the pharmaceutical industry generates technological spillovers to other productive activities, as an activity of high science-based technological intensity (Pavitt 1984), increasing the possibilities of technological catch-up through internationalisation. Accordingly, the pharmaceutical sector is constantly the target of public policies concerning manufacturing, innovation or internationalisation support (Mazzucato 2018).

The development of the Brazilian pharmaceutical industry has been marked by a major competitive imbalance between domestic firms and MNEs, fuelled by the volatile, uncertain, complex and ambiguous conditions of the HCIE. The industrial policies in the 50s' attracted the massive entrance of developed countries MNEs aimed to exploit the Brazilian market (Strucker and Cytrynowicz 2007). These companies manufactured innovative medicines in Brazil, but did not employ local R&D activities, keeping them in their headquarters (Carlsson 2006). Industrial policies that favour foreign capital prevent observing significant evidence of technological spillovers from MNEs to local firms (Strucker and Cytrynowicz 2007). The Brazilian pharmaceutical firms were competing with MNEs in a closed economy until the 1990s, supported by industrial policies following the import substitution industrialisation model (Caliari and Ruiz 2014).

The abrupt economic opening in the 1990s ended the market reserve of the previous model and imposed the reduction of tariff and non-tariff barriers on imports. As a result, MNEs participation in the Brazilian market has grown significantly complemented by imports gradually replaced of local production of inputs and medicines. Currently, the local pharmaceutical firms import about 90% of active pharmaceutical ingredient (APIs) used in domestic production (Mitidieri et al. 2015). The expressive technological backwardness of Brazilian firms compared with MNEs was intensified by the change in the pharmaceutical technological trajectory – from chemical to the biological route (Malerba and Orsenigo 2015).

The Brazilian institutional environment had also experienced regulatory and legislative changes in the end of 1990s. In 1994 Brazil became part of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO) that established sectoral non-discrimination of patents and patent recognition in the pharmaceutical area. The Industrial Property Law (IPL) (No. 9,279) was set in Brazil in 1996, with TRIPS-plus mechanisms that prevent the dissemination of knowledge and the introduction of more innovative products, in addition to generating a negative effect on public health (Mercadante and Paranhos 2022).

The creation of the Brazilian Health Regulatory Agency (Anvisa) (Law No. 9,782) in 1999 implemented Good Manufacturing Practices (GMP) for drug registration. The requirement represents enormous advances for the safety of Brazilian products, but it also created obstacles for less qualified firms, leading some to close. The implementation of the Generics Law (No. 9,787) in 1999 set bioequivalence and bioavailability requirements for drugs manufacturing. The firms that could adapt to the new rules found a new business segment available, but those firms that failed to meet the requirements faced bankruptcy (Gadelha 2002).

Thus, the unfavourable HCIE of the period, marked by abrupt pro-market reforms, inflationary pressure, regulatory and legislative changes, and collapse of industrial policies, conditioned the loss of competitiveness of local firms (Strucker and Cytrynowicz 2007). The decrease in the business activities in the pharmaceutical industry passed from 916 firms in 1995 to 479 firms in 2020 (Ministry of Labour and Social Security/Brazil 2020).

The Brazilian government tried to revert the decrease of firms' competitiveness by placing a series of industrial and science, technology and innovation (STI) policies along of the 2000s and setting the pharmaceutical industry as a priority. During 2003-2017, the policies have played an essential role in strengthening Brazilian pharmaceutical firms by implementing several measures and incentives to support production, innovation and internationalisation activities (Hasenclever et al. 2022).

These institutional events affected Brazilian pharmaceutical industrial structure and firms' strategies. The firms currently acting in the Brazilian market have created capabilities to overcome the HCIE vulnerabilities and compete. These firms became large manufactures of generic and branded generic medicines – they were 17 out of the 20 largest pharmaceutical companies acting in Brazilian market in terms of revenues in 2021 (IQVIA 2022). They also made some improvements in innovative terms: 40.6% of pharmaceutical firms implemented innovation and invested about 2.6% of their net sales revenue (NSR) in R&D (2.4% internal and 0.2% external activities) in 2017 (IBGE 2020).

Based on the contextualisation of the Brazilian pharmaceutical industry and theoretical approaches identifying HCIE conditions as possible driver for internationalisation, the research question guiding this study are: How the capabilities created to manage the home country institutional environment and compete in the pharmaceutical industry influence the internationalisation of Large Brazilian Pharmaceutical Companies?

The paper's organisation follows. The next section explains the methodology; the results of the international expansion of the LBPCs appear in the third section, and the fourth section discusses them; section five concludes the paper.

2 Methodology

The research design emerges from exploratory objectives, a deductive method, a qualitative approach and a multiple-case study. We investigate and analyse the characteristics of the LBPCs' internationalisation as a whole, rather than as individual companies. The advantage of having multiple cases reinforces the evidence and leads to more robust findings. Furthermore, the multiple-case study makes it possible to conduct more complex analyses and observe broader issues than a single-case study (Yin 2017).

2.1 Data collection and conceptual framework

The data collection consists of four steps. First, a literature review identified typical internationalisation characteristics, and the starting point was the International Business literature, using seminal works by authors including Dunning (1998, 2000, 2006) and Johanson and Vahlne (1977, 2009), who offer a framework for analysing entry modes, strategies, competitive advantages and obstacles. The evolutionary literature (Zahra and George 2002; Teece 2007, 2014; Bahl et al. 2021) reports the aggregate knowledge that supports the internationalisation process, pointing to the creation and absorption of knowledge and learning processes as a source of competitive advantage for MNEs. Finally, the review explores the developing-countries context as an influence on competitive advantage, strategies and obstacles of companies expanding internationally. Some studies (Cuervo-Cazurra and Ramamurti 2017; Luo and Tung 2018; Cuervo-Cazurra et al. 2018b) have contributed to identifying specific characteristics of EMNEs.

