INVESTIGATING THE ROLE OF REGIONAL TECHNOLOGICAL INNOVATION SYSTEMS IN ALLIANCES FOR NEW PRODUCT DEVELOPMENT IN THE BIOTECHNOLOGY INDUSTRY

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Abstract

Due to the complex nature of biotechnology, knowledge within the field tends to be fragmented and distributed among diverse organizations operating within various economic sectors, which interact through contractual strategic alliances in an effort to create, disseminate and use new products and processes. This theoretical paper proposes that the dynamism within such Technological Innovation Systems (TISs) at the regional level influences the transaction costs of the strategic alliance in developing new products and the relational capability of biotechnology companies, thus moderating the relationship between these two constructs. A combined structural and measurement model that involves these constructs is used to test this theory. The proposed theory suggests that strategic decisions regarding the location of biotechnology and pharmaceutical companies should prioritize regions with developed, structured and dynamic technological systems. From the public policy standpoint, it is suggested that government programs should include specific policies for developing biotechnology technological systems in regions of interest, thus encouraging investment in research as well as integration and interaction among regional organizations such as industry associations, universities, research institutes, companies and government agencies. Future studies in other industrial sectors that are also characterized by the use of strategic alliances in the development of new products, such as the software industry, might improve the proposed theory.

Key words: Technological Innovation Systems , Biotechnology Industry, New Product Development

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1. Introduction

Technological advances in the pharmaceutical industry through the development of biotechnology and molecular biology together with shifts in demand and the institutional environment have led firms to increase spending on research and development, innovative processes and new forms of governance (Powell & Koput Owen-Smith, 1996).

Biotechnology is an area of knowledge that is present in many economic sectors, being characterized as a Technological Innovation System (TIS), in which the knowledge or technological expertise is fragmented among various organizations and institutions that interact through contractual strategic alliances, in an effort to create, disseminate and use new products and processes. These alliances are characterized by relational contracts that promote the sharing of complementary capabilities in order to carry out joint activities (Edquist, 1997; Powell, Koput & Owen-Smith, 1996; Powell, White, Koput & Owen-Smith, 2005). The capabilities required of these companies can no longer be developed in isolation, since their performance depends on their centrality in the network of strategic alliances (Powell, Koput, Smith-Doerr & Owen-Smith, 1999).

In addition, as Powell, Packlen & Whittington (2012) have explained, the biotechnology industry has developed from clusters or regional blocks. Given the strategic importance of this industry and the need to deepen our understanding of the dynamics of its development, this paper aims to theoretically explore the relationship between the biotechnology TIS, considered at the regional level, the relational capacity of biotechnology companies and the attributes of the transactions within the strategic alliances for the development of new products. In this way, we seek to move towards providing a theoretical framework that integrates the organizational economics, organizational capabilities and innovation systems approaches and promotes the improvement of advanced management techniques within alliances for the development of new products and of public policies designed to stimulate the sector.

The article begins with a review of the theory regarding the biotechnology TIS and strategic alliances and the presentation of the biotechnology TIS. Then, the construct 'transactions within the contractual strategic alliance' is defined and its relationship with the TIS is discussed. After which, the influence of the TIS on the relationship between strategic alliances and relational capability is analyzed. Finally, the combined structural and measurement model used to test the proposed theory is introduced and some final remarks are made regarding the study.

Theoretical Background

The technological innovation system (TIS) in the biotechnology industry

Both public officials and business people have begun to discuss economic development in relation to the innovative processes of a nation or region specifies. Regionality and its peculiarities are important factors in any potentially productive development, which can produce advantages in relation to the industrial cluster and the

promotion of innovative activities (Ashein & Isaksen, 2003; Di Benedetto, Desarbo & Song, 2008). However, Florida (1995) calls attention to the fact that regionality alone is not sufficient to generate development, an institutional framework is necessary so that knowledge can be born and spread. To Mackinnon (2008), in a climate of rapid technological change and increased capital mobility, regions are able to shape their own development prospects. According to Cooke (1998), the ability of regions to support learning processes and innovation has been identified as a major source of competitive advantage, depending on the interaction between factors such as infrastructure, access to natural resources, institutional endowment, and knowledge and the skills available in the territory as well as the development of hard-to-imitate capacities that are cumulative by character.

