How diversification affects vertical integration through experience in pharmaceuticals**

Antonio Carlos Lima Nogueira[1*], *Walter Bataglia*[2]

Abstract: The objective of this study is to analyze the choice between internal and external supplier at the manufacturing stage in the Brazilian pharmaceutical industry. We developed a structural equation model with hypotheses on experience, diversification, asset specificity, and vertical integration. We collected data for 1566 drugs registry, including its pharmaceutical form, therapeutic class and operation time of the firm and group. We found that the higher the experience, the lower the vertical integration in the manufacturing stage and a clear mediating effect of experience on the relationship between diversification and vertical integration. As firms advance in experience and the spread of the capabilities throughout the industry, agents concentrate activities on the relevant stages in value creation and strategically outsource the manufacturing. As the firm increases the diversification in the product portfolio, the experience favours the building of capabilities to manage the production lines and strategies for outsourcing. This result suggests a low risk for strategic alliances at the manufacturing stage.

Keywords: governance structure; strategic alliance; drugs manufacturing

Submitted: April 3rd, 2018 / Approved: May 8th, 2018

Introduction

This study deals with the influence of capabilities and transaction costs on the adoption of governance structures in the manufacturing stage of a productive system, following previous studies on the relationships between the approaches of organizational economics and competences (Hoetker, 2005; Nakamura & Odagiri, 2005; Williamson, 1999). The research context is the pharmaceutical industry, which is highly dynamic in technological innovation and acquisitions. In Brazil, we have observed institutional changes, government incentives and the growth of local laboratories (Silva & Ruiz, 2011).

The Transaction Cost Theory (TCT) argues that the firm is a nexus of contracts as a response to the increase of transaction costs using the market (Coase, 1937) and that agents present bounded rationality and may behave with opportunism. The unit of analysis is a transaction between productive stages, with the dimensions of frequency, uncertainty, and asset specificity. The last of these is prevalent in empirical studies and shows the potential for the loss of earlier specific investment in the absence of the transaction. Thus, the choice of governance structure is a rational choice that aims to minimize the transaction costs arising from the hazard of opportunistic behavior by the counterpart in the transaction (Williamson, 1991, 1999). This framework is useful for studying contractual arrangements in productive systems, such as franchising in retail markets or strategic partnerships in R&D activities (Ménard, 2006).

The capabilities approach has sought to understand the processes of adaptation and change in organizations in changing environments (Dosi, Nelson, & Winter, 2000; Teece, Pisano, & Shuen, 1997). The concept of routine is useful in this approach as a basic unit of variation, selection, and replication that allows the firm to adapt to environmental changes. This process would explain the functioning of economic systems in the evolutionary theory proposed by Nelson and Winter (1982). There are ambiguities to apply the concept of routine in empirical studies (Becker, 2004).

To advance with a potential integration between the two approaches (Jacobides & Winter, 2005), we propose the following research question: what is the influence of transaction costs and capabilities on the vertical integration of manufacturing in the pharmaceutical industry? The general objective is to analyze the impact of transaction costs and competences on the choice between an internal and an external supplier for drug manufacturing in the pharmaceutical industry in Brazil. The specific objectives are the following. First, to develop a theoretical model with relationships between the constructs of experience, diversification, asset specificity, and vertical integration. Second, to measure the constructs with secondary data for products of the pharmaceutical industry. Third, to test the construct validity of the proposed model. Fourth, to evaluate the hypotheses of the model for the relationships between the constructs.

Concerning transaction costs, we measured asset specificity with two dimensions: the presence of differential aspects in the product (Bigelow & Argyres, 2008), and the share of products with some attributes in the firm's portfolio. To examine the capabilities, we adopted the constructs of experience and diversification. The first of these was measured using the time for which the firm or group had operated in the industry (Bataglia & Meirelles, 2009; Bataglia, Silva, & Klement, 2011; Dosi et al., 2000).

We adopted the diversification construct considering the view of the firm as a bundle of capabilities (Kogut & Zander, 1992), and our intention to measure it by the share of the firm´s product portfolio in

(1) Technological Faculty of São Paulo, São Paulo, SP, Brazil
(2) PhD Program in Business Management, Centre of Social and Applied Sciences, Mackenzie Presbyterian University, São Paulo, SP, Brazil.
** The authors thank FAPESP (São Paulo Research Foundation) and CNPq (National Council for Scientific and Technological Development) for the finan-cing support for the development of this work.
*Corresponding author: aclimano@gmail.com

ISSN: 0718-2724. (http://jotmi.org)

the set of product types available in the market. This concept is a narrower one than the deployment of the knowledge base of the firm in different markets (Klein & Lien, 2009).

As the pharmaceutical industry has grown, firms adopted the hierarchy as the predominant governance structure in the various stages of the value chain, generating large and vertically integrated corporations. From the 1980s onwards, strategic alliances increased, first abroad and, later, in Brazil (Estrella & Bataglia, 2013; Macedo & Bataglia, 2012; Powell, White, Koput, & Owen-Smith, 2005). At the manufacturing stage, the motivation for a firm with traditional products to outsource would be its competition with companies that offer similar products. When adopting outsourcing at this stage, firms may rely on multiple vendors for common industrial requirements. Thus, companies that are focused on innovative products can reduce their production costs and increase their margins in the period between the launch of the product and the entry of similar or generic products (Polastro, 1999).