Table 1 presents the concepts and references that guide data collection and analysis.

Table 1: Concepts used for data collection

Categories	Concepts	References
Entry modes	• Exports (direct and indirect) • Contractual relationships (licensing and collaborative agreements) • Foreign Direct Investment (Greenfield, merger & acquisition and joint ventures) • Gradual process/accelerated process	Johanson and Vahlne (1977, 2009), Root (1998), Dunning et al. (2008), OECD (2008)
Strategies	• Market-seeking • Resource-seeking • Efficiency-seeking • Strategic-asset-seeking • Strategic innovation-seeking	Vernon (1966), Dunning (2000), Mathews (2002, 2006), Bas and Patel (2007), Kedia et al. (2012), Cuervo-Cazurra and Ramamurti (2017), Luo and Tung (2018), Kumar et al. (2020)
Competitive advantages	• Ownership • Internalisation • Location	Dunning (1988, 2006), Kogut and Zander (1993), Narula and Zanfei (2006), Dunning and Lundan

	• Knowledge about internationalisation* • Home country institutional environment	(2008), Teece (2014), Kotabe and Kothari (2016), Aguilera et al. (2017), Cuervo-Cazurra and Genc (2008), Cuervo-Cazurra et al. (2018b)
Obstacles	• Home country institutional environment constraints • Lack of experience and knowledge about internationalisation • Entry barriers • Psychic distance	Johanson and Vahlne (1977, 2009), Rugman and Brain (2004), Narula and Zanfei (2006), Dunning and Lundan (2008), Teece (2014), Cuervo-Cazurra and Genc (2008), Cuervo-Cazurra et al. (2019)

* Competitive advantage related to the company's ability to capture, create and absorb knowledge related to the internationalisation process (Teece, 2014).
Source: Own elaboration.

The fieldwork preparation to collect primary data was the second step. The selected companies met four criteria: (a) belonging to the pharmaceutical industry. According to the National Classification of Economic Activity (CNAE);[2] (b) large in size, i.e. at least 300 million Brazilian Real or $ 77.5 million US dollars[3] in annual revenue,[4] according to the annual report; (c) Brazilian controlling capital confirmed on firms' website and later in interviews; and (d) having an internationalisation strategy identified in the annual report, newspapers articles and sectorial magazines and participation in sectoral conferences, later confirmed in the interviews. We found thirteen companies that met these criteria.

We carried out the fieldwork in the third stage, in which 8 out of 13 companies participated: Achè, Biolab, Blanver, Cristália, EMS, Eurofarma, Hebron and Libbs. These eight companies represented more than 30%[5] of the Brazilian pharmaceutical market turnover in 2018. We conducted ten interviews (eight in person at company headquarters and two by videocall) between 2017 and 2018, with the CEOs or heads of the internationalisation/innovation department. The interviews in Portuguese lasted approximately 90 minutes. The authors translated respondents' quoted comments into English. Companies are identified as LBPC1 through LBPC8, and the letters' a' or 'b' represent the first or second interview with the company, respectively. The script included questions on entry modes, strategies, competitive advantages and obstacles in the internationalisation process.

[2] Firms classified in division 21 of CNAE. CNAE's structure is based on the International Standard Industrial Classification of All Economic Activities (ISIC) of the United Nations Industrial Development Organization (UNIDO). The manufacture of pharmaceuticals is classified in section C, division 21 of ISIC, Rev.4.

[3] Exchange rate (31/12/2018): 1.00 US dollar = 3.87 Brazilian Real.

[4] According to the Brazilian Development Bank (BNDES) (2018) classification.

[5] Revenue from two of the sample companies is omitted for confidentiality reasons.

The fourth step of the data collection consisted of the literature review to collect second-hand evidence and secondary data about the fieldwork participants. Through the triangulation technique, we improve the reliability of fieldwork results with converging information from different sources (Patton 2015). Several studies (Gadelha 2002; Caliari and Ruiz 2014; Tigre et al. 2016; Paranhos et al. 2019, 2020a; Hasenclever et al. 2022) also provided evidence and data on the Brazilian pharmaceutical sector. The secondary quantitative data came from official Brazilian datasets, such as the imports and exports data from the Foreign Trade Statistics Office (ME 2023) and data on the innovative performance of firms from the Brazilian Innovation Survey (IBGE 2020).

2.2 Data processing and data analysis

Data processing started with transcribing the interviews and organising them, in addition to other collected data (companies' reports, documents received from the interviewees, CEOs' interviews with specialised magazines) with Atlas.ti software. We applied deductive coding to data with pre-established codes derived from the literature review (see Table 5 in the Appendix). The coding process occurred in two steps. The initial coding took an in vivo coding approach to attribute fairly broad codes. Then, we performed the line-by-line coding, attributing the pre-established codes and creating new codes when new information emerged. Several code revisions increased coding reliability, and we constantly compared codes during this process and created categories to guide the analysis. Finally, achieving data saturation, evaluated in terms of answering the research questions, completed the coding process (Gray 2017).

Then, we brought coding and categorisation together to develop themes. The content analysis evaluated patterns and trends by identifying the frequency with which a topic arose, examining relationships between themes and searching for negative indications that could inhibit extracting any conclusions from the data (Miles and Huberman 1994). We discussed the results according to the theoretical concepts and the empirical context of the pharmaceutical industry, comparing them to secondary data from literature review and datasets.