The Technological Innovation System (TIS) emerges as a way of characterizing the various interactions between institutions, business and government in a specific field of knowledge and the way in which each agent behaves in relation to the creation, dissemination and use of knowledge. In this sense 'system' is understood as a set of interrelated components (agents) working for a common goal. A 'system' is made up of components, relationships and attributes. 'Technology' is defined as the ability to recognize technical problems and develop new concepts and tangible solutions (Autio & Hameri, 1995).

> […a TIS is] a network or set of networks of agents interacting in a specific economic/technological area under a particular institutional infrastructure in order to generate, disseminate and use technology. TISs are defined in terms of flows of knowledge/skills instead of flows of common goods and services. They consist of dynamic knowledge and competence networks. In the presence of an entrepreneur and sufficient critical mass, these networks can be transformed into development blocks, i.e., sets of synergistic companies and technologies within an industry or group of industries. (Carlsson & Stanckiewicz, 1995, p. 49)

The concept of TIS does not imply the study of single a given technology, but it helps to understand the dynamics between technologies, the development of industries and the development of the innovation system (IS). A single technology can "transit" among many Innovation Systems (e.g., biotechnology in the national health sector) and "transit" among more than one sectoral system of innovation (e.g., biotechnology in the human health, agribusiness, and inputs sectors among others). According to Carlsson (1997), a technological system goes beyond the nation-state and focuses on knowledge about technical issues in relation to industrial networks and economic development. Therefore, the objective of the TIS is to identify the role of technological change in economic development. The structure and dynamics of the technological shift may vary considerably over time and in different domains. These variations modify the course of action adopted by institutions and economic organizations (Carlsson, et. al. 2002).

According to Stanckiewicz & Carlsson (1995), with the support of business people and a sufficient critical mass (researchers), a given TIS can transform network alliances into development blocks, i.e. sets of synergistic businesses and technologies within an industry or a group of industries. Powell, Packalen & Whittington (2012) identify these blocks in their analysis of the causes of development in the biotechnology industry in three regions in the USA. The authors conclude that the existence of an "anchor" enterprise, a dense network of local relationships and the presence of profit and nonprofit-making organizations are key factors for the emergence and development of development blocks, as conceptualized by Carlsson & Stanckiewicz (1995). According to these authors, the development and economic

growth of the blocks have their origin in the experience (when it becomes cumulative) and in the formation and management of networks of alliances. Strategic alliances are antecedent factors in the generation of patents in biotechnology companies (Estrella & Bataglia, 2013; Powell, Koput, Smith-Doerr & Owen-Smith, 1999).

Carlsson *et. al.* (2002) describe the three dimensions that form technological systems: (1) the cognitive dimension, (2) the organizational and institutional dimension, and (3) the economic dimension. The cognitive dimension defines the grouping of skills that result in new technological possibilities. The organizational and institutional dimension describes the interactions and networks of the agents involved in the creation of those technologies. The economic dimension defines the actors who turn technological possibilities into business opportunities in an economic activity. According to these authors, there is a correlation between the three dimensions, but each has its own dynamic and can be an independent source of change in the TIS.

According to Asheim & Gertler (2005), specific knowledge, skills, organizational structures and behavior are elements that characterize a TIS. The interaction of these elements within the system occurs through processes of cooperation and communication between the agents (public and private institutions), which results in the adoption of new technologies. According to Autio & Hameri (1995), the limits of a technological area follow the boundaries of an industry or group of industries.

Given the importance of these relationships, Carlsson *et. al.* (2002) suggest that TISs should be analyzed based on four basic premises: (1) the system as a whole must be considered the main unit of analysis; (2) in order to follow the evolution of the system over time, there must be constant feedback, i.e. the dynamics of the system must be recognized; (3) the recognition that the contribution of the approach lies in its ability to identify, absorb and exploit global technological opportunities; and (4) it should be recognized that each agent that within the system has bounded rationality, i.e. the agents are rational, but operate under capacity constraints and limited information. The TIS is not a static system, but evolves with technological shifts and through interaction among the agents that comprise it and, over time, new technologies appear and must be incorporated into the TIS (Rickne, 1999; Powell & Brantley, 1992).

