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LEVERAGING INTERNAL AND EXTERNAL EXPERIENCE: EXPLORATION, EXPLOITATION, AND R&D PROJECT PERFORMANCE

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Although one tenet in the alliance literature is that firms learn from prior experience, we posit that any potential learning effects depend on the type of experience. In particular, we hypothesize that alliance exploitation experience has positive effects on R&D project performance, while alliance exploration experience has negative effects. We further posit that an internal exploration competence allows firms to leverage their external exploitation experience more fully. In contrast, when firms combine internal exploitation experience with external exploration experience, the negative effects on R&D project performance become more pronounced. To test this integrative model of organizational learning, we leverage a unique and detailed dataset of 412 R&D projects in biotechnology conducted by large pharmaceutical companies between 1980 and 2000. Using a competing risk event history model predicting successful product approval versus project termination, we find support for our theoretical model. Copyright © 2010 John Wiley & Sons, Ltd.

INTRODUCTION

A firm's ability to adapt to shifting knowledge environments is a key dynamic capability to ensure continued survival and competitiveness (Eisenhardt and Martin, 2000; Teece, Pisano, and Shuen, 1997). To answer the question of how incumbent firms adapt to and even capitalize on radical technological change, one stream of research highlights the role of interfirm research and development (R&D) collaborations (Arora and Gambardella, 1990; Hill and Rothaermel, 2003; Teece, 1992; Tripsas, 1997b). Collaborative R&D as a response to shifting knowledge environments has been linked to a variety of positive outcomes including greater firm innovativeness and performance (Nicholls-Nixon and Woo, 2003; Rothaermel, 2001). A second stream of research on how incumbent firms might adapt to radical technological change has emphasized the need for firms to possess sufficient absorptive capacity (Cohen and Levinthal, 1990; Zahra and George, 2002). A number of empirical studies have found support for the notion that the capacity to recognize, value, assimilate, and apply new external knowledge is a significant predictor of successful organizational transformation (Arora and Gambardella, 1994; Helfat, 1997; Kaplan, Murray, and Henderson, 2003; Tripsas, 1997a).

An important consequence of sustained involvement in collaborative R&D is that firms with greater alliance or external experience can extract more benefits than firms with less experience (Rothaermel and Deeds, 2006; Sampson, 2005). This is because repeated engagements in the focal activity allow firms to learn from their experience

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(learning-by-doing), and to store and retrieve the inferred learning for future engagements in the focal activity (Levitt and March, 1988). Consistent with the learning curve hypothesis (Yelle, 1979), external experience has been found to be positively related to subjective and objective outcome measures of individual alliances as well as overall firm performance (Anand and Khanna, 2000; Chang, 2003; Hoang and Rothaermel, 2005; Kale, Dyer, and Singh, 2002; Zollo, Reuer, and Singh, 2002).

The link between external experience and performance, however, has been based on somewhat course-grained analyses. With few notable exceptions (e.g., Baum, Calabrese, and Silverman, 2000; Dussauge, Garrette, and Mitchell, 2000; Lavie and Rosenkopf, 2006; Park, Chen, and Gallagher, 2002; Rothaermel, 2001; Rothaermel and Deeds, 2004), prior studies have generally not systematically distinguished between alliances at different foci of the value chain and are thus at risk of aggregation bias. Ignoring the potential variance that exists across R&D alliances initiated under different motivations can lead to spurious results. Moreover, prior alliance studies generally focus on outcomes at the firm level of analysis, which are more theoretically distant from performance at the collaboration level. As a consequence, we argue that a more subtle understanding of learning within the alliance context and its relationship to the development of internal capabilities necessitates a more fine-grained analysis. We accomplish this by analyzing different types of R&D alliances and different types of internal experience combined with a focus on performance effects at the project level of analysis.

We leverage Koza and Lewin's (1998) typology of alliance activity to examine the impact of external exploration and exploitation on subsequent R&D project performance. This typology recognizes that firms emphasize external activities in different components of the R&D activity chain: some alliances are formed to explore new competencies to identify new opportunities, while others are used to exploit existing competencies in order to leverage known opportunities. By and large, efforts to link alliance activity to outcomes aggregate these different alliances and, as a result, ignore important variation across them in the different types of alliance partners and the novelty and ambiguity of their knowledge content (exceptions Baum *et al*., 2000; Lavie and Rosenkopf, 2006; Rothaermel and Deeds, 2006). A focus on the project level of analysis brings to the fore the challenges that firms face to leverage these different alliance experiences appropriately to enhance subsequent project outcomes. We use time to drug approval of biotechnology-based R&D projects undertaken by established pharmaceutical firms to assess the performance impact of external exploratory and exploitative activity. We posit that a firm's experience in external exploration versus external exploitation has opposing direct effects: external exploration experience has a negative effect on subsequent R&D project performance, while the effect of external exploitation experience is positive.

We then introduce a contingency perspective by examining how internal R&D experience moderates external exploration and exploitation experience. Internal R&D experience is critical to a firm's successful adaptation to radical technological innovation, because it builds the foundation of a firm's absorptive capacity (Cohen and Levinthal, 1990). We build on the theoretical insight that the key to understanding a firm's dynamic capabilities lies in how a critical process such as new product development interacts with a firm's ability to leverage external partnerships (Eisenhardt and Martin, 2000; Teece *et al*., 1997). By focusing on the project level of analysis and identifying how exploration and exploitation activities are interrelated in the new product development process, we seek to shed greater light on how firms tap existing internal experience to leverage externally driven innovation.

Understanding the dynamics of R&D collaborations in new product development is particularly relevant in the pharmaceutical industry, which has seen a significant increase in the opportunities to partner with new entrants who focus on drug discovery and development projects that leverage scientific advances in biotechnology. It is a context where project timeliness is also critical: when a firm is the first to introduce an innovative product, it is often able to extract temporary monopoly rents based on patent-protected intellectual property (Lieberman and Montgomery, 1988; Macher and Boerner, 2006). In the pharmaceutical industry, being fast to market and product sales are highly correlated (Grabowski and Vernon, 1990; Roberts, 1999). To empirically test our theoretical model, we draw on an unusually fine-grained dataset documenting 412 biotechnology-based drug development projects

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undertaken by established pharmaceutical companies under a variety of governance arrangements over the 21-year time period between 1980 and 2000.

THEORY AND HYPOTHESES

External exploration and exploitation

We build herein on March's (1991) exploration-exploitation framework of organizational learning, and the work of Koza and Lewin (1998) who distinguished between alliance activity that is motivated by the need to explore for new opportunities and alliances that are formed to exploit known opportunities. Applying an exploration-exploitation lens to strategic alliances is well established in the literature (e.g., Lavie and Rosenkopf, 2006; Park *et al*. 2002; Rothaermel, 2001; Rothaermel and Deeds, 2004). In addition to capturing the tensions inherent in different types of knowledge (Levinthal and March, 1993), the exploration and exploitation framework of organizational learning also maps quite well onto the research context of this study. Following the prior literature, we employed the exploration versus exploitation distinction to alliances because characterizing alliances as exploratory is highly consistent with the pharmaceutical drug discovery and early stage development process. Similarly, exploitation alliances map well onto activities that occur in later stages of the value chain that tap a firm's existing knowledge including clinical testing, regulatory affairs, distribution, and marketing/sales.

As with the broader notion of exploratory search, exploration alliances are characterized by long time horizons and unpredictable, high variance returns. Exploration alliances are conduits for organizational learning. In some cases, alliances involve the cocreation of new knowledge by partners (Lubatkin, Florin, and Lane, 2001). In other cases, each partner in an exploration alliance attempts to identify, transfer, and absorb part or all of the partner's valuable knowledge assets. In contrast, exploitation alliances involve shorter time horizons between the point of learning and the realization of predictable, low variance benefits. Exploitation alliances are motivated by (temporary) access to the partner's knowledge assets to leverage complementarities across different and unique competencies along the value chain (Bresser, Heuskel, and Nixon, 2000), while each alliance partner maintains its comparative knowledge advantage (Grant and Baden-Fuller, 2004).

Differentiating between exploration and exploitation alliances is especially salient in the context of the R&D process. In exploration alliances, partners are motivated to discover something new, frequently advancing the boundaries of basic science (Rosenkopf and Nerkar, 2001; Rothaermel and Deeds, 2004). For established pharmaceutical firms, such collaborations typically involve universities and research intensive start-ups as their partners (Arora and Gambardella, 1990; Chang, 2003; Shan, Walker, and Kogut, 1994). In exploitation alliances, firms seek to leverage their existing capabilities in areas such as clinical testing, regulatory affairs, distribution, and sales and marketing. A number of studies highlight that distinguishing between exploration and exploitation alliances allows for a more fine-grained understanding of how alliance activity can lead to differential outcomes. For example, Rothaermel (2001) documents how large pharmaceutical firms that focus on exploitation rather than exploration alliances in their network strategy exhibit higher performance when adapting to biotechnology. Rothaermel and Deeds (2004) find that biotechnology start-ups that orchestrate an integrative alliance system that leverages exploration and exploitation alliances in a sequential fashion achieve superior new product development performance. More recently, Lavie and Rosenkopf (2006) also note that the exploration-exploitation distinction reveals important nuances regarding how firms balance these different activities when forming alliances.

