



Transaction Costs and Organizational Competences: Explaining the Governance Structure for Manufacturing Stage

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Abstract

This article deals with the influence of transaction costs and organizational competences on the choice of governance structure for manufacturing stage in a productive system. The objective is to develop a conceptual model that explains the choice of supplier for manufacturing through transaction costs and organizational competences. Following earlier studies, the model proposes competences of the product's owner influence the vertical scope in a relation moderated by transaction costs. The constructs in the model are: "governance structure", the dependent variable categorized as internal or external supplier, "transaction costs", measured by asset specificity of the product and bargain power of the firm in the manufacturing stage, and "competences on operations", measured by experience and diversification of the firm. The study presents some methodological implications for applying the model in Brazilian pharmaceutical industry, through searching for secondary data on drugs and firms in a public database of the federal regulatory agency.

Keywords: Conceptual framework; pharmaceutical industry; firm boundaries.

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Introduction

This article deals with the influence of transaction costs and organizational competences on the adoption of governance structures for manufacturing stage in a productive system. The study follows a series of investigations that seek to establish relationships between the approaches of organizational economics and organizational competences (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 with Coase (1937), who presented the question on the reasons for the existence of the firm. The central argument of this seminal article is that the rising of cost incurred to conducting transactions in markets favors the incorporation of these transactions as internal activities of firms. Since the decade of 1970, these ideas have been 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 and involving external agents. The construct is the basic unit of analysis in TCE, which is described with dimensions of frequency, uncertainty and asset specificity. This last is prevalent in empirical studies and indicates the potential for loss of investments incurred in a transaction, if that does not take place. In this approach, the governance structure adopted is the result of a rational choice to minimize transaction costs, mainly due to the hazard of opportunistic behavior by the counterpart in a transaction.

The approaches of organizational competences have sought to understand the processes of adaptation and change in organizations as ways of adjusting to changing environments (Bataglia & Meirelles, 2009, 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 routine's 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 in the last decade, especially since the creation of generic drugs regulatory category, by Law no. 9.787/99 in 1999. Until the late 1990s, the market consisted of two categories "innovative drugs" produced largely by global industry leaders and launched under its own brand and "similar drugs", copies with the same active ingredients and pharmaceutical formulations of innovative products, usually released by mid-sized and small companies, predominantly with domestic capital. The advent of generics, which are obtained from formulas whose patents expired, created an alternative with products that have equivalence with the reference product and are certified by laboratories accredited by the federal drug regulation agency, entitled National Health Surveillance Agency (ANVISA - Agência Nacional de Vigilância Sanitária) (Quental et.al. 2008).

The proposed research problem in this study is: what is the influence of transaction costs and organizational competencies in the make-or-buy decision for manufacturing stage? The general objective of the study is to develop a conceptual model that explains the choice of supplier for 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 assumed that a point of contact between the approaches may be the choice of governance structure, to be explained by transaction costs and organizational competences.

The second justification is to offer methodological tools for empirical studies on the management of transaction costs and capabilities in the Brazilian pharmaceutical industry. Understanding the determinants of adoption of governance structures in the value chain can help guide public policies in the areas of financial support and innovation. Private agents could benefit from knowing the firm boundaries of competitors in manufacturing stage. The study evaluates the possibility of applying the conceptual model for the manufacturing step in a globally dynamic industry such as pharmaceuticals, which is changing in Brazil with the growth of national laboratories (Ferreira, 2010).

The study is structured in eight parts, including this introduction. The second section presents the main concepts of Transaction Cost Economics, followed by a brief discussion of the organizational competences approach in the third and the relations between the theories in the fourth. An overview of the pharmaceutical industry is the subject in the fifth section, the conceptual model with variables and hypotheses are presented in the sixth section, and in the seventh there are some methodological implications applying the model. The last section presents the final considerations.