3 Internationalisation characteristics of the Large Brazilian Pharmaceutical Companies

The Brazilian shareholders are family members owning 100% of the eight LBPCs in this case study. In business for 21 to 60 years (at this collected data), the companies employ between

430 and 6,500 employees and have revenues of about 333.2 million to 5.3 billion Brazilian Real (86 million to 1.4 billion US dollars). The expenditures on R&D are 3.5% to 10% of the NSR, proportionate to the share of employees in R&D activities, 3.2% to 11.1%. Together, the eight companies had over 30% of the 2018 total pharmaceutical market turnover.[6] The companies' portfolio comprises generic or branded generic medicines with a minority proportion of innovative medicines. Most of the raw materials – mainly APIs – for manufacturing medicines are imports from China and India. Two companies produce about 50% of their inputs.

3.1 Competitive advantages to internationalisation

The LBPCs' competitive advantages enabling their internationalisation include four types: specific ownership advantage, location advantage, knowledge about internationalisation and the HCIE. Table 2 shows the competitive advantages companies reported in the fieldwork.

Table 2: Internationalisation competitive advantages of the Large Brazilian Pharmaceutical Companies

Competitive advantages	Types
1. Specific ownership advantages	· Size: economies of scale and own financial resources · Portfolio: diversity and good quality · Capabilities created to comply with Brazilian regulatory and legislative requirements
2. Location advantages	· Market growth potential · Low psychic distance · Innovative, entrepreneurship and competitive host environment
3. Knowledge about internationalisation	· Recognition of the importance of internationalisation · Foreign sources of information
4. Home country institutional environment	· Non-financial measures, e.g. buyer projects, business intelligence, roundtables

Source: Own elaboration.

The specific ownership advantages include the attributes and accompanying resource-ownership rights that a company may create or purchase from other institutions, and those they derive from the HCIE (Dunning, 1988; 2006). Most companies (six) reported that increasing their size made possible the implementation of their internationalisation strategies. All eight companies stated that business growth resulting from the Brazilian government creating the generic-drugs segment was essential to making financial resources available to support international insertion. Moreover, the economies of scale from producing for the mass market enabled competitive pricing for the international market.

[6] It does not comprise revenue from two of the sample companies because of confidentiality reasons.

The portfolio of diverse good-quality products was a competitive advantage for five companies. Furthermore, the production and technological capabilities emerging from the companies' adaptation to meet Anvisa's GMP and the Generics Law constituted competitive advantages for internationalisation. According to the companies interviewed, Anvisa's regulatory requirements are comparable to developed country agencies, such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). In addition, many Latin American and African countries do not require testing to certify generic drugs, so Brazilian drugs have better quality than companies in those countries. The comment below illustrates how the CEO views the company's structure after adapting to Anvisa's GMP:

'Today we have a factory that everyone comments about it: "I do not know any factory as modern as this here in Latin America". If you visit the American and European factories, you can see that they are much older and inferior to the ones we have here. Today we have this advantage, but initially, it was challenging to have this notion' (LBPC1b).

The specific ownership advantages created over the years by these companies influence the selection of the host country insertion. For example, the competitive advantages, compared with other Latin American and African firms, were often mentioned. The manager of LBPC3 also perceived improvement in the quality of the products because of the Generic Laws requirements, compared with other markets:

'All generics in Brazil are bioequivalent, i.e., the drugs are equivalent to the branded medicine. It is not a requirement in other countries [Latin American and African], as in the Generics Law in Brazil. There, it does not necessarily have to be bioequivalent. When our products arrive [there] with bioequivalence, they have a competitive advantage in these markets.'

Besides that, the most crucial location attractiveness of Latin American and African countries for five companies relates to the market growth potential and the low psychic distance because of their cultural, social and/or geographical proximity. For instance, three respondents mentioned that some African countries have the advantage of speaking the same language [Portuguese] and not requiring local drug registration.

Notably, three companies reported that their good quality portfolio encouraged them to make a few attempts to enter developed markets with more business culture divergences. In addition, three companies mentioned that their specific ownership advantages allow them to choose a host country because of its innovative environment that encourages entrepreneurship and networking. Furthermore, these companies have pursued fitting into national systems of innovation that offer advantages, as the company manager reported:

'There is a technology park, which concentrates developers, start-ups, large laboratories, venture capital, government, all the players that participate in innovation in some way are together. The country's regulatory agency is very receptive to discussion and guidance. It is a very encouraging environment for innovation. That plus the logistical advantages that made us decide for the country' (LBPC5).

Companies were asked how they created specific capabilities to enable foreign expansion. Knowledge about internationalisation is a critical element in the external insertion process, as the organisational ability to create, absorb and store knowledge is an essential source of competitive advantage (Teece 2014). One of its most critical factors is recognising its value (Cohen and Levinthal 1990). The eight companies demonstrated that they recognise the necessity of internationalisation to gain growth rates and remarkable innovative performance.

Catching up on the foreign-investment process using foreign sources of information was the most recurrent learning routine to obtain knowledge about internationalisation. Six companies have already used sources, such as universities, Contract Research Organisations (CROs) and consultancies, to support their internationalisation strategies or drug-registration process. Four companies identified networking through participation in congresses and interaction with foreign actors as an internationalisation competitive advantage. Three of the eight companies reported investing in training employees to gain knowledge about international investments. Regarding the capacity to absorb knowledge, only four companies reported having formal routines, such as scientific committees, for the internal sharing of knowledge generated by the international projects.

Seven companies perceived Brazil's institutional environment as a source of competitive advantages. Companies stated that the non-financial policy measures to encourage international insertion – the Brazilian Pharma Solutions Programme that Apex-Brasil and Abiquifi[7] manage – were the most crucial support for their internationalisation. The programme measures include: (i) buyer projects, bringing potential buyers to inspect the Brazilian factories; (ii) business roundtables with Brazilian companies to seek international partnerships; (iii) promotion of

[7] Apex-Brasil is an entity governed by private law with a council formed by public bodies, created in 2003. The Agency promotes Brazilian products and services abroad through prospective and commercial missions, business roundtables, support for the participation of Brazilian companies in international fairs and developing 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 at developing the Brazilian pharmaceutical sector, such as the internationalisation project ‘Brazilian Pharma Solutions’, renamed in 2018 ‘Brazilian Pharma & Health’, in partnership with Apex-Brasil.

