# The Devil is in the Details: the contractual governance of Joint R&D

# **Biotechnology Alliances**

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#### ABSTRACT

This study aims at deepening our understanding of the contractual governance of technology alliances. For this purpose we carry out an in depth analysis of four contracts of pharmaceutical biotechnology alliances. The application of the framework contrasting transactional and relational contracts proves not sufficiently discriminating: all the contracts investigated are relational *latu sensu*, and considerable heterogeneity remains unexplained. A competing framework contrasting action-based and resource-based contracts provides a useful focusing device to analyze the texture of the different types of relations observes. Through resources the interpretation of alliance contracts is connected to fundamental sociological research on human sociality. This allows us to develop a framework that explains the configuration of contractual governance in terms of the relational model adopted by the parties. Our framework also proposes that the distribution of core competences among the parties is an important predictor of the relational model. Finally, testable propositions deriving from the study are offered as guidelines for further research.

KEYWORDS: Governance, contracts, strategic alliances, biotechnology, joint R&D

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#### 1. Introduction

While inter-firm alliances are a widely investigated issue, research concerning their governance is less plentiful (Gulati, Singh 1998, Ireland, Hitt, Vaidyanath 2002, Dekker 2004). Some authors observe that existing studies of governance focus on the comparison of discrete structural alternatives and call for a more fine-grained, micro level analysis of both networks (Grandori 1997) and contracts (Goldberg 1976: 426-7). This study aims at making a contribution in this area by investigating the governance of four joint R&D alliances, and by doing so at a considerably more micro analytical level than is commonly observed, blending economic typologies of contract completeness and articulation with social and organizational categories.

Originally, the topic of governance had been almost identified with that of contractual relations (cfr. Williamson 1979). However, soon afterwards organizational scholars began introducing also social embeddedness (Brusco 1982, Powell 1987, Belén Villalonga 2005) and behavioral dimensions (trust, equity) (Lorenz 1988, Woolthuis, Hillebrand, Nooteboom 2005) into the study of alliance governance. This may be seen as reflecting the awareness that alliance governance is more nuanced than it is implied by perspectives focusing on control. However, these studies find additional, and partly autonomous, motivation in the claim that owing to the 'incompleteness' of contracts, the governance of inter-firm alliances needs to be complemented by external sources of regulation. While not objecting to the claim that "private explicit contracts blend into implicit social contracts" (Goldberg 1976: 430), we submit that forty years after Goldberg's invitation to open it up, the "black box of contract" still conceals governance properties that await discovery, particularly when applied to inter-firm alliances. This claim may sound excessive given the attention that contracts have received from economists, and sociologists, not to mention legal scholars. Without referring to the vast literature on general contracting, and confining ourselves just to empirical investigations of contracts in high technology industries, we can mention, among else, the studies of Suchman (1994), Lerner, Merges (1998) Kaplan, Strömberg (2003, 2004). Yet, after the early intuitions of Stinchcombe (1985) scholars of organization theory and strategic management have dealt with this topic only occasionally. Recently, these disciplines have seen a resurgence of interest in contracts, as witnessed, among else by Poppo and Zenger (2002), Mayer and Bercovitz (2003), Anderson and Dekker (2005) and by several studies collected in Ariño and Reuer (forthcoming). Yet, limitations in the methods, in the data available and uncertainty about the relevant variables indicate that the field has not reached maturity yet.<sup>1</sup>

All the above provides incentive to focus this study specifically on the formal contractual governance of strategic alliances. We shall investigate this topic in the particular context of the

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<sup>&</sup>lt;sup>1</sup> For a critical assessment of recent empirical studies on inter-firm contracting see Furlotti (2005)

pharmaceutical biotechnology industry. This choice is motivated first of all by reasons of convenience. Biotechnology is by far the industry with the largest concentration of inter-firm alliances. Moreover, since its participant firms are very often small, recently established companies, they are in great need of support from the institutional environment. As a result, they are inclined to disclose otherwise confidential deal terms much more than firms in other, more traditional industries. However, alliances in the pharmaceutical industry have also another interesting property that facilitates investigation. As we shall see below, the drug discovery process is very structured and sequential (Nooteboom 2004: 8) — for both technological and institutional reasons. Accordingly, it is relatively easy to observe external conditions that can be interpreted as reasonable proxies of the uncertainty of the alliance's task, traditionally one fundamental predictor of organizational forms.

While our general research question shall be "How to design the contractual governance of inter-firm alliances?" we shall not deal primarily with the investigation of the 'fit' between alliance context and alliance design choices. This, of course, is not intended as a quest for the 'one best way' of structuring alliance governance. Rather, it is meant to focus the analysis on the internal logic of alliance contracts (Leblebici, Shalley 1996). The question of the internal logic, in turn, is by no means a trivial problem, since alliances, and their governance, have to satisfy conflicting needs of collaboration and competition (Oxley, Silverman forthcoming), of planning and adaptation (Williamson 1975).

The paper proceeds as follows. Section 2 formulates more specific research questions with the help from a review of prior research on contracting problems in alliances. In section 3 we set the stage of our empirical investigation by exposing the fundamental traits of the drug discovery process and of biotechnology alliances. Section 4 introduces the four alliances of our sample. Section 5 describes our findings, organizing them according to three fundamental constructs. In section 6 we develop a conceptual framework to interpret our findings and advance several propositions for further research. Finally, section 7 summarizes the main contributions of the study and discusses its limitations.

#### 2. Previous research

Contracting problems in alliances have been investigated to a considerable extent in empirical studies inspired by transaction costs economics (TCE) and by the property rights approach (PRA). Yet the focus of these studies has been overwhelmingly either on the antecedents or on the consequences of certain contractual forms and clauses (Shelanski and Klein 1995, Lyons

1996, Furlotti 2005) or on the performance consequences of those forms and clauses (e.g. Sampson 2004).

This focus was enabled by prior analysis made by legal scholars, notably by Ian Macneil (1974 and 1978) that had been assumed by Oliver Williamson (1979) as his starting point. Macneil had proposed that the contractual solutions to the problem of projecting exchange into the future fall anywhere in between two polar archetypes of transactional contracts and relational contracts. In Williamson's reading of this lesson the efficiency of approaching either of these alternative governance structures varies with the level of the transaction idiosyncrasy (how much the identity of the partner matters for the profitability of the transaction). Hence, it becomes important to ascertain what determines the transaction idiosyncrasy. 'Uncertainty, frequency and the degree to which transaction-specific investments are incurred', is Williamson's answer.