External exploration/exploitation experience and R&D project performance

Distinguishing between an exploration versus exploitation focus in collaborative activity can have important implications for the ease of learning and, hence, the degree to which firms can build and leverage external experience for greater performance in subsequent R&D projects. We suggest that, in contrast to the challenges of leveraging exploratory alliance experience, firms can more readily leverage their experience from exploitative alliances. Exploitation alliances are typically focused on incremental improvements to existing

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routines, and are readily codified and embodied in refinements to current products and processes, because they leverage existing complementarities between partners (Benner and Tushman, 2003; Teece, 1992). In the collaborative R&D context, the large pharmaceutical firms contribute more explicit and codifiable knowledge, including their manufacturing capabilities, regulatory know-how, and significant sales force management and deployment knowledge. This downstream knowledge has been honed over decades through cumulative experience, and as a consequence, pharmaceutical companies have developed highly efficient organizational routines and standard operating procedures to effectively manage the production and distribution process (Pisano, 1996). Biotechnology firms, in turn, contribute a potential new drug that has undergone significant preclinical development, thus considerably reducing the ambiguity and tacitness of the knowledge to be managed in the alliance. In short, exploitation alliances are based on a division of labor through a matching of specialized complementary resources and skills.

Due in part to these knowledge characteristics, firms can more readily accumulate and leverage external exploitation experience through repeated engagements in the focal activity or learning-by-doing (Pisano, 1994). Although entering, managing, and exiting alliances creates nontrivial coordination costs, an emphasis on exploitative alliances reduces these costs significantly, because the need for extensive and deep communication with partners is generally lower at later stages of the product development process (Rothaermel and Deeds, 2006). Lower effort and costs, especially in the managerial attention required to coordinate and leverage external exploitation, translates into higher learning benefits. Pharmaceutical firms, for example, may learn which problems can arise as a biotech drug candidate moves from small-scale development to large-scale production, a significant challenge that can derail successful and timely project completion (Pisano, 1996). The speed of project completion is a critical performance metric in this industry, because being fast to market and product sales are endogenous to a large extent (Grabowski and Vernon, 1990; Roberts, 1999).

The learning task is also greatly simplified in an exploitative alliance, because each firm focuses on its area of specialization. Such a focus is likely to benefit project completion speed, because it allows each partner to focus on its distinctive competence, thus leveraging comparative advantages across firms (Azoulay, 2004; Mowery, Oxley, and Silverman, 1996). Rather than sending staff into each other's laboratories to further push out the frontier of basic science, as is frequently the case in exploration alliances, firms in exploitative alliances can focus on managing the alliance interface as a particular drug moves from preclinical to clinical development. This situation is often described as a 'hand-off' from the biotechnology venture to a pharmaceutical company (Pisano and Mang, 1993). Leveraging their prior experience in their respective area of expertise requires less intensive managerial attention and resources, because firms can more readily identify sources of misalignment and rectify them before they undermine alliance performance. With a clear focus, firm investments in an alliance management capability, including an alliance management office, are likely to be more successful, prompting further investment in this capability (Kale *et al*., 2002).

In the biotechnology R&D context, exploitation alliances are well suited to be managed through such a formal business process, because exploitation alliances involve the downstream capabilities of the established pharmaceutical companies, including manufacturing, legal expertise, and sales, distribution, and marketing. For example, the pharmaceutical company Lilly established an alliance management process that is well designed to capture benefits from exploitation alliances (Sims, Harrison, and Gueth, 2001). Each alliance is managed through a three-person team, including a senior manager for high-level oversight and support, an alliance leader responsible for the day-to-day management of the alliance, and an alliance manager from the corporate office of alliance management, who serves as business integrator between the two alliance partners. Through interviews with industry experts, we learned that exploration alliances, in contrast, tend to initially remain 'under the radar' of management, because they are generally formed by the partner firms' scientists, and only later do they receive managerial attention should promising results emerge that fit the firm's strategy. Moreover, because of the tacit knowledge that is being developed in exploration alliances, they are largely incompatible with formal management processes (Benner and Tushman, 2003). Because the ease of learning from alliance experience is greater when the focus is on exploitation,

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thus allowing incumbent pharmaceutical firms to move down the learning curve of how to successfully complete R&D projects in a timely fashion, we posit that:

Hypothesis 1: External exploitation experience has a positive effect on R&D project performance.

Exploration typically involves the development of new knowledge that is tacit and of uncertain value. To be of strategic value, however, this new knowledge must then be integrated into broader organizational capabilities that allow for the execution of key tasks. In comparison to external exploitation, exploratory alliances expose a focal firm to new, cutting-edge knowledge. This, in turn, commensurately raises the challenge of learning and integrating new capabilities from partners. Difficulties arise when there are differences between firms, particularly in their dominant logics, knowledge bases, and organizational structures (Lane and Lubatkin, 1998).

In the biotechnology context, firms must often work with partners that operate under different cultures, incentive systems, and norms. Large pharmaceutical companies engage in exploratory alliances with research universities and biotechnology firms. Research universities are generally large, bureaucratic structures whose primary goal is the creation and widespread dissemination of cutting-edge, basic knowledge. Biotechnology firms are for-profit entities that place far greater emphasis on developing and leveraging applied, proprietary knowledge. In contrast to the large pharmaceutical firms, they are also able to provide high-powered incentives for breakthrough innovation with the use of stock options for their scientific and managerial staff, especially if the new venture is pre-initial public offering (IPO). Because knowledge is embedded in particular social contexts (Kogut and Zander, 1992), dissimilarity between partners increases the difficulty of knowledge transfer and learning within alliances, such that overcoming these barriers to knowledge transfer requires significant managerial resources and attention (Mora-Valentin, Montoro-Sanchez, and Guerras-Martin, 2004; Rothaermel and Deeds, 2006; Simonin, 1997, 1999).

Learning from partners and the ability to leverage prior experience is not only affected by the types of partners but also by the knowledge that is being transferred within an exploratory alliance. The primary goal of an exploration alliance with universities and entrepreneurial start-ups involves integrating leading-edge scientific discoveries into a new product or process. This process generally involves the transfer of complex and tacit knowledge between partners. Pisano (1996) insightfully highlights the differences in the type of knowledge between exploratory search in the discovery phase and exploitative activities in the commercial development phase: 'In the discovery phase of pharmaceutical R&D projects, research scientists develop crude processes for synthesizing relatively small amounts of the molecule under investigation. These laboratory methods of production, however, are almost always completely unsuitable for manufacturing the compound in commercial volumes at required cost and quality levels' (Pisano, 1996: 1104). Because the knowledge base is basic and emergent in exploratory alliances, there is considerable uncertainty about the potential applications of new knowledge and its contribution to an organization's capabilities. Moreover, partners have little or no prior experience with advancing this type of knowledge, and unlike relatively homogeneous contexts that allow for experimentation and the accumulation of systematic feedback, novel conditions increase the difficulty of building and leveraging prior experience.

Indeed, repeated exposure to novel learning contexts can lead to negative knowledge transfer, a concept that originates in cognitive psychology, and which has frequently been demonstrated at the individual level (Gick and Holyoak, 1987). Negative knowledge transfer describes a situation where experience gained in a prior activity is transferred to a new activity that appears to be similar on the surface, but is, in fact, fundamentally different. This, in turn, implies that prior experience can actually hurt rather than help future performance. For example, Cohen and Bacdayan (1994) demonstrate how individuals who accumulated experience through repeated engagements in a card game played under specific rules were outperformed by novice, untrained card players when the rules of a new game differed slightly from the game in which the prior experience was accumulated.

Within the context of biotechnology R&D projects, in particular, Pisano (1997: 216) details how attempts to leverage biotechnology project experience can lead to negative knowledge transfer, and thus reduce project performance, because

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of the immature knowledge base upon which new products and processes are developed. He documents project delays that occurred because a firm tried to apply basic process technology developed in an earlier project to a subsequent project. After following codified knowledge embodied in protocols developed from prior experience, the firm was unable to replicate the success of the prior project in the subsequent project. In this case, the method used led to a biologically inactive molecule; as a consequence it was of no therapeutic value. The significant challenges of learning between dissimilar organizations partnering under conditions of significant knowledge novelty and ambiguity thus leads us to posit that prior exploratory alliance experience will have a negative impact on the successful completion of an established pharmaceutical firm's subsequent R&D projects.

