

Navigating the Stages of Innovation: A study of the U.S. biotechnology industry

A DISSERTATION
SUBMITTED TO THE FACULTY OF THE GRADUATE SCHOOL
OF THE UNIVERSITY OF MINNESOTA
BY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

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July 2010

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Acknowledgements

My dissertation represents the culmination of my experience in graduate school. Acknowledging the people who have supported me intellectually, emotionally, and socially is as important as the content of my dissertation. First, I would like to acknowledge the assistance of my dissertation committee, which consists of Professors David Knoke, Evan Schofer, Erin Kelly, and Andy Van de Ven. I am indebted to each of them. Their influence on my academic and professional development will be evident throughout the remainder of my career. Each one has influenced how I think about organizations, search for answers to research questions, and conduct research.

Each member of my committee has contributed to my dissertation in unique ways. I have benefitted considerably from David Knoke's academic experience and sage advice, his ability to manage the many stages that constitute successfully obtaining a Ph.D., and his detailed feedback on each page of my dissertation (and my preliminary exam and prospectus), which pushed me to express my often vague and abstract ideas more clearly. Evan Schofer has provided me with always-insightful feedback on various papers, innumerable statistical models and half-baked ideas, and matters of professional development. It is impossible to overstate the help he has generously provided over the years. I benefitted greatly from working with Erin Kelly who allowed me to participate in and observe how she judiciously and instinctively proceeds through the research and writing process. Andy Van de Ven's instruction and example showed me *how* to be (1) intellectually creative and (2) pursue my research interests and passions. Those are two qualities I have always valued, but had difficulty pursuing in my research.

Other faculty members have contributed to my experience as a graduate student and development as a scholar. Ann Meier is as good as anyone at taking an interest in the personal lives of graduate students. She has also advised me regarding many professional and informal aspects of academe. Ann Hironaka showed me how to create a publishable paper from a mediocre rough draft and have fun answering tough questions in a research presentation. There is no one with whom I enjoy discussing theories of the state more than Ann. Penny Edgell is someone with whom I am always enlightened after discussions. I would not hesitate soliciting and following Penny's advice on any issue. Marie Cornwall has been a constant friend and mentor.

I especially appreciate the support of my friends and family. A number of graduate students have become trusted friends and colleagues: Xi Zhu, Erika Busse, Rachael Kulick (and Aaron Bommarito), Shawn Wick, Donna Spencer, Sam Ammons, and Keith Cunnien. My parents, Terry and Kathy, provided countless hours of emotional support during the many ups and downs of life inside and outside of graduate school. My brother, Sean, and my sisters, Britt and Mel, are always willing to humor me and provide emotional support. I will always consider them close friends. My wife Kathryn unwittingly stumbled into the world of academe and she adapted very well and quickly. Kathryn has been unconditionally supportive. She kept me grounded in reality every day as I obsessed about a narrow world inhabited by internal and external validity and non-significant statistical effects. Kathryn made the stressful times, which I tried to merely survive before meeting her, enjoyable.

Abstract

My dissertation takes a broad view of innovation by investigating product success among U.S. biotechnology firms across various stages of innovation including product discovery, product development, and product success. Current explanations of biotechnology product success examine one or two stages of innovation and underscore the importance of strategic alliances. However, current explanations are incomplete. First, they fail to examine whether their explanations hold across the entire innovation process. Second, estimates suggest that up to 70% of strategic alliances fail to meet their objectives (Kale and Singh 2009) and product development remains very costly despite the high incidence of alliances in the biotechnology industry. I propose that success across the stages of innovation is associated with the scope of learning that occurs within the firm, among strategic alliance partners, and from a focal firm's network. That is, product discovery is associated with learning within the firm, product development is associated with learning among strategic alliance partners, and product success is associated with learning from the firm's overall network.

While entering strategic alliances to pool resources to defray the costs of innovation is likely a necessary condition for innovation success current research overlooks the role of product development strategies. In this study I examine product development strategies that influence the likelihood of innovation success including exploration, exploitation, and ambidexterity (i.e., the simultaneous pursuit of exploration and exploitation strategies). Moreover, findings from interviews with executives in

biotechnology firms provide insight into the strategies firms use to develop new drugs and evaluate them at various stages of innovation.

Results from regression models support the general proposition that success at different stages of innovation varies with the scope of learning. Learning at the organizational-level (firm age and absorptive capacity) is likely to increase success at the discovery stage. Alliance partnerships are sources of learning (research alliance and development alliances) that affect product development. Network-level learning (network centrality and network experience) influences sales growth, but only for smaller firms in my sample. I also find that ambidexterity product development strategies are statistically significant predictors of success at each stage of innovation.

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CHAPTER 1:

INTRODUCTION

Innovation is extolled as a remedy for failure in today's constantly changing, global economy. However, innovation is difficult, consisting of a broad range of activities from product discovery to manufacturing to marketing and sales. Successful innovation requires diagnosing organizational-specific obstacles and implementing the appropriate solution rather than indiscriminately implementing the latest management fad (Hansen and Birkinshaw 2007). My dissertation moves past limited views of innovation that examine success at one or sometimes two stages of innovation by taking a broad view of innovation. In this study I investigate product success among U.S. biotechnology firms across various stages of innovation including product discovery, product development, and product success.

In the management literature explanations of innovation success in the biotechnology industry underscore the importance of strategic alliances. Strategic alliances allow firms to pool resources to combat the time- and resource-intensive process of product development. Explanations that focus on strategic alliances, however, are incomplete. Strategic alliances often fail to meet their objectives. Kale and Singh (2009) review research on strategic alliances and report that 30% to 70% of alliances fail to meet their objectives while Lunnan and Haugland (2008) find that 34% of alliances in their study were terminated after 5 years. Although the incidence of alliances is consistently higher in biotechnology than other industries (Hagedoorn 1998; 2002), the biotechnology industry has experienced increasing R&D costs (DiMasi and Grabowski 2007; Dimasi,

Hansen, and Grabowski 2003) even as industry performance has been stagnant (Pisano 2006) and new drug approvals by the Food and Drug Administration (FDA) have consistently declined from 53 in 1996 to 26 in 2009 (www.fda.gov).

To be sure, strategic alliances are a critical component of innovation success. But, research on innovation in biotechnology firms often overlooks or indirectly measures characteristics of the products themselves and their associated product development strategies. Product development strategies include exploring novel alternatives and exploiting existing knowledge (March 1991) or pursuing both exploration and exploitation activities simultaneously (Raisch and Birkinshaw 2008). The questions, then, guiding this research are do product development strategies improve the likelihood of innovation success beyond the effects of strategic alliances? If so, which product development strategies are the most successful? And, are there differential effects for strategic alliances (and other relevant independent variables) across the various stages of innovation?

Results from my study show that product development strategies affect success at each stage of innovation, net of the effects of strategic alliances. Simultaneously pursuing both exploration and exploitation is an important predictor of success across the innovation stages, especially in a sub-sample of large firms. Moreover, interviews with executives in biotechnology companies, which I used to supplement the quantitative analysis, illustrate the importance of building on existing knowledge in new ways and provide further insight into understanding ambidexterity in organizations, defined as the simultaneous pursuit of exploration and exploitation (Raisch and Birkinshaw 2008). I

also find broad support for the notion that the scope of learning is associated with success across the stages of innovation. That is, organization-level learning increases the likelihood of success in the early stages of innovation; joint learning among strategic alliance partners, increases success in the intermediate stages of innovation; and network-level characteristics are associated with increased success at the final stages, but only for smaller firms in the sample.

My dissertation makes several contributions to the literature on innovation. First, I add to the organizational learning literature by developing a novel measure of ambidexterity: recombination. Recombination includes recombining existing knowledge (exploitation) in novel ways (exploration). Second, analysis of interviews demonstrates that exploration and exploitation product development strategies can be subjective depending on the informant's point of view. An informant's point of view of product development can vary depending on whether it is viewed from the perspective of the firm compared to the environment or over a short period of time versus a long period of time. Whether change is interpreted as exploration or exploitation could influence an organization's innovation strategy and eventual success. Third, my dissertation examines success across the various innovation stages, from start to finish. Results from my dissertation contribute to innovation research by theorizing the entire innovation process rather than the piecemeal approach of past research.

CHAPTER 2:

INNOVATION IN THE BIOTECHNOLOGY INDUSTRY

In 1953, scientists James Watson and Francis Crick correctly identified the structure of the DNA molecule (Watson 2001[1968]). Watson and Crick laid the foundation for the emergence of the biotechnology industry (Kenny 1986). Their discovery led to a technique, published by Herbert Boyer in 1973, which involves removing DNA from a healthy cell and placing it into a diseased host cell (Rothaermel 2001). Herbert Boyer went on to cofound the company Genentech in 1976. Genentech, headquartered in San Francisco, is considered the first biotechnology company. Since the founding of Genentech, biotechnology companies have proliferated. Today, public and private biotechnology firms, university laboratories, and government agencies spend trillions of dollars searching for biochemical substances with the potential to shape the reproduction and maintenance of human life.

Biotechnology is defined by the Organisation for Economic Co-operation and Development (OECD) as “...the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services” (van Beuzekom and Arundel 2006:7). Although medical devices and agricultural applications (i.e., plant diseases and food production) fall under the purview of broad definitions of biotechnology, such as the one provided by OECD, for this study I follow Powell, Koput,

and Smith-Doerr (1996) and Rothaermel and Deeds (2004) in limiting the definition of biotechnology to internally-digested drugs (*in vivo*) for treating human disease.

Financial performance in the biotechnology industry has remained relatively constant since its inception. According to Pisano (2006), most private firms lose money and profits for public firms have hovered around zero from 1975 to 2004. Furthermore, when profit is aggregated for public firms and calculated without Amgen, the most profitable biotech firm, it is decidedly negative (Pisano 2006). What is the reason for perpetually low-performing biotechnology firms? The short answer is the high costs associated with researching and developing drugs and the diverse range of activities required for product development across various stages of innovation. These activities include everything from discovering new molecules, drug development in preclinical and clinical trials, manufacturing, marketing, and selling the drugs to doctors and patients.

Financial indicators and the number of firms are listed for the U.S. biotechnology industry in Table 1. U.S. public firms reported revenues of \$66 billion in 2008, while net income in 2008 was \$0.4 billion. Compared with prior trends toward negative financial performance, an industry report by Ernst & Young (2009:34) calls the positive net income encountered by the industry in 2008, an “historic” accomplishment. Revenues increased 34% from 2006 to 2008, and net income increased 9.8%. But, with the uncertainty of the 2008 economic downturn (Ernst & Young 2009), it remains unclear whether this “historic” accomplishment is a trend or an aberration.

While the number of employees in public biotechnology firms has declined since 2006, presumably as a result of downsizing during the economic recession, the number of

public and private companies increased. Whether the U.S. economy can support this increase is yet to be seen. For the global biotechnology industry, each item listed in Table 1 is up from 2006, with the exception of net income which has declined at an alarming rate from \$5.4 billion in 2006 to negative \$1.4 billion in 2008. The number of global public and private biotechnology companies in 2008, was 776 and 3,941, respectively (Ernst & Young 2007, 2009).

Table 2-1. U.S. Biotechnology Industry (in billions of dollars)			
Public Companies	2006	2008	Change
Revenues	55.5	66.1	16.0%
Net income	-3.5	0.4	9.8%
Employees (in thousands)	130,600	120,200	-8.7%
Number of Public Companies	336	371	9.4%
Number of Private Companies	1,116	1,383	19.3%
Source: Ernst & Young (2007, 2009)			

Biotechnology research is driven by top-trained scientists in research labs and billions of dollars are poured into R&D. In 2008, \$25.3 billion was invested in R&D in the U.S. (Ernst & Young 2007, 2009). This amount increased 9.5 percent from 2006. The ultimate outcome of R&D expenses is drugs that receive FDA approval and are sold on the market. The number of products passed by the U.S. Food and Drug Administration (FDA) has varied in recent years. In 2008, the FDA approved 27 new drugs. This number is up from 18 new drugs in 2007, which was the lowest total since 1983. In preceding years the number of new drugs approved was 22 in 2006, and 20 in 2005, and 36 in 2004 (Ernst & Young 2009:63). The number of drugs approved is

relatively small compared with the amount of (increasing) funding diverted toward research and development.

Though the length and cost of innovation varies by product, the time and money required to navigate product development is especially pronounced in biotechnology compared with other industries. The average cost of developing a drug – from discovery to FDA approval – has increased substantially over the years. The average cost of developing a new drug was \$138 million in 1975, \$318 million in 1987, and \$802 million in 2001 (in year 2000 U.S. dollars) (Dimasi et al. 2003). High costs of drug development are the result of a long and arduous R&D process. On average firms develop thousands of chemical compounds in search of one viable drug candidate. A candidate drug is tested in phases of clinical trials with hundreds and sometimes thousands of patients. The process of drug development is elaborated below.

The Innovation Value Chain

Discourse in the industry emphasizes the importance of innovation for success in the biotechnology industry. Discourse regarding this innovation imperative is illustrated in a series of articles in an Ernst & Young industry publication written by CEOs of biotechnology firms. In one of the articles, the CEO of Bristol-Myers Squibb states “...companies must reinvent themselves – or fail” (Ernst & Young 2009:19). Another example comes from the CEO of Gilead Sciences who writes, “The question of how we sustain growth in our industry is, ultimately, one of how we sustain innovation” (Ernst & Young 2009:18). In a 2005 interview Bill Hawkins, president of Medtronic,

headquartered in Shoreview, Minnesota, also comments on the importance of innovation. “Innovation is without question the lifeblood of our industry and business” (www.babsoninsight.com/contentmgr/showdetails.php/id/839, retrieved January 29, 2008). In response to the ever-present, industry-wide pressure to innovate, Arthur Levinson, CEO of Genentech, was quoted in *BusinessWeek* on December 17, 2007, as saying “I’m sick of the word ‘innovation’” (Weintraub 2007).

Innovation and eventual product adoption in any industry are challenging as indicated by high failure rates of new technology (Pfeffer and Sutton 2006). New technology takes years – sometimes decades – to diffuse (Rogers 1995). Examples of new technologies that took years and in some cases decades for firms to manufacture and sell include myriad items such as alternate automobile fuels and hybrid engines, incandescent light bulbs, MP3 players, integrated PDAs, and the computer mouse, among others. A common explanation for the time lag between product invention and diffusion is diverse firm resources and activities that are necessary to move products through the various steps or stages of innovation. The broad stages of innovation consist of invention, product development, and product success or diffusion (Arthur 2007; Hansen and Birkinshaw 2007; Rogers 1995; Van de Ven et al. 1999). Different organizational activities are associated with each stage. For example, R&D activities are expected to increase the penchant for product invention while marketing efforts are aimed at diffusing products throughout the market.

To succeed all firms must navigate the stages of innovation to some degree; whether independently, through outsourcing, or through joint ventures. Firms have

heterogeneous resources and capabilities (Barney 1991) that generate variability in competitive advantage and, consequently, success across the stages of innovation. A firm might have a flexible and creative culture and develop a multitude of inventions but lack the infrastructure to convert the novel ideas into products that are eventually adopted by customers (Hansen and Birkinshaw 2007). For instance, in the late 1970s, Xerox invented many computer technologies that are used today including the first personal computer, the mouse, and laser printing. But, other companies were the first to commercialize and sell these products because Xerox lacked the ability to implement and market them (Hargadon 2003).

In a recent theoretical article in the *Harvard Business Review*, Hansen and Birkinshaw (2007) refer to the different stages of innovation as the *innovation value chain*. Their premise is that “best innovation practices” assume firms face identical hurdles to creating and developing new products. In reality, firms face unique challenges and circumstances and require different innovation solutions. One firm’s elucidation of and success with a particular innovation strategy may be unsuccessful at another firm due to differential resources, capabilities, or culture. A firm may focus its attention to innovation, but be unsuccessful bringing those ideas to market. Such is the case with Intuit, a software firm that developed Quicken and QuickBooks. To deal with his firm’s challenges in bringing new inventions to market, Intuit’s CEO, Steve Bennett, in 2000 implemented a new policy that “...demanded clear business objectives be set for ideas in development” (Hansen and Birkinshaw 2007:122). The new policy prompted employees to link new inventions with implementation and practice, since these activities require

different and additional capabilities. After the policy was implemented, Intuit's profits increased 65% because ideas that could not be implemented were not pursued.

The innovation value chain is a framework that views innovation as an integrated process involving a variety of competing and complementary tasks. The innovation value chain is defined by Hansen and Birkinshaw (2007:122) as a "...three-phase process that involves idea generation, idea development, and the diffusion of developed concepts." Sources of idea generation, the first stage in the innovation value chain, include the focal business unit, multiple-unit collaborations, and external sourcing from strategic alliances or the industry at-large. The second stage is idea development. This stage involves converting ideas into products and implementing them. Ideas are often no longer pursued due to screening by management or the costs associated with product development. Hansen and Birkinshaw maintain that firms with difficulty implementing new ideas may be either inundated with too many ideas to pursue or plagued by a scarcity of good ideas. The third stage in the innovation value chain is diffusion. Diffusion consists of distributing products to relevant constituencies or customers in the market. An example how a firm can experience trouble distributing its products to customers includes Procter & Gamble's operations in Europe. Procter & Gamble emphasized product quality and ran their products through extensive market testing, and they were very successful introducing Pampers diapers in Germany. But because of Procter & Gamble's demanding requirements for product quality it took an additional five years to introduce Pampers in France. In the mean time, another company observed Procter & Gamble's success in Germany, introduced a new line of diapers in France, and gained

market share in France before Pampers entered the market (Hansen and Birkinshaw 2007).

A CEO's task, then, is to diagnose the stage at which the firm is deficient and implement stage-specific interventions aimed at improving innovation. Hansen and Birkinshaw (2007) assert that CEOs typically focus on their firm's strength in one particular area of innovation (e.g., idea generation) at the expense of improving another area of weaknesses (e.g., idea selection and development). Hansen and Birkinshaw offer questions for diagnosing weaknesses in the innovation value chain and they provide a number of solutions to address the weaknesses. To provide one example, the solution to fixing the problem of an "idea-poor company" consists of forging links with others outside the company to generate new ideas. To this end, the pharmaceutical company Eli Lilly has developed a Website that is accessed by a number of companies. The companies can post questions on the Website for "any of the 10,000 engineers, chemists, and other scientists registered at the site.... The individual or group offering the best acceptable solution gets a financial reward..." (Hansen and Birkinshaw 2007:127). Of course this is one of many ways to increase ties with others in order to access a diversity of ideas. The key is to adopt innovation practices that account for both the company's strengths and weaknesses.

Stages of Drug Development

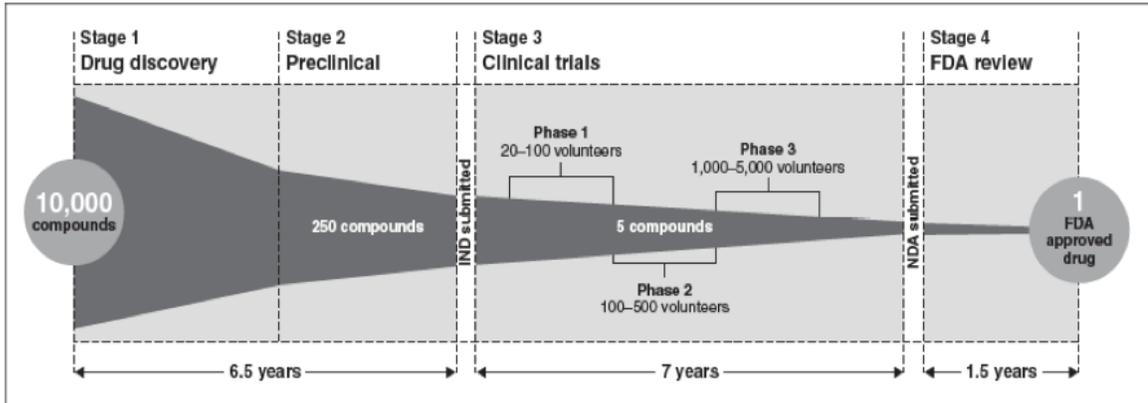
The innovation value chain (Hanson and Birkinshaw 2007) provides a useful framework for understanding the components of innovation success in biotechnology. In

the biotechnology industry product invention, development, and diffusion is arduous, costly, and requires a variety of competing and complementary tasks. The first step in biotechnology product development begins with new drug discovery. This stage takes place in the context of collaborating teams of scientists from both the public and private sectors. New drugs can take years to develop as scientists target a molecule that has potential to be treated by a new drug, test the target molecule to ensure it plays a role in a particular disease, find a chemical compound that could be developed into a drug, and then perform preliminary tests on the chemical compounds. The Pharmaceutical Research and Manufacturers of America (2007) estimates there is a 0.02 percent chance that a chemical compound at this stage of innovation eventually goes to market.

Figure 1 illustrates the time and cost required to develop a chemical compound into a new drug. According to Figure 1, an FDA approved drug is the result of anywhere from 5,000 to 10,000 newly discovered chemical compounds. The drug discovery stage, combined with the next stage, preclinical trials, lasts from 3 to 6 years. Preclinical trials involve testing the chemical compound on living cells in labs and in animals. The primary purpose of preclinical trials is to understand how the drug works and ensure its safety. About 250 out of 5,000 chemical compounds from the drug discovery stage begin preclinical trials. Upon completing preclinical trials, firms must get approval for a drug to be tested in clinical trials by filing an Investigational New Drug (IND) application with the FDA and get approval from an Institutional Review Board (IRB). An IND application provides data from preclinical trials, potential side effects in humans from

future testing, as well as plans for conducting clinical trials in the future (Pharmaceutical Research and Manufacturers of America 2007).

Figure 2-1. Stages of Drug Development



Source: Pharmaceutical Research and Manufacturers of America (2008)

After approval of the IND application companies test their drug in clinical trials. Clinical trials consist of three phases primarily. Clinical trials are overseen by physicians and the drug company to monitor the progress of volunteers. Phase 1 of clinical trials tests the drug on 20 to 100 healthy volunteers. The purpose of phase 1 is to determine whether the drug is safe for human consumption. Phase 2 tests different doses of the drug on a larger group of patients, anywhere from 100 to 500, who are affected by the medical condition from the target population. The purpose of this phase is to test for side-effects and the effectiveness of the drug. Phase 3 tests the drug's effectiveness on a large number of patients (from 1,000 to 5,000). Since this phase includes a large number of patients from various locations, coordinating phase 3 is complex; and is the costliest and longest phase to conduct. On average phases 1 through 3 of clinical trials last 6 to 7 years (Pharmaceutical Research and Manufacturers of America 2007).

Finally, firms must file a New Drug Application (NDA), which can consist of up to 100,000 pages of information, to get approval from the FDA to market and manufacture the new drug. The FDA determines whether the benefits of the drug under investigation outweigh the risks. Getting FDA approval (or getting denied) can take up to 2 years. In some instances the FDA can require additional studies – Phase 4 clinical trials – to continue monitoring drug use and its effects after the drug has been approved (Pharmaceutical Research and Manufacturers of America 2007). After FDA approval, the firm undertakes large-scale manufacturing, marketing, sales and distribution of the drug.

This portrait of the drug development process is of course ideal-typical and there are many departures from the norm. At the FDA approval stage, for example, there can be instances of prolonged delays or quick approvals by the FDA. One instance of a swift FDA approval is the arthritis drug Vioxx. Merck & Co. submitted a New Drug Application for Vioxx on November 23, 1998, and the application was approved by the FDA six months later on May 21, 1999. Future events demonstrate the FDA's haste in approving Vioxx. While on the market, evidence mounted showing that Vioxx increased the risk of heart attacks and strokes (i.e., myocardial infarctions) in patients. Subsequently, in 2004, Merck & Co. voluntarily recalled Vioxx, which might have been avoided if the FDA required additional clinical trials (Topol 2004).

