

# **Transaction costs and organizational competences: explaining the make-or-buy decision for new products manufacturing**

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The study was supported by financial resources from Instituto Presbiteriano Mackenzie.

**Keywords:** governance structures, pharmaceutical industry

## **Summary**

This article deals with the influence of transaction costs and organizational competences on the adoption of governance structures to manufacturing step of new products. The study follows a series of investigations on the relationships between organizational economics and organizational competences approaches (Williamson, 1999; Hoetker, 2005; Nakamura & Odagiri, 2005). Governance structures are related to firm boundaries in the value chain, which separate transactions coordinated by internal hierarchy from those involving external partners, through contracts or open market conditions. The launch of new products is one of the aspects related to the performance of innovation and technology management of a firm. The issue is especially relevant in sectors with rapid technological regimes cycle, as the pharmaceutical industry. One of the decisions that affect the effectiveness in launching a new product is the choice of governance structure of the manufacturing step. It is necessary to choose between an internal supplier, such as the production functional unit in the company, or external, through a contract with a partner. The proposed research problem is: what is the influence of transaction costs and organizational competencies in the make-or-buy decision for new products manufacturing stage? The general objective of the study is to develop a conceptual model that explains the choice of supplier for new products manufacturing through transaction costs and organizational competences. The specific objectives are: (1) assess the current literature on the approaches of transaction cost economics of organizational and organizational competences on the subject, (2) define measurable variables and develop hypotheses for the constructs involved, and (3) analyze the possibility of applying the model to pharmaceutical industry in Brazil. The study has two justifications. The first is to deepen knowledge about the relationships between the approaches of organizational economics and organizational competences. Organizational economics could be improved with the analysis of issues internal to the organization affected by the transactions, such as routines and competences. The second justification is the contribution to the empirical studies on the management of manufacturing in the Brazilian pharmaceutical companies, which have expanded their market share in recent years. Drawing upon Jacobides & Winter (2005), the framework proposes the competences of the product's owner define the vertical scope in a relation moderated by transaction costs. The proposed model deals with relations between the following constructs: (1) "supplier", taken as dependent variable and categorized as internal or external, (2) "transaction costs", which are measured by the asset specificity of the product and the bargain power of the firm in the manufacturing transaction and (3) "organizational competences", which are measured in the areas of operations and partnerships. The feasibility of applying the model to the Brazilian pharmaceutical industry seems to be promising. The empirical test of the model involves the search for secondary data in the federal drug regulator in Brazil, Agência Nacional de Vigilância Sanitária (ANVISA). In this entity it would be possible to one obtain the data on new drugs released in the Brazilian market, including the date of approval, therapeutic class, governance structure adopted by the owner of the drug in the manufacturing stage (vertical integration or outsourcing) and asset specificity related to innovativeness (proprietary or generic formula).

## Introduction

This article deals with the influence of transaction costs and organizational competences on the adoption of governance structures to manufacturing step of new products. The study follows a series of investigations that seek to establish relationships between the approaches of organizational economics and organizational competencies (Williamson, 1999; Hoetker, 2005; Nakamura & Odagiri, 2005). Governance structures are related to firm boundaries in the value chain, which separate transactions coordinated by internal hierarchy from those involving external partners, through contracts or open market conditions.

In organizational economics, the study of transactions and governance structures to coordinate them has its origins in Coase (1937), by questioning the reasons for the existence of the firm. The central argument of this seminal article is that the rising cost of conducting transactions in the market favors the incorporation of these transactions in the internal activities of firms. Since the decade of 1970, these ideas are taken up in several studies of Oliver Williamson, laying the foundation of Transaction Cost Economics (TCE).

Transactions are transfers of goods and services between technologically distinct productive stages (Williamson, 1999). Thus they can occur within firm or crossing its borders involving external agents. The construct is the basic unit of analysis in TCE, and described with dimensions of frequency, uncertainty and asset specificity. This last is prevalent in empirical studies and indicates the potential for loss of value of investments involved in the transaction, if that does not take place. The governance structure adopted is the result of rational choice to minimize transaction costs.