Hypothesis 2: External exploration experience has a negative effect on R&D project performance.

Moderating effects of internal exploration/exploitation experience

Scholars have long held that the ability to leverage external activities depends on the extent to which external knowledge is related and assimilated with a firm's own knowledge base (Cohen and Levinthal, 1989). The extent of a firm's absorptive capacity—understood as 'the ability of a firm to recognize the value of new, external information, assimilate it, and apply it to commercial ends' (Cohen and Levinthal 1990: 128)—can, in turn, influence its perceived returns on subsequent investments to develop new knowledge or exploit its existing knowledge. Relevant internal capabilities are thus likely to play an important role in determining whether firms are able to fully leverage their external experiences.

The successful completion of the research component of the R&D process (exploration) requires subsequent exploitative activities including regulatory expertise, manufacturing, sales, and distribution (Rothaermel and Deeds, 2004). We thus consider how complementary internal experience moderates a firm's external activities, where the definition of complementarity is based on the sequence of exploration-exploitation that characterizes the value chain of the pharmaceutical research and development process. These combinations can contribute to ambidexterity, defined as the 'ability of a firm to simultaneously explore and exploit' (O'Reilly and Tushman 2008: 185). We therefore consider: 1) whether a firm's *internal exploration experience* moderates the effects of its *external exploitation experience,* and 2) whether *internal exploitation experience* moderates the effects of its *external exploration experience.*

External exploitation and internal exploration

We suggest that the benefits to external exploitation experience on subsequent R&D project performance are enhanced when combined with internal exploration experience. In their development of the concept of absorptive capacity, scholars have repeatedly emphasized the importance of transformative skills and routines in order for firms to benefit and adjust to rapid technological change (Cohen and Levinthal, 1990; Garud and Nayyar, 1994; Lane and Lubatkin, 1998; Zahra and George, 2002). A firm's absorptive capacity is built through continuous engagements in basic research over time (Cohen and Levinthal, 1989, 1990), and, thus, through repeated engagements in exploratory activities. A firm's internal exploration experience, in turn, leads to firm-specific knowledge that enables a firm to monitor, screen, evaluate, and leverage externally generated knowledge (Helfat, 1997; Mowery, 1983).

Within the context of the pharmaceutical industry's adaptation to biotechnology, Rothaermel and Hill (2005) document that a pharmaceutical firm's internal R&D capability provides it with a superior ability to understand and value new biotechnology knowledge. This, in turn, enables the pharmaceutical firm to select the most promising alliance partners among the swarm of new entrants (Schumpeter, 1942), with over 2,000 new biotechnology firms vying for reputable alliance partners among a relatively small number of incumbent pharmaceutical companies (Stuart, Hoang, and Hybels, 1999). The ability to select the most promising alliance partners is a valuable competence, because pharmaceutical firms manage multiple new product development projects with different partners in several market domains simultaneously (Rothaermel and Deeds, 2006; Vassolo, Anand, and Folta, 2004). More generally, pursuing a larger number of external knowledge sources simultaneously without the requisite internal absorptive capacity has been linked to reduced innovative performance in

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a recent study of innovation by U.K. manufacturing firms (Laursen and Salter, 2006).

A firm's internal exploration experience builds the foundation of successfully completing R&D projects in a timely fashion, because of the sequential nature of the drug discovery and development process, where, at the level of each individual project, exploration activities precede exploitation activities (Rothaermel and Deeds, 2004). A firm's internal exploration experience also enables the firm to more fully assimilate and transform the learning benefits obtained from its external exploitation experience, because it allows for more effective interfirm capability transfer (Hamel, 1991; Simonin, 1997, 1999). As an example, the pharmaceutical firm Lilly was able to successfully transfer important biotech process capabilities through an exploitation alliance with Genentech, which Lilly applied successfully to subsequent R&D projects conducted in-house (Fisher, 1995; McDaniel, 1994). Altogether, we argue that a firm's internal exploration experience has positive implications for the firm's ability to successfully complete R&D projects in timely fashion when coupled with external exploitation experience.

Hypothesis 3: The positive effect of external exploitation experience on R&D project performance is enhanced in the presence of internal exploration experience.

External exploration and internal exploitation

We further propose that the negative effect of external exploration experience on R&D project performance is intensified when combined with internal exploitation experience. At first glance, past and current drug research and development projects share broad features that would seem to facilitate the application of internal exploitation experience. The biotechnology knowledge base, however, is still in its infancy relative to the traditional drug discovery process, and thus represents a new knowledge paradigm that undermines the value of pharmaceutical firms' prior knowledge (Rothaermel, 2001). Moreover, the pharmaceutical firms' dominant logics (Prahalad and Bettis, 1986) were developed and refined through decades of competing on drug discovery and development within the traditional paradigm of chemical synthesis. Established pharmaceutical firms, therefore, can be prone to misapplying learning from external exploration activities, because of the lack of theoretical and practical guidance to aid in subsequent projects due to the newness of knowledge explored (Pisano, 1996). This effect is likely to be more pronounced in the presence of strong internal exploitation experience that implies high levels of success within the traditional paradigm, potentially leading to a competency trap (Levitt and March, 1988).

Firms that rely heavily on external knowledge sources for basic R&D are at a relative disadvantage when it comes to building the skills and resources needed to respond to technological change (Bettis, Bradley, and Hamel, 1992; Lei and Hitt, 1995). An internal focus on building exploitation experience and complementary assets reduces a firm's ability to select the most promising exploratory research projects. Moreover, the extensive use of external sources for exploratory knowledge can invite opportunism on the part of the alliance partners. Concerning biotechnology R&D know-how, Pisano (1997) found empirical support for a lemons hypothesis in the market for collaborative drug development projects. Due to information asymmetry combined with quality uncertainty, the biotechnology ventures have a tendency to offer inferior projects for collaboration, while maintaining the more promising projects in-house for solo development and commercialization. This problem is accentuated for the large pharmaceutical companies when they focus on internal exploitation, because they lack the requisite internal exploratory experience to evaluate the quality of the R&D projects offered for collaboration by the biotechnology ventures. Moreover, firms that attempt to integrate external exploration with internal exploitation within the context of an R&D collaboration face additional complexity in the knowledge transfer process, because tacit knowledge developed within an exploratory project is difficult to transfer and apply without an adequate level of internal knowledge (Simonin, 1997, 1999).

Given the fundamental role that internal explorative activities play in building a firm's absorptive capacity, we suggest that the effect of negative knowledge transfer is stronger when a firm focuses on external exploration combined with internal exploitation.

Hypothesis 4: The negative effect of external exploration experience on R&D project performance is enhanced in the presence of internal exploitation experience.

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METHODOLOGY

Research setting

We assess the new drug discovery and development project performance of established pharmaceutical companies in biotechnology. Established pharmaceutical companies like Pfizer or Glaxo Wellcome are the firms that were in existence *prior* to the emergence of biotechnology. We concentrate on pharmaceutical companies that are engaged in the discovery, development, and commercialization of biotechnology-based drugs that are placed inside the human body (*in vivo*). Focusing on the in-vivo biotechnology segment ensures a homogeneous sample, and thus controls for variance across different industry segments. In addition, the pharmaceutical firms in the in-vivo biotechnology segment are exposed to extensive and strict regulatory oversight (i.e., Food and Drug Administration [FDA] in the United States and the European Medicines Evaluation Agency [EMEA]), which mandates that these firms disclose detailed data on new drug development projects.

Underlying biotechnology are important scientific breakthroughs in genetic engineering (recombinant DNA, 1973) and hybridoma technology (monoclonal antibodies, 1975), among others. Subsequently, the first new biotechnology drugs reached the market in the 1980s. The emergence of biotechnology, therefore, constitutes a radical process innovation in the drug discovery and development process for established pharmaceutical firms (Stuart *et al*., 1999). Responding to new technological developments has become critical as pharmaceutical firms face tremendous pressures to innovate, as illustrated by the following trends (Higgins and Rodriguez, 2006): total R&D expenditures have grown from $6.8 billion in 1990 to $21.3 billion in 2000 (17% of sales); the average new drug development costs have increased from $231 million to $802 million between 1990 and 2000, and average sales per patented drug has fallen from $457 million in 1990 to $337 million in 2001. Although the scientific expertise of incumbent pharmaceutical firms rests on chemistry and chemical engineering, they nevertheless retain extensive knowledge of specific therapeutic areas and hold critical skills in clinical trial management and drug marketing and sales that have led to extensive alliance formation with new biotechnology firms (Rothaermel and Boeker, 2008).

