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Drivers influencing the governance of inter-firm relationships in the biopharmaceutical industry: an empirical survey in the Italian context

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Drivers influencing the governance of inter-firm relationships in the biopharmaceutical industry: an empirical survey in the Italian context

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This paper focuses on factors influencing the choice of the governance form in inter-firm relationships (IFRs) between pharmaceutical and biotechnology companies. By reviewing the relevant literature on transaction cost economics, property right theory, real option and resources-based view, we located some drivers that might influence such relationships and we formulated a set of hypotheses linking them to governance forms. Such a theoretical framework has been empirically tested through a survey conducted among the Italian companies associated to Farmindustria. Empirical results provide some interesting insights on how shaping bio-pharmaceutical deals; we found that the developmental stage of the product/technology object of the agreement, the existence of previous collaborations between firms and the number of products marketed by the biotech company are able to influence the selection of a specific governance form.

Keywords: biopharmaceutical industry; inter-firm relationship; governance form; survey

1. Introduction

Since the mid 1970s, the pharmaceutical industry has experienced a technology discontinuity in its core process. Indeed, the emergence of biotechnology brought in a new framework the processes of drugs discovery, development and manufacture compared to the traditional, chemical-based, pharmaceutical method (Tushman and Anderson 1986).

Biotechnology has been representing a competence-destroying technology on the R&D hand, because it requires knowledge and technical skills fundamentally different from those developed by pharmaceutical companies. Rothaermel (2001a) estimated that the skill loss for a scientist making the transition from the traditional chemical-based framework to the new biotechnology one is between 80 and 100%. However, unlike other industries, the effect of this radical change has not been disruptive for the traditional pharmaceutical firms. Indeed, biotechnology companies

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have not replaced incumbents, because they still owned important strategic assets in developing such new biopharmaceutical products (Rothaermel 2001b)

This situation has created positive opportunities for collaborations between the new sources of technical expertise and the established firms (Pisano 1990); indeed, the biopharmaceutical industry designs and supplies drugs, which derive from biotech research, but are developed by both types of firms (Sabatier, Mangematin, and Rousselle 2010). For this reason, since the mid 1970s, this industry has been characterised by an increasing recourse to inter-firm relationships (IFRs) between pharmaceutical firms and biotechnology companies.

The explanation of this phenomenon is related to the fact that, on the one hand, a pharmaceutical firm wishing to commercialise a biotechnology-based drug needs to acquire the necessary competencies or by developing the required R&D capabilities in-house or sourcing them from outside, i.e. from a biotechnology firm (Chiesa and Toletti 2004). On the other hand, a biotech company that has developed a new compound or a technological platform and desires to bring it into the market often lacks critical functions or capabilities such as drugs manufacturing and marketing. Indeed, according to McCutchen and Swamidass (2004) biotechnology firms are 'functionally incomplete'. Moreover, non-technological assets owned by incumbents often generate more value than the technological ones: especially, marketing and distribution assets that assure the access to the market (Tripsas 1997). Furthermore, pharmaceutical firms possess other non-technological assets, such as an established reputation and capitals, which are fundamental to commercialise the new technologies (Stuart, Hoang and Hybels 1999)

Thus, the presence of strong complementarities is one of the main reasons why pharmaceutical and biotech companies are cooperating, instead of competing. Furthermore, pharmaceutical firms have been facing with some threats, such as the increase of R&D costs and the decline of R&D productivity (DiMasi, Hansen, and Grabowski 2003; Higgins and Rodriguez 2006; Bradfield and El-Sayed 2009), the expiration of many patents and the increasing competition from generic pharmaceutical firms. Conversely, biotechnology firms have technological assets that allow facing with such threats (Danzon, Epstein, and Nicholson 2007).

The last source of complementarities is on the financial side. Indeed, the drug development process is long, costly and highly uncertain: it requires 10–15 years from research to market, costs vary from US$800 million (DiMasi, Hansen, and Grabowski 2003; Goozner 2004) up to US$1.2 billion for a biopharmaceutical drug and the attrition rate can reach the 98% (DiMasi 2001). The above considerations highlight how extraordinarily important is financing in the biotech industry. Biotech start-ups usually obtain capital through two different sources: venture capital financing or by entering strategic deals with other firms (Pisano 2006). More mature companies can instead rely on products and technologies commercialisation, as well as on intellectual assets (i.e. patents) and services sale. However, biotech companies, which have never sold any product, lack enough cash flow for their R&D activities. Supporting this point of view, Pisano (2006) highlights how, despite the commercial success of companies such as Amgen and Genentech, most biotechnology firms earn no profit. On the contrary, established pharmaceutical firms have high financial resources as a result of their blockbusters and their long presence in the market. Thus, entering into agreements with pharmaceutical firms represents an extremely important strategic tool for biotech companies (Pisano 2006).

While the aforementioned complementarities provide reasons why pharmaceutical and biotech companies should cooperate, questions arise about the governance of such IFRs. Starting from the seminal work of Pisano (1990), several scholars raised the question about what kind of governance mode is preferable to manage biopharmaceutical IFRs and what drivers influence the governance choice in this industry. In particular, by analysing the most relevant literature on the drivers

influencing inter-firm relationships (IFRs) in the biopharmaceutical sector, we locate the main gaps in the literature and we state the research motivation for this study (Section 2). In Section 3 we develop our theoretical framework that is empirically tested through a survey (Section 4), whose results are discussed in Section 5. Discussion, limitation and conclusions are then presented (Section 6).

2. Literature analysis and research motivation

In literature several theoretical strands have examined drivers influencing the governance of inter-firm relationships, including transaction cost economics (TCE) (Williamson 1979, 1985, 1991), resource-based view (RBV) (Kogut and Zander 2002; Zollo, Reuer, and Singh 2002), property right theory (PRT) (Hart and Moore 1990) and real options theory (RO) (Folta 1998; Kogut 1991).