The approaches of organizational competencies have sought to understand the processes of adaptation and change in organizations as ways of adjusting to changing environments (Teece, Pisano & Shuen, 1997, Dosi et al., 2000). The concept of routines has been considered in developing such approaches for representing the expression of organizational capabilities during the performance of business processes at any stage of the value chain. For Becker (2004) routines are recurrent patterns of interactions between agents. The author highlights the role of preservation of organizational knowledge, by offering solutions to the problems built up over time.

The pharmaceutical industry in Brazil is undergoing significant changes, especially since the creation of the category of generic drugs, by Law no. 9.787/99 in 1999. Until the late 1990s, the market consisted of two categories: (1) "innovative" drugs produced largely by global industry leaders and launched under its own brand and (2) similar drugs, copies of these drugs with the same active ingredients and pharmaceutical formulations of innovative products, usually released by mid-sized and small companies, predominantly with domestic capital. With the advent of generics, obtained from formulas whose patents expired, it creates an alternative to products that have

equivalence with the reference product and are certified by laboratories accredited by the National Health Surveillance Agency (ANVISA - Agência Nacional de Vigilância Sanitária) (Quental et.al. 2008).

The proposed research problem is: what is the influence of transaction costs and organizational competencies in the make-or-buy decision for new products manufacturing stage? The general objective of the study is to develop a conceptual model that explains the choice of supplier for new products manufacturing through transaction costs and organizational competences. The specific objectives are: (1) assess the current literature on the approaches of transaction cost economics of organizational and organizational competences on the subject, (2) define measurable variables and develop hypotheses for the constructs involved, and (3) analyze the feasibility of applying the model to pharmaceutical industry in Brazil.

The study has two justifications. The first is to deepen knowledge about the relationships between the approaches of organizational economics and organizational competences. Organizational economics could be improved with the analysis of issues internal to the organization affected by the transactions, such as routines and competences. In the other way, may be useful for organizational competences approach aggregation of aspects related to the transactions and governance structures. It is considered that a point of contact between the approaches would be the choice of governance structure, to be explained by transaction attributes and competences.

The second justification is to offer methodological tools for empirical studies on the management of transaction costs and competences in the Brazilian pharmaceutical industry. Understanding the determinants of adoption of governance structures in the value chain can help guide public policies and private strategies in the areas of financial support and innovation. The study evaluates the possibility of applying the conceptual model for the manufacturing step in a globally dynamic industry that is changing in Brazil, given the growth of the national laboratories (Ferreira, 2010).

### **Transaction Costs Economics**

The main conceptual movement of ECT is to describe firms not in terms of neoclassical economics (production function), but at the organizational (governance structures). The argument is that in a world of positive transaction costs, exchange agreements need to be governed and that, depending on the transaction, some forms of governance are better than others. An example is the acquisition of an input in a production chain of an external agent or the incorporation of manufacturing inputs within the firm. This is the choice between vertical integration and external supply of a particular stage of production. The external supply can be done in market conditions or

long-term contracts. If the activity is internalized, the governance structure would be the hierarchy (Ruester, 2010).

A useful concept in the construction of the theory was incomplete contracts, initially proposed by Simon (1951) to examine the possibility of settling labor contracts in the market or within the firm. Williamson (1975) takes this concept to analyze the vertical integration. TCE has the premise that all contracts are incomplete, due to the uncertainty of events in the environment or the inability of agents to process information related to the transaction and anticipate all possible outcomes of a contractual relationship. The limitation of human information processing is known as bounded rationality and became one of the behavioral assumptions of TCE.

An economic implication for the incompleteness of contracts is that parties are vulnerable to calculated efforts by others to deceive, avoiding compliance, cheating or another way to take advantage of the vulnerabilities of the transaction partners. To protect against such opportunistic behavior, parties select institutional arrangements to minimize the total cost to consummate the transactions involved. Williamson (1979) develops the asset specificity concept and shows the relationship of this attribute of the transaction with the choice of governance structures. The author argues that opportunism is relevant to raise the transaction costs in situations where there are specific assets and contracts are incomplete. It also proposes a comparative institutional assessment of transaction costs, since each governance structure is associated with certain transaction costs.