To get the registry as a drug producer in Brazil, companies must operate according to the "good manufacturing practices" defined by the National Agency of Sanitary Surveillance (ANVISA, 2010). Firms need to achieve tight control of their processes, and this can lead to vertical integration becoming predominant. If the company outsources particular stages, the regulator must also approve the contractor. This option requires a close relationship with the contractor to perform tasks from the design of processes to the quality management of the final products.

We assumed that the "make or buy" strategic decision (Bataglia & Yu, 2008) in manufacturing corresponds to the choice between vertical integration and a strategic alliance for outsourcing. We can measure this by the presence of vertical integration at each stage of production, or by an index measuring the proportion of vertical integration at all stages, following Hoetker (2005) and Nakamura and Odagiri (2005).

The study has five sections. The second presents the theoretical framework, and the third explains the methods used in this research, including the data and procedures. We show the results in the fourth section, and we include the discussion and final considerations in the last part.

Theoretical Framework and Hypotheses

This section presents a conceptual model for the explanation of governance structures in the manufacturing stage, based on the transaction cost and capabilities approaches. Williamson (1999) suggests that the attributes of a transaction could explain the choice of generic governance structure, while aspects of organizational learning could also influence some aspects of the chosen governance structure. The theme of governance structures covers an extensive research field, especially for hybrid structures (Ménard, 2004). However, we limited our analysis of governance structures with a frequent variable in empirical studies of TCT: the choice between internal (make) and external (buy) supplier (Hoetker, 2005).

The second limiting choice was our focus on transactions at the manufacturing stage, concentrating on its relevance in infant industries like the pharmaceutical industry in Brazil. Nogueira (2011) observed this process with the Brazilian laboratory Aché, which initially grew with the support of partnerships with multinational companies for plant acquisitions and drugs licensing. In recent years the company has accumulated manufacturing expertise and resources to increase its market share and generate revenues to conduct product innovation activities.

We developed the conceptual model following the work of Jacobides and Winter (2005). They argue that the distribution of productive capabilities between firms in an industry defines the difference in vertical scope, with transaction costs presenting a moderating effect. The approach in the present model is similar, but we consider only the operating capabilities of the firm owning the product. We chose this approach considering the adoption of the product as the unit of analysis and the influence of the firm's capabilities on a specific transaction. The model of Jacobides and Winter (2005) refers to the analysis of a population of firms in an industry to measure the distribution of capabilities. Nogueira and Bataglia (2012) proposed a conceptual model to explain the choice of supplier for manufacturing, based on transaction costs and the capabilities of the firm owning the product.

Drawing upon the work of Dosi et al. (2000), Kogut and Zander (1992), and Jacobides and Winter (2005), we expect that the organizational knowledge stored and expressed in routines to be built by the limits of the firm, particularly in the manufacturing stage. According to this approach, the environment of the firm allows groups of employees to exchange experiences and to promote organizational learning. This conditions can help the definition of an appropriate level of specialization in the different stages of the value chain.

Henderson and Cockburn (1994) found two relevant types of capabilities for R&D activities in the pharmaceutical industry: component and architectural capabilities. Component capabilities refer to skills in disease categories and specific issues that support the development of medicines. Architectural capabilities address to the ability to combine the disciplines and areas of therapeutic classes within the firm. For these authors, the experience could be useful for measuring both types of capabilities.

Since the focus of this work is the manufacturing stage, we assume that experience might be relevant and measured it by how long the firm has run in the industry. Bigelow and Argyres (2008) consider the influence of the firm's experience in the industry on the choice of governance structure. These authors argue that as the firm gains experience, it will specialize in activities with higher participation in the total cost of the value chain of the product. In this sense, they expect a tendency to operate on product development and to outsource manufacturing and distribution. Along these lines, we propose the following hypothesis:

> *Hypothesis 1 (H1). The experience of the firm in the pharmaceutical industry has a negative relationship with vertical integration in the manufacturing stage of the product.*

The diversification of a company reflects the range of different types of delivered products. In the pharmaceutical industry, we can describe a product by its pharmaceutical form, therapeutic class, and regulatory category. We expect that successful pharmaceutical companies have a minimum efficient size and offer a diverse portfolio of products, to achieve economies of scale in their production systems and risk management in their R&D to deliver new products to the market (Bogner, 1996). A diversified portfolio can influence the operational capabilities by exposing this functional area to a broad range of pharmaceutical forms. In this sense, this characteristic of a company's capabilities might encourage it to internalize its manufacturing. Following this reasoning, we derive the hypotheses below:

Hypothesis 2 (H2). The diversification of the firm in the attributes of its products has a positive relationship with vertical integration in the manufacturing stage of the products.

Asset specificity is an attribute often discussed in the TCT literature as a relevant factor in the choice of governance structure. The rationale is that the investment in transaction-specific assets favours the adoption of the hierarchy to coordinate the transaction rather than contracting with external suppliers. The existence of a transaction-specific asset resulting from investment by one partner leaves this agent in a disadvantageous position and subject to opportunistic behavior by the other partner (Williamson, 1991). Under these conditions, there is a tendency for the agent to internalize the transaction for the firm. The hypothesis is as follows:

Hypothesis 3 (H3). Asset specificity in the manufacturing stage of a product in the pharmaceutical industry has a positive relationship with vertical integration at that stage.