TCE focuses on transaction characteristics such as investment specificity and uncertainty, studying how these factors increase the opportunism risk in the relationship and the associated transaction costs; in order to reduce these costs, a hierarchical governance solution is required when investments are idiosyncratic and uncertainty is high (Williamson 1985).

Consistently with TCE considerations, Pisano (1990) empirically observes how pharmaceutical companies increasingly tend to undertake biotechnology R&D projects internally, rather than outsourcing them, because of issues that influence the relational risk perception of the firms, such as small-numbers bargaining problem, biotechnology R&D experience and the firm's dependence on the pharmaceutical business. In order to seek clarity, according to Lo Nigro and Abbate (2010), we refer to 'relational risk', as the risk coming from the possibility of opportunistic behaviours of partners, while 'performance risk', that is its complementary side, is the risk incurred if partners behave as agreed (contract completeness).

Gulati (1995) is one of the first researchers who studies how trust between partners influences the choice of the governance form; indeed, he shows how trust, often measured by the number of previous ties between the same companies, reduces the relational uncertainty and the appropriation concern at the same time, leading to less hierarchy-oriented transactions. Gulati and Singh (1998) analyses how coordination uncertainty among interdependent entities, appropriation concern and low level of trust lead to more hierarchical governance forms.

Oxley (1997), by using a TCE point of view, analyses the appropriation concern, an issue related to the PRT framework; she shows how the width of the transaction focus, the range of products or technologies and the involvement of different geographical areas increase the appropriability hazard, pushing towards more hierarchical governance forms (i.e. equity joint venture). Coming to another important TCE driver influencing the structure of IFRs, that is uncertainty, while the impact of the investment specificity is quite acknowledged by the empirical literature (David and Han 2004), TCE prediction about the linkage between uncertainty and governance form remains ambiguous (Mahoney 1992). This is also because, conversely to the TCE view, the real option (RO) theory (Myers 1977) argues that uncertainty leads firms to prefer more flexible and less hierarchical governance, in order to avoid the opportunity cost of irreversible investments in shared ventures (Folta 1998).

The papers by Santoro and McGill (2005) and Van de Vrande, Vanhaverbeke, and Duysters (2009) investigate how this different view on transaction uncertainty can influence the choice of a continuum of governance forms between market and hierarchy. Santoro and McGill (2005) analyse the influence of asset co-specialisation, partner and task uncertainty and technology uncertainty on the choice among five different governance forms: one-way licensing, bilateral cross licensing, bilateral non licensing, minority equity and joint ventures (JVs). Consistently with TCE, they find

that co-specialised assets increase the likelihood of hierarchical governance and partner and task uncertainty increases this effect. Consistently with RO, technological uncertainty decreases the likelihood of hierarchical governance. Alternatively, Van de Vrande, Vanhaverbeke, and Duysters (2009) analyse the impact of environmental turbulence, technology newness, technology distance and prior ties on five different governance forms: non-equity technology alliances, corporate venture capital (CVC) investments, minority holdings, JVs and M&As. Again, appealing to TCE and RO, they obtain a controversial support to the two theoretical strands.

However, several scholars have pointed out how TCE and RO theories provide an incomplete explanation of what influence the choice of governance forms. In particular, the resource-based view (RBV) perspective emphasises how partners bring into an alliance their valuable resources and through the alliance they are interested both in acquiring their partners' valuable resources and in protecting their own resources during the alliance-making process. Thus, the RBV view about governance form is to find a structure able to balance the two issues: being able to procure valuable resources from another party without losing the control of one's own resources. According to Das and Teng (2000), the involved resources typology, property-based vs knowledge-based, strongly shapes the alliance governance; thus, although the governance form choice depends on how resource typologies of the two parties are mixed in the relationship, property-based resources push toward more market-oriented governance forms, while knowledge-based resources push toward more integrated modes. By following Das and Teng's theoretical perspective, Chen and Chen (2003) compare TCE and RBV points in shaping the choice between contractual alliances and equity JVs. They find that, while the transaction cost model is powerful in explaining the choice between JVs and contractual alliances, the resource-based perspective provides useful insights into the choice between two distinctive forms of contractual alliances, namely, exchange and integration alliances.

Moreover, Steensma, and Fairbank (1999) utilise both RBV and RO perspectives in a complementary fashion to hypothesise how certain perceived attributes of the technology such as imitability, rarity, uncertainty and dynamism influence the governance mode. The authors find significant support for both theories since, according to RBV, the more strategic in terms of imitability and rarity the resources are, the more likely firms will chose hierarchical arrangements (JVs or M&As). Also, according to RO perspective, firms are more likely to pursue arms-length licensing arrangements when uncertainty, in terms of technological and commercial success, is high.

Furthermore, Rosiello (2007) analyses the issue of the governance choice both from a TCE and a RBV perspective. He analyses transaction factors, such as sunk costs and uncertainty, and resources characteristics, such as replaceability, complexity and replicability. He shows how technological and demand uncertainty and complexity of resources make collaborative agreements more likely than standard contracts, confirming in this way both TCE and RBV perspectives.

Table 1 summarises the principal contributions previously discussed. For each paper reviewed, Table 1 highlights the theoretical focus, the main drivers addressed, the operationalisation of the drivers, the governance forms analysed and the typology of each paper, i.e. whether it is only theoretical or also empirical.

From the analysis of Table 1, the reader can see how the main drivers influencing the choice of governance form so far studied in the literature come from different theoretical strands and they are: asset specificity (TCE), uncertainty (TCE, RO), appropriation concern and resources' typology (TCE, PRT, RBV) and trust (TCE).

As also stressed by literature on the governance structure of IFRs (Leiblein 2003; Leiblein and Miller 2003; Patelli 2009; Foss and Roemer 2010) we strongly believe that the lack of empirical

Table 1. Synthesis of the main contributions on drivers influencing the governance choice.