The role of asset specificity in the choice of governance structures is discussed in Williamson (1985). The author proposes that the relevant attributes of the transaction to the choice of governance structure are: frequency, uncertainty and asset specificity. Correlations are established between certain attributes and governance structures. The theory predicts that the higher the asset specificity and higher level of uncertainty, the greater the need for subsequent adjustments from the time of making investments in specific assets. Thus, we expect the predominance of hierarchical relationship in which one party has control over both sides of a transaction, since this structure would provide greater ease of resolution of disputes with the use of authority.

With regard to identification of the governance structures, TCE proposes that they form a continuum so that one end would be in the spot market and the other would be vertical integration. Between these extremes there would be a myriad of contractual forms called hybrid, which can be associated with long-term contracts. Klein et al. (1978) consider that the long-term contracts may represent possible solutions to the threat of hold-up. One of the propositions of the article is that the smaller the quasi-rent that may be appropriated during the renegotiation process, the greater the chance that the transactions are carried out under market conditions.

Despite the existence of some criticism, the approach of TCE has stimulated a large volume of empirical studies on the choice of governance structures, considering the effects of transaction

attributes on these choices. As Joskow (2005), most empirical studies of TCE have focused on the problem of vertical integration and the development of non-standard contractual arrangements over time. The author believes that TCE has been promoting a synergy between theory, empirical analysis and public policy in the last twenty-five years, and that the empirical results have been consistent with the theory.

Some empirical studies based on the ECT can be presented as examples of this methodological approach. One is Monteverde & Teece (1982), the first econometric study that tested the hypotheses of TCE for the choice of vertical integration. The study examined the decision between buying and manufacturing 133 automotive components used by GM and Ford in 1976, testing the hypothesis that these companies would make the vertical integration of production if the production process could create a very specialized or specific knowledge. Using as proxy for specificity the amount of engineering effort to develop the product, the results supported the hypothesis generated in accordance with the theory. The work provided evidence for the importance of the specificity of human capital in the decision to integrate vertically backward.

### **Organizational Competences**

According to Dosi and Teece (1993), the firm is based on specific competences to coordinate activities and learn about new activities in complex environments and under constant change. These competences are the pillars of competitiveness of the firm and involve a coordinated set of capabilities, complementary assets and organizational routines. Routines are patterns of interactions that represent a solution to particular problems. They bring together complementary assets and skills of individuals. Therefore, it is in routine that resides the knowledge generated by learning activities. In other words, the learning processes are concerned to the development of changes in routines and competences of firms.

The construct of organizational knowledge has been treated by Dosi, Nelson & Winter (2000), which seek to identify ways in which it is acquired, maintained, increased and sometimes lost. The focus of their analysis involves forms of knowledge that affect the organization's ability to conduct its main productive activities, such as the provision or development of tangible products or services. The authors present a discussion on organizational capabilities as the know-how that enables organizations to conduct these activities. This knowledge, resulting from the resolution of problems and response to external stimuli is translated and stored in organizational routines, which are distinguished from skills, since these are individual and those are collective.

The organizational learning that underlies the evolution of the firm can be described by two key dimensions. The first is to selective environment, characterized by the demands of the competition. The second is the adaptation of firms, focusing on strategic decision making (Bataglia

& Yu, 2008; Bataglia, 2006; Bataglia, 2002), which is responsible for generation and selection of alternative changes (variations) in the routines and organizational capabilities towards a better alignment to the selective environmental system. Thus, firms seek to increase their ability to survive and efficiency in achieving its goals.

Most economic models analyzing firms as independent economic entities, an approach considered appropriate in most cases by Hesterly & Barney (1996). However, in recent years has been recognized the importance of sets of firms that cooperate as important players in the competitive landscape.

The formal strategic partnerships, which are based on contracts, were analyzed by Powell et al. (1996). An important incentive to engage in strategic alliances is to explore the sources of complementary assets (Kogut, 1988). Sources controlled by two or more firms are considered complementary when their combined economic values are larger than the value of each firm separately. Some of the main motivations for alliances are presented by Barney and Hesterly (1996, p.167): economies of scale, cost-effective entry into new markets, low-cost entry into new segments in a branch or new branches; learn with competitors, manage strategic uncertainty, manage costs and share risks, and facilitate tacit cartelization.