The application of this framework (often in combination with the resource-based view) has brought an enormous progress to the investigation of firm boundaries, and of alliances in particular (Oxley and Silverman, forthcoming). Yet, it must be borne in mind that the prototypical transactions on which this framework has been developed are vertical, buyer-supplier transactions for the exchange of physical goods. It would be unsurprising if the framework comes under stretch when applied to radically different transactions. For example, it is not clear that conditions of small numbers and high asset specificity obtain in technology alliances for the production of largely immaterial goods. Yet their contractual governance seems definitely 'complex', by many measures taken, as are the contracts associated with high transaction-specific investment. But, are alliance contracts complex in the same sense as contracts for the supply of physical goods are?

In the cases analyzed by Williamson, the main problem posed by the idiosyncrasy of transactions is the risk of expropriation of the quasi-rent generated. In turn, this problem depends mainly on the incompleteness of contracting: if the realization of some contingency reveals that the contracting terms were maladaptive the parties may haggle (Williamson 1983). The solutions Williamson proposes fall essentially into one of three classes. The first is represented by means that reduce the likelihood of the contract becoming maladaptive. This, in turn, is achieved by declaring admissible dimensions for adjustment and setting procedures about it (Williamson 1979). The second class is represented by hostages to support commitment (Williamson 1983). The third includes means that increase the buyer's reliance on the relation, like investment in capital that has value only if the relation stays in place. In the same vein as Macneil, these three solutions indicate that the problems of adaptation, on one side, and of the fulfillment of the original plans, on the other, are two of the core functions a contract must accomplish.

Thus, the first avenue of our research will explore how the competing needs of planning and adaptation are fulfilled in pharmaceutical biotechnology alliance contracts.

In addition to Macneil's classical framework that opposes transactional contracts to relational ones, our study will apply a second framework that counters activity-based to resource-based contracting. In a recent conceptual contribution Grandori (2005)argues that in contexts characterized by high uncertainty – where the focus on the foresight of contingencies would be particularly unwieldy, on top of being logically impossible – one way to reconcile the opposing needs of planning and flexibility might be to shift contracting from prescriptions of actions to higher level principles or rules and to the 'generators' of those actions, and she suggests that in economic settings such generators are resources. In the attempt of developing and operationalizing this idea, this study will also carry out a parallel investigation on the role that resources play in pharmaceutical biotechnology alliance contracts.

In Macneil's analysis, the projection of the exchange into the future that has become increasingly necessary in post-industrial states is one that draws support from the relation between the actors, besides the traditional support afforded by promise. Despite drawing considerable inspiration from Macneil, Williamson, and TCE in general, have not emphasized this aspect of governance. As noted by B. Nooteboom (2004:513) this owes a lot to their choice of transaction as the unit of analysis. Thus, to find stimulation about the role of the relation in contracting we must search elsewhere. In this regard, the relationship models theory developed by anthropologist A. P. Fiske (1991 and 1992) and others on the basis of classical sociological thinking and empirical research across the social sciences is particularly inspirational. The core concept in these models is that most aspects of sociality are organized by combinations of just four fundamental structures, which reflect elementary mental models (Fiske 1991:690).<sup>2</sup> One reason why the concepts of this framework may prove particularly apt to the interpretation of technology alliances, particularly if Grandori's hypothesis proves correct, is that, by Fiske's own admission, these structures can be described quite precisely by the terms according to which people transact resources. "Communal sharing is like a category or set, all of whose elements are equivalent (not differentiable with respect to a given property)... Authority ranking is a linear ordering in which everyone's rank can be compared with everyone else's... Equality matching is a relational structure in which people can compare quantities and use the operations of addition and subtraction to assess imbalance ... Social relationships organized with reference to market pricing are structured like the rational numbers" (Fiske 1991:690). Other elements of this theory are that people use different models simultaneously for different aspects of the same interaction, yet "the overall structure of the interaction can

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<sup>&</sup>lt;sup>2</sup> These structures are Communal sharing, Authority ranking, Equality matching and Market pricing.

frequently be described in terms of one predominant model" (Fiske 1991:693). These arguments motivate our third avenue of research, concerning which types of relations sustain biotechnology alliance contracts.

These foci of attention implicate that our analysis shall neglect some parts of the contract that are not particularly relevant to answer our research questions. In particular, we shall not take into account so-called 'boilerplates' (Kahan and Klausner 1997) as well as clauses covering indemnities, representations, warranties and insurance. Another way of saying it is that we shall focus on 'performance planning', that is, on those parts that are central to the smooth and efficient accomplishment of the aims of the parties, to the neglect of the 'risk planning' part of contracts (Macneil 1975: 639-41). But before we venture into the more analytical part, it will be useful to set the stage of our investigation.

## 3. Drug discovery and biotechnology alliances

Alliances are a common method of organizing pharmaceutical R&D. This trend has received a dramatic push from the biotechnology revolution. Such revolution has surely many facets that would be beyond the scope of this paper to describe. Just to mention one – that justifies the use of the term 'revolution' – with the introduction of the technology of the recombinant DNA in the seventies, it became possible to produce proteins, the second major class of therapeutic agents, after small molecules.<sup>4</sup>

From an industrial organization point of view, one salient characteristic of the phenomenon of biotechnology has been the sprouting of small-sized research laboratories based on one or two promising biotechnology projects. Again, describing in detail this phenomenon would be way beyond the scope of this work. However, one example suffices to point out the implications of this technological revolution for alliancing. In 1997 Merck Sharp & Dohme, at that time the world's largest pharmaceutical company, had a market capitalization of 127 billion US dollars and a workforce of about 60 thousands people. During the same year all the biotechnology firms (about 2000) had a comparable market capitalization (83 billion US\$) and a staff of almost identical number. However, while Merck had only 50 projects at the clinical development stage, all the biotech companies had more than 700.<sup>5</sup>

In other words, as a result of the biotechnology revolution, large established pharmaceutical companies found that certain promising knowledge resources were in scarce supply within their

<sup>&</sup>lt;sup>3</sup> 'Boilerplates' indicates generic fixed clauses.

<sup>&</sup>lt;sup>4</sup> For a concise but insightful overview of the revolutionary changes in this industry, the interested reader may refer to Gilsing and Nooteboom (2006) and to the many sources cited therein.