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.

3.2 Obstacles to internationalisation

The obstacles the LBPCs face in their internationalisation are HCIE constraints, entry barriers and psyche distance. Table 3 shows the types of obstacles the companies reported in the fieldwork.

Table 3: Internationalisation obstacles to the Large Brazilian Pharmaceutical Companies

Obstacles	Types
1. Home country institutional environment constraints	· Political and economic instability: lack of international culture · Ignorance of supporting policies/measures · Regulatory issues
2. Entry barriers	· Regulatory and intellectual property differences
3. Psychic distance	· Cultural differences · Liability of foreignness

Source: Own elaboration.

The main internationalisation obstacle reported by the LBPC relates to the HCIE constraints. The unstable Brazilian context in political and economic terms, especially the abrupt economic opening in the 1990s, is the reason for the delay in recognising the importance of internationalisation. According to the companies' opinion, they had to focus on surviving institutional changes and competition at home.

All companies considered the policy measures to support their internationalisation insufficient. Nevertheless, none of them reported being aware of the industrial policy agenda concerning the internationalisation of Brazilian companies. Furthermore, seven were unaware of the financial policy measures the Brazilian Development Bank (BNDES) offered to support exports and greenfield/M&A projects.

The obstacles related to regulation are the ones that most threaten companies' competitive advantages. Five companies indicated regulatory and intellectual property rights divergences – specific entry barriers to the pharmaceutical sector – as obstacles to entering developed markets. One of the regulatory barriers concerns the required dossiers to the drug registration process, which vary widely across countries. This process takes companies' time and investment to access foreign markets, and many countries require clinical trials on the local population. One company reported having experienced foreignness liability – that is, faced additional expenses

with meeting the local regulatory requirements that local companies do not have, creating disadvantages for a foreigner. The regulatory divergences between countries, complemented by psyche distance, generally were the obstacle that blocked the export process. One company reported stopping export to the USA, where medicine advertising is a vital component of product sales, whereas Anvisa prohibits it.

In recent years, Anvisa has been standardising its requirements with developed countries' regulatory agencies[8]. However, this standardisation concerns four companies, which can impact sales to countries with low-level regulatory rigour. The impact of regulatory standardisation is still unknown, but the main problem so far is the lack of communication about how the harmonisation process will take place for companies.

Another company concern is Anvisa's delay in liberalising cargoes at ports and airports and Anvisa's delayed drug registration, decreasing the ability to deliver new drugs in the international market. As one company manager stated, these obstacles have influenced the decision to invest abroad: *'The lack of strict deadlines in Brazil is tough for us. In the country where we are now investing, I know that a certain regulatory stage will last a maximum of 30 days. In 30 days, we have the consent to start a clinical trial, for example. Here [in Brazil], we do not have a deadline'* (LBPC5).

3.3 Internationalisation strategies

The international insertion of LBPCs became part of their business strategy in the last 20 years and has since been developing. Regarding the main motivation for internationalisation, the consensus was that the generic medicines segment would not sustain the business's long-term growth in the home market, due to price competition and high import penetration. Thus, companies turned toward maintaining their growth rate through internationalisation. Still, the strategies they adopt for international expansion diverge. The LBPC1b respondent's comment illustrates the behaviour change concerning the international market: '*The importance of internationalisation is conceptual, the company is innovative, seeks differentiated solutions, and this image must be associated not only with one market or one country. A company to grow*

[8] In 2016, Anvisa became a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), 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 had five years (2016 to 2021) to adapt, within ICH's guides—Pharmacovigilance, Clinical Research, implementation of the Common Technical Document (CTD) and the Medical Terminology Dictionary (MedDRA) vocabulary. Consequently, Anvisa needs to standardise its manuals according to the regulatory agencies of those countries (ANVISA 2016).

must be present in other markets; it must be exposed to competition to make it bigger, the search for new solutions makes the company grow'.

Table 4 shows the internationalisation strategies of the LBPCs' internationalisation identified in the fieldwork.

Table 4: Internationalisation strategies of the Large Brazilian Pharmaceutical Companies

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

* Radical innovation refers to creating or implementing entirely new technologies or concepts in markets where they do not currently exist or where substantial changes in consumer behaviour are necessary within established markets (McDermott and O'Connor 2002).
Source: Own elaboration.

All eight LBPCs adopted the market-seeking strategy as a primary objective of international insertion (five companies) or as a complementary strategy (three companies). Companies that focus on market-seeking have operated in the international market for many years (through indirect/direct exports). However, they designed their international strategy in 2005 (two companies), 2010 (one company) and 2015 (two companies). One strategic goal was proximity to customers in Latin American and African markets. In specific cases in EUA, Japan and Europe, companies used incremental innovation to sell differentiated products. The LBPC7' respondent illustrate the change in companies' behaviour:

'We started the internationalisation plan because we don't want to depend only on one market. There are other factors, such as bringing innovations from abroad, being in tune with

what is happening abroad, being in deep contact with your customers, knowing their needs, and so on'.

Market-seeking is part of the business-growth strategy for five companies. They intend to extend the life cycle of products to less developed countries, as Vernon's theory (1966) describes. Accordingly, companies have acquired local smaller firms to incorporate well-known brands of generic medicines and distribution channels in the host market. In other instances, companies invested in distribution channels and marketing teams in host export markets. These are critical factors of commercialising pharmaceutical products in any market. Having well-established distribution channels and a locally situated marketing team in the market creates a competitive advantage to not only sell its products but also to license products from MNEs seeking entry. MNEs licensing products to Brazilian companies happens regularly in the Brazilian market and has now happened with LBPCs acting in Latin American and African markets. Thus, a company going international opens an opportunity to diversify its portfolio by licensing medicines from MNEs. Internationalisation has a feedback process, becoming a competitive advantage in its own right:

'We are approached a lot from international companies that are interested in making some kind of partnership with us, so internationalisation opens many doors. In the case of LBPC2, when I say that I work in this company, often the person says that they already know the company, and I do not need to present its entire profile. So it facilitates the discussion of business and exchanging technologies' (LBPC2).

