Innovative capabilities and strategic alliances: Who is gaining what in the pharmaceutical industry?

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Abstract

There have been several respected studies, from a capability-based perspective, pointing to the emergence of a new division of innovative labour in the pharmaceutical industry over the past decades. We still, however, miss empirical evidence relative to the implications of collaborative arrangements, like strategic alliances, for the innovative capabilities of companies involved in such collaborative arrangements. Drawing on a scrutiny of specialised databases (*Galé, Dialog,* and *Business & Industry*) covering the 1993–2003 period, this paper examines the entry and exit composition of innovative capabilities of 25 pharmaceutical companies' capabilities involved in such alliances. They are organised in three groups: (i) large pharmaceutical companies ('big-pharma'); (ii) large bio-pharmaceutical companies ('big-pharma'); (ii) large bio-pharmaceutical companies ('big-pharma'); (ii) large bio-pharmaceutical companies ('big-pharma'); and (iii) small and research-intensive companies. The evidence shows the extent to which each of these three types companies, particularly large companies, benefit from these alliances in terms of absorption of strategic pieces of innovative capabilities. Such type of evidence is important to provide researchers, corporate managers, and policy makers with a concrete notion of some features of the nature of such division of innovative labour that occurs and the actual changes going on in the structure and organisation of innovative activities in the pharmaceutical industry.

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INTRODUCTION

Over the past 30 years, the pharmaceutical industry has undergone profound changes. Such changes have led to a transformation of its knowledge basis, know-how, and new search procedures leading to changes in the organisation and distribution of innovative activities. From the 1950s, the organisation of innovative activities was based on large firms with internal research and development (R&D) capabilities. This reflected the nature of pharmaceutical R&D and the organisation of innovative activities around a routinised regime of search.^{1–4}

Such organisational models led to consolidation, from the 1950s, of the Fully Integrated Pharmaceutical Company (FIPCO). Under such a paradigm, large pharmaceutical companies ('big-pharma') not only concentrated internally on search activities but also used this type of business model as an entry barrier.^{5,6}

Since the late 1970s, the industry has, however, been going through a process of transition: from a regime driven by 'random screening' and tacit search heuristics that involved a great deal of serendipity and co-specialised technologies that tended to be specific to given fields of application into a regime based on new tools (eg combinatorial chemistry), which has made the search processes more 'guided' and path dependent.^{4,7}

While some would argue that such changes are the result of the molecular biology 'revolution',^{7,8} others argue that such transition is a consequence of cumulative 'incremental' changes taking place within the pharmaceutical industry.⁹ Such cumulative incremental changes seem to have been driven by the gradual and steady emergence, and development of competitive technologies and biological sciences, industrial molecular and cell biology, and in biochemistry, protein search techniques, which, in turn, demand new kinds of highly specialised knowledge bases.^{10,11}

Nevertheless, there is a consensus that such institutional and technical changes have led to fundamental modifications to the structure of the pharmaceutical industry, and these have involved, for instance, the emergence of biotech start-ups. In other words, such changes have triggered a new division of innovative labour between 'big-pharma' and dedicated biotech firms (specialised suppliers and small research-based firms): while smallsized biotech firms concentrate on upstream research, the 'big-pharma' seeks to acquire from them initial drug compounds, to carry out costly clinical trials and commercialise such drugs worldwide.^{7,9,12} Such 'division of innovative labour' implies several kinds of knowledge complementarities¹⁰ which, in turn, are operationalised on the basis of different management mechanisms, namely, strategic alliances.^{13,14}

Indeed, over the past decade there have been robust and respected studies and analyses of the evolution of the pharmaceutical industry from a capability-based perspective. There seems to be, however, a scarcity of empirical evidence relative to the implications of such 'division of innovative labour' in the pharmaceutical industry, especially based on strategic alliances, for the innovative technological capabilities of companies involved in such collaborative arrangements. Such evidence is important to provide researchers, corporate managers, and policy makers with a concrete notion of the extent to which such division of innovative labour occurs and the actual changes going on in the structure and organisation of innovative activities in the pharmaceutical industry. Thus this paper seeks to make a contribution in that direction. One of its main limitations, however, is the descriptive treatment of the issues.