The Biotechnology Business Model: Strategic Alliances

Due to high costs associated with each stage of the drug development process, biotechnology firms often specialize in one stage of the innovation value chain and partner with firms with complementary capabilities; firms with expertise at other stages of product development. The typical biotechnology business model consists of small firms that specialize in new drug development. These small, innovation firms with a new product partner with large pharmaceutical companies with the resources to carry out clinical trials for the new product, the capacity to manufacture and market the product, and marketing and sales personnel to carry the product to the far corners of the market (Pisano 2006). Take the example of the drug Intron A, which is used to treat chronic hepatitis and hairy-cell leukemia. Intron A was developed by Biogen, one of the world's leading biotechnology companies. Biogen engaged in partnerships with companies (and universities) at various stages to develop Intron A. In the early stages of drug discovery, Biogen collaborated with the University of Zurich. After initial development of the drug, "...Biogen entered an exclusive licensing agreement with Schering-Plough, which took on the clinical trials and regulatory activities of the product as well as its marketing, distribution, and sales" (Rothaermel and Deeds 2004:205).

The primary solution promulgated by scholars and practitioners to the problem of costly biotechnology product development is to employ strategic alliances between multiple firms. Strategic alliances are "...arrangements between two or more firms involving the exchange, sharing, or codevelopment of products, technologies, or services" (Gulati 2007:1). Entering strategic alliances allows firms to pool their

resources, including both technology and expertise (Hamel, Doz and Prahalad 1989), and alliances can take a variety of forms including short-term contracts or long-term joint ventures. Todeva and Knoke (2005) classify alliances along a continuum between low levels of integration (arm's length ties) to highly integrated (hierarchical ties). Types of alliances include (beginning with examples of low-level integration and moving to high-levels of integration) contracts, action sets, industry standard groups, licensing, franchising, cartels, strategic, cooperative agreements, R&D consortia, equity investments, cooperatives, and joint ventures. Strategic alliances provide many advantages to firms such as developing relationship-specific assets, knowledge exchange and joint learning, combining complementary resources and capabilities, and governance structures that effectively reduce the transaction costs (i.e., the costs of administering market exchange) (Dyer and Singh 1998).

A strategic alliance represents a governance structure that can reduce transaction costs. Transaction costs occur under conditions of high asset specificity (i.e., organization-specific assets) (Williamson 1981). High asset specificity provides incentives for firms to cooperate by pooling their resources. Pooling resources through strategic alliances can reduce the costs of production and create value for each firm involved. Dyer and Singh (1998:672) provide an example of two firms with organization-specific assets that entered into an alliance, which allowed the firms to co-invest in a manufacturing process that created value for both firms.

[A] Nissan seat supplier built its plant on the property adjacent to a Nissan assembly plant. The supplier was willing to make this site-specific investment because Nissan had a minority equity position in the supplier and because the two parties had developed a high level of trust. Once this site-specific investment was

made, the two parties discovered that rather than transport the seats by truck (a general-purpose asset) [between each firm], it would be more economical to build a conveyor belt (a highly specialized asset). Consequently, they jointly invested in building the conveyor belt.

Each firm in this example specialized in one aspect of the automobile manufacturing process and needed partners (connected by Nissan) with complementary assets in order to manufacture a product that would eventually sell on the market. This example illustrates how firms are able to reduce transaction costs by creating and investing in equipment (i.e., a conveyor belt) that creates value for each firm. Similarly, in the biotechnology industry asset specificity is high due to the costs associated with each stage in the product development process and the specialized expertise required for activities associated with drug discovery, development, commercialization and marketing.

Collaborative alliances occur in biotechnology between scientists from public- and private-sector firms from all over the world. Powell and Grodal (2005) identify two examples (perhaps extreme examples) of the diversity of alliances in the biotechnology industry. The examples are biotech consortia that each published human genome sequences in February, 2001. One consortium is privately sponsored. The consortium is called The Celera Genomics Sequencing Team. It is comprised of 291 individuals from 14 companies, universities, institutes, and laboratories (*Science* 2001). The other consortium, The Human Genome Project, is publicly sponsored. Their published article includes only a partial list of authors but the list identifies 110 authors from 20 universities, research centers, institutes, and hospitals (International Human Genome Sequencing Consortium 2001). To be sure, efforts to map the human genome incurred many costs and these activities were ripe for collaborative alliance. The Human Genome

Project, the first effort to sequence all of the genes in the human genome, was initiated by the NIH in 1990. The estimated cost of the Human Genome Project was \$3 billion dollars and took over 10 years to complete (Collins, Morgan, and Patrinos 2003).

Research on international strategic alliances confirms the anecdotal evidence of the prevalence of alliances in the biotechnology industry. Hagedoorn (1993) constructs a sample of 4192 international alliances from 1980 to 1989. His data are collected from a variety of sources including newspaper and journal articles. Hagedoorn's research team collected data on the firms involved in the alliance, the terms of the alliance, the industry of the firms, among other things. Hagedoorn finds that the biotechnology industry accounts for 20% of all alliances (847 divided by 4192) in his sample (Table 3:379).

Research on the Stages of Innovation in the Biotechnology Industry

Three explanations primarily animate the discussion of product success in the biotechnology industry across three broad stages of innovation discussed in this study: discovery,¹ development, and product success. First, sociological explanations underscore the role structural inertia plays in limiting discovery (i.e., patenting) while the management literature often invokes the notion of absorptive capacity. Second, complementarity among strategic alliances is the most prevalent explanation of successful product development (i.e., products in development and products on the market). Third, cumulative advantage due to interorganizational learning due to network

¹ Although the term "invention" is used to describe the early stage of innovation in the innovation literature (Hanson and Birkinshaw 2007; Rogers 1995), I use the term "discovery" instead of invention because it is used to by practitioners in the biotechnology industry to describe the research activities that take place in the first stage of innovation. Rothaermel and Deeds (2004) also use the term discovery to describe the first stage in the "product development path" in the biotechnology industry.

centrality and network experience is shown to predict product success (i.e., firm sales). These broad explanations of success across the stage of innovation represent the current state of knowledge in innovation research. For the purposes of this study, each approach is not a competing explanation to be disproved. Instead, they provide the basis of a conceptual model for understanding the entire innovation process, which will be elucidated below.

Product Discovery

Common explanations of discovery highlight the role of absorptive capacity and structural inertia. Absorptive capacity is not just a firm's ability to assimilate knowledge and learn from the environment. It is also the ability to create new knowledge (Cohen and Levinthal 1989, 1990, 1994). The notion of absorptive capacity, simply stated, is that generating new knowledge is conditional upon evaluating, assimilating, and then utilizing relevant knowledge external to the firm.

Cohen and Levinthal's (1990) seminal study of absorptive capacity begins by citing cognitive-psychology research showing that higher levels of individual-level knowledge facilitates subsequent learning and problem solving. When it comes to learning, math students who master algebra are better able to comprehend calculus (Ellis 1965). With respect to learning a new language, knowledge of objects, relationships between objects, and linguistic structure precedes learning a new label for an object and communicating those labels in another language (Lindsay and Norman 1977). Cohen and Levinthal continue by pointing out that learning is cumulative and the diversity of

knowledge facilitates learning. Diversity of knowledge allows individuals to reduce the uncertainty that novel information is comprehended and assimilated and it facilitates links between what is already known and what is new.

The same principles are true for organizations. Of course, communication structures and network ties within the organization and between the organization and environment are important for learning, but so is the organization's repository of knowledge. Prior knowledge facilitates the exploitation of new knowledge and learning. Organizations with higher levels of absorptive capacity are able to leverage existing expertise to recognize and evaluate the utility of new technology, especially under conditions of environmental uncertainty (Cohen and Levinthal 1990).

Cohen and Levinthal (1990) maintain that a firm's R&D activity contributes to its absorptive capacity. They suggest that absorptive capacity can be operationalized as R&D intensity and measured as R&D expenditures divided by sales (to control for firm size). Cohen and Levinthal highlight the critical role of R&D for advancing industry knowledge. "The pace of advance of a field affects the importance of R&D to developing absorptive capacity because the faster the pace of knowledge generation, the larger the staff required to keep abreast of new developments.... [and] the less explicit and codified the relevant knowledge, the more difficult it is to assimilate" (140-141).

Cohen and Levinthal (1990) test their argument about the association between the construct absorptive capacity and R&D intensity using a sample of R&D lab managers from 1,719 business units and 318 firms. The independent variables – which come from a survey administered originally by Levin, Klevorick, Nelson and Winter (1983, 1987) –

are intended to capture the construct absorptive capacity. The independent variables include technology opportunity and appropriability (or spillover). Technological opportunity is the quantity and type of knowledge available in the firm's environment. The more available knowledge, the more likely a firm will capture the knowledge by investing in R&D. Appropriability is the extent to which firms protect their intellectual property or knowledge spills over in the environment. Greater spillover increases incentives to secure knowledge by investing in R&D (see also Lane, Koka and Pathak 2006:836). The independent variables are intended to proxy the extent to which a firm is able to exploit external knowledge and the type of external knowledge on which it relies. The dependent variable is R&D intensity.

Findings from Cohen and Levinthal (1990) indicate the overall effects of increasing technological opportunity (the relevance and quantity of knowledge) on R&D intensity. Appropriability or spillover (the ease of learning) is also a significant predictor. That is, results from regression models show that respondents report that R&D intensity is likely to increase in environments in which learning is easier. Cohen and Levinthal's broad contention, then, is confirmed: R&D is associated with learning, and by implication, innovation.

Many studies of innovation success have drawn from Cohen and Levinthal's (1990) study by using R&D intensity as a proxy for absorptive capacity. Lane et al. (2006) conduct a review of 289 articles from 1991 to 2002 on absorptive capacity. A number of themes have emerged in studies of absorptive capacity, one of which is innovation. The underlying logic is that "...[a]bsorptive capacity increases the speed and

frequency of incremental innovation because such innovations draw primarily on the firms' existing knowledge base" (489). Lane et al. point out that in this strand of research innovation has been largely measured as patents and several studies show that absorptive capacity is positively associated with patents (e.g., Ahuja and Katila 2001; Sorensen and Stuart 2000). With respect to the process of innovation, it should be noted that patents occur early, which is akin to the innovation stage invention.

Although Sorensen and Stuart (2000) find empirical support for the effects of absorptive capacity on patents (i.e., invention), the central focus of their study is the (nonlinear) effect of firm aging on patenting. They begin by pointing out two ostensibly contradictory effects of organizational aging on innovation. According to accounts of structural inertia, as organizations age, routines become taken-for-granted. The rigidity of routines limits the range of appropriate behaviors and leads to increasingly inert organizational structures (Hannan and Freeman 1984). Over time, organizational aging and the concomitant effects of inertia result in a limited number of innovations. Thus, newer organizations are more likely to innovate.

An alternate perspective emphasizes the role of organizational competence over time. Younger firms suffer from a 'liability of newness' and are disadvantaged because older firms have more production experience, stronger relationships with customers, and more experienced employees (Stinchcombe 1965). Further, older firms typically possess greater reliability with respect to their existing routines (March 1991; see also Hannan and Freeman 1989), the accumulation of knowledge and the ability to assimilate new ideas (Cohen and Levinthal 1990), and information-processing capabilities that promote

incremental innovation (Tushman and Anderson 1986). This argument about increasing organizational competence over time resembles arguments about absorptive capacity and a firm's ability to build on accumulated knowledge. Net of firm size (which presumably decreases innovation), accumulated knowledge and improved competencies over time increase older firms' ability to innovate (Cohen and Levinthal 1990).

Sorensen and Stuart (2000) test these competing hypotheses by compiling a sample that consists of 150 semiconductor firms from 1986 to 1992, and 237 biotechnology firms from and 1987 to 1994. The primary dependent variable is the patent rate by firm-year. The independent variable of central concern is firm age, the number of years since firm founding. In separate analyses for both semiconductor and biotechnology firms, results from regression models show that firm age and firm age squared together have a significant and net curvilinear effect on patenting. As firm age increases, patenting also increases. Then, at the highest levels of firm age the effects level-off and decrease. In addition, R&D is positively associated with the patent rate, providing empirical support for the argument of Cohen and Levinthal (1990) regarding the direct effects of absorptive capacity on innovation. In sum, Sorensen and Stuart resolve the tension between firm age and innovation by finding a nonlinear effect for firm age. While innovation success increases with age, innovation decreases for the oldest firms.

Insights from Cohen and Levinthal (1990) and Sorensen and Stuart (2000) provide theoretical justification for the first set of hypotheses.

Hypothesis 1a: Increasing absorptive capacity (R&D expenditures) is likely to increase product discovery.

Hypothesis 1b: Organizational age is likely to have a curvilinear effect (inverted U-shape) on product discovery.

Product Development

The next innovation stage is product development. In the case of biotechnology, product development includes products that enter clinical trials and products that get FDA approval, are commercialized, and reach the market. The most prominent explanation of innovation success at this stage is dyadic complementarity between biotechnology alliance partners. A number of influential studies have been carried out by Rothaermel and colleagues who examine various stages of product development and the role of complementary assets between alliance partners in innovation success (Rothaermel 2001; Rothaermel and Deeds 2004; Rothaermel and Hill 2005). Complementary assets, or “fit” between alliance partners, allow biotechnology firms to pool their resources to achieve the desired ends.

Theoretical support for the complementarity approach comes from the resource-based view (RBV) of organizations. The RBV theory assumes that firm resources are heterogeneous and imperfectly mobile. The principle explanation of competitive advantage, according to RBV, is the firm’s internal, idiosyncratic resources (Barney 1991; Mahoney and Pandian 1992; Wernerfelt 1984). Different resource endowments lead to value creation, competitive advantage, and variation in performance. Firm resources must have four characteristics to provide competitive advantage. Resources must be valuable, rare, imperfectly imitable, and nonsubstitutable (Barney 1991).

Resource heterogeneity renders firms relatively more proficient at various stages of the innovation value chain since some firms are better at discovery while others are more effective at commercialization activities, which are located downstream in the supply chain such as manufacturing, marketing, and distribution. For example, the CAT scan technology was developed by a firm called EMI. However, General Electric became the market leader in the CAT scan industry because it possessed the resources to successfully market and sell the product (Martin 1984; Rothaermel 2001; Teece 1986). Another example is cola in a can, which was introduced by RC Cola but Coke and Pepsi quickly became market leaders (Teece 1986). Examples of one firm discovering a technology and another firm commercializing it or becoming the market leader are not uncommon. As Teece (1986) explains, firms often fail to reap the rewards of their discoveries when imitation is easy or firms are able to leverage their own complementary assets to enter into a new market.

Are firms without the capability to commercialize and successfully market their discoveries doomed to failure? The answer is clearly no. One way firms can overcome their incapacity to commercialize products is through strategic alliances (Rothaermel 2001). That, firms that specialize in discovery or smaller firms with limited resources to carry out large scale manufacturing and marketing activities can cooperate with large firms to commercialize their products. Moreover, large firms constrained by structural inertia can overcome obstacles to new product discovery by cooperating with smaller, more agile firms that are proficient at generating novel alternatives. Developing specialized competencies and interorganizational cooperation are consistent with the

models of organizing utilized in the biotechnology industry. One example is Genentech. Genentech licensed its human insulin drug, Humulin, to Eli Lilly to commercialize and market in 1982, since Eli Lilly specialized in producing and commercializing insulin (Rothaermel 2001).

Firms not only specialize according to the type of drug produced, they specialize in activities associated with various stages of the innovation process. Small firms usually lack the resources and capabilities of large firms, which often specialize in commercialization or downstream supply-chain activities. Moreover, new biotechnology firms often specialize in upstream supply-chain activities such as R&D. Upstream and downstream are concepts that come from supply-chain management. Supply-chain management is concerned with managing the flow of materials from suppliers (who are upstream in the supply chain) to customers (who are downstream in the supply chain) (Frohlich and Westbrook 2001; Mentzer et al. 2001). Management scholars have used the terms upstream, horizontal, and downstream to categorize different types of strategic alliances in the biotechnology industry. Upstream alliances include partnerships designed to provide or produce early-stage research. Examples of upstream alliances include partnerships with universities, government labs, and research institutes. Horizontal alliances are partnerships with other biotechnology firms for the purpose of combining resources or expertise with respect to moving products through various stages of clinical trials. Downstream alliances are often partnerships with large pharmaceutical firms and provide assistance with manufacturing, the regulatory process, and sales and

marketing (Baum, Calabrese and Silverman 2000; Edwards, Murray and Yu 2003; Silverman and Baum 2002).

Rothaermel and Deeds (2004) empirically examine two different types of alliances in the biotechnology industry and whether they influence success at two stages of innovation: products in clinical trials and products on the market. Instead of identifying different types of alliances as upstream, horizontal, or downstream, they identify two similar types of alliances: exploration alliances and exploitation alliances (March 1991). Exploration alliances focus on invention and knowledge creation or “the ‘R’ in the research and development process” (Rothaermel and Deeds 2004:204). An example they provide of an exploration alliance is a partnership between the biotechnology firm Biogen and the University of Zurich. The outcome of this alliance was the discovery of a new drug called Intron A as mentioned earlier. Thus, Rothaermel and Deeds (2004) hypothesize that exploration alliances are likely increase products in clinical trials. Biotechnology firms also enter exploitation alliances. Exploitation alliances “focus on the ‘D’ in the research and development process” (Rothaermel and Deeds 2004:205). An example of an exploitation alliance is Biogen and Schering-Plough. Biogen and Schering-Plough entered an agreement that stipulated Schering-Plough carry out clinical trials, regulatory approval, and commercialization for the drug Intron A. Accordingly, Rothaermel and Deeds hypothesize that exploitation alliances predict the number of products on the market.

Rothaermel and Deeds (2004) test whether exploration and exploitation alliances affect product development at two stages – products in clinical trials and products on the

market – in a much larger sample of 325 global biotech firms from 1973 and 1997. In separate models predicting products in development and products on the market results support Rothaermel and Deeds’ hypotheses that exploration alliances predict products in development while exploitation alliances predict products on the market.

The study by Rothaermel and Deeds (2004) provides a key contribution to the literature on strategic alliances and innovation – namely, different types of alliances predict success at different stages of innovation. Nevertheless, the measures of exploration and exploitation alliances employed by Rothaermel and Deeds lack construct validity and the measures do not directly map onto previous notions of types of alliances: upstream, horizontal, and downstream. First, their measures lack construct validity by conflating types of strategic alliances with types of innovation activities. Their measures of exploration and exploitation alliances serve as proxies for types of organizational learning activities (i.e., exploration and exploitation). Second, while Rothaermel and Deeds’ measure of exploration alliances is similar to others’ definition of upstream alliances (Baum, Calabrese and Silverman 2000; Edwards, Murray and Yu 2003; Silverman and Baum 2002), their measure of exploitation alliances is conceptually imprecise and includes both horizontal and downstream alliances. They measure downstream alliances as a firm’s alliances that focus on clinical trials, which are associated with horizontal alliances, as well as marketing and sales activities, which are associated with downstream alliances. Including horizontal alliances and downstream alliances in one measure is problematic for my study because it conflates activities associated with two different innovation outcomes. Their measure conflates the activities

associated with horizontal alliances – intended to progress drugs from clinical trials to the market – with the activities associated with downstream alliances – intended to help market and distribute products.

To remedy these problems in my study I employ direct measures exploration and exploitation activities, which will be discussed in more detail in the following chapters. I also employ measures of upstream and horizontal in models that predict product development – products in clinical trials and products on the market. Accordingly, I hypothesize,

Hypothesis 2a: Upstream alliances are likely to be positively associated with the number of products in clinical trials.

Hypothesis 2b: Horizontal alliances are likely to be positively associated with the number of products on the market.²

Product Success

The final stage of innovation I examine is product success. Identifying the factors that lead to product success is somewhat elusive. Stories elucidating product success are found in movies, the popular press, and water-cooler conversations. It is the topic of many books, articles, and board meetings. Explanations include such difficult-to-model processes as path dependence (Arthur 1989; David 1985) and tipping points (Gladwell 2000).

² Rothaermel and Deeds (2004) limit their analysis to products in clinical trials and products on the market. But, following their rationale regarding complementarity – complementary assets between alliance partners increase the likelihood of product success at different stages of innovation – I include a variable for downstream alliances (alliances that focus on delivering drugs to customers such as manufacturing and marketing) in my model estimating product success.

One perspective that elucidates factors that influence the final stage of innovation, product success, in the biotechnology industry underscores the importance of a firm's network characteristics (Powell, Koput and Smith-Doerr 1996; Powell, Koput, Smith-Doerr and Owen-Smith 1999). While Powell et al. (1996) acknowledge that providing complementary assets is one function of alliances, they advocate an alternative view that cumulative advantage accrues from network characteristics. First, cumulative advantage results from experience gained from managing previous alliances. Learning from previous alliances spills over into future alliances, as firms that participate in more partnerships are likely to learn to manage future alliances better and more efficiently. Powell et al. suggest that firms accrue a broad range of knowledge and experience from alliances. The authors cite the CEO of Centocor who says formal alliance agreements are just "...the tip of the iceberg – [they include] dozens of handshake deals and informal collaborations, as well as probably hundreds of collaborations by our company's scientists with colleagues elsewhere" (Powell et al. 1996:120). Over time, firms learn from the social interactions that accompany strategic alliances and develop capabilities for collaborating and managing future alliances. Powell et al.'s (1996) regression analysis of 225 biotechnology firms from 1990 to 1994 bears this out. Previous alliance activities such as R&D alliances and network connectivity (measured dichotomously as being connected to a main group of firms; i.e., not an isolate) are likely to increase the total number of alliances. While it is unsurprising that past strategic alliances predict future strategic alliance formation (see also Gulati 1995; Gulati and Gargiulo 1999), this

research underscores the competitive advantages that cumulate to firms from the entire network.

In addition to network experience, cumulative advantage comes to firms from network position or network centrality. Network centrality shapes a firm's reputation, which in turn leads to better access to resources and information from other network partners. Powell et al. (1999) build on their previous study (Powell et al. 1996) by investigating the influence of network position on another outcome – financial performance. “Central position in the network provides access to both critical information and resource flows needed for internal growth” (Powell et al. 1999:131). Besides centrality, they test for other network effects including R&D ties, the diversity of ties (the number of different types of alliances), and alliance experience (years since the firm's first alliance). Their sample consists of 388 biotech firms from 1988 to 1997. Results from regression models show that R&D alliances and network centrality have positive effects on firm performance.

To summarize, Powell et al. (1996) illustrate the importance of cumulative network experience for innovation success, which they define broadly as additional alliances. Powell et al. argue that innovation success results from learning from previous alliance partners about how to manage future alliances and procuring additional information and resources. The subsequent study by Powell and colleagues (1999) demonstrates the significance of network centrality and network experience on another measure of innovation success – firm performance. Findings from Powell et al. (1996, 1999) suggest the following hypothesis.

Hypothesis 3a: Network centrality is likely to increase product success.

Hypothesis 3b: Network experience is likely to increase product success.