Paper	Theoretical focus	Main driver	Operationalised drivers	Governance modes	Type of paper
Santoro and McGill (2005)	TCE RO	Asset specificity Uncertainty	Asset co-specialisation Partner uncertainty Task uncertainty Technological uncertainty	One-way licensing Bilateral cross licensing Bilateral not licensing Minority equity alliances Joint Ventures	Empirical data bank analysis on the biopharmaceutical industry
Van de Vrande, Vanhaverbeke, and Duysters (2009)	TCE RO	Uncertainty Trust	Environmental uncertainty Technology uncertainty Prior ties	Non-equity technology alliances CVC investments Minority holdings Joint Ventures M&As	Empirical data bank analysis on the biopharmaceutical industry
Oxley (1997)	TCE PRT	Appropriation concern	Transaction focus Range of products or technologies Wideness of geographic area	Unilateral contractual alliances Bilateral contractual alliance Equity alliances	Empirical multi-industry data bank analysis
Gulati (1995)	TCE	Uncertainty Trust	Previous ties Different nationality Different firms	Non-equity alliances Equity alliances	Empirical multi-industry data bank analysis
Gulati and Singh (1998)	TCE	Uncertainty Appropriation concern Trust	Interdependence Technological uncertainty Appropriability regime uncertainty Prior ties	Contractual alliances Minority equity investments Joint Ventures	Empirical multi-industry data bank analysis
Das and Teng (2000)	RBV	Resource typology	Property-based resources Knowledge-based resources	Unilateral contractual alliances Bilateral contractual alliances	Theoretical paper

(*Continued*)

Table 1. Continued.

Paper	Theoretical focus	Main driver	Operationalised drivers	Governance modes	Type of paper
				Minority equity alliance Joint venture	
Steensma and Fairbank (1999)	RBV	Resource typology	Number of previous alliances or JVs	Licensing	Survey not on the biopharmaceutical industry
	RO	Uncertainty	Resource potential economic rent Resource uncertainty	Joint development alliances Acquisition	
Chen and Chen (2003)	TCE RBV	Asset specificity Resource typology	Asset specificity Technological and environmental uncertainty	Contractual alliance Joint Ventures	Survey not on the biopharmaceutical industry
		Uncertainty	Resource dependency and complementarity		
Rosiello (2007)	TCE RBV	Asset specificity Resource typology Uncertainty	Sunk costs Uncertainty Resource replaceability, complexity, non replicability and strategicity	Standard contracts Collaborative agreements Integrated structures	Survey on the biopharmaceutical industry

studies that integrate findings coming from different theoretical approaches is unfortunate for several reasons. First, the importance of common concepts, such as uncertainty and appropriation concern, suggests that important connections exist that may enhance our understanding of organisational governance. Also, some research has demonstrated that the failure to integrate theories of organisational governance choice may lead to misleading empirical findings (Leiblein, Reuer, and Dalsace 2002). Thus, the clear separation between these theories, namely the fact that past research focused on just one or two theoretical strands at the same time, is in our opinion, a limitation in the available literature that we would like to overcome. Therefore, the first contribution of the present research is to develop a framework combining all the aforementioned drivers, contributions and theoretical perspectives coming from all past research efforts.

Second, it should be noticed how all the reviewed research formulate their theoretical frameworks (hypotheses sets) on non operazionalised drivers; while this approach is aimed at developing a general framework, it is unable to capture the specificity of a given industry. Such a problem is quite evident with the driver "uncertainty"; indeed, although the relationship between uncertainty and firm's governance decisions is stressed in much of the existing literature, empirical studies often find contradictory results. Depending on the typology of uncertainty considered, i.e. behavioural uncertainty, technological uncertainty or demand uncertainty, researchers have demonstrated positive/negative relationship between uncertainty and integrated solutions. These contradictions may be due to the different sources of uncertainty considered and also to the variety of measures employed by researchers (Sutcliffe and Zaheer 1998). On the contrary, our goal is to formulate hypotheses directly on operationalised drivers, distinguishing for example between factors influencing relational uncertainty rather than technological uncertainty. In this way we are also able to gather factors that are very specific to the biopharmaceutical industry. Of course in this way we obtain a less general framework, but very focalised and consistent with the industry and more useful from a managerial point of view. Third, we introduce a new driver that is very specific to this industry, i.e. the level of 'functional completeness'. As previously stressed, this characteristic is the main motivation of collaborations between pharmaceutical companies and biotech ones, and in our opinion, the level of completeness of the biotech company is able to influence the choice of governance form. Because of the introduction of such a new driver, we analyse the dual perspective problem deriving from the extent of conflicting objectives and a bargaining power problem between biotech and pharmaceutical companies, an issue often neglected in literature.

Finally, we want to highlight that because of the wideness of our analysis, in term of theoretical strands and drivers, we concentrate on one single transaction of assets, as the unit of analysis; namely, we focus on the transaction of a biotech-based compound or technology under development or already developed, that comes from the biotech company's research. Thus, our focus being on how established pharmaceutical firms approach the new technology, we consider that they can select one of the following possibilities: (i) get the licence of a product already developed through a licensing agreement, (ii) share resources and efforts in order to jointly develop the compound (i.e. R&D alliances), (iii) create a new legal entity that assumes the ownership of the asset (i.e. JVs) or (iv) acquire the biotech firm in order to internalise the transaction and obtain the rights of all the products and assets of the acquired firm (M&As). We do not consider co-manufacturing, co-marketing and co-commercialisation agreements. Thus, as the reader can see from the analysis of Table 1, by considering all the spectrum of possibilities from pure market transactions to totally integrated solutions, we try to overcome another limitation in the available literature, since most of the previous research limited their analysis to the choice between different

alliance types, mainly equity vs non-equity alliances, not considering all the modalities through which firms can build relations.