According to Van Beuzekom & Arundel (2006, p.7), the term biotechnology is "the application of science and technology in living organisms or parts of them, in their natural or modified forms, in innovative ways, for the production of knowledge, goods and services, which are found in numerous sectors such as agriculture, energy, pharmaceutical, organic chemistry and environment (Powell and Brantley, 1992). Biotechnology is part of the productive base of several industries, including the pharmaceutical industry. It refers to the use of scientific principles and/or technologies based on microbiology, genetics, biochemistry, chemistry and chemical engineering, for transforming material with the aid of biological agents for obtaining goods, services and processes (Van Beuzekom & Arundel, 2006), and constitutes an area of knowledge that requires a multidisciplinary approach to its creation, dissemination and use, thus requiring the interplay of actors - government, private companies, research foundations and universities - for its development.

Corroborating this idea, Khilji, Mroczkowski & Mernstein (2006) report that the biotech industry operates within a high degree of uncertainty and rapid technological changes. This industry, in the view of these authors, faces problems with the rising costs of research and development, global competition and a lack of critical mass that interferes with the

benefits of economies of scale. For Carlsson *et. al.* (2002), these relationships favor the synergic evolution of companies and technologies within an industry or group of industries.

Transactions within the contractual strategic alliance

By focusing its attention on economic transactions, Transaction Cost Theory (TCT) adopts a microanalytical approach to the study of the economic organization. The basic argument of TCT is to recognize that in a world of positive transaction costs, trade agreements need to be governed, and that, depending on the transactions to be organized, some forms of governance are better than others. A transaction "occurs when there is a change in the technology phase – the transfer of goods through technologically separable interface" (Riordan & Williamson, 1985, p. 365).

Transaction costs arise mainly because of the limited rationality and opportunistic behavior on the part of agents (Williamson, 1985, 1991). There will always be limitations to the capture, processing and communication of information. Consequently, in a transaction, the holder of the highest level of knowledge can act to benefit from that situation. Insufficient knowledge to foresee all the contingencies involved in a transaction leads to inadequate contracts. Individuals are aware of the need to adjust and renegotiate contracts *ex-post* in order to overcome the shortcomings that are typical of such contracts.

Williamson (1985) stresses the need for governance in transactions. The governance structure of a transaction can take three forms: the market (spot), hierarchy and mixed or hybrid forms. Choosing the most appropriate form is comparative and depends on the transaction costs. The market-guided governance occurs via the price system, which governs the transaction based on demand, assuming economies of scale and scope, allowing less influence on the part of the firm. The hierarchy-guided governance, also known as vertical integration, is based on the internalization of activities for the development of the good or service necessary to the firm. It is seen as being the opposite of market-guided governance because the governance of the firm is performed by the bureaucratic hierarchy. Finally, hybrid governance assumes that the price system is not enough, thus additional coordination mechanisms are deemed necessary. However, there may be insufficient incentive for vertical integration, for example, due to the cost of futures options. Hybrid forms include strategic alliances, cooperatives, franchises and joint branding, among other organizational forms, in which the autonomy of firms participating in the transaction is maintained.

Over the years, the importance of the hybrid structure of governance has increased (Ménard, 2004, 2005; Osborn & Hagedoorn, 1997). This is due to the diversity of organizational arrangements that it can take and the fact that this type of governance allows partner companies to integrate part of the transactions in which they are involved and share a subset of decisions. Williamson (1991) conceptualizes the hybrid form as forms of collaboration – interrelation - between firms, which maintain distinct property rights, but share decision-making.

Pisano (1991) and Gulati (1998) define a strategic alliance as a long-term voluntary agreement, based on relational contracts between autonomous firms, which are designed to facilitate trade in new products and services as well as the development of new products and technological processes. An alliance should be seen as a dynamic entity, a complex interaction of interpersonal and business activities (Ranf & Todărița, 2009). The formation of alliances is anchored in the need for businesses to adapt to environmental stimuli, thus breaking with organizational inertia and promoting an increase in the strategic flexibility of firms while increasing the number of strategy options available (Doz, 1996).

In the literature, there is a variety of types of strategic alliances, which are based, especially on legal or economic criteria. The types who resort to legal attributes use the following dimensions in their classification: types of agreement relative to the legal form (type of contract) (Yoshino & Rangan, 1995) and the establishment or otherwise of a legally independent entity (Faulkner, 1992). On the other hand, the types that involve essentially economic criteria relate to the activities that are the goal of the cooperation, the involvement of capital (Faulkner, 1992), the goals of the alliance, the type of asset management and the context of the alliance (national, international or other) (Root, 1988).