Mapping Existing Explanations of Innovation Success

A broad pattern emerges when the stages of innovation and the explanations associated with success at each stage are viewed as a whole: at each successive innovation stage learning increases in scope from the organization level to the alliance-partner to the network level. At the earliest stage of innovation, the explanations emphasize learning at the firm-level. Organizational competence (Sorensen and Stuart 2000) increases with time and organizational learning, which results from increasing absorptive capacity (Cohen and Levinthal 1990), increases the likelihood of early-stage innovation success, product discovery. At the next innovation stage, product development, the source of innovation success increases in scope from characteristics of the firm to the alliance partner such that the type of partner matters for successful product development. The theoretical justification for this proposition is provided by Rothaermel and Deeds (2004) who argue that complementary assets between alliance partners allow firms to pool resources and expertise to propel products through product development. Upstream alliances, which focus on early-stage research, predict products in clinical trials and horizontal alliances are designed to advance products in clinical trials to the market. The explanation for the final stage, product success, increases in scope from the alliance partner to the entire network. The explanations proposed by Powell et al. (1996, 1999) underscoring characteristics of the firm's overall network, and the cumulative advantages

that accrue from network experience and centrality. Network centrality provides competitive advantage by exposing firms to new information about the environment and network experience provides understanding about how to manage alliances better in the future.

My research builds on existing studies by proposing a new framework that takes into account the various explanations of success across the entire innovation process. Table 2-3 provides an overview of the relationship between the scope of learning emphasized by each explanation cited above (absorptive capacity and organizational competence, complementarity, and cumulative network advantage) and the stages of innovation they examine (product discovery, product development, and product success). The columns in Table 2-3 represent scope of learning emphasized by each explanation

Figure 2-3. Explaining Success across the Stages of Innovation

		Stages of Innovation		
		Discovery	Product Development	Product Success
Scope of Learning	Firm	absorptive capacity, organizational age		
	Alliance		complementary assets	
	Network			cumulative network advantage

And the rows signify each innovation stage. As stated above, at the product discovery is predicted by firm-level characteristics R&D expenditures, firm age, and firm-age squared. The complementarity approach points to the importance of upstream and

horizontal alliances as the source of success at the middle stages. Cumulative advantage effects are likely to increase innovation success at the final stage.

While extant research identifies the salient theoretical concepts at various stages of innovation, these approaches are, nevertheless, lacking. First, they under-theorize the entire innovation process. Extant explanations of innovation success examine only one, sometimes two, stages of innovation. But, innovation must be viewed more broadly and success comes from a range of sources including the firm, alliance partner, and network. A strategic alliance may increase success at one stage of innovation, but as stated above other stages require different capabilities, which alliance partners may or may not possess.

Second, while the most prominent theoretical explanations of innovation in biotechnology cite strategic alliances as the source of success, this explanation is incomplete by itself. That is, entering alliances is likely a necessary, but insufficient, condition for innovation success. Why? The success rate of strategic alliances in all industries is contested and estimates vary, but strategic alliances experience high failure rates. In their review of strategic alliance research Kale and Singh (2009) state that 30 to 70% of alliances fail to meet their objectives while Lunnan and Haugland (2008), who followed 100 Norwegian alliances, find that 34% were terminated after 5 years. Moreover, despite high levels of alliances in biotechnology compared with other industries (Hagedoorn 2002), product failure and high costs of product development have plagued biotech firms and produced negative profits since the industry's inception (Pisano 2006).

Third, existing studies often indirectly measure innovation success through proxies such as alliance formation (Powell et al. 1996) or firm profit (Powell et al. 1999). These indirect measures pose methodological problems for several reasons. Indirect measures of product success may capture different dimensions of success and lead to inconsistent findings. Product success should be examined directly by measuring whether products complete innovation stages. Moreover, research by Rothaermel and Deeds (2004) use exploration and exploitation alliances as proxies for characteristics of technology. While these measures are ostensibly reasonable proxies for different types of activities that are associated with types of alliance partners, they do not directly measure the product technology used by the firm. Existing approaches, therefore, are theoretically imprecise and conflate exploration and exploitation alliances with observed product characteristics and fail to distinguish the circumstances in which either, or both, are salient. To increase the validity of innovation research, scholars should employ direct measures of product characteristics and product success.

Toward A Multi-level Perspective of Innovation

A new perspective is needed to disentangle the differential effects of success across the stages of innovation; to more completely theorize the effects of firm, alliance, and network characteristics; and to examine directly the effects of product characteristics on innovation success. To this end, I argue that success across stages of innovation depends on learning that occurs at multiple levels of analysis.

Taken together, existing explanations of innovation in the biotechnology industry implicitly point to a pattern of success across the innovation process. The scope of learning required for success expands at each innovation stage. The scope of learning expands from the firm (discovery) to the alliance partner (product development) to the network structure (product success). As products progress across the stages of innovation the requisite coordination, learning, and legitimacy increase in scope for products to succeed. In other words, as the scope of learning effectively expands from the firm to the overall network success is likely to increase across stages of innovation.

This proposition, that the scope of learning is associated with success across stages of innovation, is intuitive since a broader range of resources and actors are needed as products progress through innovation stages. In the beginning, relatively few actors and limited coordination are necessary for product invention, which can occur in a single lab. However, innovation activities increase in scope as products progress from invention at the firm-level to complementary alliances that engage in product development to a host of additional actors involved in supply-chain management, manufacturing and distribution, marketing, and sales. Success at early stages, then, likely results from firm-level learning while success at the latter stages is more likely to be influenced by complementary assets and broad network characteristics.

Certainly exceptions occur to this linear explanation of the expanding scope of innovation success. Invention success can result from broad network characteristics or product success and diffusion can occur as a result of a single influential or monopolistic firm. However, I contend that the expanding scope of innovation success is a useful

perspective that can be used to understand the broad organization activities that lead to innovation success. Organization theory is not intended to explain every case and exceptions are important for clarifying scope conditions. Organization theory is intended to provide an organizing framework for making sense of organization behavior. The value of organization theories is evaluated in large part by the extent to which they are generalizable (Carroll and Hannan 1995; Van de Ven 2007).

The objectives of this chapter are twofold. One objective is to review the explanations of success across the various stages of innovation. Another objective is to outline a multi-level perspective of learning and innovation. A multi-level perspective of learning as explained here suggests that increasing scope of learning, from the firm to the alliance to the network-level of analysis, is associated with success across innovation stages. I also argue that existing accounts of biotechnology success that focus solely on strategic alliances as they key to innovation success are incomplete. Strategic alliances are a critical component of success, but strategic alliances are plagued by high failure rates. As well, strategic alliances are proxies for types of learning activities (i.e., exploration and exploitation), but in this study I utilize direct measures of exploration and exploitation product development strategies, which are the topic of the next chapter.

CHAPTER 3:

PRODUCT DEVELOPMENT STRATEGIES

As stated in the previous chapter, research on biotechnology firms conflates types of alliances with the types of organizational learning activities (i.e., exploration and exploitation). Therefore, I draw from another strand of research on organizational learning to examine types of learning activities – exploration, exploitation (and combinations of both). In the proceeding chapter I discuss exploration and exploitation product development strategies as explicated in the organizational learning literature and their effects on innovation success.

Organizational Learning

Organizational learning provides a framework for studying how products and routines are adopted and transformed (Argyris and Schon 1978; Levitt and March 1988). Learning processes encode “inferences from history into routines that guide behavior” (Levitt and March 1988:320). Encoded routines preserve prior organizational experience (Levitt and March 1988; March and Simon 1993 [1958]; Nelson and Winter 1982). As organizations gain experience, learning processes tend to be self-limiting. Learning reduces the diversity of beliefs and behaviors and variation in performance (Levinthal 1991). To the extent that organizations learn, future activities are constrained and potential change from exogenous shocks is mediated (Zhou 1993).

Exploitation and exploration are different types of organizational learning strategies (March 1991). The essence of exploitation, as noted by March (1991:85), "...is the refinement and extension of existing competencies, technologies, and paradigms." Exploitative learning is incremental, based on small improvements to existing products (Levinthal and March 1993), short-term adaptation, and local search (Benner and Tushman 2002). Exploitation caters to the needs of existing customers who are interested in updated products (Jansen, Tempelaar, van den Bosch and Volberda 2009; Lubatkin, Simset, Ling and Veiga 2006).

Empirical support for exploitative product development strategies on firm performance comes from Haveman (1992). According to Haveman, innovation is more beneficial when it exploits established routines, especially in rapidly-changing environments. To assess this contention she examines the savings and loan industry in California during a period of technological, economic, and regulatory change. Her sample is 313 firms from 1977 to 1987 and the dependent variables in her analysis are financial performance (net worth and income) and firm failure. She measures product change as increasing diversification of firms in eight savings and loan markets. The results show that change into related markets (exploitation) increases financial performance. In six of the eight related savings and loan markets under investigation, change is associated with an increase in both measures of financial performance. This study provides empirical support for the benefits of change due to expanding into product markets that build on existing products and services.

The other learning strategy is exploration. Exploration involves deviating from existing technology to pursue new knowledge and generate new alternatives.

“Exploration includes things captured by terms such as search, variation, risk taking, experimentation, play, flexibility, discovery, innovation” (March 1991:71). Exploration activities seek to capture new customers (Jansen et al. 2009; Lubatkin et al. 2006).

Especially in today’s constantly changing global economy, narratives that extol the virtues of exploring new alternatives are popular fodder among scholars, practitioners, and the business press.

The value of adapting to the environment is elaborated in Siggelkow’s (2001) case study of the Liz Claiborne fashion firm, which produces a brand of workplace clothing for professional women. In the 1980s, Liz Claiborne’s policy was to sell only complete collections of clothes to large retailers so the design of clothes was consistent and clothes were easily matched one to another. Liz Claiborne had close ties to retail stores and they were, in turn, able to provide customers with support activities that included “concept shops, retail associates, sales consultants, and LizWeek department store presentations” (2001:847). The close relationship between Liz Claiborne and large retail stores increased customers’ confidence and trust in the products. In the 1990s, however, the environment changed. The work place had become more casual and changes in the department store industry, including major corporate takeovers and bankruptcy, were accompanied by the need for stores to cut costs. Liz Claiborne was forced to explore new alternatives. Not until Liz Claiborne reduced operating expenses, provided more clothing options for customers, and made changes in supply chain

management was the firm able to rebound from declining sales and reestablish itself as a leader in women's apparel.

Both exploration and exploitation have advantages and disadvantages.

Exploitation leads to more stable and quicker outcomes because organizations "...often improve their performance over repetitions of the same task" (Levinthal and March 1993:195). With each item produced, efficiency increases and costs decrease because of improved R&D and time-to-market capabilities. Exploitation also leads to increased performance in the short-term (March 1991, 2003). But, since exploitation reduces diversity in performance, exploitative activities lead to path dependence that can result in the lock-in of suboptimal alternatives (Arthur 1994; Herriott, Levinthal and March 1985; March 1991). Firms must continually adapt or else they may reproduce inefficient outcomes and encounter competency traps (Levitt and March 1988). Similarly, exploitative strategies can become obsolete in the long term as the environment changes. March's (1991) computational model shows that as the environmental changes, characterized by increasing competitors, exploitation leads to decreasing performance in the long run.

Exploration is advantageous because it encourages adaptation to changing environments and successful adaptation increases the likelihood of long-term success. Exploration activities allow employees to develop new skills and competencies (Jansen et al. 2009). There are also liabilities associated with change. Explorative firms expend valuable resources to reorganize and train employees (Haveman 1992). Besides being costly, exploration it is associated with high failure rates (Pfeffer and Sutton 2006), it can

take years for new products to diffuse (Rogers 1995), and new product success often “involves large measures of luck” (Mitchell 1989:209). Speaking of the disadvantages of exploitation March (1991:71) states, “[a]daptive systems that engage in exploration to the exclusion of exploitation are likely to find that they suffer the costs of experimentation without gaining many of the benefits. They exhibit too many undeveloped new ideas and too little distinctive competence.” There are too few returns to existing knowledge (Levinthal and March 1993:105).

The benefits and shortcomings of exploring and exploiting illustrate an inherent tension in the innovation literature as firms seek to find the proper product development strategy (Smith and Tushman 2005). This tension is illustrated by the question of whether firms should explore new alternatives or exploit existing knowledge and capabilities to increase innovation success. The short answer is that firms should do both. That is, firms need to find a balance between exploration and exploitation activities to sustain success over the long-term (Levinthal and March 1993; March 1991; March 2003). Though theorists have yet to hypothesize about a specific combination of exploration and exploitation that produces the maximum benefit, they examine sequential versus simultaneous exploration and exploitation.

Sequential Exploration and Exploitation

Since March’s (1991) seminal article, management scholars have made efforts to reconcile the tension between exploration and exploitation. One approach is through “sequential” versus “simultaneous” exploration and exploitation (Venkatraman, Lee and

Iyer 2007), or what others have termed a dynamic-oscillation model (Sachs, Dieleman, Fendt, Kaminsha-Labbé, Thomas and McKelvey 2006; Thomas, Kaminska-Labbé and McKelvey 2005) or “ambidexterity” versus “punctuated equilibrium” (Gupta, Smith and Shalley 2006). This approach is employed by firms that alternate between exploration and exploitation activities. The “oscillation model” is illustrated in a case study by Sachs et al. (2006). The firm under investigation is an international cosmetic firm that followed a period of exploration and then exploitation. Initially, the firm diversified through international acquisitions. Diversification led to competition among local plants. During this stage local plants were the primary drivers of innovation. As a result of the diversification and local-level innovation, this stage of operation was typified by exploration. However, competition between plants and overproduction increased, reducing profit. To ameliorate these problems, the firm employed a multidivisional structure and other global programs to consolidate decision-making and other routines and implemented tighter controls, resulting in a period of exploitation. In the final stage, control was loosened by headquarters and the firm continued to oscillate between control and autonomy.

Romanelli and Tushman (1994) also study the propensity of firms to alternate between exploitation (incremental change) and exploration (radical change) in their analysis of 25 U.S. minicomputer firms founded between 1967 and 1969. They begin by presenting a theory of punctuated equilibrium, which refers to organization change that is relatively stable but interrupted by brief spurts of radical change. Whereas prior studies of punctuated equilibrium were based on case studies (Bartunek 1984; Tushman,

Newman, and Romanelli 1986), Romanelli and Tushman provide quantitative analysis of the punctuated equilibrium model. They examine secondary data from media and company reports to determine changes in strategy, structure, and power distribution (i.e., change in the top management team, department budgets, or department sizes) for the firms in their sample. They operationalize radical change as change occurring in all three domains (i.e., strategy, structure, and power) within a two-year time period. Incremental change is operationalized as change in all three domains in any amount of time longer than two years. Because the authors are also interested in whether radical change is a function of the accumulation of smaller changes, incremental change is also measured as occurring “whenever changes in each of the three activity domains accumulated to 30 percent through addition of multiple small annual changes and when all three domains exhibited this level of change” (1994:1154). Their results show that the nature of change in firms is typified by punctuated equilibrium: firms vacillate between incremental and radical change. Specifically, radical change occurs more frequently than incremental change, by a ratio of six to one. When comparing change across years, radical change occurred independently of small accumulated changes.

Brown and Eisenhardt (1997, 1998) critique Romanelli and Tushman’s punctuated equilibrium model in particular, and, by implication, the strategy of oscillating between exploration and exploitation. Instead of the punctuated equilibrium model, Brown and Eisenhardt argue that successful firms constantly cultivate change and they conceptualize the degree of organization change on a continuous scale. Brown and Eisenhardt find that successful firms in their sample were located at the “edge of chaos” –

a state of constant change somewhere between incremental and radical change. On one hand, completely fluid organizational structures, or what Brown and Eisenhardt refer to as “organic” structures with few rules and flexible job descriptions, are ill-advised. Fluid structures are too chaotic. They make it impossible to coordinate activities. On the other hand, obedience to strict hierarchy and established routines prevents adaptation, encourages competency traps (Levitt and March 1988), and increases goal displacement (Scott 2003). The lesson, according to Brown and Eisenhardt (1997), is to find a middle ground or a balance between anarchy and rigidity by instituting clear organizational goals but leaving employees with flexibility to achieve those goals.

Brown and Eisenhardt (1997) come to this conclusion about finding a middle ground by using a grounded theory approach to examine six computer high tech firms, three of which have successful product development portfolios while the other three are unsuccessful according to self reports. Data on the six companies were collected through on-site surveys, interviews and observations as well as secondary sources. Findings illustrate that the successful firms in the sample are both adaptive, to use the terminology of Brown and Eisenhardt (or exploratory to use March’s [1991] term), and also have clear goals and responsibilities for employees (or exploitation, according to March [1991]). Accordingly, achieving balance between exploration and exploitation occurs in three ways. First, successful firms have “well-defined managerial responsibilities and clear project priorities” coupled with high levels of communication (1997:7). When responsibilities are clear, the successful firms also permit a high degree of flexibility in how employees could carry out their responsibilities. A high degree of communication is

apparent within and across projects including formal meetings and informal lunches. A great deal of cross-fertilization of knowledge takes place as sharing ideas fosters the application of others' ideas and technology in new ways. Unsuccessful firms are either too structured and inflexible or unstructured and chaotic. Second, the successful firms studied by Brown and Eisenhardt possess frequent, low-cost experimentation, which helps them anticipate and explore future changes. Anticipating future changes occurs when firms allow employees to probe new products and markets. Third, the successful firms have the ability to link past and future projects through "choreographed transition procedures" (1997:21). Transition procedures include periodically switching employees between new product development and existing product development and combining old and new project team members on the same project.

Recent research by Venkatraman et al. (2007) extends previous research on firms that use a combination of exploration and exploitation strategies by using fine-grained measures of alternating between exploration and exploitation, a larger sample, and direct measures of firm success to examine the effects of punctuated equilibrium, or "sequential ambidexterity" in the vernacular of Venkatraman et al. Sequential ambidexterity refers to a "...time-paced sequence of exploration and exploitation" (2007:8). Venkatraman et al. suppose that the fundamental tension between with exploration and exploitation makes it difficult for firms to pursue both simultaneously, but it is easier for firms to pursue sequentially. Thus, they hypothesize a positive effect of sequential ambidexterity on firm growth.

Venkatraman et al. (2007) evaluate their hypothesis with data on 1005 international software firms from 1990 to 2002. Following Li and Greenwood (2004), they measure exploitation as the similarity between all of a firm's products from one year to the next. Exploration is measured as new products in a given year (for a more complete explanation of how exploration and exploitation were calculated, see pages 17-18). Firm growth is the dependent variable (total revenues in year $t + 1$ divided by total revenues in year t). Sequential ambidexterity is measured as an interaction between exploitation in year t and exploration in year $t - 1$. Simultaneous ambidexterity is the explore-exploit interaction. In regression models, Venkatraman et al. compare the effects of sequential and simultaneous ambidexterity. Their findings show that sequential ambidexterity is a positive significant predictor of firm growth while simultaneous ambidexterity has no significant effect.

For the past two decades prominent scholars have sought to understand how firms combine exploration and exploitation activities. Venkatraman et al. (2007), among others, propose a model of sequential ambidexterity or oscillation. They find that firms that alternative between exploitation and exploration increase success. Alternately, Brown and Eisenhardt (1997) critique the punctuated equilibrium model, showing that successful firms operate in the appropriate space on the explore-exploit continuum, reminiscent of March's (1991; 2003) assertion that firms must find an 'optimal balance' between the two extremes (cf. Levinthal and March 1993, 2003).

Balancing Exploration and Exploitation: Ambidexterity

March (1991) was not the first to recognize the trade-offs between exploration and exploitation activities. Earlier, Thompson (1967) observed that a “central paradox in administration” was the ability to maintain both efficiency (exploitation) and flexibility (exploration). Building on these insights, a burgeoning strand of research examines firms’ simultaneously pursuit of exploration and exploitation strategies. Firms that utilize both strategies are described as ambidextrous organizations (Duncan 1976; Tushman and O’Reilly 1996). In a review of the ambidexterity literature, Raisch and Birkinshaw (2008:376) articulate organizational ambidexterity as “reconciling exploitation and exploration..., synchronizing incremental and discontinuous innovation, and balancing search and stability....”

The term ambidextrous organization was coined by Duncan (1976). Duncan maintains that different structural arrangements are associated with innovation and lead to “the design dilemma.” The design dilemma is that, due to different structures associated with initiating and implementing innovation, the structures that facilitate initiation can obstruct the implementation of change. Duncan’s claim is that as products move through these stages of innovation (i.e., initiation and implementation) the organization structure also must shift its structure to keep up and to be successful. Ambidextrous organizations, then, refer to organizations with dual structures that facilitate both initiation and implementation of innovation.

Until 2000, the concept of ambidexterity was sporadically mentioned in the literature, in only a few case studies and business review articles (Achrol 1991; Adler,

Goldoftas and Levine 1999; Tushman and O'Reilly 1996). Tushman and O'Reilly (1996) do not disaggregate between different stages of innovation, the initiation and implementation of change, as did Duncan (1976). Instead, they overlook the challenges of initiating change and they begin with the premise that all organizations face problems implementing change. To remain successful, firms must be ambidextrous.

Ambidexterity includes the ability to "...implement both incremental and radical change" (1996:8). Unlike Duncan (1976), for Tushman and O'Reilly ambidexterity has to do with the extent to which firms innovate (i.e., incremental or radical), not the stages of innovation. Tushman and O'Reilly provide numerous examples of unsuccessful firms that were unable to implement radical change as well as ambidextrous firms that overcame challenges to sustain long-term success. One example of a successful firm was Apple. Apple began as a single-product firm, selling desktop computers exclusively to homes. To compete in a changing marketplace and to appeal to a broader range of customers, Apple shifted strategies to become a multi-product and multi-market firm by expanding its customers, primarily to educational institutions.

The number of articles on ambidexterity has proliferated in recent years. In the mid 2000s, a modest number of review articles (Benner and Tushman 2003; Birkinshaw and Gibson 2004; Gupta, Smith, and Shalley 2006; Tushman and O'Reilly 2004; Tushman and Smith 2002) and quantitative studies (Gibson and Birkinshaw 2004; He and Wong 2004) also appeared. From these modest beginnings, a promising research program has emerged. The number of studies of ambidexterity in leading management journals rose from less than 10 in 2004 to more than 80 in 2008 (Raisch et al. 2009).

The first quantitative studies examining organization ambidexterity are published by Gibson and Birkinshaw (2004) and He and Wong (2004). Both provide empirical support for the ambidexterity thesis. Since then, however, there are mixed findings concerning the relationship ambidexterity and innovation success (Raisch and Birkinshaw 2008). For example, Venkatraman et al. [2007] find no significant results for the simultaneous pursuit of exploration and exploitation. The reason the effects of ambidexterity are not straightforward is likely due to a number of factors, one of which is the tension that exists between exploration and exploitation activities (Gupta et al. 2006; Raisch and Birkinshaw 2008). Jansen et al. (2009) comment on the difficulty of balancing both exploration and exploitation. They state, “Exploration and exploitation require fundamentally different and inconsistent architectures and competencies that create paradoxical challenges” (p. 797).

Gupta et al. (2006) identify several reasons for this difficult balancing act. First, resources to pursue both exploration and exploitation activities are limited. Exploration is costly (Haveman 1992) and plagued by high failure rates (Pfeffer and Sutton 2006). Second, organizations tend toward inertia (Hannan and Freeman 1984) so prior efforts toward either exploring or exploiting are reinforced over time and pursued at the expense of one another. Exploration often leads to subsequent exploration, causing firms to “...take escalating risks, attempting to negate past innovation failures while ignoring core competencies” (Andriopoulos and Lewis 2009:697). Gupta et al. (2006:695) refer to this self-reinforcing process as a “failure trap.” In contrast, efforts to exploit often lead to short-term profit, inertia, and lock-in of a particular alternative, resulting in a “success

trap.” Third, the “mindsets and organizational routines” needed for both activities are orthogonal (Gupta et al. 2006:695). Stated differently, exploration and exploitation are two fundamentally different logics. The logic associated with exploration is adaptability to changes in the environment. Exploration values bottom-up information processing and decision-making. Lower-level employees closest to organization operations, those on the front lines, are “...closest to the changing trends in customer demand” (Lubatkin et al. 2006:649). They get immediate feedback from customers and are in the best position to inform their firm when successful change occurs. The exploitation logic is incremental variation in order to benefit from best practice. Exploitation is legitimated by top-down learning processes. Exploitation represents efforts by top management that engenders conformity to existing routines. It is often constituted by top-down processes because members of the top management teams are more aware of the firm’s core technologies, existing capabilities and how to utilize them (Lubatkin 2006), and of course top management wields the power and legitimacy to insist on conformity compared to other employees.