Other factors that can be combined to justify the cooperative processes are sharing the risks, access to new markets and technology, speed to market and complementary capabilities (Kogut, 1988; Eisenhardt & Schoonhoven, 1996). Momigliano & Balcet (1983) also point to other factors to encourage cooperation agreements: (a) technology features, (b) diversity of nature and economic destination for international operations, (c) impact of new technologies on the technical scale economy and economy of the companies, (d) structural characteristics of the industry, and (e) characteristics of the countries of origin of companies.

### **Relations between TCE and Competence Approaches**

In this section we discuss the possibilities and the results obtained with the combination of TCE and organizational competencies approach, focusing on understanding the limits of the firm. A pioneering attempt to combine economic and behavioral constructs in the development of the theory of the firm was made by Cyert and March (1963).

Reve (1990) notes that the area of strategic management, with significant growth in business schools, has not advanced in developing a theory of the firm. Using concepts from the theory of transaction costs, the agency theory and dynamic capabilities approach, which is based in Nelson and Winter (1982), Reve (1990) elaborates a conceptual model in order to form the basis for a future contractual theory of the firm. He proposes expanding the concept of the firm for a set of

internal and external contracts. Thus, the firm could be defined as a set of core capabilities and organizational incentives (which form the strategic core), complementary capabilities and inter-organizational incentives (which form strategic alliances). For the author this model would cope with the view of strategy of Rumelt (1982) as a powerful set of unique resources and relationships.

The boundaries of the firm in the stage of research and development (R&D) in manufacturing firms were analyzed by Nakamura & Odagiri (2004). Through a study of data on 14,000 companies in Japan, the authors evaluate the adoption of R&D with independent activities, commissioning contracts, joint action and licensing. The model estimates at a first stage if the company performs R&D and second, if so, the volume of spending on access to external resources R&D. To explain these behaviors independent variables related to the theories of transaction costs and competences are included. The results seem to support both approaches. Evidence indicates the need of competences related to the size of the firm, intensity of internal R&D, diversification and vertical integration to be able to use external sources of R&D. The study also reveals that the patent appropriability reduces transaction costs for these contractual arrangements.

The choice of supplier for an innovative item in the computer industry is analyzed by Hoetker (2005), through the development and testing of a conceptual model. Based on concepts of TCE, the approach of competences and networks of firms, the author establishes hypotheses to explain the choice between internal and external suppliers, based on aspects of competences (number of patents), technological uncertainty, and relationship history. The results of the empirical test supported the hypotheses proposed and presented evidence that the proposed model has greater explanatory power than theories applied separately. The results indicate that in situations of low uncertainty, external suppliers are the most recommended because of specialization and reduction of production costs. If the uncertainty is the median, can still be used suppliers, but the weight of past relationship increases. In the case of extreme uncertainty, the model indicates a tendency to use internal suppliers.

Another effort of integration between the approaches of transaction costs and competences is presented by Jacobides & Winter (2005). In a theoretical study, the authors elaborate a conceptual model for co-evolution of transaction costs and competences along a productive chain. In this construction, the initial assumption is that the distribution of competencies between the actors determines the vertical scope that they adopt in the value chain, and this relationship would be moderated by transaction costs. If distribution of skills is uneven, it is expected to occur agent specialization and transactions between them, even if transaction costs are high. On the other hand, if the competences are uniform across agents, the specialization of agents would only occur if transaction costs are low.

The decision to make or buy engines by the automaker in the United States at the beginning of the industry is analyzed by Bigelow and Argyres (2008). In a quantitative study of secondary data with the total population of firms, the authors use independent variables related to transaction costs and business experience to explain the boundaries of the firm in the step of engines supply in vehicles. The results indicate that firms tend to produce more engines with unique characteristics and to acquire standard engines from independent suppliers, which confirms the hypothesis that asset specificity favors the vertical integration. The same results were found for mechanical subsystems that require more complex interfaces. Regarding the effect of evolution, the results indicate that industry experience favors the vertical integration of supply of engines. The authors consider the latter result is related to the tendency of firms seek to increase the capture of return through higher production competences over time in the industry.