To simplify the classification of alliances, Barney & Hesterly (1996) proposed two main classes of strategic alliance: contractual and joint ventures. Both are characterized by the union of two or more firms to create a cooperative relationship aimed at developing, designing, producing, marketing and distributing products or services. What differentiates one from the other is the fact that the joint venture represents the creation of a new firm, while, by contrast, in contractual strategic alliances, no new firm is created.

The strategic alliance contract occurs when two or more organizations decide to join forces to achieve a common strategic long-term goal (Dyer & Kale, 2007). According to Ménard (2004), the incentive to engage in contractual strategic alliances is the opportunity to exploit sources of complementary assets. Some of the main motivations for forming alliances are interdependence (Gulati & Gargiulo, 1999) and the institutional and cultural context (Barney & Hesterly, 1996). According to Heimeriks & Duysters (2007), a growing number of companies are using strategic alliances as a means of entering new markets, reducing the development costs of operations, increasing their market reach and providing complete solutions to the customers. Other factors that can be combined to justify cooperative processes are risk sharing, access to new markets and technologies, speed to market, creating value in products and complementary skills (Eisenhardt & Schoonhoven, 1996; Menárd, 2006; Wassmer & Dussage, 2011).

The dispersed nature of knowledge and resources among agents within the pharmaceutical industry leads to the use of contractual strategic alliances for the development of cooperative activities such as R&D, manufacturing, licensing/marketing, rights acquisition and supply/distribution (Nogueira & Bataglia, 2012; Powell, White, Koput & Owen-Smith, 2005).

Theoretical Propositions

The relationship between biotechnology TISs and transactions in contractual strategic alliances

Williamson (1985, 1991) reports on the existence of attributes that characterize transactions between companies and the transaction costs at the micro level: technological and market uncertainty, asset specificity, and frequency. Below, we develop these concepts and relate them to the regional biotechnology TIS.

Williamson (1985) defines three forms of uncertainty: (1) uncertainty that is primary linked to environmental contingencies related to technological and market changes, such as changes in consumer preferences, (2) secondary uncertainty related to informational asymmetry concerning the management decisions taken by competitors, and finally (3) strategic uncertainty that is related to bounded rationality and opportunism used to distort, conceal or mask information.

For Santoro and McGill (2005) and McGill and Santoro (2009) the uncertainty in transactions governed by strategic alliances can be classified in three ways: (1) technological uncertainty, (2) uncertainty relating to partners, and (3) uncertainty in the execution and control of tasks. Technological uncertainty is linked to the fact that changes in the use or development of a given technology makes it irrelevant within the technological system. Uncertainty regarding partners is related to the knowledge of their capabilities and confidence/trust, and is influenced by the mutual experience. Uncertainty in relation to tasks is characterized by concerns regarding the possibility of controlling the status of activities related to the alliance. Regardless of the type of uncertainty, it tends to diminish as the amount of information available increases.

According to Ahmad, Mallick & Schroeder (2013), the degree of uncertainty related to new products developed through alliances is directly linked to the degree of interaction between the partners. The greater the uncertainty, the greater is the need to integrate, monitor and control the activities and partners within a strategic alliance. Gulati and Nickerson (2008) point out that the existence of interorganizational trust leads to increased expectations in new alliances as well as a reduction in the use formal control mechanisms in alliances.

An increase in the dynamic activities in regional TIS leads to increased levels of information acquired from the training and qualification of regional manpower, arising from incubators and startups, events, courses and consultations for disseminating technology. In addition, there is an increase in the interaction between organizations in the region, whether through joint activities in regional sectoral associations or strategic alliances, which generates experience and mutual understanding between the partners and thus, reduces uncertainty within the regional innovation technological system (Ernst, Lichtenthaler & Vogt, 2011). Based on this reasoning, it can be argued that:

> **Proposition 1 (P1) -** Greater dynamism within a regional biotechnology TIS favors the reduction of uncertainty in relation to the partners, to the tasks and to the technology between the partners in the contractual strategic alliances.

The degree of asset specificity is related to the cost and the possibility of using such assets in activities unrelated to the transaction (Riordan & Williamson, 1985). As the degree of specificity of an asset in a transaction increases, the sunk costs in the event of disruption of the transaction are added to the negotiation process. Therefore, the greater the asset specificity, the greater its importance is in the transactions. Williamson (1985) describes the following categories of specificity: (a) locational specificity, (b) human asset specificity, (c) dedicated assets, (d) physical asset specificity, and (e) temporal specificity.