Sample and data

To overcome a potential survivor bias, we identified all pharmaceutical firms active in biotechnology as of 1980 through a detailed study of annual Standard Industrial Classification listings and a comprehensive set of industry databases and publications. Through this process, we identified 43 global pharmaceutical companies, which we then tracked forward over the 21-year study period, 1980–2000. The number of firms is consistent with the oligopolistic industry structure of the global pharmaceutical industry, which is dominated by a few large companies that are active in proprietary drug discovery and development.

The pharmaceutical industry has become more consolidated over the 21-year time period studied through horizontal mergers among large pharmaceutical companies. To account for this, we constructed a detailed 'family tree' for each of these 43 firms for the 1980–2000 time period. We used multiple industry publications to construct the family tree from 1980 onward, including Dun and Bradstreet's *Who Owns Whom?* and *Standard & Poor's Industry Surveys*.[1] Through this method, we identified 13 horizontal mergers among the sample firms. When a horizontal merger took place, we combined the past data of the two merging firms, and tracked the combined entity forward. We created an indicator variable for a firm that had merged with or acquired another firm in the sample. This variable was not significant, however, in explaining time to drug approval or project termination.

While the scientific breakthroughs underlying biotechnology were accomplished in the mid-1970s, we chose our study period to begin in 1980, because this year marks the start of commercializing biotechnology. This can partly be explained by four important events that occurred in 1980 (Stuart *et al*., 1999): (1) the successful IPO of Genentech, the first public biotechnology firm; (2) the passage of the Bayh-Dole act, which provides incentives for university patenting of inventions that resulted from federally funded research programs; (3) the decision of the Supreme Court that life forms can

[1] Dun & Bradstreet publish *Who Owns Whom?* annual worldwide directories that link companies to their corporate families and provide key information regarding the corporate family tree. Standard & Poor's Industry Surveys are published by McGraw-Hill, New York.

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be patented; and (4) the Cohen-Boyer patent, disclosing the recombinant DNA technology underlying genetic engineering, was granted to Stanford University (U.S. Patent 4,237,224), which licensed this breakthrough technology widely for a nominal fee.

The underlying data for analysis are at the *project level*, and capture drug discovery development projects undertaken by pharmaceutical companies in biotechnology and in their traditional domains. These data were obtained from Lifecycle©, a proprietary database maintained by IMS Health, an industry research firm specializing in the pharmaceutical industry. Lifecycle© is commercially available and provides fine-grained data on R&D projects covering a large number of pharmaceutical firms globally. To obtain these data, IMS Health associates collect information from governmental agencies, attend industry conferences, scan issued patents and scientific publications, and maintain contacts with scientists and managers within the focal firms.

Lifecycle© allows researchers to identify projects that are based on biotechnology. To ensure the accuracy of these data and to prepare them for statistical analysis, however, these data were coded by a researcher on our team holding a Doctor of Medicine degree. Taken together, we were able to collect data on 415 new biotechnology-based drug discovery and development projects commenced by 43 pharmaceutical companies between 1980 and 1998, while the observation of the outcomes of these projects ended in 2000. Missing data for one firm regarding its portfolio of traditional R&D projects led us to drop three records, which reduced our sample to 412 projects. These projects were organized as follows: 122 (30%) were conducted alone by the pharmaceutical firms, 235 (57%) were conducted in cooperation with a biotechnology firm, and 55 (13%) were initiated by biotechnology firms after they were acquired by the pharmaceutical firm.

The full set of 412 biotechnology projects had complete data on project governance, but not all projects had a project start or termination date. We filled in missing project dates through a detailed analysis of data obtained from BioScan, Recap, and PharmaProjects. In addition, we tracked projects through a fine-grained analysis of articles available on Nexis-Lexis and company Securities and Exchange Commission (SEC) 10-K reports, among other sources. This also allowed us to triangulate the accuracy of the start and termination dates reported in the IMS data. In total, 385 projects had accurate project start dates necessary for the event-history analysis (93% of initial sample). Although the product development cycle in this industry tends to be lengthy, the extended time period covered by these data allows us to observe clear success or failure outcomes in 51 percent of these cases. It is important to note, however, that the utilized hazard rate estimation enables us to take advantage of all available information in the data, including projects still ongoing at the end of the study period (Greene, 2003).

To obtain information on pharmaceutical firms' areas of focus using their traditional chemical-based method for lead compound identification and development, we obtained additional data on over 3,500 projects primarily from IMS Lifecycle©. We collected data pertaining to the lead company for each project, project start dates, and therapeutic area targets to provide information on pharmaceutical firms' traditional areas of R&D expertise. When relevant, IMS identifies patents that underpin a particular project, allowing us to use patent ownership to assign projects back to the originating firm in the case of firms that had experienced a merger. We used project data from a second database, PharmaProjects, for six firms for which IMS project records were sparse. Similar to IMS Lifecycle©, PharmaProjects is a publicly available database containing detailed information on new product development projects of pharmaceutical companies based on company questionnaires, annual reports, SEC and FDA filings, journals, investment reports, press releases, industry conferences, among others.

Furthermore, we collected historical pharmaceutical sales data for the firms in the sample. By generating a sample of retail pharmacies and drug stores, obtaining their sales data and extrapolating these data, IMS is able to report global sales figures for leading pharmaceutical firms (Nerkar and Roberts, 2004). Sales data are broken down by the firm's top 10–15 therapeutic categories, which allowed us to relate them to our project-level data, thereby providing a fine-grained measure of a firm's ability to exploit existing knowledge and capabilities.

To obtain data on alliance experience by the pharmaceutical companies, we linked the sample

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firms to alliance information obtained from various volumes of BioScan and from Recap, likely to be the two most comprehensive publicly available data sources documenting alliance activity in the biotechnology industry. Both sources are fairly consistent and accurate in reporting alliances (intersource reliability >0.90). These sources cataloged alliance activity over the time period of our study and also included alliances initiated in the 1970s that allowed us to create lagged external experience measures.

Finally, we obtained patent data assigned by the U.S. Patent and Trademark Office from 1975 onward. We focused on patents obtained in the United States, because it is the largest market for biotechnology worldwide, and thus it is almost compulsory for firms to first patent in the United States. In addition, firms active in biotechnology have a strong incentive to patent, because intellectual property protection has been held up consistently in court and patenting is thus considered to be a necessary activity to protect critical intellectual property (Albert *et al*., 1991).

Dependent variables

Drug approval. The primary dependent variable of this study is the hazard rate for drug approval. The hazard rate incorporates information on whether the event occurred and project duration, proxied by the number of months from initiation of the project to market approval by either the FDA in the United States, or the EMEA in Europe. About 80 percent of the marketed drugs were introduced in the United States before or simultaneously with their introduction in Europe.

Project termination. We also model the hazard rate for project termination, that is, when a project is discontinued. Indeed, project termination is a more common occurrence in this context and provides important complementary insights into project outcomes. In this sample, 139 projects were terminated before the end of the study period. A focus on termination in addition to project success enables us to apply a competing hazard rate model that leverages all the available data. We thus overcome a sample selection bias that would be introduced by only including successful projects.

Independent variables

External experience. We proxied *external exploration experience* by the percentage of R&D alliances entered into by the pharmaceutical firm in the biotechnology field up to, but not including, the year of the focal project. We measured *external exploitation experience* by the percentage of licensing and manufacturing agreements within the biotechnology field. Both external experience measures controlled for the cumulative total number of alliances that had been formed prior to the year of the focal project. These proxies can also be viewed as the firms' strategic orientation toward exploration and exploitation.

It is important to note that the external experience data are based on *all* such alliances that the large pharmaceutical firms and their biotechnology subsidiaries have entered into within the field of biotechnology, and, thus, the experience variables are not limited to our sample of collaborative R&D projects. The average pharmaceutical firm had entered approximately 18 exploitation and 27 exploration alliances prior to engaging in the focal R&D project.

Internal experience. We developed measures of a firm's internal exploration and exploitation experience based on a firm's past R&D efforts (exploration) and product sales (exploitation). Following prior research (Macher and Boerner, 2006; Nerkar and Roberts, 2004), we characterized a firm's experience at the therapeutic class level. Akin to product market segments, we used 15 therapeutic classes in accordance with the 'Anatomical Therapeutic Classification' (ATC) employed by IMS Health and maintained by the World Health Organization's Collaborating Centre for Drug Statistics Methodology. A firm's *internal exploration experience* is captured by the lagged, cumulative number of R&D projects that a firm had initiated in a particular therapeutic domain. Projects contribute to a firm's internal exploration experience if the focal firm is listed as the lead firm for the project. To avoid double counting with solo biotech experience, a control variable, the project must not be included in the focal sample of biotechnology-based R&D projects for this study. The firms in our sample accumulated experience by engaging on average in 10 internal R&D projects within a given therapeutic area.