The prospect of a decrease in the Brazilian market share in generic medicines has led three LBPCs to design strategic innovation-seeking to develop innovative drugs and gain market competitiveness in Brazil and abroad, as one respondent reported:

'To compete in the generics market is very difficult. There is no way to sustain the operation. Everyone is now looking for innovation, with value-added, that may have a slightly more interesting profitability. In order to innovate, it is much better to rely on the expertise and structure that other countries already have to offer' (LBPC5).

This type of internationalisation strategy was evidenced in Asian EMNEs, when the company identify gaps in some industries – such as new segments, customer needs or ways of producing – and seek to fill them to become leaders in a new market (Mathews 2006; Luo and Tung 2018). The purpose of the LBPCs' adopting strategic innovation-seeking is to intensify radical innovation efforts, usually through co-development partnerships, to fit into segments with innovative opportunities, where small players can compete in terms of size and financial and technological capacity, as one respondent pointed out: *'Big pharma has its networks, it's*

developed. So, we need to look for partners who have a more balanced relationship with us, to be fair and to be interesting for both parties, so that we can evolve together' (LBPC8).

Therefore, internationalisation was the alternative for these companies that could not develop an innovative drug by themselves to enter more profitable segments of the pharmaceutical industry as the big pharma MNEs do. To enter the radical innovation segment, the companies focus on niche markets, i.e., drugs for specific diseases not targeted by the big pharma MNEs, as explained below:

'The shareholders understood that to maintain the company's growth rate, it would be necessary to invest more in innovation, not only in incremental innovation by making improvements to some molecules and new associations, but also in radical innovation. That is when the company developed this model through subsidiary US-based, through which we identify opportunities in biotechnology start-ups researching new molecules for the orphan, neglected or niche disease' (LBPC2).

The strategic innovation-seeking entry mode was through direct investment in small and medium-sized local firms in countries with a well-recognised technological structure for the pharmaceutical industry, such as the USA, Canada and China. For example, one company created a USA subsidiary to act as venture capital to raise shareholder resources and invest in biotechnology start-up companies with radical innovation projects under development. This company has made direct investments in 10 biotechnology start-ups undertaking radical innovation in complex diseases, thus obtaining equity interest and the right to commercialise their products. In addition, to sell them in the USA, the foreign subsidiary registers the Brazilian-made incrementally innovative generic medicines with the FDA.

The other two companies adopting strategic innovation-seeking have installed R&D centres that act as a technological foresight unit to identify new product development by firms they can license in the Brazilian market. In addition, these centres interact with local universities to create collaborative research. One company also intends to transfer the main innovative activities to its foreign R&D centre in Canada.

The LBPCs also implemented two other complementary internationalisation strategies. Seven companies have adopted resource-seeking as a complement to the market-seeking and strategic innovation-seeking strategies. The common resource these companies seek is the API that companies from developed countries (high-quality inputs) and China and India (commoditised inputs) sell. All eight companies are major API importers using their international presence to build closer and exclusive relationships with suppliers.

Six LBPCs have adopted strategic assets-seeking to pursue technological expertise (four companies) or improve production capacity (two companies). The companies sought to combine improving production capacities with the market-seeking strategy, acquiring whole companies or shareholding to access the portfolio and start operating in a new segment. For example, to gain knowledge of a specific therapeutic area, one company acquired an Argentine company already exporting to Latin American and Middle Eastern countries and serving as the Brazilian head office's sales centre in Latin America.

In turn, LBPCs sought technological expertise combined with strategic innovation-seeking to support drug development, through licensing agreements or becoming a shareholder in R&D companies. One company highlighted the need to interact with actors in the international pharmaceutical market to generate innovation and address the lack of knowledge in Brazil's drug-development phase:

'As the company positions itself towards innovation, it becomes clear how we need partners to work with companies that specialise in different stages of the drug development. It no longer works as it used to when the big pharma did everything in-house. Today, innovation is much more open, more shared' (LBPN4).

Another example is the companies that acquired shares in an R&D company in Europe to guarantee priority access to knowledge. As the company's manager reported, the foreign company's knowledge was fundamental to finalising the development of complex generic drugs, products only a few companies could copy and, thus, with little competition, which the R&D centre in Brazil could not solve. Another company linked the internationalisation strategy to the strategic reorientation of starting to produce high-value-added drugs. Thus, the company discovered and initiated new-drug development and, in the pre-clinical stage, licensing for partnerships for product co-development. Accordingly, the company restructured its R&D area in 2015, creating a specific area for radical innovation and subordinating internationalisation to innovation.

Characteristic of the recent internationalisation process, none of the companies have adopted efficiency-seeking strategies. According to Dunning (2000), efficiency-seeking usually occurs with the advance of the internationalisation process, following market- or resources-seeking. Furthermore, in the early-stage internationalisation, all LBPCs in this sample do not have or did not release (due to confidentiality) relevant data to express the internationalisation results, such as foreign employees, revenues, exports, R&D.