As pointed out by Carlsson (1997), the knowledge required for the satisfactory exploitation of opportunities in the biotechnology industry is highly specific. In strategic alliances in the regional biotechnology TIS one of the major assets is the human knowledge and skills (Ernst, Lichtenthaler and Vogt, 2011).

The increased rate of manpower training and technology diffusion activities in the regional biotechnology TIS leads to higher human specificity in strategic alliances. The increased technological diffusion and organizational integration activity, such as research projects and joint investments via trade associations and public investment programs, organized regionally by government agencies, which establish technological guidelines, and technological events involving companies, research institutes, government agencies, universities and associations at the regional level, lead to greater integration among the various disciplines and areas of knowledge involved, the generation of innovative production

processes, the development of specialized equipment and the use of existing knowledge. Thus, there is an increase in the specificity of physical and dedicated assets linked to strategic alliances. Simultaneously, regional attractions are created that draw new investment and increase locational specificity linked to the region. Accordingly, it is argued that:

> **Proposition 2 (P2) -** Greater dynamism within a regional biotechnology TIS favors the increase in the specificity of the assets involved in the transactions between the partners in contractual strategic alliances.

The frequency of a transaction is associated with the number of times that the agents carry it out. Some are resolved at a single point in time, while others are recurring. The greater the frequency of a transaction, the less opportunity there is for opportunistic behavior, which could result in its disruption and consequently in a loss of earnings derived from future exchanges (Williamson, 1985). The repeatability of transactions allows reputation to be created between the links, leading to a reduction in *ex-post* changes to contracts, which consequently also decreases the preparation and monitoring costs.

An increased rate of organizational integration activities in the regional biotechnology TIS encouraged by local industry associations, government agencies, public investment programs for innovation that value partnerships and manpower qualification, increases the interaction between organizations in the region through joint activities within the associations and regional government agencies and strategic alliances between agents. This generates mutual experience and knowledge that reduces uncertainty regarding partners, so raising the level of interorganizational trust and minimizing the transaction costs of the alliance by reducing expenditure on searching for information and the creation of safeguards and mechanisms of control over the tasks foreseen in the contract. This reduces the *ex-ante* and *ex-post* costs, stimulating interactions and new alliances (Ernst, Lichtenthaler & Vogt, 2011; Gulati & Nickerson, 2008). Based on this reasoning, it is argued that:

> **Proposition 3 (P3):** Greater dynamism within a regional biotechnology TIS provides a higher rate of recurrence of transactions between the partners in contractual strategic alliances.

The influence of the TIS on the relationship between the transactions within the alliance and the relational capability

According to Carlsson and Stanckiewicz (1995), over time the growth of internal relationships via strategic alliances can transform TISs into development blocks, that is, synergistic sets of businesses and technologies within an industry or group of industries. Ring and Van de Ven (1992) argue that interorganizational relationships are a viable option for creating competitive advantage through complementary combinations of resources.

However, 50% of alliances fail to meet the expectations of the companies involved and their results are quite different from one company to another (Schilke; GOERZEN, 2010). The factors that contribute to the failure of alliances include: partners with incompatible cultures (Kale, Singh & Permutter, 2000); lack of trust, poor structuring of the alliance, the lack of formal processes for the efficient exchange of knowledge (Kale, Dyer & Singh, 2002); a lack of ability to manage conflicts (Hamel, Doz & Prahalad, 1998); and the impact of shocks and variations on the alliance (Mitchell & Singh, 1996).

The ability to manage alliances is a difficult organizational resource to obtain or imitate that may affect the profitability of firms (Thomke & Kuemmerle, 2002; McNally, Durmuşoğlu, Calatone & Harmancioglu, 2009; MacCormack & Iansiti, 2009), which

encompasses arranging the transfer of knowledge between the partners (Lorenzoni & Lipparini, 1999). Organizational capabilities are compositions of assets, individual skills and routines that fulfill organizational goals (Dosi, Nelson & Winter, 2000). Routines are patterns of collective action that develop over time in the organization for solving specific problems and situations which reflect the daily life of the company, i.e., that which regular and predictive, from decisions related to production techniques to investment decisions.

The relational capability of an organization or the ability to manage alliances is developed from incremental learning and from higher order activities or organizing principles through which individual and group knowledge is structured and coordinated in an environment conducive to interorganizational productive collaboration (Bstieler & Hemmert, 2010; Kale, Dyer & Singh, 2002). Such management comes about through the elaboration and development of organizational routines for coordinating alliances (Dyer & Kale, 2007), which, over time, modify the resource base of the organizations through the creation, expansion and modification of the knowledge and skills for managing alliances (Chai, Yap, & Wang, 2011).