The evaluation of the literature seems to indicate a considerable amount of evidence that transaction costs and organizational competences operate in a complementary way as determinants of governance structures (Jacobides & Winter, 2005).

### **Pharmaceutical Sector Overview**

During the past 25 years, the pharmaceutical industry is undergoing profound changes in: (1) technology, with the development of biotechnology and molecular biology revolution, (2) demand, affected by cost containment policies by the major consumers (private and public health systems) and (3) institutions, especially the law of property rights (McKelvy et al. 2004; Malerba, 2004).

Until the decade of 1970, the chemical technology was predominant, with research developed internally by companies. The introduction of new chemicals on the market was adequately protected by a patent law, guaranteeing protection against imitation. Besides the R&D, companies in the industry have developed expertise in managing large-scale clinical trials, in the process of obtaining approval of the medicines in regulatory agencies, as well as marketing and distribution. At this time, as McKelvy et al. (2004), especially in the United States, relations between industry and universities have become narrower, due to increased public spending on biomedical research and to increase in the rigor for the approval of new drugs.

From the 80's, begins a phase of profound change for the pharmaceutical industry, from the emergence of a new technological paradigm with the advent of molecular biology and genetic engineering (direct change of genetic material). These new technologies bring new actors into the innovation system in the industry: new dedicated biotechnology companies (NBC), constituents of the new segment of biotechnology. These companies were primarily the product of the universities,



and were usually formed through collaboration between scientists and marketers, supported primarily by venture capital. The function of NBCs was to mobilize the fundamental knowledge created in universities and turn it into marketable products and technical potential. The business model becomes, then, based on the idea of the firm (NBC), which has an intangible capital and high intellectual level, which is protected by an adequate system of protection of property rights, it becomes attractive to investment capital - venture capital, leaving the latter not only fund the projects, but also bring management competences necessary for the connection between science and markets.

The integration of NBCs with large pharmaceutical companies proved to be the ideal way for their survival. They came to stand in a cooperative attitude, as providers of research services to large corporations, which must continually acquire and develop new knowledge, on the other hand, came to NBEs necessary financial resources to finance R&D, and structure to development, testing, production and marketing of products (Coriat et al. 2004; McKelvy et al., 2004).

In Brazil, the history of the industry until the late 90's, is characterized by the dominance of large multinational drug makers, that were attracted by the potential of the Brazilian market and established the stages of production and marketing of their products. The phases of R&D and production of raw materials essential to the manufacture of drugs, with higher technological content were, mostly, kept in their home countries. As Bastos (2006), historically the participation of foreign companies in the sector was about 70% of total sales in the Brazilian market.

Regarding the production chain, in 1974 the pharmaceutical industry had 529 companies, of which 460 domestic and 69 foreign, and that same year, 50% of the active ingredients of the drugs were imported and 90% of drugs released in the market stemmed from research done abroad (SICAMESP). In the case of Brazilian companies the low relevance of R&D also resulted from the lack of financial resources and an articulated system of innovation needed to fund and encourage the development of R&D projects, which are of long maturity.

The Brazilian industry and particularly the national capital, received greater incentive to invest in production from the Generic Drug Law (Law 9787), adopted in 1999, which allows the replacement of drugs with a similar after the expiration of the patent with guaranteed quality by regulatory authorities.

According to the Brazilian Federation of Pharmaceutical Manufacturers (FEBRAFARMA, 2007), in 2005, Brazil was in 10th position in the global pharmaceutical market, with revenues of \$22.2 billion, equivalent to sales of 1.61 billion units. Despite the increase in real sales in 2005 over the previous year of 11%, there was a slight decrease in the number of units sold, about 2.3%. The Brazilian pharmaceutical market, from the perspective of supply, has changed significantly in recent

years. National companies which in 2000 accounted for about 28.2% of the value of drug sales in March 2005 had increased its stake to 40.6% (IMS Health).