Transaction Costs Economics

The main conceptual movement of TCE is to describe firms not in terms of neoclassical economics (production function), but with an organizational approach (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 from an external agent or the incorporation of input manufacturing 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. He argues that opportunism is relevant to raise the transaction costs in situations where there are specific assets and contracts are incomplete. He 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). He 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 the level of uncertainty, the greater the need for subsequent adjustments to investments in specific assets. Thus, it is expected the predominance of hierarchical relationship, in which one party has control over both sides of a transaction, since this structure can provide greater ease for the 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 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. He argues 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 can be presented as examples of this methodological approach, such as 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 adopt vertical integration 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 human capital specificity 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 and changing environments. 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, in routine 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 (Bataglia, Silva, & Klement, 2011).

The construct of organizational knowledge has been treated by Dosi, Nelson & Winter (2000) 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 (Bataglia & Meirelles, 2009). The first is selective environment, characterized by the demands of the competition. The second is the adaptation of firms, focusing on strategic decision making (Bataglia & Yu, 2008), 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 analyze firms as independent 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 with each other 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). Assets controlled by two or more firms are considered complementary when their combined economic values are larger than their value in 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 or segments; 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 access to new technology, speed to market and complementary capabilities (Kogut, 1988; Eisenhardt & Schoonhoven, 1996). Momigliano & Balcet (1983) also point to other factors to encourage international cooperation agreements: (a) technology

features, (b) diversity of nature and economic destination for international operations, (c) impact of new technologies on the scale 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 outcomes of the combination of TCE and organizational competences approaches to study 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 the area of strategic management, with significant growth in business schools, has not advanced in developing a theory of the firm. Using concepts from transaction costs theory, agency theory and dynamic capabilities approach, he elaborates a conceptual model to establish the basis for a future contractual theory of the firm. He proposes to expand the concept of the firm as 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 research and development (R&D) stage in manufacturing firms were analyzed by Nakamura & Odagiri (2004). Through a study of data on 14,000 companies in Japan, they 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 R&D resources. 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, organizational competences and networks of firms approaches, he 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.

In a qualitative case study, Di Serio et al (2011) analyzed the outsourcing process adopted by Phillips for producing LCD televisions make or buy decision. The executives pointed out that the LCD panel is an important resource and that its supply by third parties represented a high transaction cost. Some disadvantages of outsourcing can be found in the model adopted by Philips: the probable loss of capabilities that are important for operating in the LCD television segment and the difficulty in creating and managing legal contracts. The authors sought to explore the supposed theoretical complementarity between Resource Based Theory (RBT) and the Transaction Cost Theory (TCT). The TCT approach is based on an economic bias and suggests short and medium term analyses of outsourcing processes, while the RBT approach, because it has a strategic bias, ends up suggesting longer term analyses, since it is concerned with future competitive positioning.

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 the occurrence of 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 automakers 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 production. 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. They 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 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 the following aspects: (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 and the research was developed internally by companies. The introduction of new chemicals into the main developed markets 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, a phase of profound change begins in the pharmaceutical industry, from the emergence of a new technological paradigm with molecular biology and genetic engineering (direct manipulation 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 based on the idea of the firm (NBC) possessing valuable intangible capital in knowledge on products or processes, which is protected by an adequate intellectual property rights system. This kind of firm becomes attractive to investment capital - venture capital, not only to fund the projects, but also to 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, NBEs got financial resources needed to finance R&D, and structure to development, testing, production and marketing of products (Coriat et al. 2004; McKelvy et al., 2004).

The complementarities between biotechnology and pharmaceutical companies were mentioned by Hernández-Cuevas (2007), when he analyzed the future of drug discovery process in bio pharmaceutical corporations. Biotechnology firms are mainly concerned with the generation of new drugs using breakthrough technologies, while pharmaceutical corporations are usually cash-abundant and can buy innovation from Biotechs. Then, Bio Pharma can effectively take those novel drugs and navigate them through the regulatory affairs conundrum and subsequently bring them onto the global market place

successfully. The authors argue it is vital that Biotechnology and Pharmaceutical companies come up with appropriately balanced deals where the contributions, rewards and strengths of each collaborating party are clearly recognized. This is especially relevant as biotech and pharmaceutical companies are turning with increasing frequency to in-licensing and collaboration agreements.