4 Internationalisation drivers of the Large Brazilian Pharmaceutical Companies

According to the research results, the HCIE has been influencing the internationalisation of LBPCs. Political and economic instability, regulatory and legislative changes and fierce competition with MNEs pushed companies to develop capabilities to survive and succeed in the domestic market. Some of these capabilities were mentioned by companies as a competitive advantage in internationalisation. These results contribute to prove the assumptions raised by some authors (Witt and Lewin 2007; Cuervo-Cazurra and Ramamurti 2017). In addition, even exposed to the same HCIE, the LBPCs have heterogeneous internationalisation drivers. The first driver is aligned with the asset and capability exploitation concept (Cuervo-Cazurra and Genc 2008; Kotabe and Kothari 2016; Yang 2018). The second driver goes beyond the motivation to escape home conditions, as it also implies the seek for new technological capabilities. We call this last driver (escape plus new value creation) as asset and capability exploration.

4.1 Exploitation assets and capabilities in the international market

Exploiting assets and capabilities drives five LBPCs to adopt a market-seeking strategy to internationalise, complemented by strategic-asset-seeking (related to production capacity) and/or resource-seeking strategies.

The changes in the HCIE in the 1990s, such as the implementation of the GMP, Generic Law, IPL and economic opening, forced firms to adapt to the new regulatory and legislative rules. These events represented challenges to firms' competitiveness, not intrinsically because of their goal but because of their implementation, in which the interests of MNEs were put first, at the expense of local firms (Caliari and Ruiz 2014). Several firms that could not meet the new requirements faced bankruptcy (Gadelha 2002). Other firms developed capabilities supported by sector-oriented policies to survive and succeed in the local market. The companies managed to satisfy a rigorous and price-sensitive demand, overcome institutional uncertainties and face competition with the MNEs in the domestic market. These companies have become more resilient to deal with HCIE constraints and turning them into a competitive advantage in countries with similar conditions, as Latin-American and African markets. Cuervo-Cazurra and Genc (2008) identified EMNEs succeeding in internationalisation in less-developed countries as they became able to manage poorly developed governance environments at home.

Furthermore, the adaptation to the institutional changes also had other two positive impacts on companies' internationalisation. The operations in the generic-medicines segment led companies to increase in size and revenues, allowing rapid growth and accumulation of

capital to invest in international expansion and surpassing a frequent entry barrier (capital requirements) in the process. The companies managed to develop a superior quality portfolio compared to Latin American and African companies, due to the GMP and the Generic Law test requirements. This advantage enabled entering countries with an unsophisticated regulatory process that allowed selling Brazilian products without on-site registration. The Brazilian exports of pharmaceutical products have increased 323% in the last 20 years (2000–2021) and about 56% of Brazilian pharmaceutical exports go to developing countries (ME 2023).

The entry modes of this group of companies vary among FDI, exports and licensing agreements in developing countries. Companies prefer to start the internationalisation process with little commitment to foreign markets, thus exporting and licensing are the chosen modes. As companies gain experience and confidence in the market potential of their products, they build a long term commitment through acquisition or greenfield projects, as seen in Johanson and Vahlne (2009).

The ongoing regulatory change – harmonisation of Anvisa to the ICH rules – represents a threaten to companies' competitive advantages. The harmonisation at the developed countries' level could force the adaptation to unnecessary standards to attend developing markets. On the other side, it could represent a possibility for entering developed markets while maintaining the same product portfolio. In this sense, the case of Indian pharmaceutical companies deserves consideration as an example. Indian pharmaceutical companies, equally focused on manufacturing generic drugs, sought to harmonise their production with FDA and World Health Organisation requirements before expanding abroad, creating strategies for moving to developed countries. Currently, Indian companies have great prominence in the global pharmaceutical market, especially in the USA (Chittoor and Ray 2007). In Brazil's case, for ICH harmonisation to positively impact Brazilian pharmaceutical companies by opening new markets to exploit, like the Indian experience, regulatory change must follow gradual steps and support the companies' adaptation, to prevent losing share in developing countries' markets.

The HCIE proved to be a positive factor to promote the LBPCs with market-seeking internationalisation, compensating for the lack of experience and international business culture.

There are also other evidence (Fleury and Fleury 2014; Pinto et al. 2017) showing that policies the Brazilian government implemented proved to be very favourable to companies that adopt market-seeking strategies in developing countries. Policies designed to support other types of strategies (i.e., innovation-seeking) in developed countries must also be implemented to help companies to overcome the loss of competitiveness in the domestic market. This means not only enlarging the direct measures to support companies' internationalisation, as those some

Asian and Latin-American countries applied (Luo et al. 2010; Musacchio and Lazzarini 2014; Cuervo-Cazurra et al. 2018b), but also implementing industrial and STI policies that support the development of innovative capabilities at home, to gain competitive advantages to expand abroad. The study of Pinheiro et al. (2021) shows that promoting innovation by Brazilian government in pharmaceutical companies still lags far behind, mainly supporting innovation activities with a moderate degree of uncertainty.

Improvement in innovative performance also contributes to sustaining the market-seeking strategies. The cases of three companies that entered the USA, Japan and European markets, with a high level of psychic distance, to deliver differentiated products (with incremental innovation) deserve attention. Adopting organisational and technological innovation can mediate internationalisation's effect of psychic distance, as Mahadi et al. (2017) demonstrated in some Asian EMNEs. Even so, the entry modes were exports and licensing agreements, since LBPCs mentioned not being secure about making direct investments to exploit developed markets.

In sum, these five LBPCs are entering developing countries to sustain their capabilities created at home (good quality medicines and economies of scale). So far, the companies are not looking at the international market as a source of knowledge to improve their technological capabilities. Instead, internationalisation provides an alternative to maintain their growth rate and diversify their suppliers, but their competitive advantages in the international market may undermine them as they neglect focusing on innovative performance. Internationalising to exploit company capabilities only seeks increasing short-term profitability without improving its technological capital through long-term investments. The finding is aligned with the assumption of Tigre et al. (2016) that generics production generates an accommodation environment that harms technological innovation.