According to Capanema (2006) in 2002 were identified 1,077 companies operating in the industry, 688 of which employ fewer than 20 employees, a number that can be considered insufficient to characterize a pharmaceutical industry. Thus, it is estimated that there are about 500 laboratories operating in Brazil (CAPANEMA, 2006). As Caliari and Ruiz (2010), based on data from IMS Health, in 2007 four of the ten largest companies had national capital and represented 21.7% of the market. They are: EMS (7.1% in the first position), Aché (5.6% in the third position), Medley (5.5% in the fourth position) and Eurofarma (3.5%, in sixth place), the authors also point out that Brazilian companies account for about 88% of the generics market, according to the site Pro-generic (2009). Thus, policy implementation for generics has resulted in increased scale of production by domestic firms. The study by Estrella (2008) revealed a growing segment, with the support of relevant institutions incubators, maturing and financial performance, considering the size and volume of sales.

## **Conceptual Model**

This section presents a proposed conceptual model of explanation of governance structures in the pharmaceutical sector, based on transaction cost and organizational competences approaches. The basic justification for the model is presented by Williamson (1999), noting the possibility of combining the approaches of transaction costs with the competences to explain the choice of governance structures. This author even speculate whether the attributes of the transaction could explain the choice of generic governance structure, while aspects of organizational learning could influence some attributes of the chosen governance structure, which could be investigated with the analysis of routines.

In designing the model were considered two delimitations: the first to construct "governance structures" and the second concerning the transactions to be analyzed. The theme of governance structures involves an extensive field research, especially for hybrid structures. The attributes of coordinated adaptation, autonomous adaptation, incentives and administrative costs, identified by Menard (2002), can be analyzed in greater depth to allow more detailed descriptions of these organizational forms, in order to obtain categories of similar structures.

However, in this conceptual model we adopt a more focused approach to structures of governance, with the delimitation of the analysis to the choice of the supplier in transaction, following the approach Hoetker (2005). In this study we consider the choice of governance

structure identified by a type of supplier (external or internal). With that the construct becomes simpler, which facilitates the analysis of the influence of independent variables.

The second choice involves the demarcation of transactions in the pharmaceutical manufacturing. This choice is justified by the ease of description and mapping of manufacturing transactions, compared to the stages of research and development. Another reason is that the manufacturing step has received great attention from public officials and businesses in the Brazilian pharmaceutical sector.

This process can be observed in the case study of Nogueira (2009) with the Brazilian laboratory Aché, where the initial growth was based on the company's strategic partnerships with multinational companies involving acquisition of industrial plants and licensing of drugs from the partners. With this the company has accumulated manufacturing expertise and resources to increase market share and generate resources for innovation activities in new products.

Another important aspect that justifies the study of manufacturing is the increasing share of generic drugs in Brazil, a market in which excellence in the stage of operations is critical to the survival of businesses, given the difficulty of obtaining price premiums in the marketplace.

The conceptual model was designed to investigate the relationship between the constructs "supplier", "transaction costs", and "organizational competences". The diagram with the representation of these relationships is shown in Figure 1. Its preparation takes as its starting point the model proposed by Jacobides & Winter (2005). These authors argue that the distribution of competencies defines the vertical scope with moderation of transaction costs. The approach to this model is similar, but considers only the organizational competences of the product's owner. This choice is justified to facilitate data collection, as the unit of analysis is the product launched recently. The model of Jacobides & Winter (2005) seems directed to the analysis of a population of firms, which would be obtained by measures of their competences to evaluate the uniformity of distribution. The choice of focus on competence analysis of the company holding the product is supported by Bigelow and Argyres (2008), who consider the influence of the company's experience in the industry on the choice of governance structure.

The construct "transaction costs" will be measured by the variables "asset specificity" and "bargaining power". The following are the hypotheses for these variables.

The asset specificity is an attribute often discussed in the literature of ECT as a factor in the choice of governance structure. The basic concept is that the greater investment in transaction-specific assets, the greater the tendency to adopt the hierarchy to coordinate this transaction, in relation to the contracting of external suppliers. The basic argument is that the existence of transaction-specific asset resulting from investments of the buyer leaves this agent in a disadvantageous position and subject to opportunistic behavior by the partner (Ruester, 2010).

Under these conditions there is a tendency to internalize the transaction for the firm. The hypothesis is as follows:

**H1** - The asset specificity of a product's manufacturing stage supports the choice of an internal supplier for this transaction.