The literature is scarce on the relationship between transaction costs and operational capabilities and it presents some difficulties for researchers, because each of them address a different object, respectively the transaction and the firm. However, we can assume that the transactions carried out by the firm can influence its productive capabilities. According to Jacobides and Winter (2005), the productive capabilities rest on the firm's general and specific knowledge of how to do things and also involve specific investments in equipment and the training and retention of the key personnel required to put that knowledge to work.

The moderating function of transaction costs on the relationship between the distribution in an industry of the productive capabilities of firms and the vertical scope is discussed by Jacobides and Winter (2005). They offer two hypotheses. First, if capabilities are dissimilar along the value chain, then potential gains from trade across the firm's boundaries exist, and so a reduction in transaction costs will lead to substantial disintegration. Second, if capabilities are similar along the value chain, then there are no expected gains from trade across the firm's boundaries, and so a reduction in transaction costs will not lead to substantial disintegration.

Argyres and Zenger (2012) presented a critical view of this approach. They recognize that the empirical research in the literature corroborates this straightforward application of the comparative logic on capabilities to boundary choices. However, they argue that transaction costs and competences intertwine dynamically as the determinants of firms' boundaries. In the original phase of forming capabilities, transaction cost considerations have relevance to firms in deciding whether to retain, develop or sell off the competences. Argyres and Zenger focus on how organizations build their capabilities in their early and later boundary decisions and consider that, besides serendipity, the distribution of competences across firms and their suppliers reflects the transaction costs of operating in the past.

The aim of the model and the hypotheses we have presented is to deepen the comprehension of the role of capabilities and transaction costs in the choice of the boundaries of the firm in the manufacturing function. To test these hypotheses, we have developed a structural equation model (Williams, Edwards, & Vandenberg, 2003).

Methods

This section presents the methodological procedures followed in the study. We designed and conducted the research with the data from the public records on drugs in Brazil. The text contains the description of the procedures, involving the definition of the unit of analysis, the measurement of the constructs and the strategy for data analysis.

Concerning the research universe, we chose the set of drugs registered and approved for marketing in Brazil by the National Agency for Sanitary Surveillance (ANVISA). Within this universe, the object of analysis is the drug manufacturing transaction. According to the definition of ANVISA (2010), manufacturing involves the stages of production, fractioning, and packaging. For this object, we considered the constructs of Asset Specificity, Experience, Diversification, and Vertical Integration. We present the indicators of the constructs in the next section.

With these constructs, the unit of analysis is the drug's registration in ANVISA, and we opted for the collection and analysis of the total population of records in the official database called Bulário Eletrônico (<http://www.anvisa.gov.br/datavisa/fila_bula/index.asp>). In the new database created for the research, we defined the product as the combination of the active principle with the pharmaceutical form, since a drug may present two or more forms, and there may be different levels of vertical integration for each one. For example, the drug Acheflan (Aché Laboratories) is one case in ANVISA but generates two products in the new database: Acheflan cream and Acheflan aerosol. We followed four steps to construct our dataset. First, the extraction of data on the drug registration from ANVISA, second, the generation of records of products. The third step was a search and collection of the time for which the firms that own the products and their groups have operated, and fourth, a calculation of the indicators of the latent variables and constructs, as presented in the next section.

Measurement of Latent Variables

We created indicators for the latent variables with drug registration data in ANVISA. Starting with the product, we searched other sources and collected the name of the firm and its owner or holding corporation, defined as the group and the experience, measured by the length of time for which the firm and the group, respectively, had been in operation. Thus, this study provides a methodological contribution to the measurement of capabilities and transaction costs based on secondary data for products in the pharmaceutical industry.

Considering the information available in the official database, the indicators of the drug used in this study were the vertical integration, the pharmaceutical form, and therapeutic class. The pharmaceutical form is a physical aspect, such as pill, liquid or cream. There are 62 forms in ANVISA, and we converted each one in dichotomous variables of the product.

The drug's function for diseases or human organs is the therapeutic class, which we measured by 72 dichotomous indicators (Classes). Besides that, we created 13 anatomic classes, resulting from the aggregation of similar therapeutic classes by organs and systems of the human body (Agg Class). This method is an international standard for drug classification, the Anatomic Therapeutic Chemical (ATC) system of the World Health Organization (WHO, 2011).

We measured Vertical Integration by an endogenous variable with the same name and eight indicators. The drug label identifies the firm responsible for each stage of manufacturing: production, fractioning and packaging. We used the choice between vertical integration and an outsourcing contract (which, by definition, was a strategic alliance contract) (Ménard, 2004, 2006). The dichotomous indicators for the firm are "Make Prod in Firm" (internal supplier for production), "Make Pott in Firm" (internal supplier for fractioning) and "Make Pack in Firm" (internal supplier for packaging). Similarly, the indicators for the group are "Make Prod in Group," "Make Pott in Group" and "Make Pack in Group". The scalar indicators were the number of stages in which the internal supplier (or, respectively, the group) participated, as a percentage of the total number of stages ("Vertical Integ in Firm" and "Vertical Integ in Group").

Two indicators measured the variable Experience. First, "Firm Time," the time in years for which the firm had operated in Brazil. Second, "Group Time," the time in years for which the oldest firm in the group had operated.

For the variable Diversification, we adopted four indicators at the firm and group level, being two related to forms and two for therapeutic classes. First, "Firm in Forms," the number of distinct forms of the firm divided by the total number of forms. Second, "Group in Forms," the similar indicator at the group level. Third, "Firm in Classes," the number of distinct classes of the firm divided by the total number of classes. Fourth, "Group in Classes," the correspondent indicator for the level of the group.