In sum, various factors exacerbate tensions between exploratory and exploitative activities. As a result, there is no consensus about the best way to balance exploration and exploitation (Tushman, Smith, Wood, Westerman, and O’Reilly 2007) and there are different paths for achieving ambidexterity (Raisch et al. 2009). Since the effects of ambidexterity are not consistent across studies (Raisch and Birkinshaw 2008), the verdict is still out regarding how to measure and evaluate organizational ambidexterity.

The Multi-Dimensionality of Ambidexterity

Although most analysts agree that ambidexterity consists of some combination of exploration and exploitation, the construct lacks conceptual clarity, making it difficult to compare findings across studies (Cao, Gedajlovic, and Zhang 2009). There is disagreement about how ambidexterity should be pursued by organizations and operationalized by researchers. As an attempt to organize the literature, I develop a typology that includes two dimensions of ambidexterity: structure and content. The structure of ambidexterity can variously occur as differentiating between exploration and exploitation activities or integrating those two activities (Cao et al. 2009; Gupta et al. 2006; Jansen et al. 2009; Raisch et al. 2009). Content consists of technological or product characteristics or organizational characteristics.

These two dimensions of ambidexterity are presented in Figure 4. The horizontal dimension represents the structure of ambidexterity as either a differentiation or integration strategy. Differentiated organization designs include simultaneously pursuing exploration and exploitation activities, but within disparate organizational units (Tushman et al. 2007). Integrated organization designs include, for example, senior team incentives, senior team integration, and cross-functional teams (Jansen et al. 2009). The vertical dimension signifies the content of ambidexterity: organization or product characteristics. Differentiated product development strategies view exploration and exploitation orthogonally, but the pursuit of new product development and improving existing products occurs simultaneously (He and Wong 2004), likely within disparate organizational units. Very little research exists, however, that discusses technology or

product development in terms of integrating exploration and exploitation activities (for an exception see Hargadon 2003).

Figure 3-1. Multiple Dimensions of Ambidexterity and Illustrative Examples

		Structure	
		Integration	Differentiation
Content	Organizational Practice	Team integration (Jansen et al. 2009)	Pursue exploration & exploitation products in different units (Tushman et al. 2006)
	Product / Technology	Reebok Pump (Hargadon 2003)	Pursue new & existing products separately (He and Wong 2004)

Structure

Of course, some studies span the categories I impose. Andriopolous and Lewis (2009) conduct a comparative case study of five product design firms and present limited evidence to suggest that firms in their sample utilize both integration and differentiation strategies (see also Cao et al. 2009). Taylor and Helfat (2009) examine the organizational conditions under which new products are successfully adopted in IBM and NCR Corporation. They argue that without links that exploit existing knowledge between organizational units, new products are more likely to fail.

Jansen et al. (2009) (see also Birkinshaw and Gibson 2004) indicate that scholars typically describe ambidexterity in structural terms. Structural differentiation is "...the subdivision of organizational tasks into different units" (Jansen et al. 2009:798; see also Hall 1977; Lawrence and Lorsch 1967). By extension, ambidexterity usually describes

exploration and exploitation as separate structural activities, pursued in distinct organizational units. When viewed as necessitating dual structures (Duncan 1976), pursuing exploration and exploitation becomes a trade-off due to limited time and resources. A brief hypothetical illustration: inventing new products is pursued in one R&D lab while improving and managing an existing product are pursued in a separate lab or organizational unit.

Tushman et al. (2007) provide an example of ambidexterity as a differentiation strategy. They compare various organization designs – ambidexterity, functional, cross-functional, and spin-outs – and their associated innovation outcomes. Their sample consists of case studies of 13 business units, 22 innovations (innovation streams), and 34 “innovation episodes.” Multiple innovation episodes occur when there is a transition from one type of organization design to another for an innovation streams. Fifteen out of the 34 innovation episodes employed ambidextrous designs, and ambidexterity was significantly more likely to result in innovation success. Tushman et al. also discuss several businesses in their sample that employed ambidextrous designs. One such business is USA Today. The first attempt by USA Today occurred in 1995 consisted of a spin-out, where the company created a separate division to pursue online news coverage. The manager of the spin-out was promoted from within, but made every attempt to separate the unit from USA Today newspaper operations in order to promote a different structure and culture dedicated to providing instant news coverage. Most of the staff were hired from outside of the organization, 80% of online coverage did not come from print newspaper sources, and they were housed on a different floor of the building.

While the online unit was profitable, success was tenuous due to funding constraints, employee turnover, and a lack of support from top management. In 2000, a new manager was hired to oversee and improve the online unit. The new manager kept the online unit distinct, but borrowed knowledge from the newspaper-side of the business. The new manager "...initiated editorial meetings within [the CEO's] senior team and weekly lower level cross-platform editorial meetings. Further, [the CEO] shifted the senior team incentives so that they all had common bonus incentives based on both web-based and print growth" (2007:15). Since the change in unit manager, performance has improved. By keeping operations distinct for the new unit and product (exploration), combined with leveraging inter-unit communication and common-fate incentives (exploitation), USA Today successfully combined exploratory and exploitative activities in distinct units.

In contrast to approaches that view ambidexterity as structurally distinct activities, firms can integrate exploration and exploitation activities within a single organizational unit or product development strategy (Cao et al. 2009; Gupta et al. 2006; Raisch et al. 2009; Smith and Tushman 2005). Dynamic capability is a concept in the management literature that describes routines that integrate exploration and exploitation activities. Dynamic capabilities are routines (exploitation) that reconfigure resources in response to changing environmental conditions (exploration) (Dyer and Singh 1998; Eisenhardt and Martin 2000; Teece, Pisano and Shuen 1997). Dynamic capabilities are defined as "[t]he firm's processes that use resources – specifically the processes to integrate, reconfigure, gain and release resources – to match and even create market change. Dynamic capabilities thus are the organizational and strategic routines by which firms achieve new

resource configurations as markets emerge, collide, split, evolve, and die” (Eisenhardt and Martin 2000:1107). Examples of dynamic capabilities identified by Eisenhardt and Martin include product development routines that combine employee expertise from varied backgrounds, knowledge-transfer routines that broker knowledge across functional firm boundaries, and acquisition routines that bring new knowledge and resources into the firm. Dynamic capabilities provide flexibility, encourage rapid learning, and avoid the pitfalls of relying on past experience. In rapidly-changing environments especially, managers must rely on creating new routines and responding to environmental contingencies.

Jansen et al. (2009) maintain that ambidexterity as an integration strategy is a firm-level dynamic capability. Jansen et al. (2009) hypothesize that four dynamic capabilities, which facilitate the integration of exploration and exploitation activities, are associated with ambidexterity. These four dynamic capabilities are contingency rewards for senior teams where the senior team is rewarded for achieving favorable outcomes; senior team social interaction, communication, and collaboration; cross-functional practices such as liaison personnel, task forces, and teams; and the overall social integration of a firm. Jansen et al. argue that these four dynamic capabilities integrate structurally differentiated exploration and exploitation activities and increase the incidence of ambidexterity. The dependent variable in the analysis, ambidexterity, is an index that is comprised of eight questions that assess the extent to which organizations either explore, depart from existing knowledge, or exploit, build on existing knowledge (2009:803). The independent variables are integration mechanisms operationalized as

senior management team incentives such as profit sharing, senior management team social integration, cross-functional teams and projects, and connectedness of employees within the organization. Data come from a survey administered to 230 directors of private U.S. firms with at least 25 employees in 2005 and 2006. Results from regression models show that senior team incentives and integration and cross-functional teams have a positive, significant effect on ambidexterity while employee connectedness is not significant. Thus, Jansen et al. provide an important contribution to the literature by identifying routines that promote the integration of exploration and exploitation in organization design.

Birkinshaw and Gibson (2004) also view ambidexterity as exploration (alignment) and exploitation (adaptability) integrated within the same business unit. They argue that ambidexterity is most effective, not through structural separation, but when employees are encouraged to pursue alignment and adaptability simultaneously, within the same unit. Gibson and Birkinshaw's primary hypothesis is that business unit performance increases at higher levels of ambidexterity. They operationalize ambidexterity as the interaction between alignment and adaptability. Alignment and adaptability variables come from a series of survey questions that ask whether the management systems in the organization are coherent, lead to productivity, and provide conflicting objectives (i.e., alignment) and whether the management system promotes outdated practices, responding to changing markets, and rapid responses to changing priorities (i.e., adaptability). In their analysis of 4,195 senior and mid-level managers across 41 business units and 10 firms, Gibson and Birkinshaw find support for their

hypothesis that respondents who are encouraged to pursue high levels both alignment and adaptability activities also experience increased business unit performance.

Content

I contrast the differences between studies on ambidexterity by making the distinction between the structure and content of ambidexterity. My use of the term content includes organizational routines or practices that integrate or differentiate between exploration and exploitation organization designs as discussed the preceding section. As well, content includes characteristics of products or technology that can be categorized in terms of integrating and differentiating between exploration and exploitation.

He and Wong (2004) present the view that ambidexterity consists of a product development strategy that differentiates between exploration and exploitation. Their study examines combinations of exploration and exploitation product development strategies and their effects on firm sales. He and Wong operationalize exploration as entering new product domains and exploitation as those activities designed to improve existing products. Their measures of exploration and exploitation include survey items that ask about “new generation of products versus improve existing product quality” and opening “up new markets versus reduce production cost” (p. 485). They hypothesize that the explore-exploit interaction, firms with high rates of participate in both activities, yields positive effects on sales growth. As well, they employ a second measure of ambidexterity, the difference in absolute value between exploration and exploitation

activities. He and Wong posit that a high discrepancy between explore and exploit is likely associated with decreasing sales growth. Results based on their sample of 206 firms manufacturing firms from Singapore and Malaysia support both hypotheses: positive effects for the ambidexterity interaction and negative effects of ambidexterity imbalance on sales growth.

Ambidexterity increases the chances of success over time because it incorporates elements of organizational assets and capabilities that promote success in the short-term and new elements that anticipate future changes in the environmental. As such, and due to the dearth of research about the effects of ambidexterity at various innovation stages, I hypothesize that the direction of the effects of ambidexterity interaction and imbalance are the same across the stages of innovation as those found by He and Wong (2004).

Hypothesis 4a: The ambidexterity interaction (the interaction between exploration and exploitation) is likely to be positively associated with success at each stage of innovation.

Hypothesis 4b: The imbalance between exploration and exploitation is likely to be negatively associated with success at each stage of innovation.

Current conceptions of ambidexterity often overlook a similar but nevertheless distinct strategy that integrates elements of exploration and exploitation. The product development process can integrate existing knowledge (exploitation) in novel ways, in new circumstances, or for new applications (exploration). Applying existing product knowledge in new ways takes a variety of forms. One example is Design Continuum, a Boston-based award-winning product design firm. They design a variety of products for their diverse clientele, everything from squirt guns to surgical devices. In 1988, Reebok hired Design Continuum to respond to Nike AIR technology in athletic shoes. Within six

months and for less than \$250,000, Design Continuum used existing product expertise to create a new product, the Reebok Pump basketball shoe, which resulted in \$1 billion in revenue. The remarkable part of this story is that the Reebok Pump was designed in several weeks by two engineers, one of whom had experience designing inflatable splints and the other designing IV bags. Out of their collaborative efforts came the Reebok Pump, a shoe that combined a splint and an IV bag to make a “splint in a shoe.” The engineers’ experience with existing technology greatly accelerated the product design process and successful innovation. “Imagine what would have happened if Reebok’s engineers, or Design Continuum’s for that matter, had tried to invent the Pump from scratch.... Design Continuum was able to recombine objects, ideas, and people of the world it knew in ways that shook Reebok and its world of athletic shoes” (Hargadon 2003:22). The invention and development of the Reebok pump illustrates how to integrate existing products (exploitation), an IV bag and inflatable splint, in novel ways (exploitation).

My study adds to the existing literature of ambidexterity by identifying an additional way to conceptualize ambidexterity product development strategies. Integrating exploration and exploitation represents a particular type of ambidexterity: recombination. Recombination consists of utilizing existing products and new applications. Recombination differs from other current conceptions of ambidexterity in that it does not view ambidexterity as distinctive nor as an increase or decrease in the volume of exploration and exploitation activities. Rather, recombination utilizes existing product in new ways. Jensen et al. (2009:799-800) make the conceptual link between

ambidexterity routines and the recombination existing resources and assets; though they do not examine operationalize recombination in their study cited above.

We propose that organizational ambidexterity refers to the routines and processes by which organizations mobilize, coordinate, and integrate dispersed exploratory and exploitative efforts, and allocate, reallocate, combine, and *recombine* resources and assets across differentiated units. Organizational ambidexterity is a dynamic capability that creates valuable new configurations of exploratory and exploitative innovation by generating and connecting previously unconnected ideas and knowledge or *recombining* previously connected knowledge in new ways (italics added).

Teece (2007) also highlights recombination as a critical element of sustained innovation growth. He states, “A key to sustained profitable growth is the ability to recombine and to reconfigure assets and organizational structures as the enterprise grows” (p. 17).

Recombination is as an integrative product development strategy is prevalent in the biotechnology industry. Biotechnology companies often develop a drug to treat one medical condition and subsequently test its effectiveness on other medical conditions through new clinical trials. For instance, in 2001, Acadia Pharmaceuticals conducted clinical trials to test whether a drug (inverse agonist of 5-HT_{2A} receptor) effectively treated schizophrenia. In 2003, Acadia tested the same drug in a new set of clinical trials to treat a different medical condition, Parkinson's disease. Recombination occurs when a firm examines the effects of a drug in clinical trials, with which it already has experience, to treat a new medical condition with which it has no previous experience.

Instead of using existing products in new ways, the inverse also occurs. Firms can develop new products to address existing medical conditions with which the firm already has experience. In the 1980s, Ciba Vision, which develops eye-care products such as glasses and contact lens, was losing ground to industry leader Johnson &

Johnson. Sales were further threatened when Johnson & Johnson introduced disposable contacts. To combat declining sales Ciba Vision President, Glenn Bradley, decided to shift the firm's focus and R&D projects to radically new innovations in eye-care products such as disposable and extended-wear contacts. Since then, Ciba Vision enjoyed remarkable financial success and has become an innovative leader in eye care and treatment (O'Reilly and Tushman 2004). Under Bradley's leadership Ciba Vision developed new products that took advantage of their existing expertise with a particular medical condition, eye-sight problems. Recombining knowledge of existing medical conditions with new products occurs in drug development as well. A biotechnology firm may use new, different drugs to treat a medical condition with which it already has experience treating and conducting clinical trials.

Recombination in biotechnology not only draws from knowledge of existing drugs and the treatment of medical conditions, but also leverages complementary assets and capabilities required for implementation and success. For example, in the computer industry many complementary assets exist with which new products must be compatible. To operate, a CPU requires a monitor, a mouse, an operating system, and software; and each product needs the others to function properly. A more contemporary example is Apple's iPod. An iPod (and all variant versions) requires a computer, the appropriate software (iTunes), and Internet access in order to download and play songs, movies, pod casts, and games.

Organizational routines can also be complementary and enhance product success. "In almost all cases, the successful commercialization of an innovation requires that the

know-how in question be utilized in conjunction with other capabilities or assets. Services such as marketing, competitive manufacturing, and after-sales support are almost always needed” (Teece 1986:288). Of course, the complementary services listed by Teece are germane to the biotechnology industry. The success of new drugs depends of existing capabilities regarding manufacturing, marketing, and sales capabilities. Familiarity with these activities, for similar types of drugs or different drugs that treat similar medical conditions, is likely increase the proclivity of commercialization and success. Recombination product development strategies leverage expertise about drugs or disease that is familiar to the firm as well as any advantages derived from complementary services and routines. Consequently, I hypothesize that recombination product development strategies are likely to increase innovation success. Specifically,

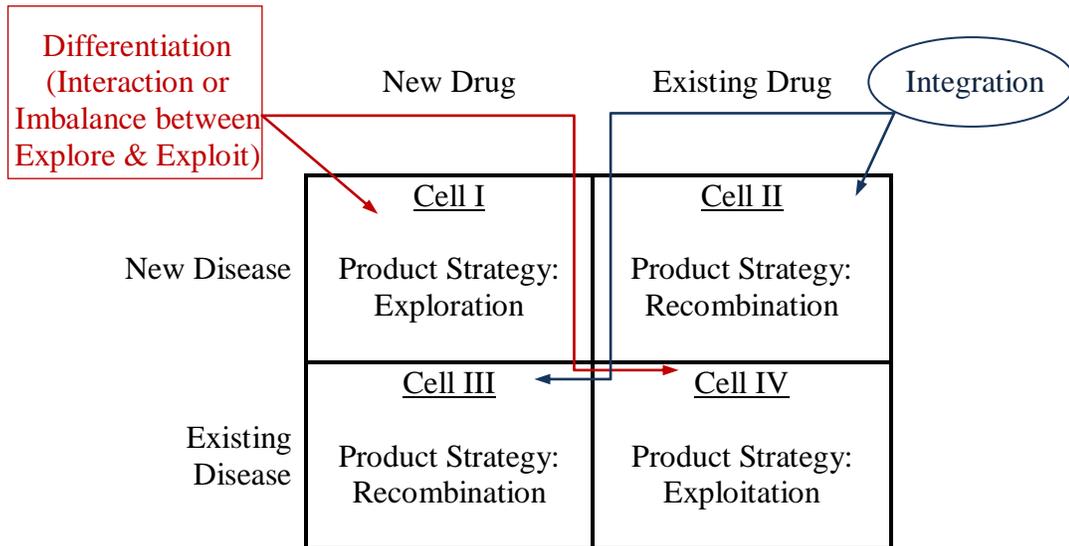
Hypothesis 4c: Recombination, building on expertise regarding drugs or diseases that are familiar to the firm, is likely to be positively associated with success at each stage of innovation.

Recombination integrates elements of exploration and exploitation in product development. The relationship between integrating and differentiating exploration and exploitation – and the associated product development strategies – are illustrated in Figure 5. The columns in Figure 5 represent the type of medical condition or disease treated in clinical trials (new or existing). The type of condition can be a new condition with which the firm has no previous experience or an existing condition with which the company has previous experience. The rows represent the types of drugs used to conduct clinical trials (new or existing). The type of drug can be a new drug with which the firm

has no previous experience or an existing drug with which the firm has previous experience.

The cells in Figure 5 represent product development strategies that result from combinations of drugs and diseases that are familiar or new to the firm. If a firm conducts clinical trials with a product that is the combination of a new drug and a new disease, the product development strategy is exploration (Cell I). If a new drug is combined with an existing disease, the product development strategy is recombination (Cell II). An existing drug combined with a new disease is recombination (Cell III). An existing drug combined with an existing disease is exploitation (Cell IV). Note that differentiation is represented by the interaction and imbalance between exploration and exploitation strategies. Integration strategies are represented by products that fall into either Cells II or III.

Figure 3-2. Product Development Strategies in the Biotechnology Industry



Current operationalizations of ambidextrous product development strategies (see He and Wong 2004) are limited to Cells I and IV: differentiation represented by the interaction of, or imbalance between, exploration and exploitation. Existing operationalizations overlook the type of disease or medical condition the drug is designed to treat, thus overlooking an alternative type of ambidexterity that is likely an important influence on product success. The typology presented in Figure 5 is a more fine-grained conception of ambidexterity than found in previous research. My research moves past extant notions of differentiation ambidexterity and suggests an additional way to integrate exploration and exploitation by recombining new alternatives with existing firm expertise. In the next chapter I provide details about the sample and measures used to test the ambidexterity, including recombination, hypotheses presented above.

CHAPTER 4:

METHODS

The biotechnology industry is an appealing context in which to study innovation. Innovation is a central focus in the biotechnology industry and a core component of firm strategy. First, biotechnology companies emphasize the need for new technology and spend billions of dollars on R&D every year. In 2006, U.S. biotechnology firms spent \$22.9 billion on R&D and \$25.3 billion in 2008 (Ernst & Young 2007, 2009). Ernst & Young (2007, 2009) report there were 1,754 U.S. biotechnology companies in 2008 (371 public companies and 1,383 private companies), with a mean of \$14.4 million spent on R&D. Second, there is also a practical reason for studying the biotechnology industry. Due to FDA regulations regarding the safety and efficacy of clinical trials, detailed data are available on the stages of product development for biotechnology firms.

In this study a “biotechnology firm” is a broad term that refers to either a pharmaceutical or biotechnology firm that conducts clinical trials involving *in vivo* therapeutics (i.e., drugs for internal human consumption). Pharmaceutical companies such as Pfizer and Schering-Plough conduct discovery research and carry out clinical trials and they employ biotechnology in their drug discovery and development efforts as do traditional biotechnology firms such as Amgen or Genentech. The analysis is limited to firms with *in vivo* therapeutics rather than biotechnology products used for other applications such as agricultural applications, medical devices, or drugs with external applications. Firms that develop products for other applications face different

manufacturing processes, regulatory requirements, and environmental obstacles since they compete for market share in different markets.

Sample

The sample consists of 111 U.S. publicly-traded biotechnology firms from 1990 to 2006. The sample is limited to domestic and public firms since product, financial, and alliance data are difficult to acquire for private and international firms. The sample is unbalanced, meaning that the years that firms are included in the sample vary, based on the years in which firms were founded or disbanded, to maximize the number of firms and cases included in the analysis. The unit of analysis is the firm-year and all variables are time-varying by firm-year.

The period under investigation, 1990 through 2006, is selected because it can take a drug up to 15 years to develop from drug discovery to market. The number of years under investigation represent more than one average product life cycle. The first year of the study is 1990 because data on clinical trials prior to this date are sparse in Recombinant Capital (Recap), my data source for products in clinical trials. The final year of the study is 2006, due to data availability for patent self-citation data (NBER Patent Data Project).

The sample was selected by searching for U.S. firms with clinical trials that are included in a database compiled by Recombinant Capital (recap.com). Recap is a San Francisco-based consulting company that collects data on drugs in clinical trials and strategic alliances for private and public U.S. and international biotechnology companies.

Recap data come from a variety of sources including 10K and other forms submitted to the SEC, annual reports, industry publications, and other media sources (such as newspapers). I gained access to Recap's basic dataset in 2008 by contacting their account representative. Recap granted access to me after receiving email confirmation from my dissertation advisor (Dr. Knoke) regarding my status as a graduate student status and my dissertation topic.

The Recap database includes detailed information about drugs that are evaluated in clinical trials, the medical conditions that the drugs are intended to treat, and the dates when drugs reach various phases of clinical trials (phases I, II, III, FDA approval, and products on the market). Recap also includes the dates when strategic alliances began, the terms of the agreement (i.e., for research, development, manufacturing, etc.), and the partners with whom firms formed strategic alliances. Recap data are organized by firm on their website and exist in the form of reports (i.e., individual web pages) for each product and alliance. I coded data for products and alliances into Microsoft Access. Once data were coded from the Recap database; firm, product, and alliance data were linked by a firm identification number (gvkey from COMPUSTAT) and then transferred via StatTransfer to STATA 10 for data analysis (StataCorp 2007).