<sup>&</sup>lt;sup>5</sup> This example as well as the assessment on the main implications of the biotech revolution are from Fumero (2003)

boundaries, and had to look for them among small and specialized firm (MacKelvey and Orsenigo, 2004). Incidentally, this natural complementarity also concealed the seeds of attrition between potential partners. For example, these firms tended to specialize in specific technologies, which were particularly useful in the early stages of the discovery process. Yet some of them cultivated the ambition of gradually reaching out into biomanufacturing and global commercial distribution. Eventually a few succeeded, as Amgen, Genentech, Biogen IDEC, Serono and Chiron today make it in the top 50 list of pharmaceutical companies.<sup>6</sup>

Three features of the drug discovery process are salient in relation to alliancing. First the whole process is extremely long and costly. As reported in Table 1 in the appendix, the process currently lasts on average about 14 years, more than six years longer that in the sixties. The cost of developing a new drug has been estimated at 802 billion US\$ (DiMasi 2001). Second, the attrition rate (the number molecules that are discarded during the process) is extremely high and is particularly severe during the very early stages (see Table 2 in the Appendix). In other words, a lot of the alliances negotiated in the early stage of the process are doomed to scientific failure. Conversely, given the difficulty of generating new products, once a new drug hits the market it keeps being sold for 10-20 years and sometimes even longer, with cash flow profiles in the black from second year and growing for about a decade (Grabowski et al 2002: 20). These three characteristics favor partnering, in order to transfer risk from firms specializing in the early stages of the discovery process to pharmaceutical companies with comparative advantages in manufacturing and commercialization.

Given this fundamental risk-sharing need, it is unsurprising that many alliances have 'vertical' elements, with one party often providing the finance in exchange for commercialization rights. Moreover, given the profile of the attrition rate – rapidly decaying, as development progresses through different stages – it is quite understandable that the pattern of interaction between the alliance partners often changes quite radically, as the collaboration sails out of the initial turbulence into the more predictable waters of late development stages.

## 4. The sample

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<sup>&</sup>lt;sup>6</sup> According to Gilsing and Nooteboom (2006: 11) the biotechnology firms "did not aim to become drug producers themselves but acted as providers of these new technologies". This may be true for the majority of them. Yet the position of biotechnology firms in the ranking lists of the pharmaceutical industry is in witness that the attrition referred to in the main text was quite real. Additionally, reading of actual alliance contracts exposes that co-promotion, co-marketing and co-manufacturing option rights were often agreed, clearly on request of the biotechnology partner, as a means to develop capabilities in downstream activities.

Before we venture in the analysis of the contractual apparatus, we shall introduce the four alliances of our sample.<sup>7</sup> The sample has been somewhat 'stratified', to enable the investigation of contractual governance not only in typical vertical alliances, but also in collaborations where both partners are biotechnology firms. A second criterion of stratification has been to choose alliances entered at different stages of the discovery process, in order to investigate whether contractual characteristics are sensitive to different uncertainty conditions. Table 3 in the Appendix recaps the main characteristics of the alliances in the sample.

For the reasons exposed earlier, it is particularly difficult to establish, in general, whether a biotechnology alliance is successful. With regards to our sample we can say that for three out of four alliances we have evidence of progress of the collaboration through successive stages of the drug discovery while the remaining one is too recent to say. Moreover, all the alliances were established between partners with extensive or substantial prior collaboration experience.

#### A - Kirin-Nuvelo

Alliance A is established in March 2005 between Nuvelo Inc. a California-based publicly traded biopharmaceutical company, and the pharmaceutical division of Kirin Brewery Company of Japan, the world's foremost brewery. The companies were parties to a prior collaboration to assign functions to genes of previously unknown function. This alliance is designed to develop and commercialize products for the treatment of inflammatory diseases, based on a particular protein (referred to as 17206) that had been identified in the prior collaboration as being involved in intestinal epithelial cell proliferation. At the time of signing this agreement, compound 17206 had reached the stage of the preclinical studies needed for an Investigational New Drug application (IND) to the Food and Drug Administration (FDA).

Under the terms of the agreement Nuvelo will lead worldwide development, manufacturing and commercialization activities. All expenses and operating profits will be shared in a 60 (Nuvelo) /40 (Kirin) ratio while the parties are both actively collaborating under the agreement. Kirin is not expected to carry out any particular task, except if Nuvelo so requests and Kirin accepts.

The contract is open ended, inasmuch as under a normal scenario the alliance would continue until either party develops or commercializes any product.

### B - Biosearch-Vicuron

<sup>&</sup>lt;sup>7</sup> The contracts analyzed have been provided by Recombinant Capital (Recap), a San Francisco Bay Area-based consulting firm specializing in biotechnology alliances, whose help is gratefully acknowledged. The contracts were originally submitted to the US Securities and Exchange Commission as part of the firms' 8K, 10K, 10Q and S-1 filings.

Alliance B is established in February 1998 between Biosearch Italia S.p.A. and Versicor, Inc. of California. (later to become Vicuron). Biosearch Italia is the former Lepetit Research Center of Hoechst Marion Roussel. Biosearch's laboratories have been a world leader in infectious disease discovery and development for several decades and they have introduced major infectious disease products into the worldwide market. Versicor, Inc. is a privately held company that integrates biology/genomics, combinatorial chemistry, high throughput screening and informatics to discover novel anti-infective drugs effective against resistant pathogens not controlled by existing therapies.

The goal of the alliance is to exploit the complementary know how of Biosearch's natural products discovery expertise, existing portfolio of lead compounds and in vivo evaluation capability with Versicor's combinatorial chemistry/library synthesis expertise, in vitro assessment of antibacterial activity, toxicity and pharmacokinetic properties. In practice, Biosearch contributes the natural product antibiotic leads and Versicor will contribute skills and efforts to optimize those leads. This situates the alliance at the 'discovery' stage. All primary care antibiotics derived from the collaboration will be partnered to large pharmaceutical companies with the revenues shared 50 - 50 between the two companies. Rights to the hospital antibiotics generated will be exclusive to Biosearch for Europe and exclusive to Versicor for North America. Hospital antibiotic rights for all countries outside Europe and North America will be jointly owned with the parties sharing the revenues 50 - 50. Initially, more than 15 novel antibacterial natural product leads will be contributed to the collaboration. The contract envisages a development program term of five yeas, extendable by mutual agreement.

# C - Sunesis-Biogen IDEC

The partners to alliance C, initiated in August 2004, are Sunesis Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company of California, and Biogen Idec of Massachusetts, a biotechnology corporation with research, development, biomanufacturing, and global commercial capabilities. This collaboration is the second between the companies, after one initiated at the end of 2002.

The focal alliance is designed to discover and develop small molecule cancer therapeutics targeting kinases, a family of cell signaling enzymes that play a major role in the progression of cancer. The companies will apply Tethering(R), Sunesis' proprietary fragment-based drug discovery technology. Under the terms of the agreement, Sunesis will receive upfront a \$7 million technology access fee and \$14 million equity investment, research funding to support Sunesis scientific personnel over an initial four-year research term, pre-commercialization milestone payments, and

royalty payments based on product sales. Sunesis retains an option to participate in the codevelopment and co-promotion of several products that may emerge from this collaboration.