While the state of the art in the global pharmaceutical industry the collaborative innovation on biotechnology, in emerging countries the technological status of domestic firms is situated some steps behind. This is the case of China, which is treated by Ding et al (2011), with a description of how the historical, legal, and institutional contexts in which China's drug R&D has evolved. According to the authors, China's drug R&D evolution can be viewed to have four phases: (1) pure imitation (1949 – 1985), (2) innovative imitation (1984 – 1993), (3) imitative innovation (1992 – 2008), and (4) independent innovation (2008 –). In Phase I, pure imitation, the pharmaceutical firms fully depended on copying synthetic methods and preparation technologies of drugs from foreign companies. In Phase II, innovative imitation, China's drug innovation was mainly based on modifying delivery methods and preparation formulations of existing drugs without changing the drug molecular structure. In Phase III, imitative innovation, drug innovation was focused on chemical modifications of the structure of existing drugs, such as changing acid or basic group, altering optical configuration, and developing isomers of original drugs to develop "me-too" drugs. Finally, in Phase IV, independent innovation, Chinese companies will be able to discover new chemical entities (NCEs) using advanced innovation technologies (Ding et al, 2011).

The value chain in the pharmaceutical industry is composed by the following four stages: (1) research and development (R&D), (2) active principle production, (3) pharmaceutical specialty production (drugs), (4) marketing and commercialization of pharmaceutical specialty. In this global context, international companies incorporate each stage activities according to the technical development level of the country where they are established (Silva & Oliveira, 2007).

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, 50% of the active ingredients of the drugs were imported and 90% of drugs released in the market stemmed from research done abroad. At that time, the low relevance of R&D in Brazilian companies was influenced by the lack of financial resources and an articulated innovation system needed to fund and encourage the development of R&D projects, which are of long maturity (Capanema, 2006).

A relevant initiative by the Brazilian government in the 90' to promote the pharmaceutical sector and others was PITCE - Política Industrial, Tecnológica e Comércio Exterior (Foreign Trade, Industry and Technology Policy Directives). Silva & Oliveira, (2007) conducted a comparative analysis of the sector between 1993 and 2003, and found few improvements in reducing the active principle and drug foreign dependence or promoting domestic production and demand in order to the country be promoted to the position of a great player in the active principle and drug world market. However, the authors argue that the PITCE measures comprise a complete answer inserted in what we here conventionally call "modern industrial policy".

The main vertical measures in this program for pharmaceutical industry are: export fomenting, including improving the export schedule and replacing imports competitively, development and integration of domestic industrial complexes, credit support for restructuring and fomenting technological upgrade, subventions and direct and indirect fiscal-financial assistance through reducing tax burden, performance and counterpart requirements for sectors assisted by governmental benefits, temporary and selective tariff protection for specific sectors to be developed, foreign risky investment performance requirements and State purchase use and direct intervention in the restructuring the sector (Silva & Oliveira, 2007).

The pharmaceutical industry in Brazil and particularly the national groups, received greater incentive to invest in production from the Generic Drug Law (Law 9787), passed in 1999, which allows the replacement of drugs

with a similar after the expiration of the patent with guaranteed quality by regulatory authorities.

In 2005, Brazil was in 10th position in the global pharmaceutical market, with revenues of USD 22.2 billion, equivalent to sales of 1.61 billion units (Capanema, 2006). 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%.

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. As Caliar & Ruiz (2010), 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. Thus, policy implementation for generics has resulted in increased scale of production by domestic firms.

Conceptual Model

This section presents a conceptual model for explanation of governance structures in the manufacturing stage 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 and organizational competences to explain the choice of governance structures. This author 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.

Two delimitations were chosen in the model design: the first for the construct “governance structure” and the second concerning the transactions to be analyzed. The

theme of governance structures involves an extensive field research, specifically for hybrid structures. In this subject, 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 governance structures, with the delimitation of the analysis to the choice of the supplier in transaction, following Hoetker (2005). In this model we consider the choice of governance structure with the type of supplier (external or internal). The model considers a variable often used in empirical studies of transaction cost theory, which is the choice between “make” (internal supplier) or “buy” (external supplier). With that the construct becomes simpler, which makes easier the analysis of the influence of independent variables in future empirical studies.