We measured the variable Asset Specificity with three dichotomous indicators. We transformed the list of 62 pharmaceutical forms from ANVISA (2011) into dichotomous measures assigned to the product. We then created new indicators called "aggregate forms" by grouping the original forms with common attributes related to asset specificity. First, "Release Attribute in Agg Form," the aggregate form composed of original forms with specific attributes related to releasing the drug in the human body. Second, "Pack Attribute in Agg Form," the aggregate form composed of original forms with specific attributes related to fractioning or packaging. Third, "Any Attribute in Form," an indicator of an original form with any specific attribute.

Strategy for Data Analysis

We evaluated the data with three steps. The first was the central tendency and dispersion in the population with descriptive statistics. The second was the partial correlation coefficients between the indicators. The third was the analysis of a structural equation model, with evaluation of the measurement model and the structural relationships to test the hypotheses using the partial least squares (PLS) method. The PLS method is a technique of structural equation modeling to analyze the causal relations between constructs. This technique does not require multivariate normality in the distribution of the variables (Wold, 1985).

We constructed the variables Vertical Integration, Experience, Diversification and Asset Specificity reflectively with their indicators (Edwards & Bagozzi, 2000). The coefficients of the structural model represent standardized regression coefficients, and the loads of the latent variables associated with the constructs are the factor loadings. The significance was determined by the Bootstrap method with 1000 repetitions. A value of $p < 0.05$ ($t >= 1.96$) was used for significance tests.

Results

In this section, we present and discuss the results of the data analysis. First, we show the general characteristics of the data with the structure of the indicators. The following part contain the evaluation of the descriptive statistics and correlations. In the last part, we present the results of the proposed structural model. In a preliminary data investigation, there were no missing values. We evaluated outliers with the Mahalanobis distance test, resulting in the identification and exclusion of 40 cases.

Descriptive Statistics and Correlations

The database contains 1566 products associated with 111 firms consolidated into 88 groups. For Vertical Integration we found the equal averages for production and fractioning in the firms at 61.00%, lower than the value for groups, 83.00%. The same is true for packing inside the firms (73.00%) and the groups (90.00%). For the scalar aggregate indicators, the value for firms (64.75%) is also lower than that for groups (85.55%).

The data for Experience reveals that the average time for which the firms had operated in Brazil (50 years) is less than this indicator for the groups (148 years), reflecting the relatively short history of manufacturing in Brazil compared with the age of foreign pharmaceutical

groups. The results for Diversification showed an average share of 25% of the total number of forms for the firms and 53.23% for the groups. This difference reflects the function of a group to increase diversification in forms. The share of the total number of classes is 25% for the firm and 32.7% for the group, revealing that a group has a relatively minor effect on this diversification, perhaps because of the higher costs involved in the development of the capabilities in different therapeutic classes.

For Asset Specificity, the average frequencies for the aggregate forms are 10% for the packing attribute and 30% for the release attribute. The shares for the aggregate class are 30.75% for firms and 25.12% for groups. We analyzed the partial correlations between the indicators and found values between 0.30 and 0.60, and in some cases values greater than 0.80, which allows the application of multivariate analysis, such as factorial analysis using structural equations.

Construct Validity

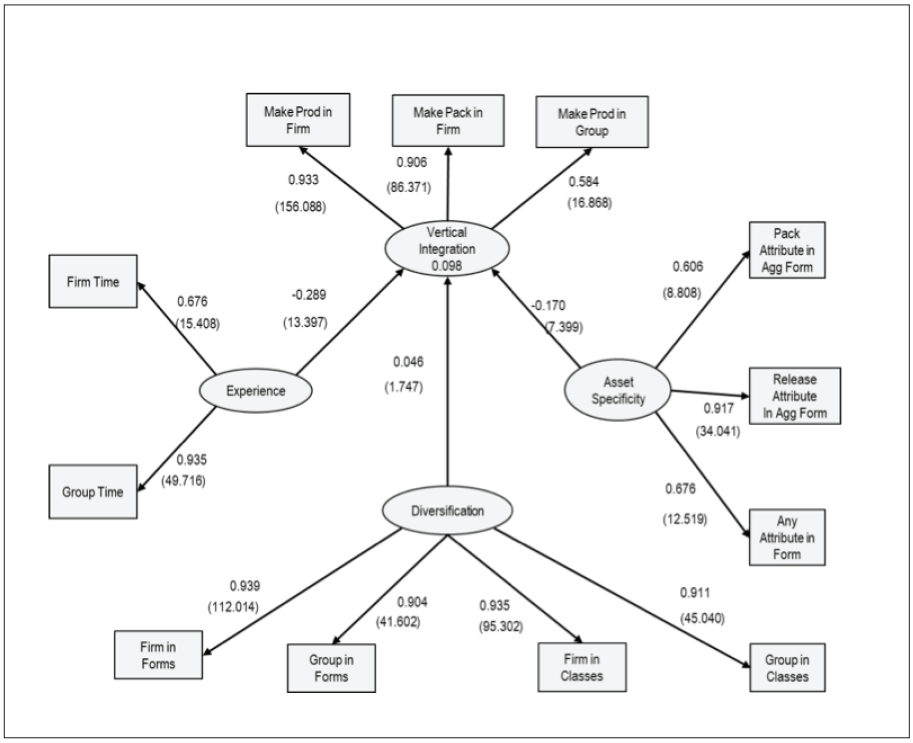
In this section, we discuss the validity of the scale used to measure the constructs. We used tests of reliability and convergent and discriminant validity with the software SmartPLS 3.2.7 (Ringle, Wende, & Becker, 2015). Figure 1 shows the measurement model estimated by PLS after the validation stage. The ovals include the variable and the percentage of variance explained by the relationships with other variables. We present the loads and t values in the arrows for latent variables and indicators. The criteria for acceptance of an indicator was the statistical significance ($p < 0.05$, $t >= 1.96$) with the value superior to 0.45 of the load. Most of the loads are above 0.60 and exhibit $p < 0.01$ ($t >= 2.576$), indicating its adaptation.