A team of Biogen Idec and Sunesis scientists will work together on the identification, optimization, and development of kinase drugs.

The contract establishes a period of four years for research activities (extendable for up to an additional two years), while ongoing activities of the alliance shall last until there are royalty payment obligations.

## D - Alexion-P&G

Alliance D is established in January 1999 between Alexion Pharmaceutical Inc. a Connecticut-based, medium size, listed biotechnology firm and a subsidiary of the health care division of Procter & Gamble Company. This alliance is designed to develop and commercialize Alexion's lead drug candidate pexelizumab. This bacterially-produced antibody fragment will be concurrently assessed in a few acute cardiovascular indications, like coronary artery bypass graft surgery and myocardial infarction. At the time of signing this agreement, pexelizumab has completed Phase IIb for certain indications.

Under the terms of the agreement Procter and Gamble will receive worldwide development and marketing rights. In return, Alexion will receive up to \$95 million in total payments (of which, 10 millions upfront), which may include up to \$39 million in pre-commercialization milestone payments. In addition, Alexion retains the right for commercial manufacturing as well as having co-promotion rights in the US.

### 5. Measures

## 5.1 Planning

The extent to which the parties plan their relation ex-ante tends to impacts on the length on the contract. Yet other factors, like attempts to incorporate adaptation mechanisms into the agreement may drive up the contract's size. Therefore, we do not consider contract length as particularly a good measure of planning. Nonetheless, supposing that length still conveys some information about this dimension, alliances A, C and D do not differ greatly from each other. On the contrary, A's contract (about 38,000 words) and B's (7,500) differ markedly under this respect.

Comparing directly the research plans and the commercialization plans in each contract also suffers from limitations, given that several details are normally excised for confidentiality reasons.

Yet, it is possible to make some positive statement. All the contracts contain a plan of the research activities. B's is definitely the shortest (108 words): it simply names ten steps that indicate the fundamental tasks of the parties, without any articulation. On the contrary, C's initial research plan is probably the most detailed. It identifies 59 distinct activities to be performed during the initial four years of the collaboration, determines the allocation of resources to each of them and provides a Gantt chart outlining each respective start and end date. The plan is further detailed through the specification of several criteria that will guide the assessment of whether to bring a certain molecule to the next phase of development or not (e.g.: a maximum IC50, or "inhibitory concentration", that is, the concentration of a drug that is required for 50% inhibition of viral replication *in vitro*). D's initial R&D plan is also fairly long (8 pages). Yet it is entirely procedural. Essentially it recaps the projects in progress as of the effective date of the agreement and assigns the basic action rights with respect to sections of the program. The plan of alliance A is entirely confidential, but by some indicia we can confidently include it again in the same class as C and D's, and contrast it to B's.

Contrary to research, downstream activities (commercialization and manufacturing) are scarcely planned in all the four alliances. Such plans are lacking altogether in collaborations B and C: in the former because the parties plan to exploit the results of their work through outlicensing; in the latter because unless Sunesis exercises a co-promotion option, Biogen has sole responsibility to undertake development and commercialization activities and it is not required to disclose its plans to the counterparty, let alone to involve it in decision making. The contract of alliance A makes extensive reference to the planning of commercial activities, but actual drafting of plans is postponed until a specified period before commercial launch. Finally, in alliance D commercialization and manufacturing are described sketchily (about one page each): the contract essentially establishes who has the right/responsibility to perform them and under what conditions.

As opposed to the planning of activities, the plans concerning the incidence of costs, benefits and resources in general are definitely less hazy. First, project costs are generally specified accurately both as to their amount and to their incidence. In alliance A the financial budgets of the activities are a cornerstone of planning (the word 'budget' is mentioned 248 times). The centrality of budgets is also apparent in the regulation of budget overruns, which sets a tight cap on the amount of development costs in excess of budget that can be included in sharing calculations. In alliances C and D the financing party achieves budgetary control of the funds it commits to the reimbursement of the research effort of the counterparty through the specification of the number of personnel full-time equivalents (FTE's) it will fund and of the FTE rate to be used in the calculation. On the contrary, alliance B stands out (no budgets), as its basic arrangement (each carries out its own activities and bears their costs) requires no foresight of monetary input factors in

the contract. In these alliances, the costs that a firm bears for the accomplishment of its contractual duties are not subject to planning, unless the contract also establishes a corresponding duty to share or to reimburse. However, in other biotech alliances, we have seen commitments of financial resources that were supposed to be used other than as monetary rewards or reimbursements of the counterparty.

The incidence of monetary revenues is always crystal clear. In alliances C and D the client firm pays the R&D firm royalties on net sales [C] or on operating margins [D]. Royalty rates are excised from the contract, but by it is unlikely they exceed 20 percent. In alliances A and B, the parties have agreed on more egalitarian sharing terms between R&D firm and client: 60-40 [A] and 50-50 [B] respectively.

Finally, the contracts never forget being specific about the incidence of intellectual property rights that are brought into the collaboration (background rights) or generated by the collaboration (foreground rights). In all the alliances the background rights licensed by the R&D firm are explicitly listed in an appendix to the contract. With regards to foreground rights, contracts A and B are rather communitarian, as already seen with monetary rewards. Inventions are to be owned jointly [A] or are to be shared [B], regardless of inventorship. On the contrary, in contracts C and D the rule is specific incidence: each owns the inventions generated by its own employees.

In sum, the degree of planning of the activities varies in different alliances. The planning of activities appears broadly similar in three alliances while in the other one [B] it is definitely more imprecise. It seems rather clear that the possibility – or the willingness – to plan is severely affected by the distance of activities in time. On the contrary, the degree of planning of research projects seems to vary only marginally between alliances negotiated at different stages of the discovery process. This suggests that the degree of environmental uncertainty may be a better predictor of the planning intensity than the degree of task uncertainty. While the evidence available is scarce, it appears that the type of planning that is carried out in alliances is largely procedural, focusing on the assignment of action rights and duties, and on the specifications of criteria to guide subsequent decision making. As to costs, benefits and resources in general, the planning of their incidence is rather accurate. The incidence regime is more egalitarian in alliances A and B, while in C and D monetary costs and benefits clearly accrue more to one party than to the other. On the contrary, non-monetary benefits are not pooled. Neither the type of relation (vertical vs. horizontal) nor task

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<sup>&</sup>lt;sup>8</sup> We would be more confident in our statement, if we could have controlled for the coordination requirements entailed by different levels of interdependence among the parties' roles. Presumably an alliance that is born with the intention of extending the scope of joint activities to marketing and sales, is more likely to acknowledge the coordination requirements these activities entail, and may plan them at least sketchily, although they may be considerably distant in time.

uncertainty seem to be good predictors of the type of the regime chosen, since alliances of both types and of different levels of uncertainty are represented in each couplet. Indeed, focusing on the underlying relational models of biotechnology alliances might be a more productive strategy, from the point of view of understanding the details of their contractual governance, than concentrating on contextual factors.