To capture *internal exploitation experience*, we collected historical pharmaceutical sales data for

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the firms in the sample, as detailed above. We used the cumulative percentage of sales derived from that therapeutic class as a proxy for internal exploitation experience. This measure captures the extent of a firm's regulatory, marketing and sales expertise, which are key downstream competencies that may be leveraged in a biotechnology-based R&D project.

Control variables

Therapeutic area fixed effects. Because unobserved characteristics of specific therapeutic areas may lead to differential project outcomes (Danzon, Nicholson, and Pereira, 2005; Macher and Boerner, 2006), we created four broad *therapeutic area dummies*, which capture the primary therapeutic area targeted by the focal project. These dummies covered 63 percent of the sample, while the reference category represented the 11 other therapeutic areas targeted by the remaining projects.

Medical indications. We proxied for the number of medical indications or diseases that a project could potentially target. If the drug development project concerns several indications, scientists are able to leverage more readily accessible knowledge, because multiple indications share underlying biological processes or target molecules that are common to those indications. Thus, the scientists can draw on a greater number of research models for testing and allow for greater knowledge transfer across the different indications, thereby increasing the odds of completing a project successfully. As such, 31 percent of projects in our sample targeted more than one indication.

Project year. To control for year effects and for right truncation, we included the year the project was initiated, with the expectation that projects initiated later in the study period are less likely to lead to successful (or unsuccessful) outcomes. Some projects did not have project start dates so we included the earliest date provided indicating the start of a particular stage of the development process. Such projects contributed to the first-stage selection model, but not to the second-stage event-history analysis.

Project patent protected. Patent protected projects are more novel and, therefore, may be expected to be more successful. Such projects are likely to attract more resources and managerial attention due to their expected, positive effect on firm performance. We controlled for whether the underlying project was protected by a U.S. and/or European patent (dummy coded '1'). In addition to novelty, whether a project is patent protected or not is also inversely related to the age of the project. When a project is young, potential patent claims tend to be less specifiable. At the time of our analysis, every second project was patent protected.

Firm patents. To control for the pharmaceutical firms' overall competence in biotechnology, we included firms' patent data. Since many pharmaceutical companies tend to patent in a wide range of areas, we attempted to eliminate unnecessary noise in the patent data by focusing on technological areas in which biotechnology patents were emerging, such as U.S. patent class 435, Chemistry: Molecular Biology and Microbiology. We weighted each patent obtained by a pharmaceutical company in the relevant patent classes by its forward citations to capture the quality of a firm's patent portfolio (Trajtenberg, 1990). Thus, we calculated a cumulative variable for each pharmaceutical firm by summing the annual citation-weighted patent counts up to the year before the initiation of the focal project.

Organization of new drug development. We coded for the governance mode of each project, with '1' for solo development (*solo project*). We also coded for whether the project was initiated by a biotechnology firm after it had been acquired by a pharmaceutical firm in our sample (1 = *biotech subsidiary*). The reference category consisted of projects that were conducted collaboratively.

Past solo experience. Prior direct engagement in the focal activity may be an additional source of learning that can affect project outcomes, and, thus, we control for this effect. The average sample firm had initiated approximately six solo biotechnology-based projects before engaging in the focal project.

Collaboration stage. Every successful project goes through the entire value chain from discovery to development, but collaborations with partners may be formed in either stage. Using this

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distinction, all solo projects are, by definition, initiated in the exploration or discovery phase, 60 percent of the collaborative projects started with drug discovery, while the remaining 40 percent of collaborations began in a later (clinical) development phase. We would expect that collaborative projects initiated in the preclinical stage (dummy coded '1') would take longer to complete than projects where a partner joins during the clinical trial stage (dummy coded '0'). In contrast to projects begun in the preclinical stage, later stage alliances are based on explicit and less ambiguous knowledge and skills, allowing for easier coordination between partners that may increase project speed.

Inverse Mills ratio. Because the initial project governance decision may be determined by unobserved firm competences, past choices, or unobserved characteristics of the project (Argyres and Liebeskind, 2002), we employed a first-stage model that allowed us to create a selection term that corrects for endogeneity in the subsequent second-stage event history analysis (Heckman, 1979). Unobserved factors that influence both the governance of the drug development project and its subsequent performance could otherwise lead to biased or spurious results (Hamilton and Nickerson, 2003).

In the first stage, we applied a multinomial logit model to estimate the probability that a firm will choose to either pursue a project solo, undertake it through a biotechnology firm that has been acquired, or pursue it collaboratively. The first-stage model consisted of our independent, control variables, and an instrument capturing the degree of competitive intensity. This measure was equal to the number of other pharmaceutical firms that had initiated projects in the same two-digit therapeutic class up to the year prior to the start of the focal project. The first-stage model returned an adjustment term, the inverse Mills ratio, which we then inserted in the second-stage event-history models to explicitly correct for self-selection.

Estimation procedure

Because the dependent variable combines the probability of and the time to a focal event, we employ event history analysis. Drug development projects are at risk to be successfully completed or terminated. Since these two outcomes are mutually exclusive, we model them as a competing risk (Allison, 1984; Greene, 2003). We apply a model that estimates the competing hazard rates of each project making the transition to either successful completion or termination. This transition is captured by the instantaneous transition rate, r, defined as

$$r_k(t) = \lim_{\Delta t \to 0} \frac{\Pr\ (t \leq T < (t + \Delta t),\ D = k | T \geq t)}{\Delta t},$$

where k refers to one of the two mutually exclusive outcomes in D, describing the possible terminal outcomes. The variable T measures the time spent at risk of making one of the two possible transitions, and the probability Pr describes the likelihood of experiencing a terminal transition during the time interval from t to $(t + \Delta t)$, conditional on the project being at risk of making a transition at time t (Tuma and Hannan, 1984). We specify each rate using the Cox (1972) proportional hazard model:

$$r_k(t) = r_0(t) \exp(\boldsymbol{\beta}\mathbf{X}),$$

where $\mathbf{X}$ is a vector of covariates, assumed to have a multiplicative effect on the baseline hazard, and $\boldsymbol{\beta}$ are the parameters to be estimated. We estimated the Cox model with a robust specification, which adjusts the standard errors to allow for the possibility of nonindependence across projects initiated by the same firm. A positive (negative) coefficient sign indicates a greater (lower) hazard of the focal event occurring (drug approval or project termination, respectively), and thus can be interpreted to mean that the variable of interest leads to a faster (slower) occurrence of the focal event. Higher (lower) hazard rates, in turn, suggest a larger (smaller) number of such events within a given time period.

RESULTS

Table 1 depicts the descriptive statistics of the variables and the bivariate correlation matrix. A total of 57 projects (10 conducted alone, 47 conducted in collaboration) were successful. When outcomes are averaged over the total number of spells (measured in project months), the average proportional hazard rate for a successful product development

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Table 1. Descriptive statistics and bivariate correlation matrix

	Mean	SD	Min	Max	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Medical indications	1.48	0.85	1.00	5.00	1.00												
2. Project year	1992	3.74	1980	2000	−0.12	1.00											
3. Project patent protected	0.51	0.50	0.00	1.00	0.15	−0.03	1.00										
4. Firm patents	1810.29	1884.85	0.00	8163.00	−0.03	0.14	0.06	1.00									
5. Biotech subsidiary	0.13	0.34	0.00	1.00	0.06	0.15	0.04	0.46	1.00								
6. Solo project	0.34	0.47	0.00	1.00	−0.07	0.11	−0.31	0.04	−0.01	1.00							
7. Past solo experience	6.37	9.45	0.00	42.00	−0.07	0.47	0.07	0.48	0.49	0.15	1.00						
8. Collaboration stage	0.73	0.44	0.00	1.00	−0.13	0.38	−0.23	−0.05	−0.04	0.43	0.21	1.00					
9. Inverse Mills ratio	0.71	0.46	0.08	2.97	−0.06	0.12	−0.18	0.10	0.19	0.35	0.11	0.20	1.00				
10. Internal exploration experience	10.30	10.90	0.00	59.00	−0.07	0.33	0.14	0.07	−0.08	0.00	0.13	0.05	−0.09	1.00			
11. Internal exploitation experience	49.00	93.79	0.00	631.10	0.02	0.09	0.09	0.14	0.04	−0.03	0.15	0.08	−0.08	0.28	1.00		
12. External exploitation experience	0.34	0.16	0.00	1.00	−0.04	0.11	−0.10	0.17	0.24	−0.14	0.21	−0.06	−0.01	−0.15	0.00	1.00	
13. External exploration experience	0.51	0.18	0.00	1.00	−0.03	0.01	0.05	−0.10	−0.15	0.11	−0.04	0.06	−0.05	0.13	0.00	−0.56	1.00

N=412. Note: Positive and negative correlations greater than 0.09 are significant at $p<0.01$ level.