3. Theoretical framework developing

As anticipated in Section 2, this paper studies the choice between four different governance modes: licensing agreements, R&D alliances, JVs and M&As. A licensing agreement represents the governance form closer to the market; it is an arm's-length transaction, in which there is a unilateral technology flow from one firm to another one (Williamson 1985). Usually, in the biopharmaceutical industry, the pharmaceutical firm gains the right to use a technology developed by the biotech company in exchange for royalty payments. Along the market–hierarchy continuum, we then locate non-equity R&D alliances, which imply a certain degree of collaboration between partners because of resources and risk sharing. Then, moving towards the hierarchy, we consider equity joint ventures that, through the creation of a new legal entity, are used to share resources and risk in a more structured and integrated way. Finally, firms may decide to internalise the transaction through a merger or an acquisition.

The theoretical framework proposed here is based on the literature review discussed in Section 2. Indeed, the analysis of past research leads us to detect five main drivers that influence the governance of IFRs: asset specificity, uncertainty, appropriation concern, resource typology and trust. Starting from these main drivers we identify some operationalised measures that are specific of the biopharmaceutical industry, on which we formulate our hypotheses.

3.1. *Investment specificity*

As highlighted in the literature review, David and Han (2004) provide strong empirical support on how asset specificity increases transaction costs and creates a greater opportunism risk. In this case, TCE suggests internalising the transaction in order to reduce these costs. In other respects, in order to protect strategic assets arising from inter-firm specific investments, also PRT suggests gaining the property of these assets. The above considerations lead us to the first driver significantly influencing the relationship, i.e. the presence of *transaction-specific investment* (*d1*); thus, we posit:

> *Hypothesis 1* (*H1*): If the level of transaction-specific investment (*d1*) is high, the pharmaceutical firm will prefer a more hierarchical governance form.

3.2. *Uncertainty*

The presence of uncertainty, coming from both performance and relational risk, is a crucial factor in governance choice of IFRs. Specifically in R&D inter-firm relationships, it is generally acknowledged how the 'technological newness' is one of the most important fonts of uncertainty (Van de Vrande, Vanhaverbeke and Duysters 2009). Moreover, as highlighted by Pisano (2006), in biotechnology R&D the levels of risk and uncertainty go well beyond what is entailed in normal R&D. Also, the emergence of biotechnology is considered a radical process innovation in the pharmaceutical industry (Stuart, Hoang and Hybels 1999), since the activities of chemical synthesis deployed by traditional incumbents are becoming quite obsolete within the new biotechnology paradigm. So, beyond the classical distinction between incremental innovation (drug enhancement) and radical innovation (new drug development) (Cardinal 2001), the depth of innovation

in this industry can be associated with the extent to which the new process paradigm, the biotech one, is used to enhance former pharmaceutical products, or even to develop new classes of drugs. Of course, the 'technological distance', i.e. the dissimilarities between the knowledge bases of the partners contributes to the depth of innovation; indeed, a pharmaceutical company that has no knowledge or experience in the biotechnology process, 'feels' a higher technological distance and therefore, a more radical innovation. However, while this last issue concerns the relational uncertainty, the former being more technical, impacts on the performance.

Thus, we identify the *depth of innovation* (*d2*) as an important driver that must be taken into account in order to cope with both performance and relational uncertainty. In this case, RO literature suggests that investment affected by high levels of uncertainty might be considered as the creation of an option, which might be exercised at a later point in time using a more integrated solution; these investments should preserve their intrinsic nature of options. This means that, when the partner's technology is quite novel, the pharmaceutical firm will be more likely to pursue market agreements, such as non-equity alliances, in order to remain flexible and to reduce the failure risk maintaining the intrinsic options (Vanhaverbeke, Duysters and Noorderhaven 2002). Pisano (1990) also suggests the use of less integrated governance forms under conditions of technological newness. From an RBV perspective, the deeper the innovation, the more the resources involved are firm-specific, property-based (for instance patents, human resources) and less transferable; this occurrence increases the relational risk, since it is quite difficult to evaluate both the strategic value and degree of transferability of such a resource. Hence, the investing firm can address the high relational uncertainty surrounding new technologies through small initial investments, so called 'learning investments' (Janney and Dess 2004), which are specific of market-oriented governance forms. Therefore, we formulate the following hypothesis:

> *Hypothesis 2* (*H2*): If the level of depth of innovation (*d2*) is high, the pharmaceutical company will prefer a more market-oriented governance form.

Another interesting driver affecting performance uncertainty in the biopharmaceutical industry is the *development stage of the product/technology* (*d3*) object of the deal. Indeed, failure risk is greater in the very early phases of the R&D process. The drug development process is composed by four macro phases prior to commercialisation: the drug discovery phase, the preclinical development, the clinical trials (composed by three stages, i.e. phase I, phase II and phase III) and the approval phase. Each of these steps is complex and uncertain, so that the more advanced the development stage, the more likely the drug succeeds in reaching the market; it should be considered that even when a drug has completed phase II-A of clinical studies, the expected probability of success does not even reach 50% (DiMasi 2001). Thus, since in early stages performance risk is high, while the relational one is quite low, according to RO, the investing firm prefers alliances to acquisitions (Lambe and Spekman 1997). Also Higgins and Rodriguez (2006) suggest that pharmaceutical firms seeking early stage research may best accomplish their goal using strategic alliances. On the other respect, as projects move further along the development process, pharmaceutical firms give up more rights if they try to access those products via an alliance. According to PRT, it may be more beneficial for firms to make an acquisition, in order to acquire the biotech product's rights and avoid any potential costly hold-up issues (Klein and Murphy 1997). So, moving along the development stage technological uncertainty (performance risk) decreases and appropriation concern, owing to the relational risk increases. Therefore, the following hypothesis can be formulated:

Hypothesis 3 (*H3*): If the development of the product/technology (*d3*) is at a late stage, the pharmaceutical firm will prefer a more hierarchical governance model.