Drawing on a systematic scrutiny of specialised databases such as *Galé*, *Dialog*, and *Business & Industry* covering the 1993–2003 period, this paper examines the implications of strategic alliances for the composition of innovative capabilities of companies that participate in such alliances. The study underpinning this paper was based on evidence of strategic alliances in a sample of 25 pharmaceutical companies. In this study, the sampled companies were organised in three different groups: (i) large pharmaceutical companies ('big-pharma'); (ii) large biopharmaceutical companies ('bio-pharma'); and (iii) small and research-intensive companies.

DESCRIPTIVE FRAMEWORK

Strategic alliances have been viewed as one of the major mechanisms to operationalise the knowledge complementarity and division of innovative labour in the contemporary pharmaceutical industry.¹³ In order to sustain innovative and economic performance, the pharmaceutical industry needs to launch new

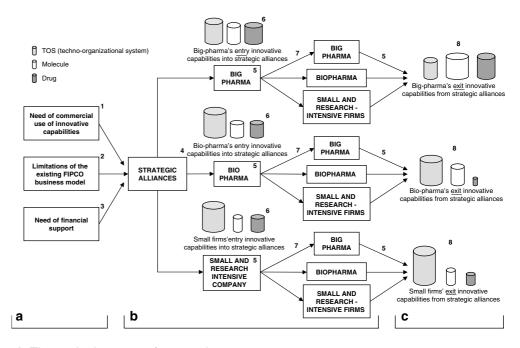


Figure I: The study descriptive framework

drugs constantly. The process of obtaining new drugs depends, first, on the technological capabilities of the molecule research and drug research and development (R&D). The necessary investment for a new drug ranges between USD 800m and USD 1bn.¹⁵ Basically, the new drug discovery process involves molecule trials, preclinical and clinical trials in humans, as well drug development. Because clinical trials require high investment, many strategic alliances take place during these stages. Considering only the ten biggest studied 'big-pharma' companies in 2003, the total annual revenue was USD 203bn.¹⁵

Pharmaceutical companies seek strategic alliances to complement their innovative resources in order to compete globally.⁶ Indeed, it has been suggested that there are different reasons for large pharmaceutical companies and small-sized and research-intensive companies to look for strategic alliances: while the former seeks to update their knowledge bases and R&D structures in order to keep up their technological and market leadership in the market on the basis of innovative drugs, the latter seek to take advantage of their innovative knowledge basis in order to capitalise themselves, to share the risks of their new investigations, and to gain access to markets.13

It should be noted that biotechnological companies have been responsible for the majority of strategic alliances. Between 1988 and 2002, 20,000 strategic alliances were registered involving biotechnological companies in the US. The exploration regime prevails on biotechnological companies when compared with the collaboration regime between the companies.^{14,16} Additionally, another reason for the establishment of strategic alliances is related to the fact that certain innovative capabilities can be under patent protection and under high difficulty of replication in the pharmaceutical field.^{14,17–19}

As a result, Figure 1 presents the descriptive framework in the light of which the evidence on strategic alliances based on innovative capabilities in the pharmaceutical industry will be examined in this paper. The framework involves three steps:

- A→ Factors influencing the establishment of strategic alliances.
- $\mathbf{B} \rightarrow$ Supply of innovative capabilities and other resources to enter into strategic alliances.
- C→ Acquisition of innovative capabilities through different types of strategic alliances.

The changing scenario is represented by numbers 1, 2, and 3 in Figure 1. This model draws on the concept that the companies gain and sustain their competitive advantage on the basis of their innovative capabilities and cognitive bases.^{10,11,20,21}

The three types of companies that participated in the scrutinised strategic alliances are represented by number 5 in Figure 1: 'bigpharma', 'bio-pharma', and small and researchintensive companies (biotech or not biotech). In this study, we adopted a broad perspective on technological capabilities involved in strategic alliances in the pharmaceutical industry. Such capabilities encompass the following components: techno-organisational systems (TOS), molecules, and drugs.