The second delimitating choice is the focus on transactions of manufacturing stage. 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 stage has received great attention from public officials and businesses in the Brazilian pharmaceutical sector. This process can be observed in the case study by Nogueira (2011) with the Brazilian laboratory Aché, a corporation with more than forty years of operation, 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 strategy the company has accumulated manufacturing expertise and resources to increase market share and generate resources for innovation activities in new products, which have been carried out in more recent years. Another aspect that justifies the study of manufacturing is the increasing share of generic drugs in Brazil, a segment where excellence in the operations stage is critical to the survival of businesses, given the difficulty of obtaining price premiums.

The conceptual model was designed to investigate the relations between the constructs “governance structure”, “transaction costs”, and “competences on operations”. The diagram with the representation of these relations 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 productive capabilities defines the vertical scope with moderation of transaction costs. The approach to the present model is similar, but considers only the organizational competences on operations of the firm that owns the product. This choice is justified by the adoption of the product as the unit of analysis and by making easier to evaluating the influence

of the firm's competences on a specific transaction. The model of Jacobides & Winter (2005) is directed to the analysis of a population of firms in an industry, where the distribution of capabilities could be measured. The focus on competence analysis of the company holding the product is supported by Bigelow & Argyres (2008), who consider the influence of the company's experience in the industry on the choice of governance structure.

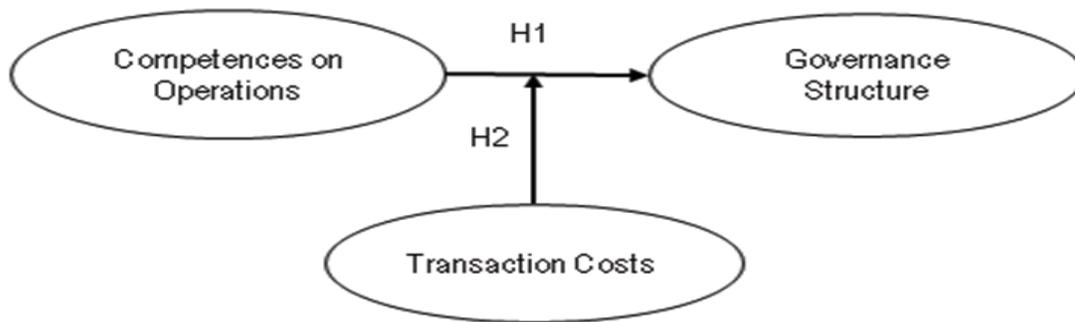


Figure 1. Logical diagram of the conceptual model to explain the governance structure choice for manufacturing stage

Drawing upon Dosi, Nelson & Winter (2000), Kogut & Zander (1992), and Jacobides & Winter (2005) it is expected that the limits of the firm be defined by the organizational knowledge stored and expressed in processes or routines, which is particularly true in the manufacturing stage. In this approach, the firm offers an environment for exchanging experiences and organizational learning by the employees in formal or informal groups, and it establishes the conditions for an appropriate level of specialization in the different stages of the value chain. It is proposed the following hypothesis:

H1 – The competences on operations of the firm that owns the product supports the choice of a governance structure with internal supplier for the manufacturing stage.

According to Jacobides & Winter (2005), the relationship between distribution of competences in a population of firms and the vertical scope in a productive chain is moderated by transaction costs. In the present model it is argued that this situation also could be present in the relationship between the competences of the firm that owns the product and the governance structure adopted by this firm for the manufacturing stage of that product. High level of transaction costs could reduce the propensity of the firm with a low level of competences on operations to choose an external supplier for the

manufacturing stage. By the other hand, when firm had the required competences a low level of transaction costs could reduce the tendency for the choice of governance structure with an internal supplier for the manufacturing stage. The proposed hypothesis for the moderation relationship is as follows.