The reader should note that the biotech firm's perspective regarding *d3* is instead opposite. Indeed, the amount invested till the agreement date to carry out a compound development up to a late stage will induce the biotech to put up greater resistance to an acquisition; indeed, if the biotech has been able to carry out the compound up to a late stage, it will try to complete the last stages by its own in order to maintain all the compound rights. Therefore, a bargaining power concern emerges in this case.

Going back to the concept of 'technological distance', it has been proved how it affects uncertainty in technology agreements (Van de Vrande, Vanhaverbeke, and Duysters 2009) Specifically, technological distance in bio-pharma R&D relationships, may occur in two main cases: (i) when the two firms are not specialised in the same therapeutic areas and (ii) when the pharmaceutical firm has never developed biotechnology in-house. It is here noteworthy to mention that a pharmaceutical firm can be catalogued as a 'biopharmaceutical' company or as a 'pure' one, depending on whether the firm has developed in-house biotech competencies.

Therefore, we detect other two fundamental drivers in the governance form choice related to uncertainty: the overlapping of *therapeutic areas* (*d4*) and the *integration of the pharma in the biotech field* (*d5*). Both drivers are signs of similarities or dissimilarities between the knowledge base of the two partners. Large dissimilarities lead to two types of problems. The first one concerns the 'absorptive capacity' (Cohen and Levinthal 1990). Indeed the pharmaceutical firm has a limited internal scientific capability first, to sort out which projects are attractive and which are 'lemons' (Pisano 2006), and second, to absorb and integrate the new technology. In this case, Gulati and Singh (1998) suggest a more integrated governance form in order to facilitate the effective transfer of distant knowledge. A large technological distance between partners may then also lead to relational uncertainty and opportunistic behaviours owing to information asymmetry. So, according to TCE higher level of integration becomes a more attractive alternative.

These argumentations bring us to the following two hypotheses:

Hypothesis 4a (*H4a*): If the partners are not specialised in the same therapeutic areas (*d4*), the pharmaceutical firm will prefer a more hierarchical governance model.

Hypothesis 5a (*H5a*): If the pharmaceutical firm is not integrated in the biotech field (*d5*), it will prefer a more hierarchical governance model.

In contrast other researchers, such as Pisano (1990), observe how a firm that is not yet familiar with the technological know-how of its partner will have first to learn from the partner through an arm's length transaction before being able to accumulate knowledge. Indeed, Pisano (1990) argues that a firm's ability to internalise new projects may depend on the number of its previous in-house projects in the relevant technology. This reasoning is consistent with the concept of 'dynamic capabilities' in the RBV theoretical stream (Eisenhardt and Martin 2000). As matter of fact, dynamic learning capabilities have been observed in the biopharmaceutical industry in contexts such as product development (Deeds, DeCarolis, and Coombs 1999), project development (Pisano 2000) and international diffusion of technology (Madhok and Osegowitsch 2000). Therefore, if a pharmaceutical company is integrated in the biotech field or, alternatively, is specialised in the same therapeutic area of its biotech partner, it has already developed internal knowledge-based resources in the field and therefore it will prefer a more hierarchical governance form,

because learning occurs most efficiently inside the organisation rather than across organisational boundaries. On the contrary it will prefer a market transaction. Therefore, looking at these drivers from a RBV perspective as resource typologies owned by the pharmaceutical firm we hypothesise two alternatives to *H4a* and *H5a*:

Hypothesis 4b (*H4b*): If the partners are specialised in the same therapeutic areas (*d4*), the pharmaceutical firm will prefer a more hierarchical governance model.

Hypothesis 5b (*H5b*): If the pharmaceutical firm is integrated in the biotech field (*d5*), it will prefer a more hierarchical governance model.

3.3. *Trust*

Several scholars highlight the importance of characteristics such as trust, reputation, commitment, cooperation and communication for the success of IFRs (Gulati 1995; Gulati, Nohria, and Zaheer 2000). Delerue (2004) finds that relational risk perception is mitigated by trust in biopharmaceutical relations. Indeed, trust and reputation establish norms and expectations about appropriate behaviour, lowering the perception of opportunism risk. The existence of *previous relations* (*d6*) between the partners is generally assumed as a measure of trust in a relationship, because it allows a better evaluation of partner's resources, capabilities and reliability (Gulati 1995). Thus, the number of previous ties influences the choice of the governance in the subsequent relation modifying the assessments of transaction costs associated with a specific alliance and limiting the fears of opportunistic behaviour.

Authors such as Gulati (1995) and Parkhe (1993) suggest that trust can be a substitute for hierarchical contracts in many exchanges and serves as an extra-contractual control mechanism. Several authors (Gulati 1995; Ring and Van der Ven 1994; and Santoro and McGill 2005) have found empirical support that the familiarity established among partners mitigates the hold-up risk and leads to market-oriented models. Finally, trust improves the absorptive capacity of the partners in a relationship, reducing also the performance risk. Therefore, we posit:

Hypothesis 6 (*H6*): The existence of previous relations (*d6*) between partners will be positively related to a more market-oriented governance form.

3.4. *Functional completeness*

Finally, beyond the drivers already analysed in literature, we consider a new one that is very specific of this industry, i.e. the level of functional completeness of a firm. We refer to the ability of the biotechnology firm to bring products into the market, thus we operationalise it by the *number of commercialised products* (*d7*). This is a measure of the biotech's expertise to complete its value chain by bringing its products to the market, obtaining in this way cash to finance its research activity. Surely, a company that has already marketed products is more attractive for a possible acquisition. Indeed, first, the pharmaceutical company can easily evaluate the economic value of its partner, and second, by an acquisition it inherits the control of the marketed biotech products. In this case, the performance risk being very low, the pharmaceutical firm will try to minimise the relational risk and therefore the appropriation concern, by acquiring the partner. This reasoning leads us to formulate the following hypothesis:

Table 2. Synthesis of the theoretical framework.