There advantages and disadvantages for using data from Recap. The primary advantages are access to data and detailed information on products and medical conditions, clinical trials, and strategic alliances. The primary disadvantage is that the products and firms in the Recap database are a non-random sample of the population of U.S. publicly-traded biotechnology firms and their products. Since Recap collects data

from public sources there is a bias toward large, firms for which public data are more readily available. Although Recap constantly updates its database, it is unlikely to include data on all drugs that have entered into clinical trials, especially older drugs that may have failed in clinical trials.

To assess whether firms from the Recap sample are representative of U.S. publically-traded biotechnology companies, I extracted employee and sales data from COMPUSTAT for the years from 1990 to 2006, with North American Industry Classification System (NAICS) codes 325412 (“Pharmaceutical Preparation Manufacturing”) and 325414 (“Biological Product [except Diagnostic] Manufacturing”).³ The mean number of employees for firms in the COMPUSTAT sample is 3,257, with a range of 10 to 122,000. The number of employees for firms in the Recap sample range from 30 to 122,000, with a mean of 4,034. Recap firms averaged \$1219 million dollars in sales while COMPUSTAT firms averaged \$799 million. Recap firms are clearly larger than the firms listed in COMPUSTAT, but this is expected since the Recap sample is limited to firms with clinical trials. Carrying out clinical trials is expensive and firms with clinical trials are more likely to be larger than firms that limit their activities to drug discovery, for instance.

I also compare product and firm data from the Recap sample with Bioscan (2006); a biotechnology industry directory that includes information from domestic and

³ Since biotechnology firms can refer to firms that produce a variety of products including agricultural applications, medical devices, and drugs taken externally and internally, I limit the sample extracted from COMPUSTAT to firms with NAICS categories of 325412 (“Pharmaceutical Preparation Manufacturing”) and 325414 (“Biological Product [except Diagnostic] Manufacturing”). Comparing COMPUSTAT data for companies with these categories is reasonable since member-firms of Pharmaceutical Research and Manufacturers of America (PhRMA), the foremost association for pharmaceutical and biotechnology firms in the U.S., primarily have these two NAICS codes (Golec and Vernon 2008:1006).

international biotechnology firms on strategic alliances, products in development, and other company and financial information. Table 3 compares data on the number of products at in clinical trials from *BioScan* in 2006 with data from Recap for the same year.⁴ As indicated in Table 3, there is a discrepancy between Recap and Bioscan in the number of U.S. public firms with clinical trials and products in clinical trials. There are 291 U.S. public firms in *BioScan* compared with 109 firms in Recap. The substantially larger number of firms in *Bioscan* suggests that firms in *Bioscan* are more likely to be representative of the population. Additionally, the average number of clinical trials per firm is higher for Recap than *Bioscan*. The number of clinical trials per firm is 6.41 for Recap and 5.93 for *BioScan*. Since clinical trials are so costly, the discrepancy suggests that firms in the Recap sample are, on average, larger than firms in *Bioscan* and also the population.

Category	<i>BioScan</i> (2006)	Recap (2006)
Public firms w/clinical trials (US)	291	109
Products in clinical trials	1726	699
Trials per firm	5.93	6.41

Again for comparison sake, I extracted data from COMPUSTAT from the years 1990 to 2006, for all of the public firms with clinical trials listed in the *Bioscan* sample in Table 3. Recap firms are larger on average than Bioscan firms as well. The average

⁴ In early 2007, I was provided access to Bioscan with a free 30-day registration. I was able to download limited data from Bioscan's website (<http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioScan>), which allow me to compare the number of firms and products for the year 2006.

number of employees per firm-year in *Bioscan* is 2,900 (Recap: 4,034). The average amount of sales for *Bioscan* firms is \$811 million (Recap: \$1219 million).

Although *Bioscan* contains a larger sample of biotechnology firms than Recap, *Bioscan* has its disadvantages. First, data on alliance agreements, drugs, and medical conditions treated by the drugs are less detailed in *Bioscan* compared to Recap. Second, *Bioscan* directories are difficult to obtain. *Bioscan* issues are published six times annually, in February, April, June, August, October, and December, since 1987. Each issue consists of two volumes: one volume for firms that begin with A through I and one volume for firms that begin with J through Z. One-year online and print subscriptions to *Bioscan* data cost \$1,599, for the most current year. Unfortunately, online and print subscriptions exclude data for previous years.

A number of libraries have limited or no access to printed *Bioscan* volumes for previous years. The University of Minnesota library system has three *Bioscan* volumes in its collection and two of them are different volumes for the same year. The August, 2002, volume is non-circulating and located in the Magrath Library Reference area; the February, 2002 volume is located at the University of Minnesota-Duluth library; and the December, 2000, volume is also located at the Duluth library. Volumes of *Bioscan* are also difficult to obtain via inter-library loan. I was told by a reference librarian at Brigham Young University (personal communication, August, 2007) that when the BYU inter-library loan office tried to acquire various *Bioscan* volumes, other libraries declined (The Brigham Young University library has no volumes of *Bioscan*.) The reason cited for not loaning *Bioscan* volumes was that they are scarce and difficult to procure from the

publisher. *Bioscan* directories also exist in print form at the Library of Congress, but a visit to the Library of Congress on March 8, 2010, revealed that volumes in their stacks are incomplete as well. A Business Reference librarian at the Library of Congress searched its restricted stacks on my behalf and found complete volumes (i.e., two volumes) for limited issues in only three of the 17 years under investigation in this study. The years for which they have only one volume, which includes data for firms with names that begin with either A through I or J through Z, are 1987 (issue not specified), 1988 (issue not specified), 1991 (issue not specified), and 2001 (issue not specified – volume A-I). The Library of Congress reference librarian found complete volumes for 1999 (August issue), 2004 (June, October, and December issues), 2005 (April and October issues), 2007 (June, August, October, and December issues), 2008 (February, April, June, August, October, and December issues), and 2009 (February, April, June, and December issues).

Besides being available through a subscription to their online database, issues of *Bioscan* allegedly exist on disc with similar information on products and alliances in the print directories. But, I have been unable to locate any of these discs. Therefore, coding product, firm, and alliance data from existing print directories would require additional, large scale research, and would depend on the availability of print directories. By contrast, Recap data exist in electronic form – in the form on online reports or pages with detailed information on products and alliances – and prove much easier to access.

Although product and firm data differ between *Bioscan* and Recap, success rates for drugs passing various phases of clinical trials for Recap compare favorably with other

sources, namely DiMasi, Hansen, and Grabowski (2003) and DiMasi, Feldman, Seckler, and Wilson (2010). DiMasi and colleagues report success rates for drugs progressing through phases I, II, and III for a smaller sample in 2003 and larger sample in 2010. The data for the study from DiMasi et al. (2003) come from 68 randomly selected drugs from 10 multinational pharmaceutical firms. The products used in their analysis began human clinical trials between 1983 and 1994 and their study concluded in 2001. The 10 firms in this sample account for 42 percent of R&D expenditures for the entire pharmaceutical industry from 1994-1997, and 8 of the 10 firms are among the top 20 internationally in sales. Thus, their sample is biased toward large pharmaceutical firms, more so than Recap. Even though the DiMasi et al. sample is small, their results are the widely cited in the industry and by academics (see for example, Pisano 2006:57).

The percentage of product success for the various phases of clinical trials compare favorably for the studies by DiMasi et al. (2003; 2010) and for the firms in the Recap sample as illustrated in Table 4-2. The products included from Recap include new drugs that began phase I clinical trials during the years 1990 to 2001 and their status – which phase of clinical trials they completed – was evaluated in 2006. The years 1990 through 2001 represent the same number of years (i.e., 11 years) used to in DiMasi et al.'s (2010) study, which examined new drugs that entered clinical trials from 1993 to 2004. The status of each new drug in Recap is evaluated 5 years later, in 2006, similar to DiMasi et al. (2010) who evaluated the new drugs in 2009, five years after drugs in their sample entered clinical trials.

Table 4-2. Percent of Drugs that Complete Each Stage of Clinical Trials.

Phase Completed	DiMasi et al. (2003) (N=68)	Recap (N=470)	DiMasi et al. (2010) (N=1,738) ⁵
Phase I	71%	73%	65%
Phase II	31%	30%	26%
Phase III/FDA Approval	21%	13%	16%

The percent of new drugs successfully completing each stage are listed by study across columns in Table 4-2. In the DiMasi et al. (2003) study, 71% of products successfully passed from phase I to phase II clinical trials. For Recap the percent of successful drugs for the same stage of clinical trials is only slightly higher at 73%. Out of the total number of drugs that entered phase I, the percent of new drugs passing phase II is similar for Recap (30%) compared to DiMasi et al. (2003) (31%). The percentage of successful drugs that pass phase III and gain FDA approval is about one-third lower for Recap (13%) compared to DiMasi et al. (2003) (21%). The lower percent of successful drugs for Recap (13%) compared with DiMasi et al. (2010) suggests minimal bias for product data compared to the other samples with large firms.

A new study published in *Nature* by DiMasi et al. (2010) for the 50 largest international pharmaceutical firms (based on sales in 2006) builds on prior estimates of new drug success rates in clinical trials (DiMasi et al. 2003). Their logic for examining products in large firms is that they represent a large proportion of the total number of new drugs that enter clinical trials (DiMasi et al. 2010:276). The sample consists of 1,738 new drugs that entered phase I clinical trials from 1993 to 2004, evaluated in June, 2009.

⁵ Although DiMasi et al. (2010) present success rates for new drugs entering phase I for two different time periods (1993-1998 and 1999-2004) (Figure 1:274), the average of the both intervals is reported in Table 4, since the difference between the two periods is minimal at each phase and the percent of new drugs that begin in phase I and end up gaining FDA approval is the same for both periods – 16%.

Their analysis includes success rates of new drugs for each phase as well as success rates by product type, therapeutic class, and internal or external sourcing. Results show that one out of six new drugs (16%) is successful in the DiMasi et al. (2010) sample. This finding is slightly lower than in their original research for the percent of new drug success for phase III (21%), but it about the same as the Recap sample (13%).

Although the Recap sample is not ideal, since it is biased toward large firms, the sample is larger and more diverse than those used to examine new drug success rates by DiMasi et al. (2003, 2010). Moreover, I propose that studying the effects of exploration and exploitation in large firms is theoretically interesting, since large firms are much more likely to be hindered by structural inertia while small firms are much more likely to be nimble, exploratory, and navigate quickly between exploration and exploitation. It becomes incumbent upon large firms, encumbered by highly complex and differentiated structures, to find successful routines and technologies that improve innovation. Further, because the product development process is resource intensive, it is rare for biotechnology firms to travel the ‘innovation journey’ alone and common to partner with firms with complementary assets. For this reason, it is imperative that all firms, including small firms, understand the product development strategies that are successful in large firms.

I address this potential source of bias by splitting the sample into two groups. One group includes the largest 50% of the firms in the sample and the other group includes the smallest 50% of the firms. The group of large firms includes firms whose mean number of employees (across firm-years) exceeds 1,824 employees – the median

number of employees for all firms in the sample. The group of small firms includes firms whose mean number of employees (across firm-years) is less than or equal to 1,824 employees. The number of large firms in the sample is 56 and the number of small firms is 55. I report summary statistics and results from regression models for large and small firms, as well as for the entire sample.

I should point out that the distinction between large and small firms and the coding of large and small firms is relative and simply compares two groups of firms in the sample. A number of the firms coded as “small firms” include firms with over 1,000 employees, which could be considered large. However, conducting the analysis by large and small firms provides a point of comparison between firms.

Measures

Dependent Variables

I employ four dependent variables to represent the various stages of innovation. The first dependent variable is *discovery*. This variable is measured as the number of patents granted by the U.S. Patent and Trademark Office (USPTO) per year for each biotechnology firm in the sample (natural log to account for skew). Data for this variable were gathered by searching the USPTO online search engine (<http://patft.uspto.gov/>) for each firm in the sample by year. The range of this variable is 0 to 222 patents. Merck & Co. has the highest number of patents granted (222) in 1993. The mean is 9.6 (standard deviation: 26.9), but the median is 1 patent since there is a large number of zeros per firm-year. There are 629 firm-years of 1,298 in which firms have zero patents granted.

The second dependent variable is *products in clinical trials*. Products in clinical trials is measured as the number of products in any phase of clinical trials (i.e., phases, I, II, or III, or filed an application for approval to the FDA) for each firm per year. Products that are either terminated or sold on the market are subtracted from the firm's total. Data for this variable are collected from product reports in the Recap database. The number of products in clinical trials ranges from 0 to 43. The mean is 4.5 (standard deviation: 5.4) and the median is 3 products per firm-year. Amgen is the firm with the highest number of products in trials in 2002. It should be noted that although terminated products and the date of termination are identified by ReCap, this is a possible source of bias if no company report or media source reports product termination.

The third dependent variable is *products on the market*. Products on the market are measured as the number of products on the market for each firm per year. The data source is Recap. The number of products on the market ranges from 0 to 17. The mean is 0.9 (standard deviation: 2.0) and the median is 3 products per firm-year. Genzyme Corp. is the firm with the highest number of products in trials in 2006.

Product success is the final dependent variable. I operationalize product success as firm sales growth. Firm sales is measured as gross sales per firm-year "...reduced by cash discounts, trade discounts, and returned sales and allowances for which credit is given to customers, for each operating segment" (<http://wrds-web.wharton.upenn.edu/wrds/ds/documentation/comp/seg/sale.cfm>) (COMPUSTAT). Sales growth is calculated by subtracting sales in year $t - 1$ from year t , divided by year t .

Sales growth is then averaged over a three-year time period (compare with He and Wong 2004) including year $t - 1$, year t , and year $t + 1$.

Firm sales growth has been used in prior ambidexterity research as an indicator of product success (He and Wong 2004; Venkatraman et al. 2007). Although more direct measures include units sold or market share, these measures are difficult to obtain, especially going as far back as 1990. Sales growth is a reasonable proxy for product success for two reasons. First, firm sales are associated with profitability and performance (Henderson 1999; Timmons 1999). Second, firm sales provide a more direct measure of products sold than other common indicators of firm performance such as return on investment (ROI), return on equity (ROE), or return on assets (ROA).

Independent Variables

As stated above, firm-level variables are used to test Hypotheses 1a and 1b – absorptive capacity and firm competence (i.e., firm age) have positive and nonlinear effects on product discovery, respectively. Alliance-partner variables test Hypothesis 2a, upstream alliances are positively associated with products in clinical trials, and Hypothesis 2b, horizontal alliances are positively associated with products on the market. Hypotheses 3a and 3b specify relationships between network variables and product success. Network centrality (Hypothesis 3a) and network experience (Hypothesis 3b) are likely to increase product success. Hypotheses 4a, 4b, and 4c involve product development strategies: there is a positive relationship between ambidexterity interaction and innovation success (Hypothesis 4a), there is a negative relationship between

ambidexterity imbalance and innovation success (Hypothesis 4b), and there is a positive relationship between recombination and innovation success (Hypothesis 4c).

Firm characteristics. I examine whether there are positive and curvilinear effects of firm-level variables on product discovery. These variables are included as control variables in subsequent models and also to compare their effects across the stages of innovation. Absorptive capacity is operationalized as R&D intensity. *R&D intensity* is measured as R&D expenditures in millions of U.S. dollars (natural log) (COMPUSTAT) (Cohen and Levinthal 1990). I also include a measure of organizational competence, operationalized as firm age. *Firm age* is the number of years since founding. *Firm age*² is the number of years since founding squared (Sorensen and Stuart 2000).

Alliance-partner characteristics. Rothaermel and Deeds (2004, 2006) provide theoretical justification for estimating the effects of alliance type of success at various stages of innovation. Different types of strategic alliances proxy the types of complementary assets and capabilities that increase the likelihood of success as a product progresses through different stages in the innovation process. As such, upstream alliances are more likely to predict products in development and horizontal alliances are likely to be associated with products on the market.

Upstream alliances are measured as the number of alliances dedicated to product research (Recap). *Horizontal alliances* are measured as the number of alliances dedicated to product development. Each alliance variable is the cumulative number of alliances across all preceding years. But, since the dates of alliance dissolution or

termination are not listed in Recap, I subtract alliances from each alliance variable when the products with which the alliances are associated are terminated or go to market. Data for strategic alliances come from Recap. In each product report, Recap lists details of the partners who collaborate with the focal firm to develop and produce a product. Recap lists the alliance partner name, the date the alliance was entered, and the terms of the agreement such as research, development, manufacturing, and marketing. *Downstream alliances* are the number of alliances dedicated to manufacturing, marketing, and sales activities. These activities represent downstream supply-chain activities that are likely to improve the distribution of new products, new product diffusion, to customers. The downstream activities associated with these alliances are likely to improve firm sales, the final dependent variable and the final stage of innovation I examine in this study.

Network characteristics. Network experience and centrality also have been shown to predict success at various stages of innovation in the biotechnology industry (Powell et al. 1996; Powell et al. 1999; Rothaermel and Deeds 2004). *Network centrality* (degree centrality normalized) is measured as a firm's total strategic alliances divided by total alliances in network (multiplied by 1000). This measure is calculated for three different time periods (1990-1995, 1996-2000, and 2001-2006) for each firm to account for changes in a firm's network over time.

The most common measure of network experience is the total number of strategic alliances (for example, Hoang and Rothaermel 2005; Rothaermel and Deeds 2004), but more nuanced measures exist. Powell et al. (1996, 1996) measure network experience as the number of years since the firm's first alliance. But, since alliances are so prevalent

among biotechnology firms, this measure is strongly correlated with age. In Powell et al. (1999), network experience and age are correlated at 0.936. Alternatively, Rothaermel and Deeds (2006:443) measure network experience as the "...cumulative sum of the alliance duration for each of the firm's alliance" in years. For example, if a firm participates in two alliances with the first alliance 3 years old and the second alliance 4 years old, the firm's network experience is 7 years. This operationalization, compared with others, more precisely measures the extent to which firms have experience managing a diversity of alliances over time and is correlated with firm age at 0.03 in Rothaermel and Deeds (2006:446). Following Rothaermel and Deeds, *network experience* is measured as the total number of years firms have engaged in each strategic alliance (natural log). Rothaermel and Deeds (2006) also find an inverted-U relationship between product development and network experience. Consequently, I include a squared term, *network experience squared*, in my analysis. Recap is the data source for both of the network variables.

Product development strategies. Measures of ambidextrous product development strategies identified in Chapter 3 include the interaction between exploration and exploitation, an imbalance between exploration and exploitation, and recombination. Product development strategies are coded for every product in the dataset according to whether the product represents a new or existing product relative to previous firm products, and according to whether the medical condition it is intended to treat is new or existing relative to medical conditions with which the firm has experience. Product data used to code these variables come from product reports in the Recap data

that list detailed information about the drug, the medical condition the drug is designed to treat, and the dates when the drug entered each phase of clinical trials.

Exploration is measured as the number of drugs in clinical trials coded as a new drug and a new disease as a percent of total drugs in clinical trials by firm-year. In other words, a drug is coded as an exploration drug development strategy if the firm has no previous experience testing the drug in clinical trials and no experience with the medical condition in clinical trials. *Exploitation* is measured as the number of drugs in clinical trials coded as an existing drug and an existing disease as a percent of total drugs in clinical trials. As a measure of exploitation in the models predicting product invention (the number of patents), the first innovation stage, I include the variable *patent self-citations*, which is analogous to exploiting firm knowledge. This variable is measured as the number of self-citations to prior firm patents and is aggregated for all firm patents in any given year. Sorensen and Stuart (2000) distinguish between patents that cite prior firm patents, which they call self-citing patents, from nonself-citing patents. Self-citing patents are “related to prior endeavors,” while nonself-citing patents “do not build on the firm’s earlier patented inventions and are departures from a focal firm’s previous innovative activity” (p. 92). *Patent nonself-citations* correspond to exploration activities and are measured as the number of citations that are not granted to the firm, but to other firms. Data for these patent citation variables come from the NBER Patent Data Project (Hall, Jaffe, and Trajtenberg 2001). The updated version of this dataset was downloaded in July, 2009 (<http://www.econ.berkeley.edu/~bhhall/NBER06.html>).

Ambidexterity product development strategies are measured three ways. The first measure is an *ambidexterity interaction*. This measure is an interaction term, calculated by multiplying exploration and exploitation. *Ambidexterity imbalance* is the absolute value of the difference between exploration and exploitation. *Recombination* is a combination of new and existing knowledge. It is measured as drugs in clinical trials that are coded as an existing drug and new disease – or vice versa as a new drug and existing disease – as a percent of total drugs in clinical trials by firm-year. The data source for each product development strategy variable is Recap and each product development strategy is time-varying. I have not collected data on the uses or applications of patents – an analogue to the type of disease that a drug is intended to treat – since patents granted for biotechnology have many different applications. Such a data collection effort would be difficult and time intensive. Therefore, the models presented in my analysis predicting patents granted do not include a variable for recombination product development strategies, but they do include the variables ambidexterity interaction and ambidexterity imbalance.

Two of the ambidexterity measures – the interaction and imbalance – are conceptually similar to other studies of ambidexterity, especially He and Wong (2004), but they are distinctly operationalized. The measures are conceptually similar because they combine exploratory and exploitative strategies as a multiplicative interaction of exploration and exploitation and the absolute value of the difference between the two. But, the measures are distinct from He and Wong in two ways. First, the measures are different because they do not come from subjectively answered survey questions about

exploration and exploitation strategies. The variables in this study directly measure new and existing products. Second, He and Wong (2004), as well as others who study ambidexterity, limit their conception of ambidexterity to whether products are new or existing. My study adds another dimension by also examining the application of the product; or in the case of biotechnology, the medical condition that the product is intended to treat. Measuring the extent to which firms recombine existing knowledge allows me to examine the space on the exploration-exploitation continuum in more detail. Instead of using two broad categories to examine ambidexterity, product recombination allows me to examine more combinations of exploration and exploitation and provides a more fine-grained measure of the ambidexterity construct.

Table 5 includes examples from the biotechnology company Celgene to illustrate how each product development strategy is coded for products in the dataset. In 1994, Celgene began clinical trials for the drug thalidomide and for the treatment of schizophrenia AIDS-related cachexia. This clinical trial represents the first time Celgene studied thalidomide and its effects, so the drug and disease are both considered new, and the product development strategy for this drug is coded as exploration. In 1999, Celgene began testing the same drug, thalidomide, in clinical trials for another disease, myelodysplastic syndrome. Since Celgene had experience testing this drug in clinical trials, but it did not have experience testing this disease in clinical trials, when thalidomide entered phase I clinical trials in 1999, it represents the combination of an existing drug with a new disease. Therefore, the product development strategy is coded recombination. Next, the clinical trial that began in 2000 is comprised of a new drug

(structural analog of thalidomide – 5013), with which the firm had no experience, and a new disease (multiple myeloma). The product development strategy is exploration. The last product in the table includes an existing drug (structural analog of thalidomide – 5013) and an existing disease (myelodysplastic syndrome) and it is coded as exploitative product development strategy.

Drug	Disease	Clinical Trials	Product Strategy
thalidomide (new drug)	AIDS-related cachexia (new disease)	1994	Exploration
thalidomide (existing drug)	myelodysplastic syndrome (new disease)	1999	Recombination
structural analog of thalidomide - 5013 (new drug)	multiple myeloma (new disease)	2000	Exploration
structural analog of thalidomide - 5013 (existing drug)	myelodysplastic syndrome (existing disease)	2002	Exploitation

Control Variable. The analysis also includes a number of control variables.