H2 – Transaction costs reduce the significance of the support offered by competences on operations by the firm that owns the product for the choice of a governance structure with internal supplier for the manufacturing stage.

In the present model, the construct “competences on operations” will be measured by the variables “experience” and “diversification”. The construct “transaction costs” will be measured by the variables “asset specificity” and “bargain power”. The diagram of the model with these variables and respective hypotheses are presented in the Figure 2 and discussed in the following paragraphs.

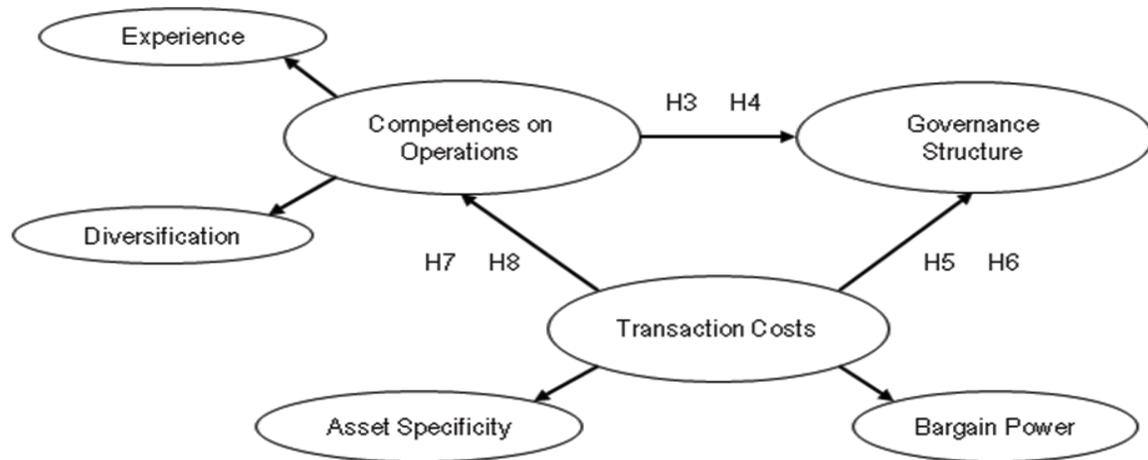


Figure 2. Diagram of conceptual model with constructs and respective variables, for explaining the governance structure choice in manufacturing stage.

The adoption of variable “experience” follows Henderson & Cockburn (1994), who propose the measurement of competencies in the pharmaceutical industry. For these authors, the relevant competencies 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 disease categories and specific subjects that support the development of medicines. 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 stage, it is assumed that “experience” may be relevant and could be measured by time of the firm in the industry and scale of production. This variable is associated with the relevant component competences, which in turn could influence the choice of governance structure. It is proposed the following hypothesis:

H3 – The experience on operations of the firm that owns the product supports the choice of a governance structure with internal supplier for the manufacturing stage.

The variable “diversification” reflects the range of different types of products delivered by the firm. In the pharmaceutical industry the product could be described by the pharmaceutical form, therapeutic class and regulatory category. It is expected that successful pharmaceutical firms should have an efficient minimum size and offer a diversified portfolio of products, in order to obtain

economies of scope in the productive system and the management of risks in the R&D for delivering new products in the marketplace (Bogner, 1996). A diversified portfolio can influence the competences on operations by exposing this functional area to a broader range of pharmaceutical forms. In this sense, these characteristics in capabilities could favor the firm to carrying out in-house manufacturing. The hypothesis is as follows:

H4 – The diversification in operations of the firm that owns the product supports the choice of an internal supplier for the manufacturing stage.

The asset specificity is an attribute often discussed in the literature of TCE 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 one partner leaves this agent in a disadvantageous position and subject to opportunistic behavior by the other partner (Ruester, 2010). Under these conditions there is a tendency to internalize the transaction for the firm. The hypothesis is as follows:

H5 – Asset specificity supports the choice by the firm that owns the product of a governance structure with internal supplier for the manufacturing stage.