These three dimensions of capability are identified by number 6 and are part of the technological capabilities that were used to enter the strategic alliances. The different kinds of collaborations among the three types of companies and strategic alliance mechanisms are represented by number 7, whereas number 8 refers to the technological capabilities that result from strategic alliances established by each type of pharmaceutical company (exit capabilities).

STUDY DESIGN AND METHODS

Central question

The study underlying this paper has been structured to address this central issue: the implications of collaborative arrangements for the configuration of innovative capabilities of three types of pharmaceutical companies (big-pharma, bio-pharma, and small and research-intensive companies). Such collaborative arrangements involve the following types of strategic alliance mechanisms: in/out licenses of technological capabilities, creation of TOS, molecule research, drug development, and marketing and sales development.

Technological capabilities are understood here as knowledge-based resources that are needed to generate and manage technological innovation. Such resources are embodied in techno-physical systems, people, and managerial and organisational systems.^{11,22,23} Thus, in this paper, innovative capabilities involve different knowledge bases relative to a new drug development process: TOS; molecules; and drugs. The TOS can be a tool for the molecule research equipment development, equipment for molecule research, and equipment for drug development.

Sampling

We have scrutinised the strategic alliances implemented during the 1993–2003 period by three types of companies as shown in Table 1. The criterion to select big-pharma and bio-pharma was based on revenue in 2003. For the five small and research-intensive companies, the criterion was the frequency of strategic alliances agreed with big-pharma.

Our search of empirical evidence drew on three large databases: *Business & Industry, Dialog,* and *Galé.* The homepages of each studied company and specialised publications (eg IMS and Pharma) were also examined. The survey of empirical evidence considered publications between 1993 and 2003. The search terms for the strategic alliances survey were related to strategic alliance, molecule research, and drug development (see details in Table 2).

In order to simplify the assessment of the collected data, each technological capability

Table 1: Sample of the study

Types of companies	Companies			
Large multinational pharmaceutical company ('big-pharma')	Pfizer; Glaxo SmithKline; Merck; Johnson & Johnson; Aventis; AstraZeneca; Novartis;			
	Bristo-Myers Squibb; Roche; and Eli Lilly			
Large multinational	Amgen; Genentech; Serono;			
bio-pharmaceutical	Biogen Idec; Genzyme; Chiron;			
companies	MedImmune; Gilead; Millennium;			
('bio-pharma')	and Intermune			
Small and research- intensive companies	Incyte; Icagen; Lexicon; Ligand; and OSI Pharmaceuticals.			

Table 2: Terms used for searching the selected databases

Search (SI)	Alliance or agreement or licenses or
	partnership or collaborative development
Search (S2)	Molecule discovery or drug discovery
	or early discovery
Search (S3)	Name of the company*
Search (S4)	SI and S2 and S3 and PY=1993:2003

*The names of the 25 companies (sample).

(which was made available at the strategic alliance or which was acquired through strategic alliance) was considered as one strategic alliance. All qualitative information related to each strategic alliance was represented as one technological capability in the table of the corresponding company. The frequency of each technological capability generated quantitative data. Such data were organised in tables and graphics in order to obtain a meaningful evaluation and discussion of evidence. Mergers, takeovers, and joint ventures were outside the scope of this scrutiny.

MAIN RESULTS AND DISCUSSIONS

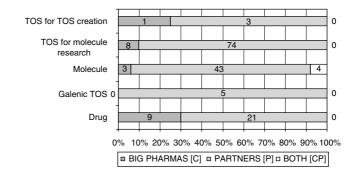
In this section, we present the main results obtained from our empirical search. The results are presented in three subsections in order to provide a better understanding of how the sampled companies made their capabilities and other resources available in order to enter into strategic alliances and the composition of innovative technological capabilities of the companies when they exited from the corresponding strategic alliances.