With respect to the variable "bargaining power", it is related to the possibility of opportunistic behavior by the partner in the transaction by the phenomenon of "small numbers". This phenomenon occurs when a potential partner has a position of market power for that transaction, because he has few competitors, which can lead to hold-up behavior to take advantage of this situation of more bargaining power. When this is present, the other partner tends to avoid the transaction at market conditions, preferring vertical integration. This phenomenon was analyzed in the study of Pisano (1991), analyzing the governance structure choice for R&D activities in biotechnology. Thus, one can formulate the following hypothesis:

**H2** – The bargaining power of the product's owner, measured by the number of potential suppliers for the manufacturing stage of the product, supports the choice of an external supplier.

For the construct "organizational competences" the variables involved are "operations" and "partnerships". These categories follow Henderson & Cockburn (1994), who propose the measurement of competencies in the pharmaceutical industry. For these authors, the relevant competences in order to have success in R&D in the pharmaceutical industry are classified into two types: component and architectural competences. The component competences refer to knowledge about specific subjects that support the development of medicines and disease categories. The architectural competences are related to the ability to combine knowledge from sources outside the firm and between disciplines and areas of therapeutic classes within the firm. As the focus of the model is the manufacturing step, it is assumed that the variable "operations" reflects the component competences and the variable of "partnerships" will represent the architectural competences.

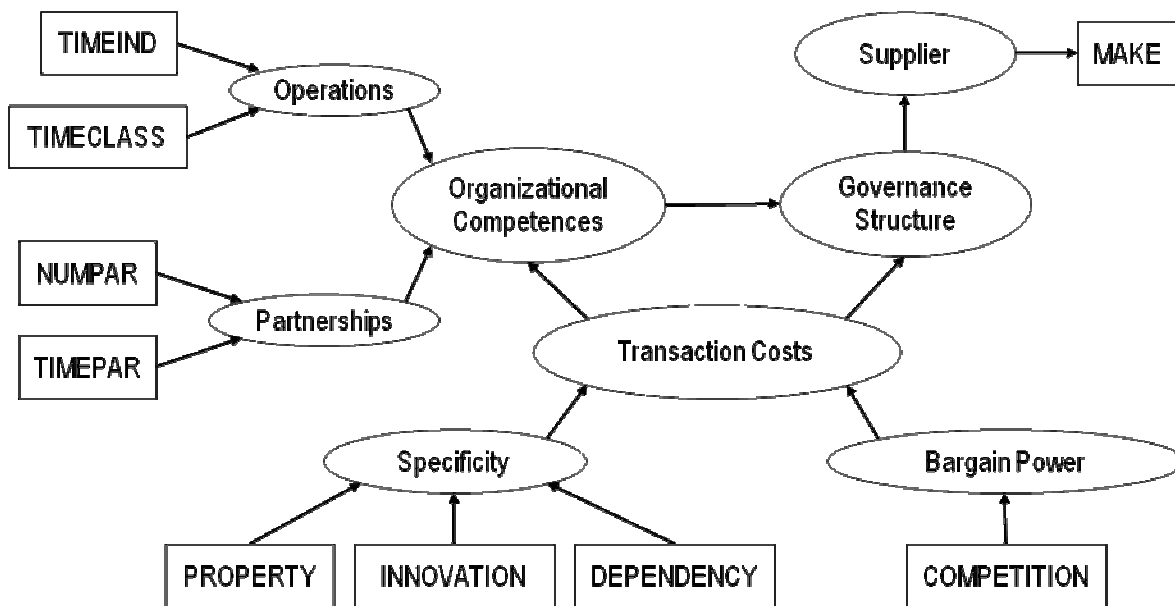
For the "operations", it is expected companies with more experience in manufacturing and in therapeutic class of the product have the necessary resources to carry out in-house manufacturing. Thus, we present the following hypothesis:

**H3** – The organizational competences in operations of the product's owner supports the choice of an internal supplier for manufacturing stage.

On the other hand, if the company has distinctive competencies in the creation of partnerships, expressed by the experience in this strategy and the amount of current partners, it is expected that she would prefer an external supplier for manufacturing. The hypothesis is as follows:

**H4** – The organizational competences in managing partnerships of the product's owner supports the choice of an external supplier for manufacturing stage.