Operationalised driver	Main driver	Theories supporting the hypothesis	Hypothesis	Empirical support
d1: Transaction-specific investment	Asset specificity	TCE PRT	*H1*	NO
d2: Depth of innovation	Uncertainty Resource typology	RO RBV	*H2*	NO
d3: Development stage of the product/technology	Uncertainty Appropriation concern	RO PRT	*H3*	YES
d4: Therapeutic areas	Uncertainty	TCE Absorptive capacity	*H4a*	NO
	Resource typology	RBV	*H4b*	NO
d5: Integration of the pharma in the biotech field	Uncertainty	TCE Absorptive capacity	*H5a*	NO
	Resource typology	RBV	*H5b*	NO
d6: Previous relations	Trust	TCE Absorptive capacity	*H6*	YES
d7: Number of commercialised products	Functional completeness Appropriation concern	TCE PRT	*H7*	YES

Hypothesis 7 (*H7*): The higher the number of commercialised products (*d7*) by the biotech firm, the more the pharmaceutical company will prefer a more hierarchical governance form.

We underline, however, that the biotech company point of view is very different. Indeed, the higher the number of commercialised products, the more the company is functionally complete and able to finance new R&D projects individually, the more it will avoid being acquired. Therefore, because of the opposite objectives of the parties, the governance mode, in this case, will also depend on who has the greater bargaining power.

A synthesis of the theoretical framework discussed above is reported in Table 2.

4. Empirical analysis

4.1. *Research setting*

To test the above hypotheses set, we analysed the Italian biopharmaceutical sector through a survey that was conducted in collaboration with Farmindustria (the Italian Association of Pharmaceutical and Biotechnology companies). Farmindustria aggregates approximately 204 companies (biotechs, biopharmaceuticals and pure pharmaceuticals), most of which are Italians. Out of these 204 firms, 18 are pure biotech companies; these companies were not included in the survey because they were too few and, principally, because, in all those cases in which we expect conflicting outcomes, our hypotheses are formulated by expressing the biopharmaceutical company perspective. Finally, a substantial part of the firms contacted, which are either foreign subsidiaries of big pharmas, with only sales departments in Italy, or small Italian biopharmaceutical companies, explained to us that they could not answer our questionnaire because they do not make any strategic decisions about bio-pharmaceutical agreements. Therefore, the eligible sample for our survey was reduced to 52 companies.

4.2. *Data collection and sample*

Data collection was based on a survey that was conducted using a questionnaire that, with the support of Farmindustria, was pre-tested on two sample companies. Subsequently, the questionnaire was illustrated to a representative of each company by a phone call interview. Finally, each company representative returned us the completed questionnaire by e-mail. The duration of the investigation was of about 3 months. We received a total of 40 questionnaires out of 52, from pharmaceutical and biopharmaceutical companies. A large proportion of the respondents (75%) were large Italian companies with more than 250 employees and annual turnovers exceeding €50 million. Despite the rather small size of the sample, it must be kept in mind that our sample represents nearly 20% of the total population (204 firms) and 77% of the eligible population (52 firms). Moreover, the respondents account for 35% of the whole turnover of the industry and, by considering that 50% of the whole turnover results from Italian subsidiaries of foreign firms only selling products in Italy, one recognises how our sample is representative of the Italian biopharmaceutical industry.

From the respondents we collected data on 51 bio-pharmaceutical IFRs divided into 11 licensing agreements, 16 non-equity R&D alliances, four joint ventures and 20 mergers or acquisitions. Finally, since a certain number of companies in the sample failed to respond we controlled for a non-response bias. Comparing the respondents with the non-respondents on company sales volume and number of employees, and comparing the early and late respondents on the model variables, the *t*-tests showed no significant differences, suggesting that the response bias is not a significant problem in this study.

4.3. *Variables and measures*

4.3.1. *Dependent variable: governance form*

We model governance forms *G* as a three-level nominal variable taking values of: 0 for licensing agreements, 1 for non-equity R&D alliances and 2 for joint-ventures and M&As. The reason of such a modelling choice is straightforward. As explained in Section 3, we consider licensing agreements as the governance form closest to a pure market transaction through which the pharmaceutical firm seeks to gain the right to use the technology developed by the biotech company. In contrast, we consider JVs and M&As as the closest to hierarchical structures, because of the increasing level of vertical integration. In particular in our analysis, we grouped JVs and M&As together because the number of JVs in our data is quite irrelevant, just four, in comparison with M&As. Finally, R&D contractual alliances lie in the middle between market and hierarchy. The reader should notice how almost every scholar reviewed in Table 1 has adopted a quite similar modelling of the governance form variable addressing the same motivations as above.

4.3.2. *Independent variables*

The scale used for each independent variable derives from a specific question addressed in the questionnaire. Depending on the possible answers, the independent variables are of three main types: two are based on a five-point Likert scale of importance, four are binary and one is a six-level ordered variable.

The five-point Likert scale variables result from an assessment of the respondent about the importance of the driver for the specific agreement; thus, the value 1 means not important at all, 2 unimportant, 3 of medium importance, 4 important enough and 5 very important. These variables are:

- *Transaction-specific investment* (*d1*); the variable expresses how much the respondent believes that transaction investments are idiosyncratic.
- *Depth of innovation* (*d2*); the variable expresses how much the respondent believes that the object of the agreement (product or technology) is a deep innovation. As already discussed, the higher the extent of biotechnology process in the object of the agreement, the deeper has been considered the innovation. Moreover, deep innovations have been considered also in consideration of the 'technological distance'. Thus, respondents have autonomously expressed their evaluation on innovation depth once the interviewer has clarified the above concepts.

The following variables are dummy:

- *Therapeutic area* (*d4*): 0 if the agreement concerns a therapeutic area where the pharmaceutical company is already specialised; 1 otherwise.
- *Integration of the pharma in the biotech field* (*d5*): 0 if the pharma is a biopharmaceutical firm; 1 if it is a pure pharma.
- *Previous relations* (*d6*): 0 if the two companies have never entered into any agreement in the past; 1 if they have already signed at least one agreement.
- *Number of commercialised products* (*d7*): 0 if the biotech has never marketed any product in the past; 1 otherwise.