In re-specification of the model, we eliminated the indicators Make Pott in Firm and Vertical Integ in Firm because of multicollinearity, as indicated by offensive loads. The second round of model calculation excluded the indicators Make Pott in Group (load = -0.174, t = 0.073), Make Pack in Group (load = 0.111, t = 0.058) and Vertical Integ in Group (load = 0.220, t = 0.037) because of the lack of significance of the loads.

Concerning Experience, both indicators showed significance. It is noteworthy that Group Time has a higher load than Firm Time. This result may reflect the high share of foreign products in the population (70%) since all belong to firms with a higher average age than the domestic firms. For Diversification, all the indicators showed loads higher than 0.600 and appropriate significance. Asset Specificity had loads suitable for the first-order variables used in its measurement. Form Specificity showed a load about twice as large as that for the variable Class Specificity.

The reliability of the constructs was based on three criteria: reliability of lower-level variables; composite reliability (the construct) (acceptable values > 0.70); and average variance extracted (AVE) (acceptable values > 0.50) (Chin, 1998). We assessed the reliability of the variables related to the constructs by the magnitude of the respective factor loads. Most loads must be at least 0.60, and ideally, they should be at or above 0.70 (Chin, 1998; Falk & Miller, 1992). We can see in Figure 1 that the only one item present a load bellow 0.60 (Make Prod in Group) and eight loads are higher than 0.90. Table 1 shows the composite reliability and average variance extracted (AVE). Both meet the established suitability criteria.

Figure 1 – Mensuration model re-specified with coefficients*



The analysis presented in Table 2 supports the convergent validity for the constructs of the model, as it indicates higher loads in absolute value for the indicators related to the latent variables, as predicted by the model, with smaller loads for the other variables (Chin, 1998).

Table 1

Measurement of construct reliability

Variable	AVE	Composite Reliability
Experience	0.666	0.795
Diversification	0.851	0.958
Asset Specificity	0.555	0.784

We tested the discriminant validity using the method of Fornell & Larcker (1981). All constructs in the model showed discriminant validity, as the square root of the AVE for the latent variables, displayed in bold on the diagonal of the correlation matrix (Table 3), are higher than the other latent variables.

Table 2

Cross loads for evaluation of convergent validity

Indicator	Asset Specificity	Diversification	Experience	Vertical Integration
Pack Attribute in Agg Form	**0,606**	0,052	0,060	-0,070
Release Attribute in Agg Form	**0,917**	-0,042	-0,057	-0,180
Any Attribute in Form	**0,676**	0,044	0,037	-0,075
Firm in Classes	-0,011	**0,935**	0,572	-0,135
Group in Classes	-0,023	**0,911**	0,468	-0,096
Firm in Forms	0,024	**0,939**	0,592	-0,117
Group in Forms	-0,002	**0,904**	0,463	-0,082
Firm Time	-0,032	0,139	**0,676**	-0,128
Group Time	-0,001	0,660	**0,935**	-0,267
Make Prod in Firm	-0,175	-0,146	-0,247	**0,933**
Make Pack in Firm	-0,139	-0,092	-0,260	**0,906**
Make Prod in Group	-0,069	-0,004	-0,046	**0,584**

Table 3

Cross correlation of first level latent variables

	Asset Specificity	Diversification	Experience	Vertical Integration
Asset Specificity	0,745			
Diversification	-0,003	**0,922**		
Experience	-0,013	0,577	**0,816**	
Vertical Integration	-0,166	-0,120	-0,261	**0,823**

Analysis of Structural Model

As shown in Figure 1, the explained variance for the dependent variables of the model (R^2) is below but near 10%, revealing an adequate predictive power of the PLS model (Falk & Miller, 1992). In Table 4, we present the hypotheses and test results, where the structural factors were significant except for H2.

Table 4

Test of hypotheses of the model

Hypothesis	Proposed Effect	Regression Coefficient	Observed *t* Value	Hypothesis Supported
Effect on Vertical Integration (R^2 = 0.098)				
H1: Experience ➔ Vertical Integration	-	-0.289	13.397	Yes
H2: Diversification ➔ Vertical Integration	+	0.046[a]	1.747	No
H3: Asset Specificity ➔ Vertical Integration	+	-0.108	2.663	No

[a] Non-significant

Hypothesis H1 proposes a negative relationship between Experience and Vertical Integration. We found a negative and significant structural coefficient, which does support this hypothesis.

Hypothesis H2 establishes a positive relationship between Diversification and Vertical Integration. The model shows a positive and not significant structural coefficient, which do not support the hypothesis related to the view of the firm or group as a bundle of capabilities. To deep the comprehension on this result, we investigated the presence of mediating and moderating effects of the constructs Experience and Asset Specificity in this relation. We tested more five new models, whose results are in the following paragraphs.