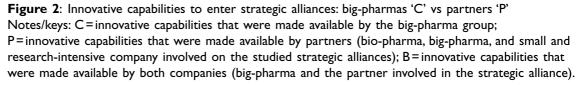
Companies' capabilities and other resources to establish strategic alliances

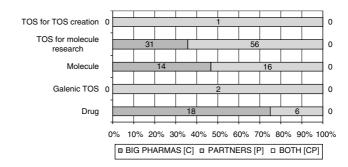
Figures 2–4 illustrate the types of capabilities that were used by each group of companies to enter strategic alliances.

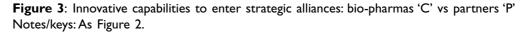
Figure 2 indicates a small participation of big-pharma in the examined strategic alliances in terms of innovative capabilities. For instance, from all strategic alliances agreed between big-pharma and the correspondent partner involving drugs as the technological capability, only about 30 per cent came from big-pharma.

On the other hand, Figure 3 shows a balanced participation of bio-pharma in terms of technological capabilities in the strategic









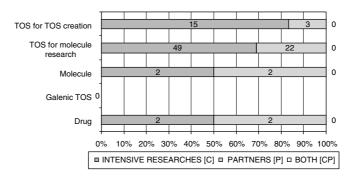


Figure 4: Innovative capabilities to enter strategic alliances: small and research-intensive 'C' vs partners 'P' Notes/keys: As Figure 2.

alliances. The more relevant participation of bio-pharma was based on drugs (more than 70 per cent) and, numerically, on TOS for molecule research (31 from 86).

Differently, the evidence in Figure 4 indicates a strong participation of small and research-intensive companies in the strategic alliances in terms of technological capabilities. Within the examined strategic alliances, they had an impressive participation both in proportional terms and in absolute terms: 49 out of 71 TOS for molecule research.

The above empirical evidence suggests that there was a higher participation of small and intensive-research companies in the strategic alliances in terms of innovative technological capabilities. Big-pharma contributed mainly with financial support, and marketing and sales structure. Bio-pharma participated with technological capabilities and financial support, depending on the partner involved in the alliance.

Indeed, big-pharma adopted strategic alliances as a way of acquiring new technological capabilities as a response to their internal limitations such as low productivity of their internal R&D structures, reduction of profit from new drug's launch, and external limitations such as, on the one hand, the increased scientific sophistication of products and, on the other, the enlargement of the market for generic products.⁶ In relation to bio-pharma, it seems that their engagement in strategic alliances was driven by the need to complement technological capabilities in order to improve their financial structure and to obtain innovative drugs. Small and research-intensive companies entered strategic

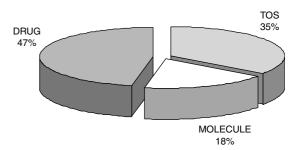


Figure 5: Big-pharma's innovative capabilities entering to strategic alliances

alliances to achieve commercial application of their in-house innovative technological capabilities and to engage in new activities (eg drug commercialisation in the global pharmaceutical market).²⁴

Composition of capabilities used by each of the three groups of companies to enter strategic alliances

This section provides a more specific view of the composition of innovative capabilities made available by each of the three types of companies during the establishment of the examined strategic alliances (see Figures 5–7).

Of the 18 technological capabilities that were made available by big-pharma, the great majority of them referred to drugs (47 per cent). The empirical evidence suggests that the majority of these drugs were on the verge of losing their patent protection or had already lost it. Big-pharma also participated considerably with TOS for molecule research (Figure 5).

Of the 63 technological capabilities that were made available by bio-pharma within

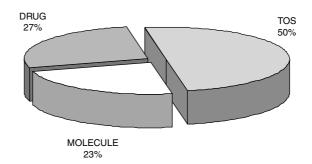
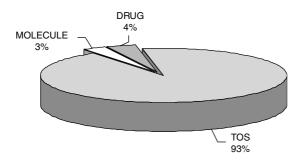


Figure 6: Bio-pharma's innovative capabilities entering to strategic alliances



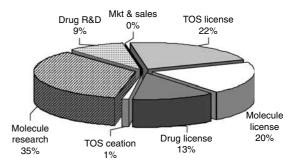


Figure 7: Small and research-intensive companies' innovative capabilities entering to strategic alliances

the studied strategic alliances, it was observed that the great majority of them were TOS for molecule research (50 per cent). Empirical evidence indicates that most part of these TOS were made available to big-pharma. This, in turn, suggests that bio-pharma participated considerably in molecules and drugs (Figure 6).