With respect to the variable “bargain 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 treated by Pisano (1991), who analyzed the choice of governance structure for R&D activities in biotechnology industry. Thus, the proposed hypothesis is as follows:

H6 – The bargain power in relation to other firms supports the choice by the firm that owns the product of a governance structure with external supplier for the manufacturing stage.

The relationship between “transaction costs” and “competences on operations” are less explored in the literature and present some difficulties to be depicted by researchers because each one is associated to distinct objects, respectively the transaction and the firm. However, it can be assumed that that the transactions carried out by the firm can influence its productive capabilities. According to Jacobides & Winter (2005), the productive capabilities rest on the firm’s general and specific knowledge to do things and also involve specific investments in equipment, training and retention of key personnel required to put that knowledge to work.

The assumption of the moderation function of transaction costs on the relationship between distribution of productive capabilities in a population of firms in an industry and the vertical scope is argued by Jacobides & Winter (2005) in the short-term model they present. These authors offer two hypotheses: (1) if capabilities are dissimilar along the value chain, then latent gains from trade across firm’s boundaries exist, then a reduction in transaction costs will lead to substantial disintegration, and (2) if capabilities are similar along the value chain, then there are no latent gains from trade across firm boundaries, then a reduction in transaction costs will not lead to substantial disintegration.

A critical vision on this approach is presented by Argyres & Zenger (2011). They recognize that empirical research in the literature corroborate this straightforward application

of comparative capabilities logic to boundary choices. However, they argue that transaction costs and capabilities determinants of firm boundaries are intertwined in a particularly dynamic way, namely, in forming capabilities originally, and in deciding whether to retain, develop or sell them off, transaction cost considerations have relevance. They focus on how organizations consciously develop their capabilities in their early and later boundary decisions, and consider that, in addition to simple serendipity, the distribution of capabilities across firms and their suppliers at any point in time reflects transaction costs operating in the past or present.

In the present model it is argued that transaction costs, besides their direct influence on the choice on governance structure with internal supplier, could be a driver for the development of competences on operations. When the organizational learning strategy is feasible, this could be done in order to allow the choice of a more coordinated governance structure, such as the hierarchy, for the specific transaction. In this sense, it is expected that in the short term, the higher the transaction costs in transactions carried out by the firm, the higher the competences of the firm required for that transactions. The hypothesis is as follows.

H7 – Asset specificity in manufacturing stage support the competences on operations of the firm that owns the product, which support the choice of a governance structure with internal supplier for the manufacturing stage.

The bargain power of a firm in a transaction in the value chain of a product depends on at least two factors: (1) the dissemination of the technology involved in the transaction, (2) the number of suppliers operating with the technology in that transaction. The dissemination of the transaction’s technology is the frequency or the percentile participation of its adoption in the population of products in the industry. This level of adoption is associated to the technological evolution and emergence of standards in the industry for this transaction. The dissemination of the transaction favors the number of suppliers and increases bargain power of the firm that owns the product, since it reduces the risk of opportunistic behavior by potential suppliers. In this sense, the adoption of a product with technological attributes widely spread in the market reduces the need for the development of all the required competences to carry out the activity, since an external supplier could be contracted under favorable conditions due to the bargain power of the firm that owns the product.

Given the dissemination level of the technology, it is necessary to evaluate the number of suppliers for the transaction, or the market factor concentration. The more the number of suppliers greater the bargain power of the firm that owns the product. If the firm possesses this bargain power due to the large number of suppliers, this could be a negative incentive for the development of competences required for the activities involved in the transaction and the subsequent choice of a more coordinated governance structure, such as the hierarchy. This expected effect on competences could be in support of the direct influence of bargain power on the choice of a governance structure with an external supplier. The hypothesis is as follows.

H8 – Bargain power of the firm that owns the product in relation to other firms in the manufacturing stage reduces competences on operations.