There are four different types of organizational routine that constitute the relational capability - they are interorganizational coordination, learning, proactivity and the transformation of alliances (Schilke & Goerzen, 2010). Interorganizational coordination routines focus on resource allocation, task assignment and synchronization activities. Learning routines are concerned with the process of integrating knowledge among the partners. Proactive routines involve scanning, research and the exploration of new opportunities from existing alliances, allowing the organization to understand the environment, identify market needs, new opportunities and new potential partners. Lastly, transformation routines are related to the degree of flexibility in generating adaptations to existing alliances, making the necessary adjustments in relation to changes in the competitive environment, such as economic, market and technological changes (Battaglia & Meirelles, 2009).

Increasing the relational dynamism between the agents in the regional biotechnology TIS via contractual strategic alliances, stimulated by the actions of government agencies and regional industrial associations, over time, provides for the creation, exercise and preparation of organizational routines related to the capacity to manage alliances, either through 'learning by doing' or 'learn from partners' (Di Benedetto, DeSarbo, & Song, 2008; Krishnan, Martin, & Noorderhaven 2006; Schilke & Goerzen 2010).

According to the reasoning presented above, it is argued that:

Proposition 4 (P4) - Greater dynamism within a regional biotechnology TIS favors the development of relational capability in the enterprises.

Coordination costs are inevitable in a strategic alliance due to the need to plan, adapt and monitor the activities and partners (Williamson, 1991). Those costs are explained by behavioral assumptions bounded rationality and opportunism. In order to minimize potential transaction costs, partner companies exercise and create organizational routines for managing alliances. These routines tend to describe what actions the agents should take when faced with problems that were not foreseen in the contract.

The performance of these routines and their evolution will depend on the degree of environmental uncertainty and the degree of specificity of the assets involved in the alliance. According to Williamson (1985) the greater the asset specificity and the greater the level of uncertainty, the greater the need is for *ex-post* adjustments. The lack of interorganizational

trust increases the need for formal coordination of the managerial activities in a strategic alliance (Gulati & Nickerson, 2008). Thus, it is argued that:

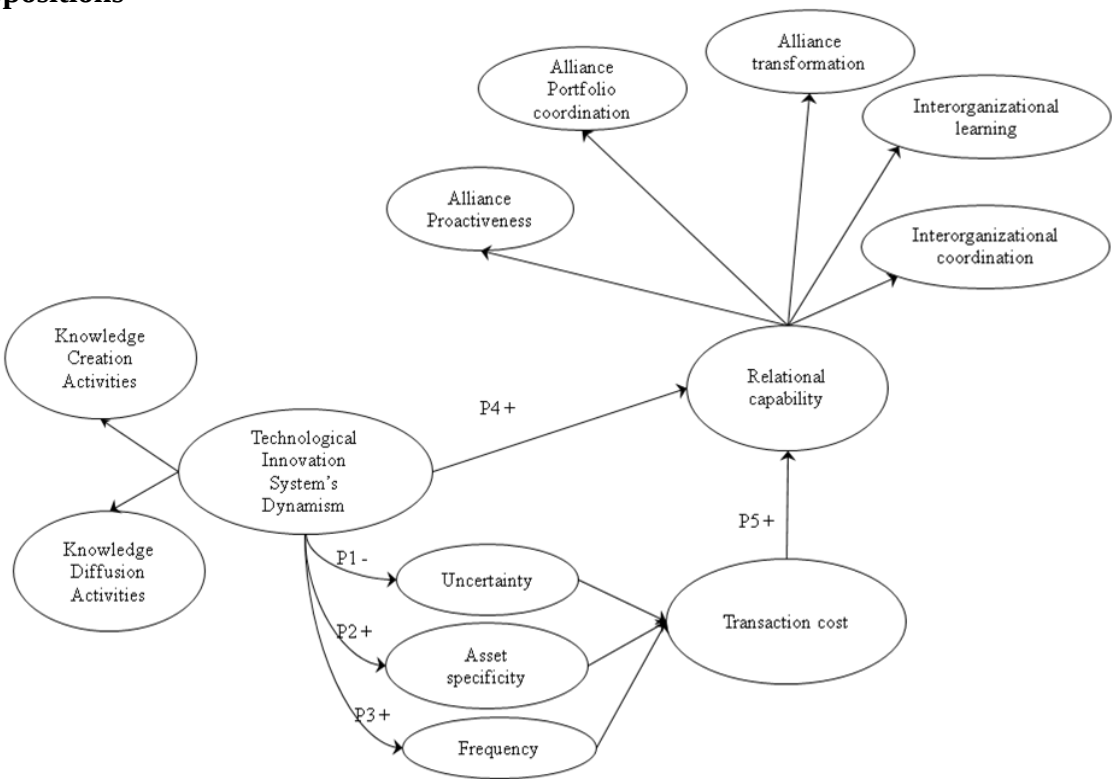
> **Proposition 5 (P5) –** The transaction costs of the contractual strategic alliance positively influence relational capability of the enterprises.