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outcome is 0.001 and the average time to drug approval for successful projects is 100 months. The proportional hazard rate for project termination is 0.002 and the average time to termination for failed projects is 59 months.

We present the results predicting new drug approval and project termination in Table 2. Models 1 and 2 are the respective baseline estimations containing fine-grained project-level and firm-level controls, as well as the inverse Mills ratio, which was obtained in the first-stage Heckman selection model described above. In Models 3 and 4, we entered the internal and external experience variables, distinguished by the exploration-exploitation dimension, in order to test the direct effect hypotheses (Hypotheses 1 and 2). In Models 5 and 6, we entered the interaction effects to test the contingency hypotheses (Hypotheses 3 and 4).

We proposed opposing direct effects of external experience on R&D project performance: a positive effect for external exploitation experience (Hypothesis 1) and a negative one for external exploration experience (Hypothesis 2). We found support for Hypothesis 1 in the analysis of project success, because the effect of external exploitation experience is positive and significant (Model 3, $p < 0.05$). The results obtained in Model 3 also provide support for Hypothesis 2, because the effect of external exploration experience is negative and significant ($p < 0.05$).

Because project terminations are an important complementary outcome to project success and allow for a more complete understanding of R&D performance, an analysis of the factors that affect project termination rates can provide additional insights. A comparison of Models 3 and 4 reveals that the factors that increase the rate of project success do not necessarily decrease the rate of project termination. Instead, subtle but important differences appear. Namely, greater external exploitation experience increases the hazard rate of project termination by 22 percent with a one standard deviation increase in external experience (Model 4, $p < 0.05$). It appears that firms may be able to leverage their exploitation experience to improve product approval rates, but at the cost of increasing project termination rates.

We further hypothesized that the positive effect of external exploitation experience on R&D project performance is enhanced in the presence of internal exploration experience (Hypothesis 3), while the negative effect of external exploration on R&D project performance is accentuated when combined with internal exploitation experience (Hypothesis 4). We present the results for the interaction hypotheses in Models 5 and 6. We find that internal exploration experience positively moderates the impact of external exploitation experience, because the interaction term is positive and significant (Model 5, $p < 0.01$). This indicates that firms with greater internal exploration experience in the focal therapeutic area are better able to leverage the benefits of external exploitation experience.

The results presented in Model 5 also provide support for Hypothesis 4 ($p < 0.001$), indicating that as internal exploitation experience grows, the impact of external exploration experience on the hazard rate for product approval grows increasingly negative. This implies that firms with greater internal exploitation experience are at a distinct disadvantage in mitigating the difficulties associated with leveraging external exploration experience. This finding seems to reflect the challenges of organizational learning in a collaborative context when knowledge is highly novel and tacit.

The analysis of Model 6 examines the competing risk of project termination. We found that the interaction effects for project termination were in the opposite direction to their effects for product approval. Firms with greater internal exploration experience are able to leverage external exploitation experience to decrease the rate of project termination ($p < 0.05$). On the other hand, increasing internal exploitation experience coupled with greater external exploration experience increases the rate of project termination ($p < 0.10$). This pattern of results reinforces the notion that R&D performance is enhanced in the case of internal exploration experience while it is dampened with increasing internal exploitation experience.

To gain an intuitive understanding of the results obtained, we graphically display them in Figures 1 and 2. In Figure 1, we depict the results for Hypotheses 1 and 3. The bottom line of the graph provides a baseline estimation for the cumulative hazard rate of product approval derived from the independent variables evaluated at their mean. The middle hazard rate line indicates that a one standard deviation increase in external exploitation experience results in a 36 percent increase in the hazard rate for time to drug approval compared to firms with an average level of such experience. The hazard rate for drug approval improves even further when firms combine internal exploration

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Table 2. Predicting new drug approval and project termination

	Model 1 Drug approval	Model 2 Project termination	Model 3 Drug approval	Model 4 Project termination	Model 5 Drug approval	Model 6 Project termination
Therapeutic area fixed effects	*included*	*included*	*included*	*included*	*included*	*included*
Medical indications	0.5123***	−0.1583*	0.4854***	−0.1507*	0.4773***	−0.1465*
	(0.1484)	(0.0913)	(0.1491)	(0.0851)	(0.1430)	(0.0847)
Project year	−0.0510	0.0540†	−0.0778	0.0323	−0.0803	0.0429
	(0.0869)	(0.0383)	(0.0896)	(0.0429)	(0.0887)	(0.0464)
Project patent protected	1.9579***	−2.1241***	2.1652***	−2.1501***	2.0588***	−2.1073***
	(0.4274)	(0.2740)	(0.4502)	(0.2883)	(0.4522)	(0.2880)
Firm patents	0.0001	−1.67E-05	0.0001	−1.61E-05	0.0001	−1.12E-06
	(0.0001)	(0.0001)	(0.0001)	(0.0001)	(0.0001)	(0.0001)
Biotech subsidiary	−1.0837**	0.0293	−1.4126***	0.0016	−1.4249***	−0.0628
	(0.3808)	(0.4565)	(0.3845)	(0.4315)	(0.4424)	(0.4384)
Solo project	1.0668†	0.3651†	1.2510†	0.4072†	0.8483	0.4155†
	(0.8731)	(0.2567)	(0.8323)	(0.2812)	(0.9100)	(0.2986)
Past solo experience	0.1043	−0.1470	0.1825	−0.1719†	0.2310	−0.1347
	(0.2645)	(0.1440)	(0.2878)	(0.1365)	(0.2788)	(0.1371)
Collaboration stage	−1.3455**	0.1007	−1.4979**	0.1631	−1.6518**	0.1163
	(0.5719)	(0.2860)	(0.5396)	(0.2851)	(0.5335)	(0.3024)
Inverse Mills ratio	0.0634	0.1029	0.1678	0.1160	0.1125	0.1552
	(0.3493)	(0.2438)	(0.3151)	(0.2366)	(0.3431)	(0.2369)

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Table 2. (*Continued*)

	Model 1 Drug approval	Model 2 Project termination	Model 3 Drug approval	Model 4 Project termination	Model 5 Drug approval	Model 6 Project termination
Internal exploration experience			−0.1187	0.1371†	−0.1647	0.0139
			(0.2562)	(0.0940)	(0.2730)	(0.1175)
Internal exploitation experience			−0.0139	0.0852	−0.0031	0.0899
			(0.1448)	(0.1173)	(0.1340)	(0.1289)
External exploitation experience			0.3119*	0.2024*	0.5654**	0.0967
			(0.1624)	(0.1187)	(0.2159)	(0.0963)
External exploration experience			−0.2643*	0.1049	−0.2786*	0.0541
			(0.1565)	(0.1011)	(0.1597)	(0.0850)
Internal exploration × external exploitation					0.7995**	−0.2482*
					(0.2768)	(0.1268)
Internal exploitation × external exploration					−0.2757***	0.1062†
					(0.0822)	(0.0671)
Spells	62,268	62,268	62,268	62,268	62,268	62,268
Log-likelihood	−263.40	−759.22	−259.46	−756.85	−254.83	−753.32
Chi square	281.46***	214.19***	489.65***	209.25***	864.22***	485.41***

Robust standard errors are in parentheses.
† $p < .10$; * $p < .05$; ** $p < .01$; *** $p < .001$.

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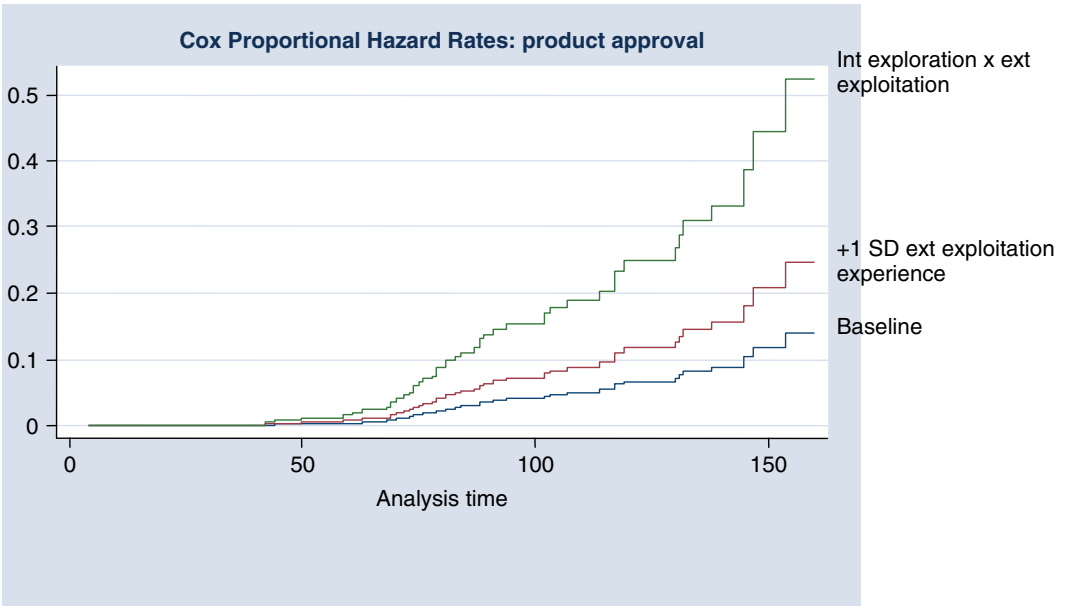