Firm size is the number of employees in thousands (standardized) (obtained from COMPUSTAT). Sorensen and Stuart (2000) expect that large firms, measured as the number of firm employees, are more inert and have a negative effect on patenting. However, they find that large firms are significantly more likely to predict patenting in some, but not all, of their models. Rothaermel and Deeds (2006) find a positive association between firm size (i.e., number of employees) and products in development.

Estimation Procedure

I use a fixed-effects regression model specification (Maximum Likelihood Estimation) to examine success across the stages of innovation. I use a fixed-effects model (FEM), rather than a random-effects model (REM), for theoretical and practical reasons. A FEM is appropriate for this study because it adjusts standard errors to account for firm-specific unobserved heterogeneity across time (Powers and Xi 2000). To account for unobserved heterogeneity a fixed-effects model specification is the equivalent to including a dummy variable or a fixed-effect for each unit over time; thus, precluding the inclusion of a dummy variable in the models since their inclusion would result in perfect collinearity with the fixed effects (Littell et al. 2006).

Since FEM coefficients may not be as efficient as REM coefficients, a Hausman (1978) test is used to compare coefficients for the FEM and REM. The null hypothesis is that there is no systematic difference between FEM and REM coefficients. A significant finding from a Hausman test indicates that the FEM is preferred on the grounds that the coefficients are presumably unbiased and the FEM is the appropriate specification. The result of Hausman tests performed for models specified for each dependent variable in this study are significant at $p < 0.05$.

Interviews

Interviews with executives at biotechnology firms are used to supplement the quantitative analyses on the stages of innovation. While quantitative analyses identify product, firm, alliance, and network characteristics associated with success at each stage;

results from regression models do not address the reasons why products proceed from one stage of innovation to the next. Interviews provide more detail regarding and contextualize the innovation stages. Interviews provide a more complete understanding of the criteria used by biotechnology firms to advance products from one stage of innovation to the next.⁶

I have interviewed five employees of biotechnology companies during March and April 2010. The interviews were conducted with four members of management (i.e., one CEO and three Vice Presidents) and one engineer at biotechnology firms. The job titles of each informant include President and CEO, Vice President and Director of International Clinical Development, Vice President of Development, Vice President of Product Development and Manufacturing, and Product Lab Engineer. Each member of management holds a Ph.D. in a science-related field, which is common in biotechnology companies, and the lab engineer is currently working on a Ph.D. One of the informants is female (one of the Vice Presidents) and the rest of the informants are male. The informants come from firms of various sizes. Three of the informants come from firms with less than 100 employees, one informant comes from a firm with approximately 2,500 employees, and the other informant comes from a large pharmaceutical firm with tens of thousands of employees.

I interviewed one product lab engineer in addition to executives, because during preliminary meetings in May, 2008, with several biotechnology research scientists, I learned of that management sets the strategic direction of the firm and stipulates the products to be pursued, which may differ from the preferences of the research scientists or

⁶ A copy of the interview guide is included in the Appendix.

engineers, who have less discretion about which products to pursue. An interview with an engineer who works with products in a lab is important to provide an alternative view about how decisions are made about which products to pursue and advance through stages of innovation. Management is more likely to pursue products deemed the most profitable, especially in the short-term, while this is not necessarily the primary objective for scientists. For example, scientists may want to create products that solve serious health or other technical problems regardless of profit margins. While some managers may foster an environment of creativity for the sake of innovation and potential profit at some unknown time in the future, others are certainly likely to view product development as a means for increasing short-term profit. Both types of managers can affect the type of products that scientists are allowed to pursue and the criteria scientists use to evaluate products during the innovation process.

Sample selection of informants was nonrandom and took place as follows. I conducted an online search of biotechnology firms that conduct clinical trials in the Baltimore-Washington D.C. metro area. The D.C. area is the third-largest site for biotechnology companies in the world and a large concentration of biotechnology companies are headquartered in Montgomery County, Maryland. One reason for this biotechnology cluster is the area's supply of academic resources, government agencies (especially NIH), and industry and government ties that support the biosciences. Upon identifying 18 biotechnology firms in the Baltimore-DC metro area, I contacted them and asked to interview someone who is informed about how decisions are made regarding the product development process. My interview request was forwarded to the appropriate

person at the firm and interviewees were selected someone at the firm. The informant's contact information was either forwarded to me or the informant contacted me directly to set up the interview. Findings from the interviews are discussed at the end of the next chapter after the results of the regression models are reported.

CHAPTER 5:

RESULTS

In this study I test a number of hypotheses regarding product success across the stages of innovation. Hypotheses 1a and 1b specify a positive relationship between firm-level learning (absorptive capacity and organizational competence) and product discovery. In Hypotheses 2a and 2b, I propose that complementarity between alliance partners and the focal firm influence product development. Hypotheses 3a and 3b indicate that network characteristics are significant predictors of success at the last stage of innovation, product success. I also draw from literature on organizational ambidexterity and argue that ambidexterity – simultaneously engaging in exploration and exploitation activities – increases the likelihood of innovation success. I find broad support for these hypotheses.

I begin this chapter by describing the distribution of product development strategies for products in clinical trials and products on the market for the firms in my sample. Next, I present descriptive statistics for the dependent and independent variables used in the analysis and report multivariate analyses predicting success at various stages of innovation: product discovery (patents granted), product development (products in clinical trials and products on the market), and product success (sales growth). After discussing the results associated with each stage of innovation I provide summary tables that list the significant coefficients for each stage of innovation. I provide summary tables as a broad overview of significant effects; as a way to compare significant effects

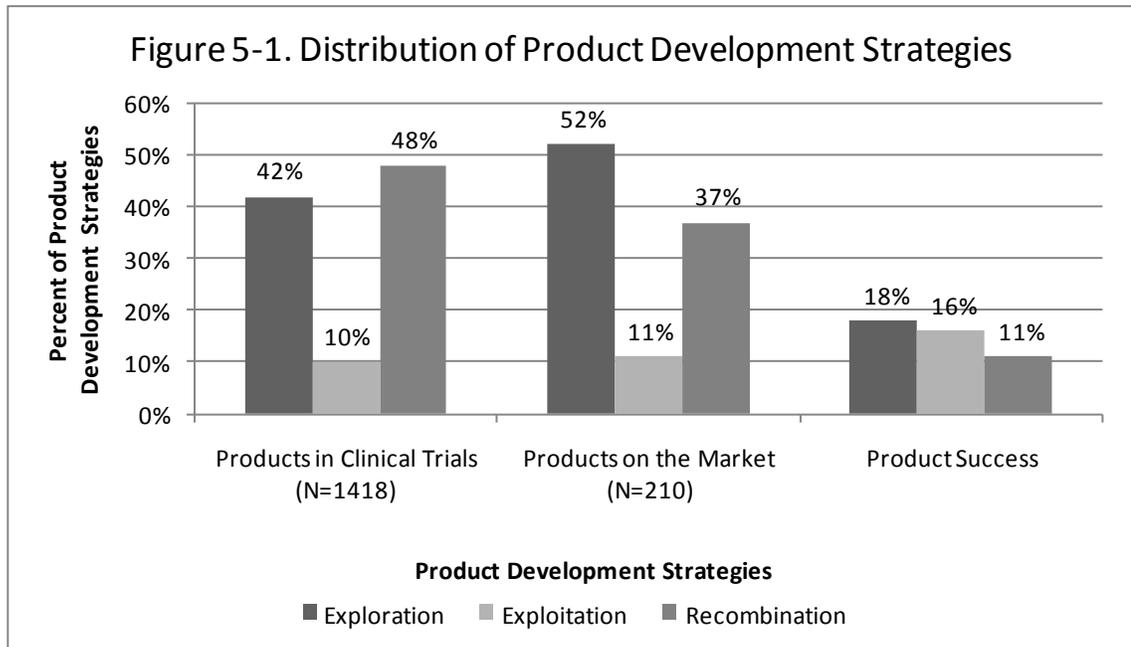
across models. Lastly, I discuss the decision-making criteria used to evaluate products at various stages of innovation based interviews with informants from biotechnology companies.

Distribution of Product Development Strategies

There are 1418 drugs in clinical trials from 1990 to 2006, for U.S. public firms in the Recap sample. Of the 1418 drugs, 210 gained FDA approval and were sold on the market. This represents a 0.14 (14%) success rate for the drugs clinical trials. In the sample, 152 drugs entered clinical trials during the years 1990 to 1994, 411 drugs entered clinical trials from 1995 to 1999, 596 drugs entered clinical trials from 2000 to 2004, and 259 drugs entered clinical trials from 2005 to 2006. Although the number of drugs in trials steadily increases over time, it is unclear whether this increase represents sample selection bias compared with the population of drugs in clinical trials since public data on products in clinical trials are very difficult to obtain retroactively for of the years under investigation. One researcher, however, has estimated that the number of drugs in trials has increased since the industry's inception (Smith 2000). Moreover, the number of biotechnology firms has increased since the early-to-mid 1990s, as has R&D funding (DiMasi et al. 2003; DiMasi and Grabowski 2007).

The following figure, Figure 5-1, illustrates the distribution of product development strategies for drugs in the Recap sample. Exploration and recombination are the most common types of strategies pursued and exploitation is the least common. Exploration product development strategies are pursued for 42% of the total products in

the sample, exploitation strategies are pursued for 10% of the products, and recombination occurs for 48% of the products. Of the 210 products sold on the market, 52% use exploration product strategies, 11% use exploitation strategies, and 37% use recombination strategies. Besides showing the distribution product development strategies, Figure 5-1 presents the percent of products in trials that reached the market for each product strategy (i.e., the number of products that reached the market divided by the number of products in clinical trials for exploration, exploitation, and recombination). In this sample, products with exploration strategies end up reaching the market 18% of the time, products with exploitation strategies end up reaching the market 16% of the time, and products with recombination strategies reach the market 11% of the time.



Descriptive Statistics

Descriptive statistics for the dependent and independent variables are located in Appendix B. The descriptive statistics show a statistically significant difference between large and small firms for the dependent and many of the independent variables. Means for the dependent variables, including means for large and small firms, are included in Table B-1. Table B-1 shows a statistically significant difference for each dependent variable for large and small firms. Large firms in the sample have more patents, more products in clinical trials, and have more products on the market. All firms experience negative sales growth on average with large firms experiencing smaller amounts of negative growth.

Table B-2 reports the means for each independent variable for the full sample and for large and small firms. The means for each of the firm, alliance, and network variables are statistically different for large and small firms. To provide an easy-to-interpret profile of firms in the sample, the means in Table B-2 do not include transformations of variables for use in regression models. On average, large firms in the sample are older, spend much more on R&D (absorptive capacity), have more upstream and horizontal but fewer downstream alliances, are more centrally located in their networks, and have less experience in strategic alliances. Large firms likely have less experience than small firms because they have more resources to carry out activities in-house rather than smaller firms who are more likely to require partners with which to pool resources to see a project through from start to finish. Regarding product development strategies, there are some differences. Large firms exhibit more patent self citations and non-self citations,

which no doubt reflects their propensity to engage in more patenting activity. Large firms also tend to pursue more exploitation product development strategies. The mean differences for exploration and recombination are not statistically significant by firm size.

Bivariate correlations for the independent variables are found in Table B-3. The correlation matrix reveals that a number of independent variables are strongly correlated (above 0.700), which is unsurprising due to serial correlation across firm-years and the association between organizational activities that often vary with firm size. The strongest correlation is between firm age and firm size (0.792) illustrating that surviving firms grow larger with time. To assess potential problems associated with collinearity between firm age and firm size, I ran each model without firm size and the results (not shown) do not differ significantly from those reported below. Absorptive capacity, proxied by R&D expenditures, is strongly correlated with firm age (0.716). The correlation indicates that older firms spend more on R&D than newer firms. Downstream alliances are strongly correlated with network experience (0.720). There is a strong correlation between exploration and downstream alliances (0.725), revealing that firms with higher levels of exploratory strategies are more likely to engage in downstream partnerships to commercialize those novel products. Patent self citations and non-self citations are also strongly correlated (0.713). The strong correlation points to an association between patenting activity more generally and both types of patent citations. In other words, patent citations are an artifact of patents granted. Patenting activity leads to increases in both patent self citations and non-self citations. Additional analysis shows that the bivariate correlation between patents granted and self-citations is 0.67 and patents and

nonsell-citations is 0.71. Lastly, the correlation between recombination and exploitation is 0.708. This correlation is intuitive since recombination is a necessary condition for exploitation. Once recombination product strategies have been pursued, exploitation is more likely to occur because each additional recombination strategy that is pursued increases the chances of exploitation. In other words, pursuing drugs or medical conditions with which the firm has previous experience (recombination) increases the likelihood that any additional product tested in clinical trials exploits previous knowledge regarding the drug or medical condition.

To assess potential problems due to multicollinearity associated with strongly correlated variables, I estimate variance inflation factors (VIFs) for each independent variable. The average VIF for all independent variable is 2.55. The maximum value is 3.93 for firm age. The second highest value is 3.37 for firm size. The VIFs are well below the recommended cut-off point of 10.0 (Kleinbaum, Kupper, and Muller 1988).

Multivariate Analysis⁷

Fixed-effects models are estimated for each innovation stage in biotechnology: product discovery (patents granted), product development (products in clinical trials and products on the market), and product success (firm sales growth). For each innovation stage, groups of independent variables are entered into models in a step-wise fashion:

⁷ In additional analysis not shown, following He and Wong (2004), I operationalize exploration as new products and exploitation as existing products as a percent of total products, irrespective of the type of disease the product is designed to treat. The effects of ambidexterity confirm the findings of He and Wong (2004). In fixed-effects regression models, the ambidexterity interaction is significant and positively predicts products in clinical trials. The effect of the ambidexterity interaction is a positive but non-significant predictor of products on the market. The effects of ambidexterity imbalance are negative and significant for products in trials and negative and non-significant for products on the market.

firm and alliance-partner characteristics in Model 1; network characteristics in Model 2; exploration and exploitation in Model 3; and ambidexterity product development strategies in Models 4 through 6 (the interaction term in Model 4, imbalance in Model 5, and recombination in Model 6). I estimate separate models for each ambidexterity variable to avoid potential problems of multicollinearity between each measure. When either firm age-squared or network experience-squared is not significant, I drop the squared term for the sake of parsimony. The models are also estimated separately for large and small firms and the results are reported after the models are discussed for the entire sample.

Patents Granted

Table 5-1 shows the unstandardized coefficients for models predicting the number of patents granted (logged) for all firms in the sample. Each firm-level variable is statistically significant across models, net of other independent variables. These results confirm Hypotheses 1a and 1b – absorptive capacity, measured as R&D expenditures, increases discovery and firm age has a curvilinear effect discovery. Firms with greater absorptive capacity have a greater capacity to learn by incorporating knowledge external to the firm that builds on existing knowledge and, in turn, generates additional innovations (Cohen and Levinthal 1990). The significant coefficients for firm age and its squared term have an inverse U-shaped association with patents granted. This finding is consistent with Sorensen and Stuart's (1990) general prediction: firm age is associated

with increased patenting for the newest firms. Patenting activity then levels off and decreases for as firm age increases.

Table 5-1. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Patents Granted (All Firms)

Variable	Model 1	Model 2	Model 3	Model 4	Model 5
Firm Size (standardized)	0.129 * (0.061)	0.113 (0.062)	0.026 (0.063)	0.047 (0.062)	0.026 (0.063)
Firm Characteristics					
Absorptive Capacity (log)	0.133 *** (0.031)	0.136 *** (0.032)	0.131 *** (0.031)	0.116 *** (0.031)	0.131 ** (0.031)
Firm Age	0.079 *** (0.010)	0.085 *** (0.013)	0.079 *** (0.013)	0.085 *** (0.012)	0.079 *** (0.013)
Firm Age ²	-0.001 *** (0.000)	-0.001 *** (0.000)	-0.001 * (0.000)	-0.001 ** (0.000)	-0.001 * (0.000)
Alliance Characteristics					
Upstream Alliances	0.126 *** (0.035)	0.125 *** (0.035)	0.096 ** (0.034)	0.061 (0.034)	0.097 ** (0.035)
Horizontal Alliances	-0.033 (0.018)	-0.031 (0.018)	-0.027 (0.017)	-0.019 (0.017)	-0.027 (0.017)
Downstream Alliances	0.010 (0.012)	0.017 (0.014)	0.015 (0.013)	0.016 (0.013)	0.015 (0.013)
Network Characteristics					
Network Centrality (X 100)		-0.025 (0.029)	-0.017 (0.028)	-0.024 (0.028)	-0.016 (0.029)
Network Experience (log)		-0.036 (0.037)	-0.045 (0.037)	-0.048 (0.036)	-0.045 (0.037)
Product Development Strategies					
Exploration (<i>Patent Non-Self Citations</i>)			0.057 ** (0.019)	0.172 *** (0.025)	0.067 (0.039)
Exploitation (<i>Patent Self Citations</i>)			0.117 ** (0.034)	0.291 *** (0.043)	0.118 ** (0.034)
Interaction (<i>Self Cites* Non-Self Cites</i>)				-0.041 *** (0.006)	
Imbalance (<i>Self Cites – Non-Self Cites</i>)					-0.014 (0.044)
Constant	0.079 (0.077)	0.104 (0.087)	0.003 (0.088)	0.011 (0.086)	0.001 (0.088)
R-square	0.25	0.23	0.33	0.39	0.33
Firms	111	111	111	111	111
Cases	1187	1187	1187	1187	1187

p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

Although hypotheses 2 and 3 (and their variants) stipulate relationships between alliance and network characteristics at other stages of innovation, I briefly mention the effects of alliance and network at this stage. One of the alliance-partner variables is statistically significant. The upstream alliances variable is a positive, significant predictor of patents granted. The positive effect of upstream alliances indicates that these alliances perform their intended function in this sample of biotechnology firms,

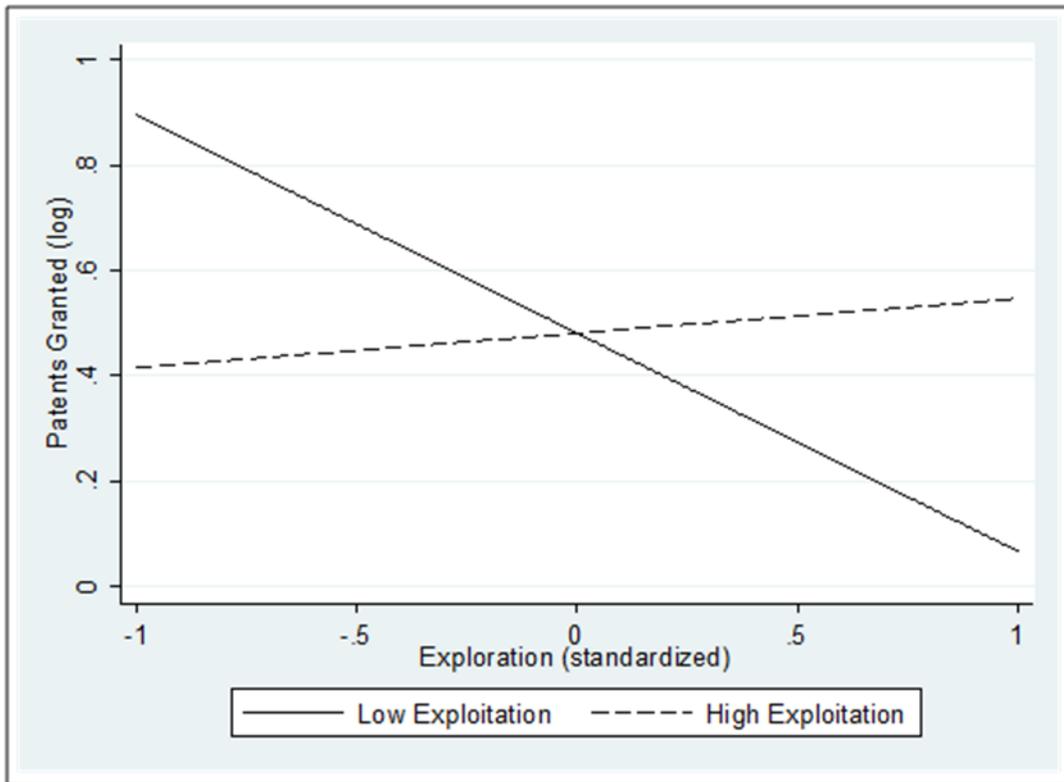
increasing the incidence of discovery. Horizontal and downstream alliances have no significant effect. The variables measuring network characteristics have negative effects, but neither effect is statistically significant.

The type of product development strategy is important for patents granted. Patent non-self citations (exploration) and self citations (exploitations) significantly increase a firm's likelihood of having patents granted. These results are perhaps unsurprising given the endogeneity between patents granted and patent citations. As stated above, the bivariate correlation between patents granted and self citations is 0.67 and patents and non-self citations is 0.71. In other words, patents are comprised of lots of self-citations and nonself-citations and patenting is positively associated with both types of citations. Hypotheses 4a states that one indicator of ambidexterity, the interaction between exploration and exploitation, is expected to increase product success at each stage of innovation. The results reported in Table 5-1 indicate that this hypothesis is disconfirmed. The negative effect is surprising given the ambidexterity literature, which finds positive effects for the multiplicative interaction (e.g., He and Wong 2004). However, the negative interaction effect is misleading. In post-hoc analysis, I included a series of dummy variables in the model predicting patents granted for low values of the ambidexterity interaction (standardized) (less than the 25th percentile), middle values of the ambidexterity interaction (standardized) (from the 25th to the 75th percentile), and high values of the ambidexterity interaction (standardized) (greater than the 75th percentile). Further analysis indicates that when dummy variables are included in the regression model for the low values and high values of the ambidexterity interaction

term, they have a significant and positive effect on patenting and a significant and negative effect on patenting, respectively (mid-range values are the omitted reference category). Thus, at low levels of ambidexterity the number of patents granted increases, but at high levels of ambidexterity the number of patents granted decreases. The results for these dummy variables indicate that the ambidexterity interaction term has a nonlinear effect (inverted U-shape) on patents granted.

Figure 5-2 illustrates the nonlinear relationship between the ambidexterity interaction and patents granted. In the case of Figure 5-2, ambidexterity is represented as the moderating effect of exploitation on the relationship between exploration and patents granted. The solid line represents low levels of exploitation and the dashed line represents high levels of exploitation. The slope of each line is based on predicted values of dummy variables for low values of exploitation (less than the 25th percentile) and high values of exploitation (greater than the 75th percentile), net of other control variables, in the model predicting patents granted. Figure 5-2 demonstrates that given a high level of exploitation, an increase in exploration is associated with an increase in patents granted. But, given a low level of exploitation, an increase in exploration is associated with a decrease in patenting activity.

Figure 5-2. The Interactive Relationship between Exploration and Patents Granted



Hypothesis 4b states that an imbalance between exploration and exploitation is expected to decrease success at each stage of innovation. Consistent with Hypothesis 4b, the results from Table 5-1 indicate that an imbalance between exploration and exploitation decreases patenting. Taken together, the effects of ambidexterity suggest firms should simultaneously pursue exploration and exploitation activities. But, there is a caveat. Firms should find a balance between exploration and exploitation activities, and avoid focusing on one activity to the exclusion of the other, thereby decreasing the likelihood of product discovery.

Since there are a number of statistically significant differences for the dependent and independent variables by firm size (see Tables B-1 and B-2), models are also

estimated separately for large firms and small firms. In Table 5-2, Models 1 through 3 report the results from fixed-effects models that are specified for large firms. Models 4 through 6 contain the results of fixed-effects models that are specified for small firms.