## 5.2 Adaptability

In all four alliances contract plans are specific enough to define the business arena of the alliance and the fundamental roles of the parties. However, all the contracts acknowledge that both the planning of actions and of resources are only tentative when they venture toward a more operational level:

- 3.4 Changes to Development Plan and Budget. Development Plans and Budgets may need to change in the course of a calendar year.  $\left[C\right]$
- 1.10  $\dots$  it is anticipated that the level of effort will change over time reflecting changes in the status of the compound, product and the market involved. [D]

As a result contracts concede that plans will undergo modifications

- 3.4 Changes to Development Plan and Budget. Development Plans and Budgets may need to change in the course of a calendar year...  $\cite{A}$
- or will be agreed after the start of the alliance:
- 4.3 Launch Plan and Budget. (a) Initial Launch Budget. Because of the current preclinical research stage of 17206, the Parties are not able at this time to generate a reasonable initial launch budget at a level of detail similar to the Overall Plan for the Collaboration Product... [A]

What differ among alliances are the structures and processes the contract establishes to carry out the required adaptation. In all the alliances a Joint Steering Committee (JSC)<sup>9</sup> has some role in the process of revision and further specification of existing plans and of approval of entirely new plans. In alliance B the JSC is composed of an equal number of members from each party, decides by unanimous vote, alternates the Chairmanship between the parties on a yearly basis (with the Chairman holding no tie-breaking vote) and is vested with the full and undivided powers to make these changes. In the other alliances the powers of the JSC suffer from various limitations. In alliance C the client has a final say when the JSC is unable to reach consensus and negotiation between senior executive officers also fails to bring about an agreement. In alliance A, Nuvelo (the

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<sup>&</sup>lt;sup>9</sup> While its denomination may vary, all the alliances are endowed with at least one multi-party decision-making body with tied seats, entrusted with supervisory responsibilities over the alliance.

R&D firm) always have a right to make a final determination for changes of ordinary yearly development plans. In alliance D, P&G (the client) holds almost unfettered decision rights regarding the strategy and tactics of selling and commercializing marketed products and can decide termination unilaterally when scientific or commercial failure can be unambiguously measured through the Success Criteria set forth in the Research & Development Plan.

While the assignment of unilateral decision rights to one party exposes the other to risk, contracts generally limit such exposure through various safeguards. In alliance D, as we have just seen, these are in the form of verifiable criteria, set ex-ante 'under a veil of ignorance', that must be met in order to exercise the decision right. In alliance C the safeguard is provided by the requirement of consistency with the contract:

5.1.4. ... Biogen Idec shall not have the right to exercise such deciding vote in a manner that is not consistent with the other terms and conditions of this Agreement or that imposes a material obligation on Sunesis.

Finally, in alliance A, for activities down the road, for which the reference framework of the plans laid out in the contract is largely tentative, if not missing at all, the adaptation mechanism switches from authoritative to democratic, particularly when the decisions involved are high in potential conflict:

4.3 Launch Plan and Budget. (a) Initial Launch Budget. Because of the current preclinical research stage of 17206, the Parties are not able at this time to generate a reasonable initial launch budget at a level of detail similar to the Overall Plan for the Collaboration Product... Consequently ... the Parties intend that budgetary limitations for Commercialization for the Initial Launch Period shall be set by mutual agreement of the Parties, with neither Party having a final say.

Sometimes contracts plan for flexibility through the explicit foresight of contingencies. One such case is the provision, in alliance D, that royalty payment be reduced if sales of non-infringing generic equivalent products exceed a certain market share. Other cases are the provisions that Alexion's right to co-manufacture [D] and Biosearch's right to manufacture [B] are subject to proven capacity to meet a number of criteria. All in all, the foresight of contingencies is used rather sparingly, to provide flexibility with regards to issues that would be too contentious to be solved

through negotiation or through unilateral decisions, yet too important to give up the value entailed by adaptation.<sup>10</sup>

In sum, owing to the nature of the activities involved in the alliances, the parties acknowledge that planning is tentative and requires adaptation. In most cases contracts are appreciative of the contributions to adaptation that may come from both parties and guarantee 'voice' opportunities to each party, either through formal consultation processes or through outright co-decision rights. Sometimes, adaptation is provided for by unilateral decision making. This seems to occur mainly in areas where the party holding decision rights 'knows better' [A and D]. While unilateral decision rights are not uncommon, seldom if ever they are totally unrestrained. Restraints are particularly salient when adaptation impacts on the resources contributed. Finally, decision-making style seems to correlate well with the approach chosen on the incidence of costs and benefits: where the latter establishes equal obligations and rights for both parties, decision-making tends to be unabashedly democratic.

## 5.3 Relationality

According to Macneil, one element of exchange that cannot be dispensed with, whatever the contracting style chosen, is the projection of exchange into the future: doing something now that limits choices in the future (Macneil 1974: 696 and 719). In post industrial states – he contends – the most important way by which exchange is projected into the future is through expectations that exchange motivations and dependence on exchange will continue in the future (Macneil 1974: 718). In turn, these expectation and dependence are founded on presently existing relations. In this section we assess to which extent the relation is a source of socio-economic support for the exchange in the focal alliances. We do so by inquiring into the parties' own perception of the requirement of future cooperation, by looking at the constraints that the contractual relation imposes on the activities outside the relationship itself and at conditions for assigning the relation to a different partner. Further, we look at the apparatus that is intended to salvage the relation when it comes under strain. Finally, we consider the circumstances under which the relation itself can be dissolved.

Most contracts acknowledge that the success of the alliance cannot be guaranteed by the sheer fulfillment of promises, and explicitly require that the parties collaborate during the life of the agreement:

10.2.4 Cooperation. Each Party will cooperate fully with the other Party and provide all information and data, and sign any documents, reasonably necessary and requested by the other Party for the purpose of preparing,

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<sup>&</sup>lt;sup>10</sup> Contingency clauses are also used occasionally as enforcement mechanisms. E.g.: in case of failure to exercise Diligent Effort to Commercialize in a country, all rights for the country revert to the other party [A].

filing and prosecuting patent applications pursuant to this Section 10.2  $\cite{C}$ 

or

(ii) Transitional Assistance. The Removed Party shall provide all cooperation and assistance reasonably requested by the Non-Removed Party … to enable the Non-Removed Party (or its designee) to assume and/or continue, with as little disruption as reasonably possible, the continued Development and Commercialization of Collaboration Compounds [A]

Paradoxically, where cooperation is the least invoked is in the alliance were the promises mutually exchanged are of minimally specified content [B].