Figure 1. Effect of external exploitation and internal exploration on cumulative hazard for product approval. This figure is available in color online at www.interscience.wiley.com/journal/smj

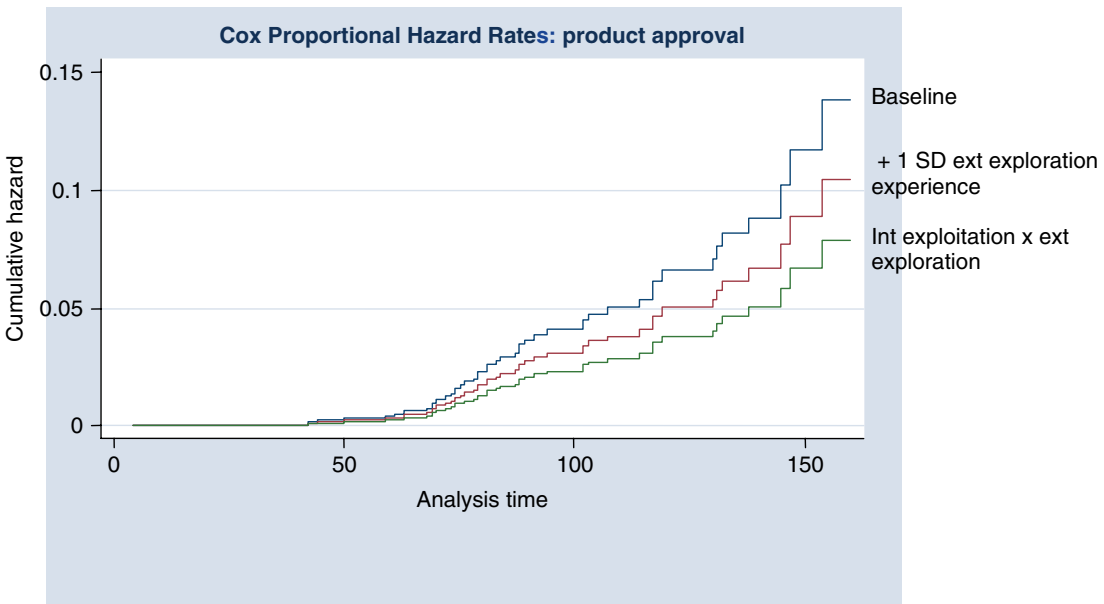

Figure 2. Effect of external exploration and internal exploitation on cumulative hazard for product approval. This figure is available in color online at www.interscience.wiley.com/journal/smj

experience with external exploitation experience (top line). A one standard deviation increase in both internal exploration experience and external exploitation experience more than doubles the hazard rate for time to drug approval compared to the baseline model.

Figure 2 displays the results for Hypotheses 2 and 4. With increasing external exploration experience, firms experience a significant decrease in the hazard rate for drug approval: a one standard deviation increase in external exploration experience leads to a 23 percent decline in the hazard

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rate for drug approval (middle line). The hazard rate for drug approval declines even further when firms combine internal exploitation experience with external exploration experience (bottom line). A one standard deviation increase in both internal exploitation experience and external exploration experience results in an additional 24 percent decrease in the rate of drug approvals compared to the baseline.

The results also reveal that a number of project-level controls are significant predictors of product approval and project termination rates. The results obtained in Models 5 and 6 indicate that projects with more indications and those with patent protection have significantly higher hazard rates for approval and a corresponding lower hazard rate for project termination. Both controls capture aspects of project quality, which implies that these projects are likely to attract more scientific, managerial, and financial resources that, in turn, aid in speeding these high-return projects to completion and commensurately decrease their potential for termination. The results also indicate that collaborative projects undertaken at a later stage of development are faster to market than projects initiated in the preclinical stage. Because the pharmaceutical firm can choose to collaborate after a project has proven to be viable by entering into clinical trials, accounting for collaboration stage appears to capture underlying project quality. Projects that were begun by biotechnology firms that had been acquired by large pharmaceutical firms were associated with decreased project approval rates, while conducting a project alone increased the hazard rate for project termination.

Robustness checks

To confirm the robustness of our results, we reanalyzed the data using the cumulative number of exploratory and exploitative alliances in place of the ratio-based experienced measures (McNamara and Baden-Fuller, 2007; Rothaermel, 2001; Rothaermel and Deeds, 2004). Firms tend to engage in both exploratory and exploitative alliances as indicated by their high intercorrelation when applying simple count measures ($r = 0.84$). However, because we track firms longitudinally, this correlation is also capturing the fact that exploratory and exploitative experience grows over time. While the high correlation is not surprising, it does introduce a limitation when using cumulative counts to assess alliance experience. A high correlation between independent variables increases standard errors and results in a greater likelihood of making a type II error or accepting a null hypothesis of no effect when it should be rejected. High correlations between our independent variables may also make it more difficult to interpret the interaction terms that are created from the predictors (exploration and exploitation alliance activity) and our moderator variables (internal exploration and exploitation ability).

With these concerns in mind, we continue to find support for Hypothesis 1 (positive impact of alliance exploitation experience on project outcomes) and Hypothesis 2 (negative impact of alliance exploration experience) in the model predicting project approvals. Regarding our interaction effects, all the signs are in the expected direction for both the models of project approval and termination. The interaction effects are significant with respect to Hypothesis 3 (combining internal exploration and external exploitation), but not for Hypothesis 4. Overall, we found that our results are robust to a different definition of our predictor variables. The model we present in the paper has the advantage of having lower correlations between exploration and exploitation thereby facilitating interpretation of our results.

We included potentially reinforcing interactions between internal and external experience in the exploration and exploitation domains, respectively. Neither interactions between internal and external exploration experience nor between internal and external exploitation experience were statistically significant.

We used data from company annual reports, Lexis-Nexis, and Recombinant Capital, to reconstruct sales figures for 47 percent (27/57) of our product approvals beginning in 1986. With this caveat in mind, we found that 33 percent (9/27) of the approved drugs for which we have sales data did reach the milestone of generating over $1 billion in sales in a given year (this is usually the cutoff used to define a blockbuster drug). Those with the highest levels of sales in their therapeutic category were among the first to market. In our data, the first entry had a probability of 66 percent to be the leading drug in terms of sales. No drug later than being third to market was able to capture the top sales spot. Time to product approval and product sales tend to be endogenous.

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Because there is no standard treatment for both problems of endogeneity and unobserved heterogeneity in hazard rate models, we undertook a number of additional analyses that provide an indication of the robustness of our results. Following Dolton, Makepeace, and Treble (1994), we reran our analyses using an accelerated failure time model with treatment effects. The results of the analyses were consistent with the hazard rate results reported in Model 5. For the model predicting project termination, the results differed from Model 6 to the extent that the interaction effect between internal exploration and external exploitation experience became marginally significant ($p < 0.10$).

We also ran hazard rate models akin to random-effects models in linear regression to capture unobserved heterogeneity. Using a shared frailty model in which an additional estimated parameter with a known (gamma) distribution enters multiplicatively on the hazard rate for each firm, we found the same pattern of results for our main independent and interaction variables in models of both project approval and termination. Since the parameter did not reach statistical significance in either model, we have further confidence that unobserved firm-level heterogeneity did not materially influence the results.

DISCUSSION

The emergence of biotechnology represents a radical exogenous change in terms of drug discovery and development for pharmaceutical companies. A focus on these incumbents, in turn, provides a natural laboratory for researchers to investigate whether experience gained in collaboration is an effective means by which to build a new set of product development capabilities. Thus far, accumulating empirical research has generally linked alliances to positive firm-level outcomes; however, the few studies that examine knowledge transfer more directly indicate more equivocal outcomes (Hoang and Rothaermel, 2005; Reuer and Zollo, 2005; Zollo *et al*., 2002).