Finally, the last variable is an ordinal one:

- *Development stage of the product/technology* (*d3*): 1, if the product/technology is in the discovery phase or preclinical development; 2, if in phase I of clinical trials; 3, if in phase II; 4, if in phase III; 5, if in approval stage and 6, if already approved or commercialised.

As previously described, our sample is fairly homogeneous in terms of the size of firms, typology and decision structure, so that no control variables were needed for our model.

5. Results

In order to analyse data we first conducted a descriptive statistic and a correlation analysis (see Table 3). Only two variables (*d4* and *d6*) are slightly but significantly correlated; therefore we decided not to exclude any variable from the regression analysis. The descriptive statistic reveals a first important result concerning the *transaction-specific investment* (*d1*): a mean of 4.47 over a maximum of 5 indicates that no matter which form of governance adopted, companies believe that investments are always highly idiosyncratic. So we do not expect the significant results for this variable that, nevertheless, have been considered in the model.

Then, we conducted a Principal Component Analysis (PCA) on the independent variables in order to understand if they could be reduced in a smaller number of underlying latent dimensions. By using a factor loading analysis based on the correlation matrix and by applying the varimax rotation method, we found that variables *d4* and *d5* have high loading factors in the fourth component (respectively 0.70 and 0.60). This result suggests to us that variable *d5* can be omitted by the regression analysis.

Since the dependent variable is modelled as nominal one at three levels, we have used a multinomial logistic regression. Results are organised in Table 4, where the reference category is assumed to be $G = 2$, that is JVs and M&As.

Table 3. Descriptive statistics for independent variables and correlation matrix.

	Independent variables	Mean	SD	Min	Max	*d1*	*d2*	*d3*	*d4*	*d5*	*d6*
d1	Transaction-specific investment	4.47	1.06	1	5						
d2	Depth of innovation	3.58	1.52	1	5	0.069					
d3	Development stage of the product/technology	3.52	1.97	1	6	0.221	−0.130				
d4	Therapeutic area	0.35	0.48	0	1	0.223	0.038	−0.032			
d5	Integration in the biotech field	0.35	0.48	0	1	0.100	−0.177	−0.011	0.056		
d6	Previous relations	0.27	0.44	0	1	−0.143	−0.093	0.013	−0.362**	−0.178	
d7	No. of commercialised products	0.29	0.45	0	1	−0.166	−0.165	0.045	0.064	−0.026	0.085

*,**Correlation is significant at the 0.05 and the 0.01 level respectively.

Table 4. Multinomial Logit regression model results.

G		Coef.	SE	Wald	*p*-value
0	Intercept	2.016	2.868	0.494	0.482
	d1 Transaction-specific investment	−0.254	0.509	0.250	0.617
	d2 Depth of innovation	−0.209	0.341	0.376	0.540
	d3 Development stage	−0.050	0.311	0.026	0.872
	d4 Therapeutic area	−0.737	1.051	0.492	0.483
	d6 Previous relations	1.368	1.050	1.697	0.193
	d7 No. of commercialised products	−2.739	1.270	4.655	0.031**
1	Intercept	11.914	5.563	4.587	0.032**
	d1 Transaction-specific investment	−0.415	0.602	0.476	0.490
	d2 Depth of innovation	−0.908	0.737	1.518	0.218
	d3 Development stage	−3.071	1.199	6.555	0.010**
	d4 Therapeutic area	1.178	1.892	0.387	0.534
	d6 Previous relations	5.717	3.019	3.587	0.058*
	d7 No. of commercialised products	−9.596	3.965	5.857	0.016**

Note: $^{*}p < 0.1$; $^{**}p < 0.05$; $^{***}p < 0.005$. The reference category is 2. McFadden pseudo R^2: 0.543; Cox and Snell pseudo R^2: 0.682; Negelkerke pseudo R^2: 0.776; Log likelihood: −47.747. χ^2: 58.488 ($p < 0.01$).

As can be seen, despite the small size of our sample, the model has a significant explanatory power, as demonstrated by the χ^2 test on the observed log likelihood. Also the McFadden Pseudo R^2 reveals an acceptable value. However, most likely owing to small sample size, only three of the independent variables have significant coefficients. In particular, variables *d3* and *d6*, namely the *development stage of the product* and the existence of *previous relations* are significant only at level $G = 1$. In particular, the negative coefficient for *d3* (−3.071) confirms that, as hypothesised in *H3*, hierarchy-oriented governance forms, such as JVs and M&As, are more likely than non-equity alliances when *d3* assumes high values. Also the positive coefficient for *d6* (5.717) confirms, as hypothesised in *H6*, that the existence of previous relations makes non-equity alliances more likely than JVs or M&As. On the contrary, variable *d7*, namely the *number of commercialised*

products by the biotech firm is significant at both levels of *G*. The negative value of the coefficient at $G = 1$ (−9.596) confirms that high values of *d7* are more likely associated with JVs or M&As, when compared with non-equity alliances, supporting hypothesis *H7*; however, the increasing negative level of the coefficient at $G = 0$ (−2.739), while it confirms that higher values of *d7* are more likely associated with JVs or M&As than with licensing agreements, does not confirm that these last governance forms are less likely than non-equity alliances. Thus, in this case, we find a sort of U-shaped behaviour when moving along the governance forms continuum.