Parallel to the requirement for future cooperation, the requisite that the parties do not engage in external activities that can be detrimental to the relation has special prominence in all contracts:

- 3.7. Non-compete. Neither Alexion nor Procter & Gamble shall itself or in conjunction with a Third Party enter into the development or commercialization of a Competing Product during the Term of this Agreement  $\dots$  Any actions by Alexion under these conditions is contingent on such actions being approved by the Research & Development Steering Committee and not being to the disadvantage of the collaborative efforts under the Research & Development Plan. [D]
- 2.4 EXCLUSIVITY. During the six (6) month period in which Versicor is evaluating a Biosearch Lead Compound under Section 2.2(b), Biosearch agrees that it shall not transfer, license, sell or otherwise provide such Biosearch Lead Compound to any Third Party for any use. If any Biosearch Lead Compound is selected by Versicor for Versicor Studies under Section 2.2 (b), Biosearch agrees that it shall not transfer, license, sell or otherwise provide such Biosearch Lead Compound to any Third Party unless and until the date any such Biosearch Lead Compound is returned to Biosearch as an Abandoned Compound under Section 2.3. [B]

Restrictions to the assignment to third parties of the rights under the alliance agreement are also common to all of the focal contracts. The correspondent covenant of alliance A is representative of the typical obligations on this matter:

15.10 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other; but a Party may make such an assignment without the other Party's consent to an Affiliate or in conjunction with a merger,

acquisition, or sale of all or substantially all of the assets of such Party to which this Agreement...

However is some cases the contract acknowledges the uniqueness of the counterparty's identity in even stronger terms. In alliance C, the contract establishes that upon a change of control some rights of the acquired party shall terminate. In alliance D, if the R&D firm experience a change in control, P&G can sell its interest in the alliance to the R&D firm itself or to third parties. Incidentally the fact that the converse is not true (the R&D firm is not allowed to leave in case P&G changes control) corroborates the idea of a 'resource-based' contracting. At least in some biotech alliances it is VRIN<sup>11</sup> resources (Barney 1991) that matter. On the contrary the identity of the financier is rather irrelevant. However, the empirical literature inspired by the PRA tends to interpret this lopsidedness of the allocation of rights only in terms of conflict of interests (Lerner and Merges 1998, Kaplan and Strömberg 2003 and 2004).

The importance of the relation is underscored also by the provision, common to all the alliances, of mechanisms to keep it afloat when disputes surface. Alliance A expresses the parties' attitude underlying such mechanisms:

14.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the term of this Agreement ... It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation.

The typical set of mechanisms (typical in the sense that it is commonly found also in alliances outside the focal sample) envisages the escalation of disputes to senior executives for settlement in an amicable way through negotiation. Failing that, the procedure provides for arbitration by a panel of legal experts [B]. Normally, arbitration is final, meaning that the dispute cannot be brought also to court. In addition to arbitration by legal experts, some of the alliances in our sample provide also for even leaner dispute resolution mechanisms. For instance, alliance D reserves the judgment on the collapse of the scientific rationale of the collaboration and on the inventorship of inventions made under the research plan to industry experts. Alliance C resorts to experts to determine whether disputed compounds are active with respect to a specified target protein. Alliance A, quite remarkably, provides abundantly for resolution by industry experts, not only when disputes involve complex scientific know-how, but also when they relate to matters (Initial Launch Budget, Required Study, Sales Force Expense Mechanism), that are strongly

<sup>12</sup> Yet it is not uncommon that the contract allows to enter judgment for the award rendered by the arbitration, or to submit claims to a court for injunctions and other equitable relief.

<sup>&</sup>lt;sup>11</sup> Valuable, Rare, Imperfectly Imitable, Non-Substitutable.

influenced by the parties' respective interests. For each of them the contract establishes a particular procedure, assigns decision rights to an Industry Expert, and prescribes the standards that shall guide his/her determination of the dispute:

14.3 (iii) ... the standards for a Sales Force Expense Dispute are that the Industry Expert shall select between the two mechanisms for determination of Sales Force Expenses proposed by the Parties based upon which is more within industry norms for products with similar commercialization requirements and more closely approximates, or calculates, such Party's actual costs reasonably chargeable to the Collaboration in this category.

Thus a wide array of soft dispute-resolution mechanisms is available. Nonetheless, there seem to be cases when disputes undermine the relation beyond repair to the point that the parties turn to uncompromising confrontation. This is the case in alliance C (for matters relating to intellectual property, and for breaches of warranties and representations) and D (default of payments, breaches of confidentiality, indemnification and insurance). Interestingly, one of the triggers of litigation in both alliances is disputes on resources.

Indeed, all the above underscores the importance of the relation. But where exactly do relations terminate? One obvious answer would be to look at the term of the contract. However, this is problematic. Since the goal of each alliance is the development and commercialization of products based on patentable know how, the term of the contract usually coincides with the expiration of royalty payment obligations, which, in turn, are determined by the later of the expiration of the last valid claim on licensed patents or a predetermined number of years since the start of commercialization (usually 10 or 15). This means that in a number of alliances, after the research program is completed, only one party – usually the client – carries out all the actions, and the other becomes a passive receiver of royalty payments, if any. If the essence of relation is coordination and complementarity of two parties' actions, such exchange could be hardly qualified as relational.<sup>13</sup> What is the case in the focal alliances? In alliances [A], [C] and [D] the baseline scenario is that the R&D firm [A] and the client [C and D], shall carry out all the action in downstream activities. In alliance A the other party can become involved only upon request of the R&D firm. In alliances C and D, involvement may arise upon the exercise of co-promotion option by the R&D firm. In alliance B, the parties have planned an earlier termination of their relation, since in one particular commercial field they will license the results of the collaboration to large pharmaceutical companies while in another field the parties have agreed to a splitting of

<sup>&</sup>lt;sup>13</sup> We believe that such general definition would be generally accepted in the social sciences. At a minimum, it is one backed by A. P. Fiske and by followers of the relational model theory. Cfr. http://www.sscnet.ucla.edu/anthro/faculty/fiske/relmodov.htm

commercialization rights on a geographical basis. However, in all four the alliances the contract term is either defined with the criteria stated above [B, C, D] or it is not envisaged at all, unless a cause for termination occurs [A].