**Figure 1** – Conceptual framework of the study



Source: Authors'

Below are discussed the indicators for the model variables.

The variable "specificity" is measured by indicators PROPERTY, INNOVATION and DEPENDENCY. The following are the arguments for the choice of indicators.

The indicator PROPERTY measures whether the released product has proprietary formula, using a dichotomous variable. The product with proprietary formula, with or without prescription, presents a company's brand. This indicates a condition of intellectual property of the molecule with therapeutic properties that could affect the perceived risk in choosing between internal or external supplier. It is assumed that if the formula is proprietary, the specificity is higher than the generic product whose formula is in the public domain.

The indicator INNOVATION is measured by a dichotomous variable to assess the presence of innovation in manufacturing stage of the product. Innovative products can be sold for higher prices than older drugs. Given the possibility of obtaining a contribution margin greater than the average for its portfolio, the company may choose to use an internal supplier to the manufacturing, although the cost of operation is superior to an external supplier. This option could also be justified by reducing the risk of opportunistic behavior of the supplier, such as hacking, industrial espionage or providing product information to competitors.

The indicator DEPENDENCY is measured by the percentage share of sales of the product class in relation to total company sales. In this case it is intended to capture the condition of the company's main products. The condition of higher sales product indicates a greater specificity and greater risks in hiring an outside vendor, since failure in this stage can damage a reputation built on the history of the product.

The variable "bargaining power" is measured by the indicator COMPETITION. As noted above, it represents the number of potential partners to hire as external supplier for manufacturing. It is assumed that the greater the number of possible partners, the greater the bargaining power of the product's owner.

The variable "operation" is measured by the indicators of competence related to the experience TIMEIND and TIMECLASS. The following are the arguments for the choice of these indicators.

The indicator TIMEIND is the operating time in the pharmaceutical industry. It reflects the product's owner experience, which tends to be reflected in increased capacity and lower production costs due the path followed on the learning curve. It is expected that companies with more experience can choose an internal supplier. The indicator TIMECLASS measures the operating time in the therapeutic class of the product. This experience can bring manufacturing competences that favor the choice of an internal supplier.

The variable "partnerships" is measured by the indicators of competence related to the experience TIMEPAR and NUMPAR. The following are the arguments for the choice of indicators.

The indicator TIMEPAR measures the time that the product's owner operates with partners. It is expected that the higher this time, the higher the propensity to choose an external supplier. The indicator NUMPAR measures the number of partners that the product's owner has at the moment. It is expected that the higher this number, the greater the propensity to choose an external supplier.

Data collection involves the following steps: (1) initial survey of products launched in the last 5 years in databases in ANVISA and industry associations, (2) aggregation and combination of information from various sources into a single database; (3) seeking information about the products on their websites, (4) search for information about corporate partnerships on their websites and archives of specialized media, (5) make a list of companies whose products, (6) to contact the companies to enable interviews to collect the missing information about products or send the questionnaires to be filled directly by them.

## **Final Considerations**

The article presented an effort to establish relationships between the approaches of transaction costs and organizational competences in order to explain the definition of governance structures. To that end, we developed a conceptual model to be applied in an empirical study on the structures of governance in the Brazilian pharmaceutical sector. According to the literature, there is a growing number of studies with similar goals and applied to various economic sectors. The application of the model seems promising in the pharmaceutical sector, given the possibility of obtaining secondary data products with ANVISA.

Despite this positive outlook, the study has limitations. The first, which is related to transaction costs, refers to the choice of indicators to measure the attributes of the transaction. Despite the attempt to construct objective indicators, they are still subject to the usual critical empirical studies of TCE. The case seems to be the most critical of asset specificity, which still depend on a subjective evaluation. The second limitation is related to the competence approach. The use of the experience of companies, while simplifying data collection, can be questioned in the case of any radical innovations in manufacturing, which could cause the loss of value of knowledge accumulated by firms.

The contribution of the study may be relevant for providing a research model adapted to the pharmaceutical industry, which is experiencing profound changes in technology and management. In addition, Brazilian companies have enormous growth potential, with appropriate support from public policy and institutional environment. Besides the application as proposed, it can be evaluated in the future to adapt the model for other industries.

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