6. Discussion and conclusion

This research aims at identifying factors affecting decision making on the governance mode of IFRs in the Italian biopharmaceutical industry. The main findings of this paper are that the *development stage of the product/technology* (*d3*) object of the agreement, the existence of *previous relations* (*d6*) between the partners and *the number of commercialised products* (*d7*) by the biotech firm actually influence such decision. As far as *d3*, the empirical evidence highlights that when the object of the collaborative agreement is a late-stage product the pharmaceutical company prefers a hierarchical governance form (JV or M&A). This result supports the RO and PRT view of the relation between technological uncertainty and governance form; indeed, through an integrated governance, the pharmaceutical firm can acquire the product's rights avoiding any potential costly hold-up issues. Also, this result confirms the prevalence of the pharmaceutical company point of view, since, as we have already stressed, the biotech company will have an opposite view regarding this driver. It is also quite interesting to notice how Santoro and McGill (2005) find an opposite result for this driver that, in the authors' view, is supportive of TCE considerations; they find that alliances in early stages rely on more hierarchical governance. In our opinion, this difference might be due to the distinct characteristics of firms in the two data sets; indeed, Santoro and McGill (2005) use data on US and non-US public biotech and pharma firms and surely biotech companies in their sample have greater bargaining power than the Italian ones, pushing the agreement towards a more contractual one in case of late stage products. On the contrary, Italian biotech companies are, for the most part, very small and they are not able to put up resistance to the excessive power of pharmaceutical companies; moreover, the limited development of the venture capital industry in Italy compared with the other countries strengthens these differences.

Then, as far as the result for the existence of previous relations (*d6*), it is quite expected and it confirms the view that trust can be a substitute for hierarchical contracts, as in Gulati (1995) and Santoro and McGill (2005).

Finally, with regard to the number of commercialised product (*d7*) by the biotech firm, we believe that the explanation of the U-shaped result for *d7* comes again from the controversial perspective problem between the partners; indeed, there are two possible cases when the number of commercialised products is high: (i) the pharmaceutical firm succeeds in integrating the biotech, acquiring all its products rights; (ii) the pharmaceutical firm fails to achieve an integration, because the biotech's bargaining power is high enough to hold out against an acquisition and thus the pharmaceutical part can only obtain the products rights through licensing agreements. Thus, M&As and JVs from one side and licensing agreements from the other side are more likely to happen when *d7* is high, the most likely governance forms being M&As and JVs because, as hypothesised in *H7*, these are the governance forms preferred by the pharmaceutical company.

Thus, our research contributes to the existing literature on alliance governance in the following ways. First, we provide insights on the complementarity of transaction costs, resource-based,

property rights and real option perspectives in explaining firm governance preferences, contributing to a literature strand that supports the integration of several theoretical approaches for a deeper understanding of rationales for governance of IFRs (Leiblein, 2003; Foss and Roemer, 2010). Indeed, this is, to the best of our knowledge, the first empirical research in the biopharmaceutical industry, integrating drivers belonging to different theoretical perspectives. Furthermore, our results confirm the validity of this integrated approach; indeed, looking at Table 2 and focusing just on the confirmed hypotheses, the reader can see how several theoretical contributions (TCE, RO, PRT, the concept of absorptive capacity) provide explanations to the problem of the governance choice. This is certainly an advance with regard to the available literature that mainly provides a comparison of pairs of the main theoretical strands. Also, we want to emphasise again the importance of the concept of 'absorptive capacity' in explaining the governance of IFRs, as also stressed by Contractor and Ra (1992). To our best knowledge, however, there is no other empirical study, apart from a case study analysis conducted by O'Dwyer and O'Flynn (2005), confirming the prediction that the concept of 'absorptive capacity' poses on governance form selection.

Second, our research highlights the importance of considering the dual perspective in biopharmaceuticals IFRs, since pharmas and biotechs often have conflicting goals about the governance mode selection, thus, it strongly depends on their relative bargaining powers. We are aware that, in this paper we just pose this problem from a theoretical point of view, but we do not face it from an empirical point of view, since we do not have data from pure biotech firms in our survey. Of course, this will be a path for further development of this research.

Third, this paper empirically confirms how uncertainty, appropriation concern and trust influence the governance choice in biopharmaceutical IFRs, results already discussed in the literature. However, we find that a new driver, i.e. the functional completeness of a firm, measured here by the number of commercialised products by the biotech company, is also important in determining this choice. The variable is particular significant in our analysis and we think it can be a good proxy of the contractual power of the biotech company. Nevertheless, it has never been considered in the literature; thus, our framework enlarges the set of drivers influencing the governance modes in biopharmaceutical industry beyond those most considered by the literature.

Our study has several managerial implications. First, we propose an operationalised framework for making governance decisions in biopharmaceutical IFRs. The advantage of our approach, from a managerial perspective, consists of having a formulated hypothesis directly on operationalised measures – this makes the theoretical framework easily applicable in the industrial practice. Indeed, most of the scholars having faced the same subject, formulate hypotheses on general issues such as 'technology uncertainty', 'technology newness', 'partner uncertainty', 'task uncertainty' and so forth. However, all these issues may be operationalised through different measures. For instance technology uncertainty in the biopharmaceutical industry might depend on the development stage, but also on the integration of the pharma in the biotechnology field. Thus, in this case managers consider the question of 'how can I measure technology uncertainty?'. In our framework we provide a specific answer to this question, because we formulate hypotheses directly on an operationalised driver such as the development stage; thus, managers can have an indication of how such a specific driver influences the choice of governance form. This, indeed, is an important managerial implication of our work.

Second, our focus on bargaining power provides interesting indications to managers in charge of IFRs in this industry. They must be aware that the industry context, the Italian one in this case, matters – indeed, in some more mature contexts, the contractual power between the partners could be significantly different, leading to different governance solutions. Then, managers need

to carefully evaluate measures of functional completeness, such as the number of commercialised products of the biotech firm, when approaching IFRs in biopharmaceutical industry.

There are limitations to this study. The most important one is that we rely solely on field-based primary data of a specific country and that the small sample size deriving from this choice may undermine the reliability and generalisability of our results. The small sample size might also provide an explanation for the non-significance of some variables. Therefore, we recognise that, despite the confirmative approach used in this paper, the theoretical framework needs a further confirmation through a larger dataset including other countries with a similar industry structure or through a worldwide comprehensive databank analysis.

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