The model and hypotheses presented are an effort to deepen the comprehension for the role of capabilities and transaction costs for the choice of the limits of the firm in the manufacturing stage of a product. The variables in the model must be deployed in measurable indicators to allow data collection and hypotheses testing by multivariate analysis. In the next section a brief discussion on possible approaches to be followed by researchers in order to test the model in the Brazilian pharmaceutical industry.

Methodological Implications

The study of a strictly regulated industry by federal legislation and regulatory agencies such as pharmaceutical industry can offers the advantage of data availability in public databases. In the Brazilian pharmaceutical industry, the federal regulator ANVISA has increased in recent years the amount of information publicly available in the website of the institution. One of the public databases that can help researchers to apply the model presented in this study is called *Bulário Eletrônico*, (Electronic Drug Label Database). It is a searchable database hosted in the website of ANVISA (<<http://portalanvisa.gov.br>>) containing drugs labels in PDF files to be found by the following fields: name of drug, name of pharmaceutical formulae, name of the firm that owns the drug, pharmaceutical form, presentation and concentration, and regulatory category of the drug.

When a consultant submits a query, the system shows all the fields cited above plus the pharmaceutical form, the type of drug label with respect the legislation, the date of approval of the drug label, and a link for the PDF file of the drug label, to be presented in the web browser or to be downloaded. In the drug label it is possible to identify the pharmaceutical form, the therapeutic class and the governance structure of the manufacturing stage, since ANVISA must inspect and approve the industrial plants of the firm that owns the drug and of the partners in contracts for supplying manufacturing services. In this sense, this system and each drug label provide the information about the limits of the firm in the productive system for each product, which can be used as the dependent variable in the proposed conceptual model.

In order to find the indicators for the independent variables of the model, the following attributes of a drug could be explored: pharmaceutical form, therapeutic class and regulatory category. The pharmaceutical form of a drug is the physical aspect adopted to deliver the drug. The main categories are related to physical states, such as solid (pills, capsule, and others), semi-solid, liquid and gases. Besides these basic properties, the form may present some specific functionality relative to the application of the drug in the human body. An exhaustive analysis of the database can reveal the existence of at least seventy different pharmaceutical forms, which could be grouped according basic and specific attributes.

The therapeutic class is the attribute relative to the function of the drug, which can be classified in two levels: 13 anatomic categories, relative to organs and systems of the human body, grouping specific 72 therapeutic sub categories, relative to different diseases or effects generated by the drug. This method of classification is called *Anatomic Therapeutic Chemical (ATC)*, which was defined by the World Health Organization (WHO, 2010) and is suggested as an internationally standard for drug classification. The regulatory category of the drug is defined by ANVISA and is related to intellectual property (new, similar or generic drugs) and technological aspects (drugs derived from plants or biotechnological processes). Searching and classifying drugs with these criteria could be useful for researchers in order to analyze the competences of operations of the firm that owns the product, which is deployed in experience and diversification, and transaction costs in the manufacturing stage of the product, which is deployed in asset specificity and bargain power.

Data collection could be done in the following steps: (1) collection of data on drugs in the Bulário Eletrônico, (2) classification of pharmaceutical form and therapeutic class based on standards accepted in the industry (3) to search information about the firms that owns the drugs on their websites, (4) run the multivariate analysis to test the hypotheses. (5) to analyze and discuss the results, contrasting with the theory.

Final Considerations

The paper presented an effort to establish relationships between the approaches of transaction costs and organizational competences in order to explain the choice of governance structures in the manufacturing stage of a product. To that end, we developed a conceptual model to be applied in an empirical study on the governance structures 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 of drugs in a public database of ANVISA.

Despite this positive outlook, the study has limitations. The first refers to the choice of estimating transaction costs only by asset specificity and bargain power. The option of neglecting the attributes of frequency and uncertainty could be justified by the lack of operational measures in the database to be used to test the model in the pharmaceutical industry. The case of bargain power adoption is an attempt to contribute to deep the comprehension of the influence of this aspect on the choice of governance structure, which has been neglected in the TCE literature. The second limitation is related to the competence approach. The use of the experience of companies as a proxy for the competences on operations, 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 the fitness of the model for other industries.

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