The Structural and Measurement Model

In summary, Figure 1 presents the structural and measurement model (Williams, Edwards & Vandenberg, 2003), comparing the constructs of interest via the propositions developed in the sections above, in order to test the theory proposed by means of the structural equations technique (McNally, Akdeniz & Calatone, 2011; Reinartz, Haenlein & Henseler, 2009). The model describes the influence of the dynamism within the regional biotechnology technological innovation system (TIS) on the transaction costs of alliances for the development of new products and the relational capability of the agents, and proposes that the TIS moderates the relationship between these constructs.

The construct 'regional biotechnology TIS', modeled reflectively, consists of the first-order latent variables: cognitive structure, organizations and institutions (Carlsson & Stanckiewicz, 1995). The construct 'transaction costs', modeled formatively, consists of the first-order latent variables: frequency, uncertainty and asset specificity (Williamson, 1985, 1991). The construct 'relational capability', modeled reflectively, is comprised, according to Dussauge and Wassmer (2011) and Schilke and Goerzen (2010) of the first-order latent variables: interorganizational coordination, coordination of the alliance portfolio, learning, transformation of the alliance and the alliance proactiveness.

Figure 1. The Structural and Measurement Model for Testing the Theoretical Propositions



Source: Elaborated by the authors.

Final Remarks

This theoretical paper presents the problem developing a pharmaceutical biotechnology industry based on regional clusters. Its main contribution lies in the theory it develops which proposes that in regions where the dynamism within the Technological Innovation System (TIS), considered at the regional level, is intense, the relational capability of biotechnology enterprises is more developed, thus benefiting the enterprises since, in that sector, contractual strategic alliances are central to growth.

It is also suggested that the regional TIS influences the transaction costs of companies in the region, due to the reduction of uncertainty regarding the partners, the tasks and the technology, so favoring the increased specificity of the assets involved, and providing a higher rate of recurrence of transactions, generating experience and mutual understanding of the organizational skills and promoting greater trust among the partners.

From the methodological point of view, collaboration involves the preparation and presentation of a combined structural and measurement model of the constructs used to test this theory. Applying the model in the biotechnology industry is appropriate because of the strategic nature of the industry, which is characterized by a large number of contractual strategic alliances, and has presented evidence of developing through regional clusters.

The proposed theory suggests that strategic decisions regarding the location of biotechnology and pharmaceutical companies prioritize regions with developed, structured and dynamic technological innovation systems.

The implications for public policy are also clear. For the development of the biotechnology and pharmaceutical industries to be effective in specific geographic regions, the government should create programs that include the development of biotechnology technological innovation systems in the regions of interest. Public investment should be based on professional training programs for the academic and business sectors in the region and stimulate projects designed to generate new products and processes based on biotechnology and related fields with a focus on regional development. Nonetheless, in addition, there must be simultaneous invest in the creation of a structured and dynamic biotechnology technological innovation system in the region.

That is to say, in addition to grants for research and training at post-graduate level, there should be policies designed to encourage the development of existing universities and where necessary the creation of new universities (public or private) in the region as well as the creation of courses in biotechnology at various levels - post-graduate programs, MBAs, undergraduate and technical courses and the development and establishment of local research institutes. It is necessary to encourage investment in research at the enterprise level by providing research grants for technological innovation involving companies in the region and incentives for local industrial associations to integrate with other organizations such as universities and research institutes in order develop biotechnology.

Studies in other sectors that also typically adopt strategic alliances as a core part of the competitive process, such as the software, aerospace, aviation, oil sectors, may improve the theory proposed herein, by producing specific knowledge of the relationship between regional TISs and enterprises in different business sectors.

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