Results from models predicting patents granted for large firms in Table 5-2 mirror the effects of firm characteristics for the full sample (Table 5-1). The effect of absorptive capacity is significant and the coefficient is positive. There is a significant and nonlinear effect (inverted U-shape) for firm age. Two of the alliance characteristic variables are significant. Upstream alliances have a positive, significant effect on patents granted while horizontal alliances have a negative and significant effect. The negative effect of horizontal alliances suggests that, on average, firms with alliances focused on development tend to siphon resources away from discovery activities. Similar to the models for all firms in the sample (Table 5-1), network centrality and experience are negative, but not significant. For large firms, the coefficients for patent self citations and non-self citations are positive and significant. The coefficient for the ambidexterity interaction is negative and significant. But, similar to the models that include all firms in the sample, additional analyses show that there is a nonlinear effect for ambidexterity imbalance: low levels of ambidexterity interaction increase the likelihood of patenting and high levels decrease the likelihood of patenting. Once again, the nonlinear effect of

Table 5-2. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Patents Granted by Firm Size

Variable	Large Firms Model 1	Large Firms Model 2	Large Firms Model 3	Small Firms Model 4	Small Firms Model 5	Small Firms Model 6
Firm Size (standardized)	0.030 (0.066)	0.043 (0.067)	0.029 (0.068)	-2.473 (9.167)	-2.444 (9.161)	-2.606 (9.155)
Firm Characteristics						
Absorptive Capacity (log)	0.133 ** (0.043)	0.117 ** (0.043)	0.133 ** (0.043)	0.027 (0.053)	0.024 (0.053)	0.026 (0.053)
Firm Age	0.104 *** (0.019)	0.109 *** (0.018)	0.104 *** (0.019)	0.065 *** (0.015)	0.066 *** (0.015)	0.065 *** (0.015)
Firm Age ²	-0.001 ** (0.000)	-0.001 *** (0.000)	-0.001 ** (0.000)			
Alliance Characteristics						
Upstream Alliances	0.111 ** (0.038)	0.073 (0.038)	0.117 ** (0.038)	-0.102 (0.097)	-0.099 (0.097)	-0.091 (0.097)
Horizontal Alliances	-0.047 * (0.020)	-0.039 * (0.020)	-0.049 * (0.020)	0.002 (0.039)	-0.002 (0.039)	0.003 (0.039)
Downstream Alliances	0.020 (0.019)	0.024 (0.018)	0.020 (0.019)	0.002 (0.019)	-0.002 (0.019)	0.001 (0.019)
Network Characteristics						
Network Centrality (X 100)	-0.039 (0.032)	-0.047 (0.031)	-0.030 (0.032)	0.051 (0.070)	0.053 (0.070)	0.054 (0.070)
Network Experience (log)	-0.057 (0.048)	-0.058 (0.047)	-0.058 (0.048)	-0.041 (0.058)	-0.042 (0.058)	-0.040 (0.057)
Product Development Strategies						
Exploration (<i>Patent Non-Self Citations</i>) (divided by 100)	0.055 ** (0.021)	0.163 *** (0.029)	0.134 ** (0.050)	0.207 ** (0.062)	0.233 *** (0.066)	0.550 * (0.241)
Exploitation (<i>Patent Self Citations</i>) (divided by 100)	0.082 * (0.040)	0.277 *** (0.054)	0.065 (0.041)	0.325 *** (0.069)	0.447 *** (0.117)	0.607 ** (0.203)
Interaction (<i>Self Cites* Non-Self Cites</i>)		-0.039 *** (0.007)			-0.239 (0.187)	
Imbalance (<i>Self Cites – Non-Self Cites</i>)			-0.097 (0.055)			-0.365 (0.247)
Constant	-0.022 (0.138)	-0.020 (0.135)	-0.049 (0.138)	-0.476 (2.512)	-0.465 (2.510)	-0.527 (2.509)
R-square	0.26	0.32	0.27	0.09	0.10	0.11
Firms	55	55	55	56	56	56
Cases	685	685	685	502	502	502

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

ambidexterity interaction demonstrates the challenge of simultaneously engaging in high levels of both exploration and exploitation activities in large firms.

For small firms, there are limited significant effects for firm-level and alliance-level learning. The effects of firm age on patenting are positive and significant. Similar to the models for large firms and for the models that include the entire sample, patent self citations and non-self citations are positive and significant. The ambidexterity interaction is negative, but not statistically significant. The effect of the interaction term is negative, though the effect is non-significant as well.

In summary, Hypotheses 1a and 1b are largely confirmed for patents granted: firm-level learning is a consistent predictor of success at the earliest stage of innovation. However, these results are contingent on firm size. Hypothesis 1a holds for large firms but not small firms. Hypothesis 1b holds for large and small firms. Results from regression models provide partial support Hypothesis 4a – a positive effect for ambidexterity interaction – for large firms but not small firms. The interaction between exploration and exploitation has a nonlinear effect for large firms. Results from regression models do not confirm Hypothesis 4b at this stage of innovation. Ambidexterity imbalance does not significantly decrease the proclivity to patent.

Products in Clinical Trials

Table 5-3 lists the unstandardized coefficients for the next stage of innovation, products in clinical trials. First, the coefficient for firm size is positive and significant across models, which indicates that larger firms are more likely to have products in

clinical trials. Once again, firm characteristics are robust predictors of innovation, accounting for the other independent variables. Firm age has a nonlinear effect on clinical trials and absorptive capacity is positively and significantly associated with products in clinical trials.

While the other hypotheses involve other stages of product development Hypothesis 2a suggests that complementarity between alliance-partners is likely to increase the number of products in clinical trials. As expected, the findings reported in Table 5-3 indicate that upstream alliances have a positive and significant effect on the number of products in clinical trials. This result substantiates similar research by Rothaermel and Deeds (2004). An increase in the number of upstream alliances is positively associated with products in development. Moreover, horizontal alliances have a positive and significant and the effect of downstream alliances is significant in Models 1 and 2, but the effect is mediated by product development strategies in subsequent models. When exploitation is included in the model, downstream alliances becomes non-significant. The positive effect of downstream alliances is somewhat puzzling since downstream alliances have no theoretical correlation with products in development. However, as shown below in this chapter, interviews reveal that firms anticipate products in the pipeline. Perhaps as products successfully progress through a firm's clinical program, they are entering downstream alliances in preparation for commercialization. One of the network characteristics variables is negative and statistically significant. Having more experience managing strategic alliances is negatively associated with having products in clinical trials. This result indicates that for this stage,

Table 5-3. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Products in Clinical Trials (All Firms)

Variable	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Firm Size (standardized)	0.749 ** (0.269)	0.684 * (0.275)	0.792 ** (0.259)	0.717 ** (0.253)	0.794 ** (0.257)	0.829 ** (0.253)
Firm Characteristics						
Absorptive Capacity (log)	0.573 *** (0.139)	0.558 *** (0.141)	0.435 ** (0.131)	0.454 *** (0.128)	0.403 ** (0.131)	0.459 *** (0.129)
Firm Age	0.300 *** (0.045)	0.367 *** (0.056)	0.329 *** (0.052)	0.358 *** (0.051)	0.335 *** (0.052)	0.290 *** (0.051)
Firm Age ²	-0.002 (0.001)	-0.002 (0.001)	-0.002 * (0.001)	-0.002 * (0.001)	-0.002 * (0.001)	-0.002 (0.001)
Alliance Characteristics						
Upstream Alliances	0.449 ** (0.153)	0.463 ** (0.154)	0.521 *** (0.143)	0.508 *** (0.140)	0.520 *** (0.142)	0.440 ** (0.141)
Horizontal Alliances	0.653 *** (0.078)	0.660 *** (0.078)	0.648 *** (0.073)	0.668 *** (0.071)	0.662 *** (0.072)	0.668 *** (0.071)
Downstream Alliances	0.379 *** (0.053)	0.439 *** (0.061)	0.052 (0.064)	-0.035 (0.064)	0.032 (0.064)	-0.040 (0.064)
Network Characteristics						
Network Centrality (X 100)		0.013 (0.126)	-0.045 (0.117)	-0.130 (0.115)	-0.082 (0.117)	-0.102 (0.115)
Network Experience (log)		-0.329 * (0.164)	-0.412 ** (0.157)	-0.335 * (0.154)	-0.382 * (0.156)	-0.467 ** (0.154)
Product Development Strategies						
Exploration (<i>New Drug & New Disease</i>)			0.450 *** (0.062)	0.335 *** (0.063)	1.095 *** (0.173)	0.422 *** (0.061)
Exploitation (<i>Exist Drug & Exist Disease</i>)			1.443 *** (0.132)	0.422 * (0.192)	1.020 *** (0.169)	0.986 *** (0.144)
Interaction (<i>Explore * Exploit</i>)				0.163 (0.023)		
Imbalance (<i>Explore – Exploit</i>)					-0.684 *** (0.172)	
Recombination (<i>Exist/New Drug & New/Exist Disease</i>)						0.401 *** (0.057)
Constant	-2.019 *** (0.343)	-2.164 *** (0.387)	-1.759 *** (0.364)	-1.654 *** (0.356)	-1.589 *** (0.364)	-1.610 *** (0.357)
R-square	0.29	0.22	0.29	0.30	0.30	0.33
Firms	111	111	111	111	111	111
Cases	1187	1187	1187	1187	1187	1187

*p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

network characteristics restrict innovation. Since strategic alliances consume valuable resources, perhaps this finding reveals that past experience with alliance partners produces structural inertia that constrains current activities. Or, to the extent that network experience is a proxy for the number of total strategic alliance partners, these results may suggest that managing lots of strategic alliances diverts attention and resources away from clinical trials.

Product development strategies play a prominent role in predicting the success of products in clinical trials. Exploration and exploitation have positive and significant effects on the number of products in clinical trials. Each of the variables measuring ambidexterity has the expected effect, as surmised in Hypotheses 4a, 4b, and 4c. The hypothesized relationships suggest that the ambidexterity interaction and recombination have a positive effect on innovation success while ambidexterity interaction has a negative effect. Table 5-3 shows the interaction between exploration and exploitation is a positive predictor of products in clinical trials. An increase in the imbalance between exploration and exploitation negatively predicts products in trials. Taken together, these results suggest the need to engage in exploration and exploitation activities simultaneously, but firms need to find the right balance between them (i.e., avoid an imbalance between explore and exploit). The results show that recombination is positive and significantly associated with products in clinical trials. Recombination, therefore, is another type of ambidexterity and a product development strategy that deserves attention in future studies of ambidexterity and innovation.

Even though the dependent variable is lagged one year, there is likely to be a high degree of endogeneity between product development strategies and the number of products in clinical trials. There is likely to be a high degree of endogeneity because each product in clinical trials is comprised of a product development strategy. Consequently, it is not surprising that product development strategies predict product success at this particular innovation stage. But, it should be noted that organizational learning is an inherently endogenous process. Learning is dependent on and it involves building on past experience. Organizational learning processes are inherently path dependent because prior organizational structures embody rules and routines that affect future outcomes. The endogeneity of organizational learning does not diminish the statistical effects of learning strategies as long as there is variation in the types of learning strategies that are examined. The key is in demonstrating which different types of learning strategies are most effective.

Table 5-4 reports the results for products in clinical trials for large and small firms. For large firms, firm size is positively associated with clinical trials. Firm age has a nonlinear significant effect (inverted-U) on products in clinical trials and absorptive capacity has no significant effect. Upstream alliances have a positive effect, which confirms Hypothesis 2a, but the significant effect is limited to Models 1 and 3 and is not significant in Models 2 and 4 when controlling for particular measures of ambidextrous product development strategies. Horizontal alliances have a positive, significant effect across models. Exploratory and exploitative strategies have positive effects on clinical trials. Similar to the models for the full sample, the hypotheses pertaining to significant

Table 5-4. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Products in Clinical Trials by Firm Size

Variable	Large Firms Model 1	Large Firms Model 2	Large Firms Model 3	Large Firms Model 4	Small Firms Model 5	Small Firms Model 6	Small Firms Model 7	Small Firms Model 8
Firm Size (standardized)	1.020 ** (0.302)	0.954 ** (0.301)	0.995 ** (0.307)	0.980 ** (0.300)	-3.745 * (1.760)	-3.906 * (1.756)	-3.720 * (1.764)	-3.633 * (1.681)
Firm Characteristics								
Absorptive Capacity (log)	0.058 (0.201)	0.133 (0.197)	0.068 (0.200)	0.151 (0.196)	0.553 *** (0.148)	0.548 *** (0.148)	0.556 *** (0.149)	0.456 ** (0.142)
Firm Age	0.539 *** (0.084)	0.574 *** (0.082)	0.527 *** (0.084)	0.472 *** (0.082)	0.285 *** (0.042)	0.290 *** (0.042)	0.285 *** (0.042)	0.278 *** (0.040)
Firm Age ²	-0.005 *** (0.001)	-0.005 *** (0.001)	-0.005 *** (0.001)	-0.005 *** (0.001)				
Alliance Characteristics								
Upstream Alliances	0.353 * (0.175)	0.333 (0.171)	0.353 * (0.174)	0.186 (0.172)	0.774 ** (0.282)	0.744 ** (0.281)	0.768 ** (0.283)	0.985 *** (0.271)
Horizontal Alliances	0.630 *** (0.094)	0.663 *** (0.092)	0.650 *** (0.094)	0.664 *** (0.091)	0.215 (0.112)	0.195 (0.112)	0.214 (0.112)	0.224 * (0.107)
Downstream Alliances	0.099 (0.098)	-0.024 (0.098)	0.054 (0.099)	0.066 (0.095)	0.096 (0.063)	0.066 (0.064)	0.097 (0.063)	-0.053 (0.064)
Network Characteristics								
Network Centrality (X by 100)	-0.040 (0.146)	-0.149 (0.143)	-0.089 (0.146)	-0.157 (0.142)	-0.460 * (0.203)	-0.441 * (0.203)	-0.463 * (0.203)	-0.464 * (0.194)
Network Experience (log)	-0.283 (0.228)	-0.160 (0.223)	-0.229 (0.228)	-0.400 (0.222)	-0.673 *** (0.166)	-0.647 *** (0.166)	-0.673 *** (0.166)	-0.726 *** (0.158)
Product Development Strategies								
Exploration (New Drug & New Disease)	0.387 *** (0.097)	0.228 * (0.099)	1.187 *** (0.299)	0.346 *** (0.094)	0.350 *** (0.062)	0.336 *** (0.062)	0.293 (0.167)	0.315 *** (0.059)
Exploitation (Exist Drug & Exist Disease)	1.607 *** (0.178)	0.465 (0.263)	1.008 *** (0.276)	0.887 *** (0.206)	0.419 * (0.178)	0.093 (0.238)	0.432 * (0.182)	0.058 (0.179)
Interaction (Explore * Exploit)		0.172 *** (0.030)				0.075 * (0.036)		
Imbalance (Explore – Exploit)			-0.826 ** (0.292)				0.060 (0.164)	
Recombination (Exist/New Drug & New/Exist Disease)				0.562 *** (0.087)				0.364 *** (0.055)
Constant	-2.273 *** (0.623)	-2.304 *** (0.607)	-2.088 ** (0.623)	-1.997 ** (0.605)	0.328 (0.326)	0.369 (0.326)	0.322 (0.327)	0.544 (0.313)
R-square	0.21	0.21	0.23	0.28	0.16	0.16	0.16	0.20
Firms	55	55	55	55	56	56	56	56
Cases	685	685	685	685	502	502	502	502

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

effects for large and small firms. Similar significant effects include firm age (but not firm-age squared), horizontal alliances, exploration, exploitation, the ambidexterity interaction, and recombination. One of the differential effects includes firm size. For small firms, firm size is negatively associated with clinical trials. Also, unlike the models for large firms, absorptive capacity significantly and positively influences clinical trials for small firms. Neither of the alliance-partner characteristics is statistically significant. Both of the network-learning variables are negative and significant. Exploration has a positive, direct effect on clinical trials, but exploitation is not significant. Taken together, these results suggest that smaller firms are better at specializing in exploration. In contrast with the models for large firms, there is not a significant effect for firms with an imbalance between exploration and exploitation.

To summarize, the hypotheses associated with this stage of innovation (Hypotheses 2a, 4a, 4b, and 4c), products in clinical trials, have the expected effects. Hypothesis 2a – upstream alliances have a positive effect on clinical trials – is confirmed. The hypothesized effects of ambidextrous product development strategies (Hypotheses 4a, 4b, and 4c) are confirmed as well. Ambidexterity interaction and recombination have positive effects on products in clinical trials and ambidexterity imbalance has a negative effect.

The results demonstrate that firm characteristics are important predictors of products in clinical trials, but the results vary slightly by firm size. Although there is a positive effect for absorptive capacity for small firms, though there is no significant effect for large firms. What makes absorptive capacity critical for small firms? A tentative

answer is that small firms have less room for error and R&D expenditures enhance smaller firms' effectiveness in learning from the environment. Certainly, R&D is important for large firms, but for small firms in this sample, R&D expenditures provide a clear advantage. Upstream alliances and horizontal alliances are significant predictors for large firms while upstream alliances are significant for small firms. Lastly, product development strategies are important for both firms, but the effects are limited for small firms. Exploitation and ambidexterity imbalance have no effect for small firms.

Products on the Market

Results for regression models predicting products on the market are reported in Table 5-5. First, net of the effects for the other independent variables, there is positive effect for firm age. But, firm-age squared is not significant and, therefore, it is dropped from the models. Upstream alliances are statistically significant across models. Hypothesis 2b states that horizontal alliances are likely to be positively associated with the number of products on the market. Indeed, the coefficient for horizontal alliances is positive and significant. Downstream alliances have a positive effect on products on the market in all models except Model 4, controlling for ambidexterity interaction. One of the network characteristics variables, network centrality has a significant effect on products on the market. An increase in a firm's network centrality increases the likelihood of having products on the market.

Exploration has no significant effect on products on the market, except when controlling for ambidexterity imbalance. Exploitation has a positive and significant

Table 5-5. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Products on the Market (All Firms)

Variable	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Firm Size (standardized)	-0.117 (0.091)	0.014 (0.095)	0.077 (0.094)	0.031 (0.092)	0.064 (0.093)	0.086 (0.094)
Firm Characteristics						
Absorptive Capacity (log)	0.007 (0.056)	-0.047 (0.056)	-0.069 (0.056)	-0.057 (0.054)	-0.083 (0.055)	-0.067 (0.056)
Firm Age	0.110 *** (0.014)	0.115 *** (0.019)	0.103 *** (0.019)	0.113 *** (0.018)	0.103 *** (0.019)	0.100 *** (0.019)
Firm Age ²						
Alliance Characteristics						
Upstream Alliances	-0.197 ** (0.063)	-0.179 ** (0.063)	-0.155 * (0.062)	-0.160 ** (0.060)	-0.155 * (0.061)	-0.163 ** (0.062)
Horizontal Alliances	0.247 *** (0.032)	0.236 *** (0.032)	0.246 *** (0.031)	0.256 *** (0.030)	0.254 *** (0.031)	0.247 *** (0.031)
Downstream Alliances	0.148 *** (0.022)	0.140 *** (0.025)	0.076 ** (0.028)	0.036 (0.027)	0.065 * (0.027)	0.067 * (0.028)
Network Characteristics						
Network Centrality (X by 100)		0.256 *** (0.051)	0.250 *** (0.050)	0.212 *** (0.049)	0.231 *** (0.050)	0.244 *** (0.051)
Network Experience (log)		0.038 (0.067)	0.083 (0.068)	0.119 (0.066)	0.100 (0.067)	0.078 (0.068)
Product Development Strategies						
Exploration (<i>New Drug & New Disease</i>)			-0.005 (0.027)	-0.052 (0.027)	0.339 *** (0.075)	-0.007 (0.027)
Exploitation (<i>Exist Drug & Exist Disease</i>)			0.366 *** (0.057)	-0.099 (0.083)	0.140 (0.073)	0.324 *** (0.064)
Interaction (<i>Explore * Exploit</i>)				0.074 *** (0.010)		
Imbalance (<i>Explore – Exploit</i>)					-0.364 *** (0.074)	
Recombination (<i>Exist/New Drug & New/Exist Disease</i>)						0.037 (0.025)
Constant	-0.733 *** (0.139)	-1.053 *** (0.154)	-0.925 *** (0.153)	-0.885 *** (0.149)	-0.843 *** (0.152)	-0.908 *** (0.153)
R-square	0.14	0.12	0.15	0.16	0.16	0.15
Firms	111	111	111	111	111	111
Cases	1187	1187	1187	1187	1187	1187

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

direct effect (Models 3 and 6). Two out of the three ambidexterity measures are statistically significant, confirming two out of the three related hypotheses. The ambidexterity interaction term has a positive effect on products on the market (confirms Hypothesis 4a). Ambidexterity imbalance is negatively associated with products on the market (confirms Hypothesis 4b). Recombination has no statistically significant effect (disconfirms Hypothesis 4c).

Results for the split sample are reported for products on the market in Table 5-6. For large firms, firm age and absorptive capacity are statistically significant firm-level variables. Similar to previous models for the entire sample (Table 5-5) there is not a nonlinear effect for firm age. There are negative effects for upstream alliances, but positive effects for horizontal and downstream alliances across models. The positive effects of horizontal and downstream alliances are consistent with the results for the full sample and confirm existing research. Similar to the sample with all firms, network centrality is a positive predictor of products on the market.

With respect to product development strategies, there is a positive effect for exploitation for products on the market. The ambidexterity interaction and recombination are statistically significant and positive predictors as well, confirming hypotheses 4a and 4c. The effect for imbalance is negative. The coefficient for the ambidexterity imbalance variable has the expected effect as well (Hypothesis 4b).