To better understand the role of alliance experience, our study identified R&D alliances in different parts of the value chain and assessed the impact of different types of external experience on R&D project-level performance. Recognizing exploration and exploitation alliances explicitly is critical, because it highlights how leveraging external experience is systematically related to characteristics of the knowledge exchanged, demands for knowledge integration, and differences in organizational contexts between the partners. Our finding that external exploration experience leads to poorer R&D project outcomes suggests that these impediments may overwhelm firm attempts to learn. In contrast, when firms engage in exploitation alliances, which involve the transfer of less ambiguous knowledge and require lower knowledge integration between partners, they are better able to leverage external experience in order to improve R&D project performance.

Our findings indicate support for the notion that new product development alliances are best aimed at gaining access to partners' resources and capabilities to reap gains from specialization (Grant and Baden-Fuller, 2004; Teece, 1992). Exploitation alliances seek to leverage existing complementarities between partners. In this context, pharmaceutical firms hold important downstream capabilities that their partners often lack, including manufacturing, legal expertise, and sales, distribution, and marketing. Leveraging such specialized capabilities in alliances has been an important strategic response to technological innovations introduced by numerous, smaller biotechnology-based entrants, and is facilitated by the highly structured and sequential nature of the pharmaceutical new product development process that allows for manageable 'hand-offs' between biotechnology and pharmaceutical firms.

In addition to the benefits of exploitation alliances, our results also suggest that certain kinds of internal capabilities play an important role in fully leveraging external activities. By taking a detailed look at the internal exploration and exploitation activities of our focal firms, we identified an important, additional source of complementarities. Specifically, a firm's internal exploration experience, as indicated by greater R&D activity in a given therapeutic area, played a key role in enhancing the benefits that accrued from engaging in exploitation alliances. The role of internal exploration experience likely increases a firm's absorptive capacity, thereby allowing it to not only initiate more promising new R&D projects but also to recognize and exploit the external opportunities afforded by new technological developments.

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This interpretation of our results is strengthened by the findings presented in an article pertaining to innovation in the Spanish manufacturing sector (Beneito, 2006), where significant innovations were initiated in-house (through exploration), while contractual (exploitation) alliances provided access to knowledge that was more incremental in nature. Our findings at the project level of analysis also resonate with recent research on antecedents to innovation at the firm level of analysis, which found a positive reinforcing effect of firms' R&D expenditures and strategic alliances when predicting the number of new patents assigned in biotechnology to pharmaceutical firms (Rothaermel and Hess, 2007). However, we differentiate between different types of R&D alliances and their effects on project-level outcomes, which allowed for more subtle results to emerge pertaining to the interaction between internal and external capabilities.

Internal exploitation experience appears to offer no complementary benefits to a firm's external exploratory experience. Indeed, the negative interaction effect indicates that the challenges of leveraging this type of external experience are even greater for firms that have gained more of their historical sales revenues from the focal therapeutic area. Firms with greater internal exploitation experience who simultaneously pursue exploration alliances may lack the internal knowledge necessary to recognize the most viable early-stage partnership options. This leads to a scenario where negative learning may occur. Their extensive product market experience in a particular therapeutic domain may also come with greater complementary assets and the potential for scale benefits; in order to better exploit both factors, firms may be less stringent in their selection of collaborative projects and thus face higher failure project rates. Taken together, this may be indicative of a situation where core competencies in internal exploitation can turn to core rigidities (Leonard-Barton, 1992) when combining them with external exploration experience.

Recently, the pursuit of cross exploration-exploitation activities has attracted significant attention in research on ambidexterity (O'Reilly and Tushman, 2008; Raisch and Birkinshaw, 2008). This is because pursuing exploration and exploitation simultaneously creates a significant tension due to divergent goals and different time horizons (Levinthal and March, 1993; March 1991). Yet firms that are able to balance and reconcile this tension through technology sourcing appear to achieve greater innovative and financial performance based on a study of the U.S. manufacturing sector (Rothaermel and Alexandre, 2009). When applying an ambidexterity lens to R&D projects in the biopharmaceutical industry, however, more nuances emerge because we are able to study each individual project rather than outcomes at the more aggregate and theoretically distant firm level. We find that ambidexterity is beneficial when firms focus on internal exploration combined with external exploitation. In contrast, ambidexterity can have negative performance consequences when internal exploitation is combined with external exploration.

Managerial implications

The overall pattern of results suggests that the leveraging of internal and external experience is challenging. It may even have deleterious effects in part because the partnering process and the value chain activities on which it is overlaid operate with distinctive logics and time horizons that can only be effectively combined in certain ways. In new product development, internal and external experiences appear to be reinforcing if the focal firm has extensive internal exploration experience and exploitative collaborative experience. Given the shorter time horizons of strategic alliances compared to the R&D timeline, opportunities to learn from partners may be best achieved in relatively short-term, codifiable exploitation alliances.

In contrast, the highly uncertain and tacit nature of early stage pharmaceutical R&D may favor internal organization rather than collaborative structures. Given the difficulty of learning in highly uncertain exploratory alliances, internal experience does not appear to be synergistic when it is based on expertise in downstream capabilities that may contribute little to a firm's ability to identify and leverage external opportunities. To the extent that firms have invested to enhance learning and knowledge transfer, they typically focus on transferring knowledge within a particular stage of the product development process or across contiguous stages. The current use of structures such as multidisciplinary project teams may be insufficient to fostering complex learning across project and firm boundaries. Managers may need to make more significant investments in terms of resource allocation

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and organizational structure to build internal exploration competences before attempting to leverage external exploitation experience.

Limitations and future research

Our study contains a number of limitations that open the door for future research. Although clearly important, performance metrics such as time to product approval and project duration may not fully reflect how firms leverage their external exploration experience. Knowledge conversion may be reflected in firms' publication and subsequent patent output, which are important precursors to products in the market. This is an interesting proposition that should be taken up in future research. From a strategy perspective, however, bringing new products to market in a timely fashion is imperative to gaining and sustaining competitive advantage in this industry (Grabowski and Vernon, 1990; Graham and Higgins, 2006; Roberts, 1999). A future study that links internal and external experience to economic performance, such as sales revenue generated from each product introduction (in the spirit of Nerkar and Roberts, 2004), would be welcome since many pharmaceutical companies compete on the introduction of blockbuster drugs.

In addition, although time to project completion is clearly an important performance metric, especially for new drug development in the pharmaceutical industry, we do need to caution that speed represents only one dimension of performance. One can argue that an excessive focus on speed to secure a patent-protected first mover advantage could lead to decisions that might compromise the safety of a product. For example, additional safety and side effect studies are not conducted once a minimum acceptable standard is reached for FDA approval, or critical data are not investigated in sufficient depth. These are possible explanations for the dramatic drug recalls, such as that of Merck's Vioxx, which we have witnessed in the recent past. A future study, therefore, is clearly needed to illuminate the trade-offs between quality and speed in new product development.

We are also in need of a deeper understanding of the factors that determine project termination. While Reuer and Zollo (2005) sought to determine whether terminated alliances had been successful or had failed, we were not able to discriminate between appropriate and inappropriate project terminations. Indeed, project terminations might be considered a success if the firm was able to stop committing resources to a low-potential project. Or, managers may find a failed project valuable if the project was undertaken initially as an option on an emerging technological area (Zollo *et al*., 2002). Unsuccessful terminations, in contrast, would involve prematurely ending a potentially viable project, and thus committing a type II error. To allow for a wider array of outcomes, future research might usefully combine subjective and objective assessments of project outcomes.

CONCLUSION

Our empirical findings provide some initial boundary conditions for the dynamic capabilities perspective when applied to an industry setting that experienced radical technological change. The pharmaceutical industry seems particularly well suited to test theoretical conjectures derived from this perspective due to the importance of strategic alliances and new product development in this industry setting. Indeed, Eisenhardt and Martin (2000) view those organizational activities to be at the core of the dynamic capabilities perspective: 'Dynamic capabilities include well-known organizational and strategic processes like alliancing and product development whose strategic value lies in their ability to manipulate resources into value-creating strategies' (Eisenhardt and Martin, 2000: 118). Moreover, one key theoretical tenet of the dynamic capabilities perspective is that the astute combination of internal and external competencies can enable firms not only to adapt, but also to take advantage of rapidly changing environments: 'We refer to this as the "dynamic capabilities" approach in order to stress exploiting existing internal and external firm-specific competences to address changing environments' (Teece *et al*., 1997: 510). Combining internal and external competencies allows for a dynamic strategic fit, which has been shown to improve firm performance (Zajac, Kraatz, and Bresser, 2000).

While the combination of external and internal competencies is critical to address rapidly changing environments, it is only *certain* combinations that are beneficial to performance, while others can actually be harmful. In particular, we find that a combination of internal exploration with external exploitation improved R&D project performance,

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while a combination of internal exploitation and external exploration reduced R&D project performance. It appears that internal exploration competencies lay the necessary foundation to leverage external experience.

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