4.2 Exploration assets and capabilities in the international market

Exploring assets and capabilities is the internationalisation driver for three strategic innovation-seeking LBPCs, complementing it with strategic-asset-seeking (particularly technological expertise) and resource-seeking, in developed countries, e.g. USA, Canada, and China. The companies have generic or branded generic medicines portfolios and are going international to access higher value-added segments in the pharmaceutical industry. The entry modes chosen to explore the international market is FDI through acquisitions or greenfield projects. As innovation projects requires intrinsically a long-term investment, companies had to make a long-term commitment in the host countries too.

The changes in the HCIE also impacted the companies with exploration motivation. The GMP, Generic Law, IPL and economic opening were events that forced these companies to adapt, to meet the requirements and maintain competitiveness. The same factors that impact the companies with exploitation motivation, such as price-sensitive demand, institutional uncertainties, and MNEs competition in the domestic market, have also affected the companies in this group. However, the companies with exploration motivation take advantage of the technological capabilities built to overcome the obstacles in the domestic market, to expand to developed countries. The goal of these companies is pursuing new market niches with radical innovation that could make them leaders in the home markets, facing MNE competition.

The Brazilian Innovation Survey (2020) data helps to illustrate the improvements that LBPCs made in terms of innovative efforts in the last 10 years. They invested 6% of their NSR in innovative activities, with most of these resources (4.9%) directed towards internal (4.6%) and external (0.3%) R&D activities in 2017. A constant increase in investments in internal R&D (growth of 171.5%) occurred between 2008 and 2017. The internal infrastructure for carrying out R&D activities also expanded, as the researchers accounted for 65.2% of staff employed in R&D in 2011, increasing to 81% in 2017. The data also demonstrate advances in the companies' efforts in the biological route: growth of 21.5% in the number of companies that carried out innovative activities in biotechnology, and 11.2% more companies pursuing nanotechnology activities between 2014 and 2017. In terms of innovative results in 2017, 4 large Brazilian companies introduced product innovations for the world market, 7 for the domestic market and 11 for the company (IBGE 2020). The survey data corroborate the primary data collected, as the three companies in this group have also announced investing in innovative capabilities, especially the absorption capacity of the knowledge that has been developing in other countries, such as creating scientific committees and setting up radical innovation departments.

The companies are not only escaping from the HCIE constraint, but also seek more steady environments, where public policies, regulatory, legislative and financial apparatus align to stimulate pharmaceutical industry innovation. For these three LBPCs, the solution to surpassing the regulatory issues, with no deadlines for drug and clinical trial approvals, is moving part of the innovation efforts to the USA and Canada, where the deadlines are clearer. Paranhos et al. (2019) also pointed out that the sluggishness of Brazil's regulatory process is one of the main obstacles to interaction between universities or research institutes and the pharmaceutical companies. Still, in regulatory terms, the Anvisa harmonisation seems to have no significant impact on companies' production, as they already follow the international standards as a condition for being in North American and European markets.

Uncertain HCIE pushed companies to go international, seeking to move part of their R&D activities to more consistent innovative environments. These companies also benefit from the HCIE. The three companies pursuing the exploration driver were the main companies accessing the financial resources of the industrial and STI policies during 2003–2017 (Paranhos et al. 2020b). These companies accessed 23.5% of the resources of the Brazilian Innovation Agency (FINEP) and 24.5% of the Brazilian National Bank's (BNDES) for pharmaceutical production and innovation projects, substantiating the construction of technological capabilities later transformed into competitive advantages in internationalising (Perin and Paranhos 2023). The interruption of industrial and STI policies in 2016/2017 highlights once again the vulnerabilities of the Brazilian institutional environment. Future studies should investigate effects of policy disruptions on companies' innovative and international strategies.

5 Conclusion

Studies (Buckley et al. 2016; Cuervo-Cazurra et al. 2019; Chidlow et al. 2021) have pointed out the influence of the institutional context on firms' internationalisation. Particularly in the cases of EMNEs, some studies (Cuervo-Cazurra and Genc 2008; Kothari et al. 2013; Cuervo-Cazurra et al. 2018b) show that the HCIE constraints could, eventually, push the firms to develop capabilities that become competitive advantages to go international following two drivers – exploiting the international market or escaping the conditions of the domestic market. This study contributes to the IB and evolutionary literature by providing pioneering empirical evidence at country- and industry-level on this topic. The HCIE indeed forced LBPCs to develop capabilities used as competitive advantages in the foreign expansion. Nevertheless, the drivers of companies' internationalisation are exploitation and exploration assets and capabilities. In addition, this study also shows that the HCIE can be a positive factor when the government directly promotes companies' internationalisation or provides industrial and STI policies to strengthen the local capabilities of companies.

The LBPCs analysed in this research encountered the same institutional environment constraints and conditions, going through the same uncertainty and instability to survive and succeed in the domestic market. As a result, all eight companies are going international as a strategy to overcome the current institutional and competitive challenges – maintaining their share in the Brazilian market, accessing good-quality APIs, and entering higher value-added segments of the pharmaceutical industry – but following different drivers. For instance, a group of companies exploits developing markets to deal with the threat to their market share/profitability and diversify API suppliers. At the same time, another group goes abroad to

explore developed markets, improve their innovative performance and access diverse API sources. The difference between these two is specific to each company's routines, as noted by Nelson and Winter (1982), and what they interpret as predominant for their competitiveness: market diversification or innovative performance.

The results may be subject to some generalisation, even if the multiple case study is not the most appropriate for this. However, the institutional environment constraints presented here are very similar to those of Brazilian industries, in general, and of some Latin American countries. In addition, the present study also provides examples for managers by showing that the capabilities created in the domestic market are competitive advantages to internationalise in developing and developed countries. It is also worth considering the limitations of the study regarding the small sample size and the lack of quantitative data to support the qualitative results, which may hinder the ability to quantify the extent and scope of LBPCs' internationalisation.