In sum, during most of the contracts' life the relations in the alliances of our sample are very skeletal affairs. Thicker relations only stay in place for much shorter periods (four or five years).

All this notwithstanding, as seen above all the contracts acknowledge the importance of the relation, and try to salvage it as much as feasible from possible disputes. Yet, contracts also acknowledge that relations alone cannot rescue an alliance that has completely lost its economic rationale. The contracts in our sample differ considerably as to the latitude granted to the parties for not-for-cause termination. Alliance D, that requires either mutual consent or the determination by an independent third party of the "collapse" of the scientific rationale, is the most restrictive. On the opposite end of the spectrum, alliance A grants termination rights to both parties on a country-by-country, product-by-product basis, in addition to the right to terminate the alliance in its entirety without cause:

4.12 Opting Out at Commercial Stage. If in any country the Parties' Product Profit (Loss) is negative (i.e. the Parties are experiencing net losses)...either Party may opt out of Commercializing the Collaboration Product in such country on  $[*]^{15}$  written notice to the other Party.

Paradoxically, this alliance, that by some arrangements may appear rather communitarian, is rather fragile, as it is to be expected in a relation motivated mostly by extrinsic rewards, with little or no involvement of one party in the process that generates them.

Alliance C also grants unilateral termination rights for convenience quite generously, but only to the financing party. The only restriction is that such party serves a notice period and, in the case that termination occurs very early in the life of the alliance, it pays a cancellation amount.

In alliance B unilateral termination is available to both parties, with limits. The party contributing the core-resources – Biosearch – is not allowed to withdraw from the alliance until the completion of pre-clinical studies (that is, for approximately two to three years). For later stages, individual withdrawal of Biosearch as well as of Versicor is allowed, but somewhat discouraged through a lower share of future revenues that the non-investing party shall be entitled to. Yet, by that time, optimized compounds should have already received an IND approval from the FDA so

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<sup>&</sup>lt;sup>14</sup> Other causes of termination commonly provided for in alliance contracts are bankruptcy, breach of the contract, dissolution or winding up. However, these provisions tend to be rather standardized across contracts. Hence we regard them as boilerplates.

<sup>&</sup>lt;sup>15</sup> [\*] denotes confidential information omitted and filed separately with the regulatory authorities.

that replacing the leaving partner's financial resources with those of an external licensee should not pose major problems. Unlike Biosearch, Versicor can unilaterally leave at an earlier stage, but that would be quite contrary to its incentives, since all rights to collaboration compounds would revert to Biosearch and Versicor would receive neither monetary compensations for the work accomplished, nor any share of future revenues.

In sum, relations are not sacred: extreme adaptation through early termination is possible in all the alliances of our sample. Reciprocity in the rights to terminate tends to follow reciprocity in the other arrangements. As hinted by alliance A (negotiated at a late stage), uncertainty may positively correlate with the accessibility of termination as a remedy to maladaptation. However, alliances B and C – both negotiated at the discovery stage – indicate that the earlier termination is exercised, the more severe the 'wound' to the implicit association of resources underlying the alliance. Hence, early termination must be restricted [B] or made conditional to compensatory payments [D]. Finally, alliances high in 'financial' components [A and C] may be the most fragile.

#### 6. Discussion

These cases confirm that contracts regulating pharmaceutical technology strategic alliances definitely approach the relational archetype much more than the transactional one. This is clearly evident in the low specificity of planning, in its tentativeness, and in the pervasiveness of post-commencement planning. Amid an intrinsic difficulty of planning activities that are characterized by substantial uncertainty and need to be accomplished over considerable time spans, contributions of resources and the incidence of the resources generated by the collaboration take center stage. Resources are accurately specified and whenever possible they are also accurately measured. Any change to resource contributions, if any change is permitted at all, is anchored to the levels set in the original plans, and can be decided through more consensual procedures than it is possible for adaptations impacting other decision domains. Thus contracts analyzed provide a validation of the usefulness of the distinction between the 'managerial' (command over persons) and the 'rationing' (command over resources) aspects of the transactions (Leblebici 1985) for the interpretation of observed governance solutions.

Alliance contracts draw considerable support from the relation between the parties. In turn, relation is determined largely by the resources that are brought in the collaboration. As a result, the relation needs not be characterized by the thickness of embedded ties (Uzzi 1997). This is in agreement with the relatively 'arms-length' nature of these contracts that has been observed by other researchers (Gilsing and Nooteboom 2006).

These findings provide encouragement to try connecting resources, relation and governance with the help of the relationship models theory mentioned in Section 2. One fundamental assessment the parties to an alliance have to do, concerns how to evaluate the resources they contribute. When both parties bring core intellectual resources it could be difficult, if not impossible, to measure them. This may favor the adoption of an Equality matching interpretive model, whereby one's contribution matches the other's in kind. The establishment of such framework would help defining particular aspects of the relation. The exchange would be inspired by balanced reciprocity of all subsequent contributions, if any. Distribution would be inspired by distributive justice (each gets identical shares). Work organization would be based on the division of the task into specific assignments that must necessarily be different, due to the different competences of the parties, and yet are assessed as responsibilities of equal weight. Alliance B in our sample closely resembles this archetype.

In contrast, it would be much harder for the parties to interpret an alliance to which only one of them contributes core intellectual resources according to a model of in-kind reciprocity. In principle, such contribution could be matched by a sufficient amount of complementary, ancillary competences and/or by a sufficient financial contribution. However, both are rather easily amenable to measurement, and doubts could always surface on the congruence of the exchage. The adoption of an Authority ranking framework would provide a clear-cut reply to such suspicions. In such a model the firm higher in rank gives beneficently to the alliance, receives a higher share of the outcomes and is allocated more decision rights. In the organization of work the superior tends to be allocated direction and control responsibilities, while its share of the practical job is often considerably smaller. Alliances A, C and D seem inspired by an Authority ranking framework. Figure 1 illustrates the relationship between the relational model of an alliance and the configuration of its contractual governance variables.

This model does not suggest directly which firm (the R&D firm or the financier) should be higher in ranking. Actually, one of the alliances investigated [A] matches rather closely the pattern of an Authority ranking relation where authority is assigned to the R&D firm. Yet there are at least two factors in the biotechnology alliances that favor the assignment of authority to the financier. The first is that the cash constraint faced by many dedicated biotechnology firms, particularly in their pre-IPO years, renders the contribution of cash resources from the financier particularly valuable to them. The second is that assigning authority in the R&D firm would further increase relational risk in an alliance where the R&D firm, by necessity, has to carry out most of the action, and the financier struggles to monitor what is happening.