Of the 68 technological capabilities that were made available by the small and research-intensive companies, it was observed that the great majority of them were based on TOS for molecule research (93 per cent). Most of these TOS were made available to big-pharma. Additionally, empirical evidence suggests a considerable contribution with TOS for molecule research (Figure 7).

The evidence in Figures 5–7 allows us to observe a stark contrast between big-pharma and small and research-intensive companies in terms of composition of the innovative technological capabilities offered to enter their strategic alliances. While the participation of the former was mainly based on drugs (47 per cent), the latter contributed heavily

Figure 8: Big-pharma's innovative capabilities exiting from strategic alliances

with TOS for molecule research (93 per cent). It should be noted that the participation of bio-pharma companies in terms of innovative capabilities was relatively more balanced when compared to big-pharma's and bio-pharma's. Additionally, at least within the alliances we have scrutinised, bio-pharma made considerable contribution based on molecules (23 per cent).

Composition of innovative capabilities resulting from strategic alliances

Figures 8–10 illustrate the composition of the technological capabilities during the exit of companies from the examined strategic alliances. As shown in Figure 8, of the 206 technological capabilities resulting from the studied strategic alliances, 143 of them were retained by big-pharma (55 per cent of them were molecules). This type of company also acquired a considerable number of TOS for molecule research, reinforcing the idea that the main interest of this type of company is in molecules.

On the other hand, Figure 9 indicates that of the 170 technological capabilities resulting

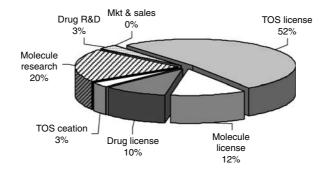


Figure 9: Bio-pharma's innovative capabilities exiting from strategic alliances

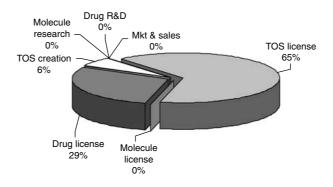


Figure 10: Small and research-intensive firms' innovative capabiliities exiting from strategic alliances

from the studied strategic alliances, 59 were retained by bio-pharma (55 per cent of these were TOS for molecule research). Evidence showed that the majority of these TOS for molecule research resulted from in-licensing with small and research-intensive companies and other bio-pharma companies. Bio-pharma also acquired a considerable number of molecules (32 per cent) through in-licensing and molecule research mechanisms. This, again, confirms their interest in molecules.

Conversely, as shown in Figure 10, of the 109 technological capabilities that resulted from the studied strategic alliances, only 17 were retained by small and research-intensive companies. It was observed that the majority of them were based on TOS for molecule research (71 per cent). This type of company also acquired a considerable number of drugs, which, in turn, seems to suggest their interest in gaining share in the pharmaceutical market. In summary, we have found that:

- (1) In terms of contribution with technological capabilities to strategic alliances:
 - (i) big-pharma participated with 11 per cent of 169 technological capabilities;

- (ii) bio-pharma participated with 44 per cent of 143 technological capabilities;
- (iii) small and research-intensive companies participated with 71 per cent of 195 technological capabilities.
- (2) In terms of the composition of technological capabilities obtained from strategic alliances when compared with the configuration of the technological capabilities that were made available at the beginning of the examined strategic alliances:
 - (i) big-pharma increased the proportion of molecules (16–55 per cent);
 - (ii) bio-pharma increased the participation in molecules (22–32 per cent) and inTOS to molecule research (49–55 per cent);
 - (iii) small and research-intensive companies started new activity: drug commercialisation on pharmaceutical market with a corresponding increase of drugs (3–29 per cent). Furthermore, this type of company also updated its TOS for molecule research.