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Appendix

Table 5: Codebook used to process the qualitative primary data

Categories	Codes	Definition	Example
Entry modes	Direct exports	The company sells goods and/services directly to the importer/buyer located in a foreign country.	Distribution/direct agent: an intermediary in the foreign country takes care of the product marketing. Direct subsidiary: requires a capital investment in marketing located in the foreign country.
	Indirect exports/ad-hoc exports	The company sells goods and/or services through an intermediary to a foreign country. The company that makes indirect exports has no control over the strategy of entering the international market.	The merchandise passes through another company (e.g., trading company) in Brazil before its shipment so that the necessary export procedures can be carried out.
	FDI	Investment in the form of a controlling ownership in a pharma business in one country by a Brazilian entity.	M&A, greenfield projects, joint venture.
	Contractual relationship	The company carries out some kind of partnership with another company that is located in the foreign country.	Licensing: transfer of a specific asset essential for the production, in which the receiving company resides outside the country of the company holding the asset. It may be a combination of brand, operational expertise, manufacturing process technology, access to patents and trade secrets. Collaboration agreement: includes all interfirm collaboration activities, which can be strategic alliances or customer-supplier networks.
	Gradual internationalisation	Internationalisation process follows stages of commitment with the foreign market	Ad-hoc exports, exports via representatives, sales office, production/manufacturing.
	Fast internationalisation	There is no gradual steps. Usually, it is emerging markets characteristic.	First entry mode is FDI.
Strategies	Market-seeking	Internationalisation strategy that aims to access the market. It is carried out to reach a specific foreign market or a demand oriented to a type of market.	Size of local markets and/or growth potential; physical and institutional infrastructure capable of helping to exploit markets; policies to help exploit the markets and which do not restrict the activities of MNEs; proximity to consumers; explore the company's technological competitive advantages in regions/countries that are weak in this area
	Resource-seeking	Internationalisation strategy that aims to access financial and natural resources, specialised labour and inputs.	Availability of natural resources at low prices and quality; infrastructure for resource exploitation; investment incentives, such as tax reductions and export subsidies; offer of capital at low cost for loan; presence of local companies with sufficient competitiveness to act as suppliers.
	Strategic asset-seeking	Internationalisation strategy that aims to access strategic assets by incorporating innovation-oriented skills and strategic assets.	Availability of resources and markets that allow the promotion and development of competitive advantages, and institutional environment that helps to obtain these resources. Pre-existing marketing channels; opportunities to increase knowledge and learning through interaction with other producers;
	Strategic innovation-seeking	Internationalisation strategy specific of EMNEs.	Strategic asset seeking + seeks to fill a technological gap in the home country (such as new segments/niches, new customer needs or new ways of producing) to become the leader of a new market segment.
	Efficiency-seeking	Internationalisation strategy that aims to access efficiency. It is intended to promote a more efficient division of labour or specialisation in	Low production cost compared to other potential countries; availability to trade intra-firm intermediary goods; presence of specialised clusters; public policies to promote investment.

		a portfolio of assets, thus seeking to rationalise international production.	
Competitive advantages	Ownership	Competitive advantages that the company can create or buy from other institutions and, in this way, have property rights over these resources.	Patents; registered trademarks; product differentiation; ownership of technology, labour and capital; access to a specific input; exclusive control of a particular market; superior R&D capabilities; related to the size of the firm, such as economies of scale. Advantages create from institutional: macro-institutional infrastructure of the home country (e.g. patent protection, banking regulations, transparency in security laws and procedures, incentives offered or imposed by the industry of which it is a part).
	Location	Fixed qualities, natural or created, of a country or region that favour the company to operate abroad.	Economic, political and social stability; trade policy and stable exchange rate Market size and market growth; psychic/institutional distance; cost and quality of inputs; availability, quality and cost of qualified labour; quality of technological, managerial, relational and other created assets. Macro-innovative, entrepreneurial and competitive content reinforcing educational institutions; mentalities, institutions and policies for economic growth/development; facilities for companies; incentive to entrepreneurship.
	Home country institutional environment	Home country institutional aspects that encourage the internationalisation of companies.	Policies: tax incentives; low interest loans; political risk insurance; creation of government agencies focused on the international expansion of private companies; double taxation prevention agreements; articulate bilateral and regional treaties to protect investment abroad; support for companies deal with host country government or legislative institutions. Stable macroeconomic conditions. Regulations and legislation align with the international level.
	Internationalisation knowledge	Knowledge based on the company's experience, resources and skills to operate in the international market.	Knowledge: creation, sharing and interaction. It is made up of information (business process design) and know-how (company procedures/activities manual). Learning process way of obtaining knowledge; capacity to absorb new knowledge. The recognition that the foreign market is a source of opportunity and growth.
Obstacles	Entry barriers	Factors that can prevent or impede newcomers into a market/country, and so limit competition.	The difficulty or inability to have access to capital and resources, economies of scale and scope, in general, and regulation (drug approval/price control/marketing and distribution), intellectual property laws and established competition.
	Psyche distance	Factors that can hamper the flow of information between companies in different countries.	Language, education level, business practices, culture, economic and social development, geographic distance. Liability of foreignness: additional expenses that a company operating in a foreign market incurs that a local company does not incur. Liability of outsidership: disadvantage of not being inserted in networks of relationships.
	Lack of experience and knowledge about the internationalisation	No experience in acting in international market.	Lack of staff prepared to manage the internationalisation process, including the CEO. No investment in knowledge creation and absorption.
	Home country institutional environment constraints	Home country institutional aspects that prevent the internationalisation of companies.	Absence of industrial and STI policies; inadequacy/lack of measures to support the internationalisation; political and economic instability; regulatory issues.

Source: own elaboration based on literature review.