In what follows we shall suggest a few propositions that have been inspired by the evidence found in the four case studies, which can contribute to the formulation of further research. These propositions assume knowledge-intensive collaborations for the production of intangibles, like biotechnology and refer to the arrangements stated in the formal contract, though not necessarily also to those followed in practice.

#### Antecedents of the relational model

P1: the distribution among the parties of the core technologies contributed to the alliance affects the way the parties frame their relation;

*la:* where the contribution of core technologies is balanced the relation will be framed in terms of Equality matching;

1b: where the contribution of core technologies is concentrated the relation will be framed in terms of Authority ranking.

## **Configuration of Equality matching alliances**

P2: In alliances framed in terms of Equality matching

2a: the planning of actions will be limited to the basic roles of the parties

2b: the planning of the monetary resources brought into the alliance is sketchy or absent, since each bears its own

2c: the incidence of monetary benefits and costs will be regulated according to a regime of equal sharing

2d: post contractual planning and the further specification of original plans will be effected mainly through joint decision-making

2e: the contract will provide a lean, fairly standardized, dispute resolution apparatus

2f: termination for convenience will be available to both parties but will be mildly discouraged either through incentives or restraints

## Configuration of Authority ranking alliances

P3: In alliances framed in terms of Authority ranking

3a: planning of actions will be rather articulated, and shall specify criteria to make decision at important junctions

3b: the planning of monetary resources will be very accurate, and budgets will feature prominently in planning

3c: the incidence of monetary benefits and costs will often be unequal, with the party getting a majority share of them often being a residual claimant

3d: contracts will often establish different rules for managerial decisions and for rationing decisions

3e: in managerial decisions, unilateral decision-making will be often observed, at least for particular decisions or as a tie-breaking mechanism

3f: the dispute resolution apparatus provided for in the contract will often be rather articulated, and provide for more than just negotiation and arbitration

3g: termination for convenience will often be available only to the party having more decision rights and, when occurring at early stages, will often require the payment of cancellation amounts.

## Propositions common to alliance under both relational models

P4: Regardless of the type of framing,

4a: all alliances will always plan accurately the core technology resources brought into the alliance

4b: post contractual rationing decisions will be taken either by mutual consent, or by neutral third parties, through clauses stated in contingent terms or through easily observed standards, outside the control of either party

#### 7. Conclusions

This study has analyzed the contractual governance of four strategic alliances in the pharmaceutical biotechnology sector, focusing in particular on those aspects in the contract which are central to the smooth and efficient accomplishment of the aims of the parties. The findings of the study corroborate the view that in collaborations where conditions of substantial uncertainty obtain, resources take a central place in the contract. Moreover, contrary to the image conveyed the literature on incomplete contacts, these contracts can be quite complex, though complexity arises more from the specification of procedures and from the assignment of rights, than from the specification of contingencies.

This study proposes that the details of the contractual governance are principally determined by the relational model chosen by the party, which, in turn, is largely influenced by the distribution of the core competences brought by the parties into the alliance.

This study also suffers from several limitations. First and foremost is the small number of cases from which the theory is build, which forbade the replication of the 'experiment'. Second, this

study has neglected other important aspects of the contractual governance. In particular we have not investigated the enforcement apparatus provided for in the contract (monitoring, hostages, stipulated damages, etc.). Accordingly we cannot answer confidently to questions about how well these contracts satisfy the enforceability constraint. We plan to reserve this question to a future investigation.

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# **APPENDIX**

Table 1 – Stages of the drug discovery process

Phase		<b>Patients involved</b>	Focus			
Drug discovery			Modify compound to reduce side effects			
			Lab and animal testing performed to test for			
Pre-Clinical			potential adverse effects			
	Phase I	20-100 volunteers	Find safe dose and side effect			
		100-500	For efficacy and side effect			
Clinical	Phase II	volunteers				
	Phase	1000-5000	Check for adverse effects to long-term drug use			
	III	volunteers	and efficacy			
FDA Review			Strong evidence of safety needed for approval			
Large-scale						
manufacturing						

Adapted from PhRMA 2006, www.bio.org, and Fumero (2003)

Table 2 - The drug discovery process: length, costs and attrition rates

Molecules entering the phase	Phase		PhRMA 2004 expenditures (bln USD)	Length (years)		
5000-10000	Drug discovery		9.6	5.5		
250	Pre-Clinical		9.0	1		
5	Clinical	Phase II Phase III	15.9	1.5 2.0 2.5		
	FDA Review		3.4	1.5		
1	Large-sca manufact					

Adapted from PhRMA 2006, www.bio.org, and Fumero (2003)

**Table 3 - Cases** 

Alli- ance	R&D firm	Client	Effective date	Parties*	Stage at signing	\$ Terms (mln USD)					
						Size	Upfront	R&D	Mile- stones		
A	Nuvelo	Kirin Brewery	03/2005	B/D	Pre-clinical	N/A	2	N/A	0		
			Disease	Disease Tea				echnology			
			Inflammatory bowel disease			Peptide	s				
В	Biosearch Italia SpA	Vicuron	02/1998	B/B	Discovery	N/A	0	N/A	CON		
			Disease			Technology					
			Infection - Antibiotics, Infection - Antivirals			Combinatorial, Screening					
С	Sunesis Pharma- ceuticals	Biogen IDEC	08/2004	B/B	Discovery	81	7	19.2	60.5		
			Disease			Technology					
			Cancer			Rational Drug Design: Computational and Synthetics					
D	Alexion Pharma- ceuticals	Procter & Gamble	01/1999	B/D	Phase II	95	10	11.7	39		
			Disease			Technology					
			Anti-inflammatory Cardiovascular			Monoclonals - Humanized & Fully Human Abs					

Notes:

\*B/D: Biotech/Drug; B/B: Biotech/Biotech CON: Confidential information excised from the contract

N/A: Not applicable

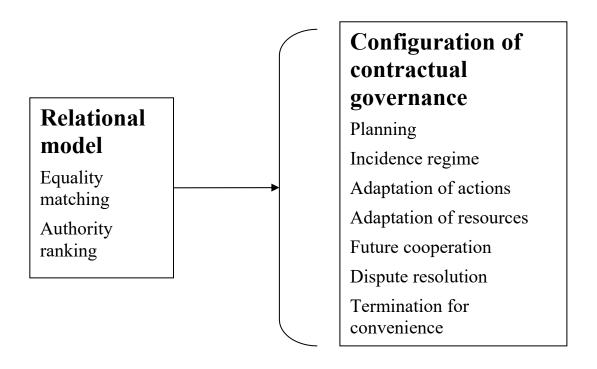


Figure 1. Relational model and configuration of contractual governance in biotechnology alliances