The second model tested the influence of Diversification on Vertical Integration, grouping just these two constructs, resulting in a negative structural coefficient (-0.134) with significance (t = 6.84) and a lower explanation power for Vertical Integration ($R^2 = 0.018$) than the first model of the Figure 1. The third model tested the simultaneous influence of Diversification and Asset Specificity on Vertical Integration, keeping just these three constructs. The structural coefficient for the relation between Diversification and Vertical Integration was lower than the second model, but still negative (-0.123) and significant (t = 5.262). The structural coefficient for the relation between Asset Specificity and Vertical Integration was also negative (-0.168) and significant (t = 7.417), and this model showed a higher explanation power ($R^2 = 0.043$) for Vertical Integration than the second one. These results indicate the inexistence of mediating effect of Asset Specificity on the relationship between Diversification and Vertical Integration.

The fourth model tested the relationships of Diversification and Experience on Vertical Integration. The explanation power of this model for Vertical Integration was higher than the second and third model ($R^2 = 0.071$). The structural coefficient for the relation between Diversification and Vertical Integration was positive (0.047) and not significant (t = 1.669), while the structural coefficient for the relation between Experience and Vertical Integration was negative (-0.292) and strongly significant (t = 14.245). These results show a clear mediating effect of Experience on the relation between Diversification and Vertical Integration. Thus, the original negative and significant effect of Diversification on the Vertical Integration of the second model disappeared.

Along these lines, we may add the following new propositions in this work:

> *Proposition 1 (P1). The diversification of the firm in the attributes of its products has a negative relationship with the vertical integration in the manufacturing stage of the products in the pharmaceutical industry.*
>
> *Proposition 2 (P2). The experience mediates the relation between diversification of the firm and the vertical integration in the manufacturing stage of the products in the pharmaceutical industry.*

The fifth and sixth models tested the moderation effect of experience and asset specificity on the relationship between Diversification and Vertical Integration. The results showed the inexistence of moderating effects.

Hypothesis H3 suggests a positive relationship between Asset Specificity and Vertical integration. The model presented a negative and significant coefficient, which contradicts the proposed hypothesis. It appears that the manufacturing does not have the strategic relevance to justify vertical integration when asset specificity increases. This result suggests a low perceived risk of opportunistic behavior in the outsourcing of manufacturing stage.

Discussion and Final Considerations

The study aimed to analyze the influence of transaction costs and capabilities on vertical integration for the manufacturing stage in the pharmaceutical industry in Brazil. The objective was to contribute to the research agenda on the relationship between the transaction costs and capabilities approaches, particularly about the adoption of a governance structure in a production system. While the TCT has been successful in confirming its hypotheses in empirical studies, the capabilities approach still faces some difficulties in the measurement of constructs, but there has been a growing application of some aspects of this approach in the area of strategy. In this section, we present the main implications of the results of the testing of the hypotheses of this work.

The result of the test of hypothesis H1 indicated that, in the pharmaceutical industry, the higher the experience, the lower the vertical integration. In the pharmaceutical industry, pioneer firms had an integrated structure because of the industry regulation and the low initial dissemination of capabilities among agents. As time passed with the firms operating and the spread of the capabilities throughout the industry, it seems that these firms focused on activities with relatively higher participation in value generation. In this sense, the firms limited their operations in the most relevant stages in the value chain, considering the participation in the total cost of the product, outsourcing the manufacturing stages with less relevance on these criteria, whenever suppliers are available in the market. We can also see this behavior in the automotive and telecom industry.

We rejected the hypothesis H2 (a positive influence of Diversification on Vertical Integration) and analysed some alternative models to investigate the mediating and moderating effects of the experience and asset specificity in this relation. The results of these models showed a clear mediating effect of Experience on the relationship between Diversification and Vertical Integration and the inexistence of moderating effects. The effect of the inclusion of Experience was the cancelling the original negative effect of Diversification and the increase of the total explanation power of the model for the Vertical Integration.

By this result the influence of diversification on vertical integration occurs only in presence of the experience. There are some theoretical reasons for this statement. First, the experience must help the firms in this industry to decide the level of vertical integration for the portfolio of products. The operation time favour the firm to concentrate its activities on the more relevant stages in value creation of each product. As the firm increases the diversification in the product portfolio, the experience will support the decision on vertical integration, balancing production costs and the participation on the revenue of each product.

The second reason for the influence of experience on diversification is the building of capabilities to manage the production lines, regarding therapeutic classes and the administration forms of the products. For each movement of launch products with diverse therapeutic class and form, increasing the diversification, the capability to manage the production lines will direct the decisions to explore the available productive assets with adaptations, to invest in new equipment's or to contract an external supplier for the new product if available.

The third reason for the dependence of diversification on experience in vertical integration decisions is the capability to manage the strategic alliances related to the manufacturing stage. Since the experience with the management of earlier alliances is central to increase this capability, the decision of vertical integration when the firm raises the diversification is affected by the operation time.

The fourth reason of the relationship of diversification and experience is that both are associated with scale of production. We expect the increase of diversification with experience, in order to reduce the market risks with a balanced portfolio with innovative and older products. In this sense, the increase of diversification could be associated to the scale of production. The decision of vertical integration when the scale is raising depends on the availability of capital for new plants and the profitability of establishing strategic alliances for the manufacturing stage.