Types of innovative capability	Big-pharmas		Bio-pharmas		Small and research- intensive companies	
	Entry*	Exit**	Entry*	Exit**	Entry*	Exit**
Drugs	47%	22%	29%	13%	3%	29%
Galenic TOS	No participation	No capability addition	No participation	No capability addition	No participation	No capability addition
Molecules	16%	55%	22%	32%	3%	None
TOS for molecule research	32%	23%	49%	55%	72%	71%
TOS for TOS creation	5%	No capability addition	No capability addition	No capability addition	22%	No capability addition
Total	100%	100%	100%	100%	100%	100%

 Table 3: Entry and exit innovative capabilities of pharmaceutical companies involved in strategic alliances

*Innovative capabilities that were made available at strategic alliances.

**Innovative capabilities that were obtained from the strategic alliances.

Finally, Table 3 summarises these results in terms of percentage of each technological capability, which was made available during the start of the studied strategic alliances by each kind of company. It also shows the percentage of each technological capability that was obtained by each of the three types of companies from the same strategic alliances.

The evidence in Table 3 suggests some modifications in the compositions of the technological capabilities of the companies involved in strategic alliances that we scrutinised in this study. In general, bigpharma participated in strategic alliances in order to obtain innovative capabilities, biopharma sought to complement their capabilities, while small and research-intensive companies were interested in starting new activities and gaining access to the pharmaceutical market.

CONCLUSIONS

This paper sought to examine the entry and exit composition of innovative technological capabilities of a sample of 25 pharmaceutical companies involved in strategic alliances during the 1993–2003 period. Our sampled companies were organised in three groups: big-pharma, bio-pharma, and small and research-intensive companies.

Indeed, there have been a number of studies pointing to an increased 'division of innovative labour' between these three groups of companies. There, however, was still a scarcity of empirical evidence about the extent to which pharmaceutical companies benefit from their strategic alliances in terms of innovative technological capabilities. Out study sought to generate a contribution in that direction. One of the major limitations of our paper, however, is the descriptive treatment of these issues.

Nevertheless, our descriptive evidence seems to suggest that the key criterion for the choice of a partner to form a strategic alliance was conditioned by the type of technological capability that each partner would offer. It also seems to suggest that large companies, mainly big-pharma, have been seeking to adapt their FIPCO business model into a model based on capability complementarity via strategic alliances and other collaborative arrangements. In addition to exceeding big-pharma in terms of innovative drugs, bio-pharma seems to have been making efforts to reach higher revenues than big-pharma by entering into strategic alliances. In turn, small and research-intensive companies can take advantage of their innovative knowledge basis (capabilities) to enter the pharmaceutical market through the commercialisation of the drugs acquired by strategic alliances.

Indeed, the types of technological capabilities used to enter strategic alliances reflected the interests of each of the three types of companies: molecules to guarantee market competitiveness for big-pharma; molecules to improve the financial structure of bio-pharma; and drugs for small and research-intensive companies to enter the pharmaceutical market.

Considering that big-pharma companies have obtained the largest amount of innovative technological capabilities from the strategic alliances in which they engage, particularly in the form of molecules, it seems that their interest in strategic alliances reflects a gradual response to internal knowledge limitations and external pressures from new search techniques and from competing technologies. This, in turn, seems to force them to complement their knowledge basis via strategic alliances in order to keep up their competitive performance. Such types of responses by large companies also seem to be contributing to modifying the industry structure by gradually undermining (or re-shaping) the FIPCO business model.

One of the implications of these changes for large pharmaceutical companies is that, in order to carry out their innovation process in a competitive manner, they will have to improve their corporate management mechanisms to *integrate* and *coordinate* different pieces of innovative knowledge that are increasingly distributed not only internally, but mainly, externally, among different partners. And, more importantly, they will have to stimulate such partners to develop specific types of knowledge that they need (and at the pace they need) in order to carry out and speed up their innovation process, especially on the basis of product innovation, to sustain their competitive advantage.

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