One contribution of the study is that we could highlight the difference in the kind of capabilities measured in each proxy, since diversification measures the number of different competences of the firm in form and class, while experience relates to the learning curve related with productivity gains.

We found a negative relationship between asset specificity and vertical integration (hypothesis H3). The rejection of the hypothesis, rather than suggesting the invalidity of TCT, seems to be due to aspects of the industry and of the transaction in question. The result seems to indicate that the drug manufacturing transaction has low strategic value in the value chain of the pharmaceutical industry. We suspect that companies tend to outsource the manufacturing of products with specific attributes, preferring in some cases to use the capabilities of a partner rather than those of the internal supplier, as the TCT prediction. The result indicates that these specific attributes do not appear to represent sources of transaction costs arising from the risk of opportunistic behavior by partners. We can argue that a strategic alliance at the manufacturing stage for products with specific attributes presents a low risk that the service provider will hold up the supply. The reason for this assumption is the appropriating structure for the R&D investment made by agents in this industry, centred on the patenting of active principals of the drugs.

One limitation of the study relates to its exploratory nature. Attempts to establish relationships between the transaction costs and capabilities approaches are still at a nascent stage, although empirical evidence is already accumulating about the possibilities of a complementary application of the theories. However, the literature has not yet reached a consensus on the feasibility of a more general and integrated theory. We suggest that the results and the implications derived from this work require a precautionary interpretation in view of the characteristics of the indicators and the structural model used. Our attempt to use secondary data about products as a starting point to generate data about firms may contain biases related to capabilities. We could not evaluate the origin of products, whether developed internally or came into the portfolio by mergers or acquisitions. The second limitation of this study relates to the distribution of cases between domestic and foreign firms and groups. The population that we tested reflects a market segment with a predominance of new drugs mostly produced by foreign companies. Future studies should also evaluate the influence of the categories of innovative and generic on the vertical integration of manufacturing stage.

References

ANVISA (2010). *Guia para a condução de estudos não clínicos de segurança necessários ao desenvolvimento de medicamentos*. Brasília: Agência Nacional de Vigilância Sanitária.

ANVISA (2011). *Vocabulário controlado de formas farmacêuticas, vias de administração e embalagens de medicamentos*, 1st edition. Brasília: Agência Nacional de Vigilância Sanitária.

Argyres, N. S., & Zenger, T. R. (2012). Capabilities, transaction costs, and firm boundaries. *Organization Science*, *23*(6), 1643-1657. doi: https://doi.org/10.1287/orsc.1110.0736

Bataglia, W., & Meirelles, D. S. E. (2009). Population ecology and evolutionary economics: Toward an integrative model. *Management Research*, *7*(2), 87-102. doi: https://doi.org/10.2753/jmr1536-5433070201

Bataglia, W., Silva, A. A., & Klement, C. F. F. (2011). Dimensões da imitação entre empresas: um estudo na indústria de transformação brasileira. *Revista de Administração de Empresas*, *51*(2), 160-174. doi: https://doi.org/10.1590/s0034-75902011000200004

Bataglia, W., & Yu, A. O. S. (2008). A sincronização da tomada de decisão estratégica com o planejamento estratégico formal. *Revista de Administração Mackenzie*, *9*(5), 82-111. doi: https://doi.org/10.1590/s1678-69712008000500005

Becker, M. C. (2004). Organizational routines: A review of the literature**.** *Industrial and Corporate Change*, *13*(4), 643-677. doi: https://doi.org/10.1093/icc/dth026

Bigelow, L. S., & Argyres, N. (2008). Transaction costs, industry experience and make-or-buy decisions in the population of early U.S. auto firms. *Journal of Economic Behavior and Organization*, *66*(3-4), 791-807. doi: https://doi.org/10.1016/j.jebo.2006.01.010

Bogner, W. (1996). *Drugs to market: Creating value and advantage in the pharmaceutical industry*. Oxford, UK: Elsevier Science.

Chin, W. W. (1998). The Partial Least Squares approach to structural equation modeling. In G. A. Marcoulides (Ed.), *Modern methods for business research* (pp. 295-336). Mahwah, NJ: Lawrence Erlbaum Associates. doi: https://doi.org/10.4324/9781410604385

Coase, R. H. (1937). The nature of the firm. *Economica*, *4*(16), 386-405. doi: https://doi.org/10.2307/2626876

Dosi, G., Nelson, R., & Winter, S. G. (2000). Introduction: The nature and dynamics of organizational capabilities. In G. Dosi, R. Nelson, & S. G. Winter (Eds.), *Nature & dynamics of organizational capabilities* (pp. 1-22). New York, NY: Oxford University Press. doi: https://doi.org/10.1093/0199248540.003.0001

Edwards, J. R.; & Bagozzi, R. P. (2000). On the nature and direction of relationships between constructs and measures. *Psychological Methods*, *5*(2), 155-174. doi: https://doi.org/10.1037//1082-989x.5.2.155

Estrella, A., & Bataglia, W. (2013). A influência da rede de alianças no crescimento das empresas de biotecnologia de saúde humana na indústria brasileira. *Organizações & Sociedade*, *20*(65), 321-340. doi: https://doi.org/10.1590/s1984-92302013000200008

Falk, R. F., & Miller, N. B. (1992). *A primer for soft modeling*. Akron, OH: University of Akron Press.

Fornell, C., & Larcker, D. F. (1981). Evaluating structural equation models with unobservable variables and measurement error. *Journal of Marketing Research*, *18*(1), 39-50. doi: https://doi.org/10.2307/3151312

Henderson, R., & Cockburn, I. (1994). Measuring competence? Exploring firm effects in pharmaceutical research. *Strategic Management Journal*, *15* (Winter Special Issue), 63-84. doi: https://doi.org/10.1002/smj.4250150906

Hoetker, G. (2005). How much you know versus how well I know you: Selecting a supplier for a technically innovative component. *Strategic Management Journal*, *26*(1), 75-96. doi: https://doi.org/10.1002/smj.453

Jacobides, M. G., & Winter, S. G. (2005). The co-evolution of capabilities and transaction costs: Explaining the institutional structure of production. *Strategic Management Journal*, *26*(5), 395-413. doi: https://doi.org/10.1002/smj.460

Klein, P. G., & Lien, L. B. (2009). Diversification, industry structure, and firm strategy: An organizational economics perspective. In J. A. Nickerson & B. S. Silverman (Eds.), *Economic Institutions of Strategy*. *Advances in Strategic Management, Vol. 26* (pp. 289-312). Bingley, UK: Emerald, JAI Press. doi: https://doi.org/10.1108/s0742-3322(2009)0000026013

Kogut, B., & Zander, U. (1992). Knowledge of the firm, combinative capabilities, and replication of technology. *Organization Science*, *3*(3), 383-397. doi: https://doi.org/10.1287/orsc.3.3.383

Macedo, A. D., & Bataglia, W. (2012). A relação entre ambiente organizacional e imitação entre empresas: Um estudo na indústria de biotecnologia brasileira. *Revista Eletrônica de Gestão Organizacional*, *10*(2), 229-253.

Ménard, C. (2004). The economics of hybrid organizations. *Journal of Institutional and Theoretical Economics*, *160*(3), 345-376. doi: https://doi.org/10.1628/0932456041960605

Ménard, C. (2006). Hybrid organization of production and distribution. *Revista de Analisis Economico*, *21*(2), 25-41.

Nakamura, K., & Odagiri, H. (2005). R&D boundaries of the firm: An estimation of the double-hurdle model on commissioned R&D, joint R&D, and licensing in Japan. *Economics of Innovation and New Technology*, *14*(7), 583-615. doi: https://doi.org/10.1080/1043859052000344697

Nelson, R., & Winter, S. (1982). *An evolutionary theory of economic change*. Cambridge, MA: Harvard University Press.

Nogueira, A. C. L. (2011). Estratégia e estrutura no setor farmacêutico: o caso do Laboratório Aché. In D. S. Meirelles (Ed.), *Formação e evolução da grande empresa brasileira: Estudos de caso embasados nas teorias da firma* (pp. 219-246). São Paulo, Brazil: Universidade Presbiteriana Mackenzie.

Nogueira, A. C. L., & Bataglia, W. (2012). Transaction costs and organizational competences: Explaining the governance structure for manufacturing stage. *Journal of Technology Management & Innovation*, *7*, 159-174. doi: http://dx.doi.org/10.4067/S0718-27242012000100011

Polastro, E. (1999). Outsourcing in the pharmaceutical industry: Quo vadis? *Chemical Market Reporter*, *256*(13), SP-1-5.

Powell, W. W., White, D. R., Koput, K. W., & Owen-Smith, J. (2005). Network dynamics and field evolution: The growth of interorganizational collaboration in the life sciences. *The American Journal of Sociology*, *110*(4), 1132-1205. doi: https://doi.org/10.1086/421508

Silva, T. C., & Ruiz, R. M. (2011). Uma avaliação exploratória do Fundo Setorial da Saúde. *Revista Brasileira de Inovação*, *10*(2), 343-370. doi: https://doi.org/10.20396/rbi.v10i2.8649019

Ringle, C. M., Wende, S., and Becker, J.-M. 2015. "SmartPLS 3." Boenningstedt: SmartPLS GmbH, http://www.smartpls.com.

Teece, D. J., Pisano, G., & Shuen, A. (1997). Dynamic capabilities and strategic management. *Strategic Management Journal*, *18*(7), 509-533. doi: https://doi.org/10.1002/(sici)1097-0266(199708)18:7<509::aid-smj882>3.0.co;2-z

Walker, G., & Weber, D. (1984). A transaction cost approach to make-or-buy decisions. *Administrative Science Quarterly*, *29*(3), 373-391. doi: https://doi.org/10.2307/2393030

WHO Collaborating Centre for Drug Statistics Methodology (2011). *Guidelines for ATC classification and DDD assignment 2011,* Oslo: World Health Organization.

Williams, L. J., Edwards, J. R., & Vandenberg, R. J. (2003). Recent advances in causal modeling methods for organizational and management research. *Journal of Management*, *29*(6), 903-936. doi: https://doi.org/10.1016/s0149-2063_03_00084-9

Williamson, O. E. (1991). Comparative economic organization: The analysis of discrete structural alternatives. *Administrative Science Quarterly*, *36*(2), 269-296. doi: https://doi.org/10.2307/2393356

Williamson, O. E. (1999). Strategy research: Governance and competence perspectives. *Strategic Management Journal, 20*(12), 1087-1108. doi: https://doi.org/10.1002/(sici)1097-0266(199912)20:12<1087::aid-smj71>3.0.co;2-z

Wold, H. (1985). Partial least squares. *Encyclopedia of statistical sciences*. doi: https://doi.org/10.1002/0471667196.ess1914.pub2