For small firms, firm age positively predicts products on the market (Table 5-6). There is a negative effect for absorptive capacity. These results are consistent with the results for large firms and for the entire sample. There is no significant effect for alliance

Table 5-6. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Products on the Market by Firm Size

Variable	Large Firms Model 1	Large Firms Model 2	Large Firms Model 3	Large Firms Model 4	Small Firms Model 5	Small Firms Model 6	Small Firms Model 7	Small Firms Model 8
Firm Size (standardized)	-0.075 (0.113)	-0.117 (0.110)	-0.085 (0.112)	-0.066 (0.111)	5.004 (7.735)	4.600 (7.742)	4.809 (7.748)	4.962 (7.737)
Firm Characteristics								
Absorptive Capacity (log)	-0.190 * (0.083)	-0.153 (0.081)	-0.186 * (0.082)	-0.169 * (0.082)	-0.125 ** (0.044)	-0.127 ** (0.045)	-0.126 ** (0.045)	-0.119 ** (0.045)
Firm Age	0.146 *** (0.029)	0.156 *** (0.028)	0.141 *** (0.029)	0.132 *** (0.029)	0.092 *** (0.013)	0.093 *** (0.013)	0.092 *** (0.013)	0.092 *** (0.013)
Alliance Characteristics								
Upstream Alliances	-0.228 ** (0.076)	-0.235 ** (0.074)	-0.228 ** (0.075)	-0.283 *** (0.075)	-0.002 (0.084)	-0.007 (0.084)	0.001 (0.084)	-0.013 (0.084)
Horizontal Alliances	0.269 *** (0.040)	0.284 *** (0.039)	0.277 *** (0.040)	0.277 *** (0.040)	-0.037 (0.033)	-0.040 (0.033)	-0.036 (0.033)	-0.037 (0.033)
Downstream Alliances	0.184 *** (0.043)	0.131 ** (0.043)	0.166 *** (0.043)	0.173 *** (0.042)	0.034 (0.020)	0.031 (0.020)	0.034 (0.020)	0.039 (0.021)
Network Characteristics								
Network Centrality (X by 100)	0.288 *** (0.063)	0.243 *** (0.062)	0.268 *** (0.063)	0.248 *** (0.062)	0.592 *** (0.163)	0.587 *** (0.163)	0.595 *** (0.163)	0.595 *** (0.163)
Network Centrality ²					-0.287 *** (0.057)	-0.283 *** (0.057)	-0.287 *** (0.057)	-0.287 *** (0.057)
Network Experience (log)	0.095 (0.099)	0.148 (0.097)	0.116 (0.099)	0.057 (0.098)	0.220 (0.068)	0.236 (0.070)	0.224 (0.068)	0.211 (0.069)
Network Experience ²					-0.047 ** (0.014)	-0.050 *** (0.014)	-0.048 ** (0.014)	-0.044 ** (0.014)
Product Development Strategies								
Exploration (New Drug & New Disease)	-0.022 (0.042)	-0.089 * (0.043)	0.290 * (0.130)	-0.037 (0.041)	-0.073 *** (0.019)	-0.076 *** (0.019)	-0.046 (0.050)	-0.070 *** (0.019)
Exploitation (Exist Drug & Exist Disease)	0.394 *** (0.077)	-0.093 (0.114)	0.161 (0.120)	0.168 (0.090)	-0.112 * (0.055)	-0.162 * (0.071)	-0.117 * (0.055)	-0.100 (0.056)
Interaction (Explore * Exploit)		0.073 *** (0.013)				0.012 (0.011)		
Imbalance (Explore – Exploit)			-0.322 * (0.127)				-0.029 (0.049)	
Recombination (Exist/New Drug & New/Exist Disease)				0.178 *** (0.038)				-0.016 (0.018)
Constant	-1.217 *** (0.263)	-1.242 *** (0.257)	-1.144 *** (0.263)	-1.110 *** (0.260)	1.304 (2.124)	1.201 (2.125)	1.252 (2.127)	1.285 (2.124)
R-square	0.11	0.12	0.12	0.14	0.16	0.16	0.16	0.16
Firms	55	55	55	55	56	56	56	56
Cases	685	685	685	685	502	502	502	502

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

characteristics. For small firms, both of the network-learning variables have nonlinear effects. Network centrality has a nonlinear effect (inverted-U) on products on the market. Thus, advantages of centrality accrue for small firms, but only up to a point. At that point, products on the market decline.

There are differential effects for product development strategies among large and small firms. For small firms, there are significant, but negative effects, for exploration and exploitation product development strategies. Each of the ambidexterity measures is non-significant.

Overall, the significant results predicting products on the market provide a profile for success at this stage of innovation, which, for large firms, is generally consistent with the hypotheses. According to Hypothesis 2b, horizontal alliance increase products on the market. This hypothesis is supported for large firms but not small firms. Each of the ambidexterity measures is statistically significant at this stage, providing support for the hypotheses associated with the positive effects of ambidexterity interaction (Hypothesis 4a) and recombination (Hypothesis 4c), the negative effect of ambidexterity imbalance (Hypothesis 4b).

For large firms, learning from horizontal and downstream alliance partners and exploitation product development strategies increases propensity for products on the market. For small firms, the primary positive predictors include network characteristics, providing robust evidence for Hypotheses 3a and 3b. Yet, network integration and lots of network experience comes with a price for small firms. Small firms should avoid excessive network integration, which may inhibit success by encouraging firms to hinder

the flow of critical information about the environment (Uzzi 1997). With respect to product development strategies, the picture is bleak, but not unexpected, and includes suggestions about what to avoid for small firms. Exploration decreases success for small firms. The likely reason is that innovation is difficult and requires slack resources, which are more likely to be deficient in smaller firms.

Sales Growth

I estimate regression models predicting sales growth, the final stage of innovation in my analysis. A limited number of variables are statistically significant compared with results from previous stages. Two firm characteristics have significant effects.

Absorptive capacity has a positive effect on sales growth, net other effects. Firm age has a negative effect. This result indicates that older firms have less innovation success, as measured by sales growth. The negative effect of firm age is surprising, but suggests that structural inertia constrains success at the final stage of innovation, for firms in this sample. The coefficient for firm-age squared is positive across models. Though marginally significant ($p < .10$) in Models 1 through 5, firm-age squared is significant at $p < .05$ in Model 6 only.

The variables that measure alliance characteristics are not significant, except for downstream alliances in Models 3 through 6. The positive, significant effect of downstream alliances follows the logic put forth by Rothaermel and Deeds (2004) that alliances between firms with complementary assets increase the likelihood of innovation success. Accordingly, strategic alliances that assist focal firms with manufacturing,

Table 5-7. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Firm Sales Growth (All Firms)

Variable	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Firm Size (standardized)	-0.717 (0.697)	-0.885 (0.713)	-1.085 (0.722)	-1.127 (0.722)	-1.084 (0.721)	-1.055 (0.721)
Firm Characteristics						
Absorptive Capacity (log)	0.844 * (0.360)	0.877 * (0.366)	0.941 * (0.366)	0.952 ** (0.366)	0.907 * (0.367)	0.961 ** (0.366)
Firm Age	-0.440 *** (0.117)	-0.370 * (0.145)	-0.352 * (0.145)	-0.336 * (0.145)	-0.346 * (0.145)	-0.384 ** (0.146)
Firm Age ²	0.005 (0.003)	0.005 (0.003)	0.005 (0.003)	0.005 (0.003)	0.005 (0.003)	0.006 * (0.003)
Alliance Characteristics						
Upstream Alliances	0.012 (0.398)	0.005 (0.399)	-0.049 (0.399)	-0.056 (0.399)	-0.049 (0.399)	-0.116 (0.400)
Horizontal Alliances	0.258 (0.202)	0.274 (0.203)	0.257 (0.203)	0.268 (0.203)	0.272 (0.203)	0.273 (0.203)
Downstream Alliances	0.235 (0.137)	0.304 (0.157)	0.465 ** (0.178)	0.418 * (0.181)	0.444 * (0.179)	0.389 * (0.182)
Network Characteristics						
Network Centrality (X by 100)		-0.258 (0.328)	-0.237 (0.327)	-0.283 (0.329)	-0.277 (0.328)	-0.284 (0.328)
Network Experience (log)		-0.379 (0.427)	-0.476 (0.438)	-0.434 (0.439)	-0.444 (0.438)	-0.522 (0.438)
Product Development Strategies						
Exploration (<i>New Drug & New Disease</i>)			-0.004 (0.173)	-0.062 (0.178)	0.691 (0.485)	-0.028 (0.174)
Exploitation (<i>Exist Drug & Exist Disease</i>)			-0.883 * (0.367)	-1.444 ** (0.546)	-1.340 ** (0.472)	-1.265 ** (0.410)
Interaction (<i>Explore * Exploit</i>)				0.089 (0.065)		
Imbalance (<i>Explore – Exploit</i>)					-0.737 (0.481)	
Recombination (<i>Exist/New Drug & New/Exist Disease</i>)						0.335 * (0.162)
Constant	-1.571 (0.891)	-1.364 (1.005)	-1.700 (1.014)	-1.643 (1.015)	-1.518 (1.021)	-1.576 (1.014)
R-square	0.00	0.00	0.01	0.01	0.01	0.01
Firms	111	111	111	111	111	111
Cases	1187	1187	1187	1187	1187	1187

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

marketing, and sales activities are likely to help firms distribute their products to customers. Although Rothaermel and Deeds (2004) do not examine sales growth or downstream alliances, the effect of downstream alliance is consistent with and is an application of their complementarity argument to a subsequent stage of innovation.

Hypotheses 3a and 3b suggest there is a positive relationship between network centrality and network experience, respectively, and sales growth. Results from the analysis in Table 5-7 do not support these hypotheses. Results show the relationship between network characteristics and sales growth is not significant. However, a post-hoc analysis (results not shown) shows that network experience measured as the total number of strategic alliances per year has a positive and statistically significant effect on firm sales. This effect is robust across models (controlling for product development strategies). The positive effect of total alliances provides partial support for my general proposition that increasing the scope of learning is associated with success across the innovation stages.

Product development strategies have limited significant effects on sales growth. Exploitation has a negative, significant effect while recombination has a positive effect. Ambidexterity interaction and imbalance have no statistically significant effect. The results for the ambidexterity measures provided limited support for the ambidexterity hypotheses (Hypotheses 4a, 4b, and 4c) suggesting that product development strategies have limited influence. At this, the final, stage of innovation recombination is the most useful ambidexterity product development strategy.

The effects of firm, alliance, network, and product characteristics are presented

Table 5-8. Unstandardized Coefficients for Fixed-Effects Regression Models Predicting Firm Sales Growth by Firm Size

Variable	Large Firms Model 1	Large Firms Model 2	Large Firms Model 3	Large Firms Model 4	Small Firms Model 5	Small Firms Model 6	Small Firms Model 7	Small Firms Model 8
Firm Size (standardized)	-0.233 (0.250)	-0.308 (0.247)	-0.296 (0.238)	-0.232 (0.250)	10.232 (11.537)	10.188 (11.562)	10.250 (11.561)	10.386 (11.498)
Firm Characteristics								
Absorptive Capacity (log)	0.202 (0.183)	0.268 (0.181)	0.227 (0.174)	0.204 (0.184)	1.651 (0.973)	1.650 (0.974)	1.653 (0.975)	1.458 (0.974)
Firm Age	-0.041 (0.064)	-0.023 (0.063)	-0.072 (0.061)	0.043 (0.064)	-0.675 * (0.285)	-0.673 * (0.286)	-0.675 * (0.285)	-0.698 * (0.284)
Alliance Characteristics								
Upstream Alliances	-0.070 (0.168)	-0.083 (0.165)	-0.070 (0.160)	-0.076 (0.170)	1.176 (1.846)	1.168 (1.851)	1.172 (1.851)	1.624 (1.854)
Horizontal Alliances	0.075 (0.089)	0.102 (0.088)	0.127 (0.085)	0.076 (0.089)	0.550 (0.732)	0.544 (0.735)	0.549 (0.733)	0.564 (0.729)
Downstream Alliances	0.256 ** (0.094)	0.162 (0.095)	0.137 (0.091)	0.255 ** (0.094)	0.824 * (0.413)	0.816 (0.425)	0.824 * (0.414)	0.519 (0.439)
Network Characteristics								
Network Centrality (X by 100)	-0.078 (0.139)	-0.159 (0.138)	-0.209 (0.133)	-0.083 (0.140)	11.819 ** (3.503)	11.825 ** (3.508)	11.811 ** (3.513)	12.115 ** (3.494)
Network Centrality ²					-4.967 *** (1.231)	-4.967 *** (1.232)	-4.965 *** (1.234)	-5.082 *** (1.228)
Network Experience (log)	-0.166 (0.219)	-0.071 (0.217)	-0.024 (0.209)	-0.170 (0.220)	-0.560 (1.108)	-0.553 (1.113)	-0.560 (1.109)	-0.648 (1.105)
Product Development Strategies								
Exploration (New Drug & New Disease)	0.014 (0.093)	-0.105 (0.095)	2.127 *** (0.275)	0.013 (0.093)	-0.126 (0.407)	-0.130 (0.410)	-0.164 (1.095)	-0.203 (0.408)
Exploitation (Exist Drug & Exist Disease)	-0.954 *** (0.171)	-1.824 *** (0.255)	-2.536 *** (0.253)	-0.978 *** (0.203)	0.229 (1.164)	-0.140 (1.561)	0.237 (0.188)	-0.516 (1.219)
Interaction (Explore * Exploit)		0.131 *** (0.029)				0.020 (0.239)		
Imbalance (Explore – Exploit)			-2.182 *** (0.268)				0.040 (1.075)	
Recombination (Exist/New Drug & New/Exist Disease)				0.018 (0.087)				0.754 * (0.377)
Constant	-0.157 (0.582)	-0.201 (0.573)	0.336 (0.557)	-0.145 (0.585)	-8.790 ** (2.549)	-8.779 ** (2.555)	-8.790 ** (2.552)	-8.472 ** (2.545)
R-square	0.01	0.03	0.03	0.01	0.03	0.03	0.03	0.04
Firms	55	55	55	55	56	56	56	56
Cases	685	685	685	685	502	502	502	502

* p < .05, ** p < .01, *** p < .001 (two-tailed tests) (standard errors)

for large and small firms in Table 5-7. The effect of firm age is negative and significant for small firms. This effect provides additional insight into the result found in the sample for all firms in the sample (Table 5-6). That is, the negative effect of firm age in the models for the entire sample is specific to small firms. Smaller, older firms are more likely to experience negative sales growth.

Several alliance and network measures have significant effects on sales growth. For both large and small firms, downstream alliances positively, significantly predict sales growth. Although the results for downstream alliances are not robust across all models, the positive effect in Model 1 (large firms) and Model 5 (small firms) provides evidence for the complementarity explanation of innovation success in biotechnology firms proffered by Rothaermel and Deeds (2004). Network centrality has a significant curvilinear effect on sales growth for small firms. This effect provides support for Hypothesis 3a that centrality increases sales growth, though Hypothesis 3a should be modified to include curvilinear effects for small firms in future research. In additional analysis (not shown) another measure of network experience, measured as the total number of network alliances, has a positive and significant effect on sales growth for small firms.

Each ambidexterity hypothesis is statistically significant, but the results vary by firm size. The ambidexterity interaction (Hypothesis 4a) is significant for large firms, the ambidexterity imbalance (Hypothesis 4b) is negative for large firms, and recombination (Hypothesis 4c) is positive for small firms. The results for the ambidexterity measures suggest that large and small firms both pursue ambidexterity strategies, but different

types of strategies. Large firms increase the likelihood of sales growth when they simultaneously pursue and balance exploration and exploitation activities and on average small firms increase sales growth to the extent that they recombine existing knowledge and new opportunities.

To summarize, regression models predicting sales growth supply evidence for the broad proposition that the scope of learning increases success at this innovation stage, but the evidence is largely limited to small firms. For small firms, network centrality and network experience (measured as the total number of alliances) influence sales growth. Ambidexterity is also a key predictor for firms at this innovation stage, but the effects differ for large and small firms. Accordingly to the results reported in Table 5-8, the largest firms are better equipped to simultaneously pursue exploration and exploitation activities, while smaller firms should leverage existing knowledge in new ways.

Summary Tables

Tables 5-9 and 5-10 provide an overview of the positive and negative significant effects ($p < 0.05$) for the independent variables across the various stages of innovation. Table 5-9 summarizes results for the entire sample and Table 5-10 includes significant results for the split sample: large firms and small firms. In Table 5-9, the results reported for firm, alliance, and network characteristics come from Model 3 for each stages of innovation. The results for each product development strategy come from several models. The exploration and exploitation effects come from Model 3 while the ambidexterity effects come from Models 4 through 6. Several effects are included in

parentheses (for downstream alliances and network experience) in Table 5-9 and 5-10. In both tables, the effects of the ambidexterity interaction are reported in parentheses for patents to illustrate the nonlinear effects that come from additional analyses not shown. As well, in both tables the results of post-hoc analyses are included that show the significant effects of network experience, measured as total alliances, on sales growth.

Table 5-9 provides broad support for the notion that the scope of organizational learning is associated with success across stages of innovation as outlined in Chapter 2, but not without exceptions. Accordingly, each firm characteristic is statistically significant and has the expected effects for patents granted, and they are statistically significant predictors of products in clinical trials. Firm age has consistent effects for patents, clinical trials, and products on the market. But, Hypothesis 1a and 1b, developed in Chapter 2, are that firm characteristics are most relevant for early stages of invention. According to the analysis, these hypotheses can be expanded to product development since many of the effects hold for clinical trials. The effects, however, are limited in the latter stages of innovation.

Alliance-partner characteristics have the hypothesized effects and support the notion of the increasing scope of learning across innovation stages. Hypothesis 2a puts forth a positive relationship between upstream alliances and products in clinical trials and Hypothesis 2b states that there is a positive relationship between horizontal alliances and products on the market. The effects of upstream alliances are positive for the early stages of innovation (patents and clinical trials). Horizontal alliances positively predict products

on the market (and clinical trials). Additionally, downstream alliances are positive and significant in the latter stages of innovation.

Table 5-9. Summary Table for Significant Coefficients (All Firms) ($p < .05$, two-tailed tests)				
Variable	Patents	Clinical Trials	Market	Sales
Firm Size		+		
Firm Characteristics				
Absorptive Capacity	+	+		+
Firm Age	+	+	+	-
Firm Age ²	-	-		
Alliance Characteristics				
Upstream Alliances	+	+	-	
Horizontal Alliances		+	+	
Downstream Alliances			+	+
Network Characteristics				
Network Centrality			+	
Network Experience (Years of Experience)		-		
Network Experience (Total Alliances)				(+)
Product Development Strategy				
Exploration	+	+		
Exploitation	+	+	+	-
Interaction	(+ / -)	+	+	
Imbalance		-	-	
Recombination		+		+

Network effects provide partial support for Hypotheses 3a and 3b. Hypothesis 3a states that network centrality is likely to increase product success. Hypothesis 3b states that network experience is likely to increase product success. Although network experience is not significant for product success (i.e., firm sales) for the entire sample, network experience (i.e., total alliances) has a positive effect and is associated with increasing sales growth. Literature on strategic alliances argues that managing alliances is a firm capability (e.g., Rothaermel and Deeds 2006) that is becoming central to many

business activities. Results from this study underscore the importance of managing the entire network as well.

The effects of exploration are positive for the earliest stage of innovation. The effects of exploitation are positive for each stage, except for the final stage. The statistically significant ambidexterity product development strategies differ by stage of innovation, but the significant effects have the anticipated effects with one exception (the nonlinear effect of ambidexterity interaction on patents granted). The ambidexterity interaction has a positive (or nonlinear) effect on patents granted, clinical trials, and products on the market (Hypothesis 4a). The ambidexterity imbalance has a negative effect on clinical trials and products on the market (Hypothesis 4b). Recombination has a positive effect for clinical trials and sales growth (Hypothesis 4c). These results suggest that the most consistent way to increase success at the across the stages of innovation is to combine exploratory and exploitative product strategies (simultaneously pursue or recombine elements of both).

Overall, the results reported in Table 5-10 lend further support to the hypotheses associated with learning scope and the stages of innovation (Hypotheses 1a, 1b, 2a, 2b, 3a, and 3c). One of the most consistent effects across innovation stages includes firm age, which is positive and significant for large and small firms at the early stages of innovation (Hypothesis 1b). Upstream alliances have positive effects for large firms in the early stages of innovation and for clinical trials for large and small firms (Hypothesis 2a). Increasing horizontal alliances is influences the middle stages of innovation – clinical trials (Hypothesis 2b) and products on the market – for large firms. These results

for large firms' alliance characteristics are consistent with conventional wisdom regarding existing business models in the biotechnology industry. Firms should engage in upstream alliances to increase product success at the early stages of innovation. Then, firms should find horizontal (and downstream) partnerships and pool resources to increase product success at the latter stages. Network characteristics are important for small firms at the final stage of innovation: centrality is a positive predictor in the final stage for small firms (Hypothesis 3a), but the effects are nonlinear, and network experience (Hypothesis 3b) is a positive predictor as well for small firms.

Table 5-10. Summary table for Significant Coefficients by Firm Size (p < .05, two-tailed tests)								
Variable	Patents		Clinical Trials		Market		Sales	
	Large	Small	Large	Small	Large	Small	Large	Small
Firm Size			+	-				
Firm Characteristics								
Absorptive Capacity	+			+	-	-		
Firm Age	+	+	+	+	+	+		-
Firm Age ²	-		-					
Alliance Characteristics								
Upstream Alliances	+		+	+	-			
Horizontal Alliances	-		+		+			
Downstream Alliances					+		+	+
Network Characteristics								
Network Centrality				-	+	+		+
Network Centrality ²						-		-
Network Experience (Years of Experience)				-		+		
Network Experience ² (Years of Experience)						-		
Network Experience (Total Alliances)								(+)
Product Development Strategy								
Exploration	+	+	+	+		-		
Exploitation	+	+	+	+	+	-	-	
Interaction	(+/-)		+	+	+		+	
Imbalance			-		-		-	
Recombination	NA	NA	+	+	+			+

Large firms that pursue exploration and exploitation simultaneously tend to be more successful across the stages of innovation (Hypothesis 4a), but for small firms it is only significantly associated with products in clinical trials. This effect for the ambidexterity interaction by firm size is not surprising. Smaller firms are much more likely to have a difficult time engaging in both exploration and exploitation because simultaneously pursuing both activities requires qualitatively different capabilities, and small firms possess limited resources to pursue such diverse activities. An imbalance between exploration and exploitation is negative and significant for large firms at three stages of innovation: clinical trials, products on the market, and sales growth. Recombination is significant for most of the models, aside from products on the market for small firms and sales growth for large firms.

Although differential effects exist for large and small firms, a few key themes emerge from Tables 5-9 and 5-10. First, the positive effects of firm characteristics are more pronounced at the earlier stages of innovation. Second, the type of alliance partners matter; but they matter for large firms in the sample, on average. Upstream alliances are significant predictors of success in the early stages and horizontal alliances are significant for products on the market for large firms. Third, network characteristics have positive effects – including nonlinear effects – in the latest stage for small firms. Fourth, product development strategies matter beyond the effects for strategic alliances underscored by extant research on innovation in the biotechnology industry. Exploration strategies are more likely to lead to innovation success in the early stages while exploitation predicts success until the final stage for large and small firms (and products on the market for

small firms). Finally, integrating elements of exploration and exploitation is a successful product development strategy across the stages of innovation.

Interviews

Results from interviews supplement, and more importantly contextualize, the quantitative analyses reported above. The interviews provide a deeper understanding of the challenges of innovation endemic to the biotechnology industry. As well, informants discuss many of the criteria used to evaluate drugs at the various stages of innovation. I should note that informants' comments about stages of innovation are limited primarily to patenting and drug development – including clinical trials and commercialization – since those I interviewed are from relatively smaller biotechnology firms that primarily engage in these activities (compared with large pharmaceutical companies).

Although informants mention the importance of strategic alliances, the need for strategic alliances is a taken-for-granted aspect of the business of biotechnology product development, especially for small firms. Informants assume strategic alliances are necessary for carrying out phase III clinical trials (which require the recruitment and involvement human participants on a large scale), manufacturing, and sales, in particular; all activities that are well beyond the capacity of small biotechnology firms. Since informants take the utility of strategic alliances as given and since most of the informants I spoke with have little interaction with alliance partners, in the interviews the informants spent little time discussing strategic alliances or the role of alliances in the innovation process. Thus, the hypotheses associated with strategic alliances and the stages of

innovation (the hypotheses that specify the relationship between upstream alliances and clinical trials is Hypothesis 2a, horizontal alliances and products on the market is Hypothesis 2b, and network characteristics and product success are Hypothesis 3a, and Hypothesis 3b) are avoided in informants' explanations of the decision-making criteria used to evaluate product success at the various stages of innovation. Instead of emphasizing the role of strategic alliance in product discovery, development, and success, informants discuss scientific criteria as well as criteria from subsequent stages of innovation. For example, when making decisions about which molecule among several in discovery to pursue in clinical trials, all things being equal, one molecule is pursued over another if the firm already has the experience manufacturing a similar molecule.

The interviews also provide additional insight into how firms operate ambidextrously. Each informant indicated their firms pursue new drugs that build on experience with existing drugs or medical conditions. Several of the informants I interviewed indicated that their firms operate in narrow market segments to take advantage of existing competencies. But, informants identified additional ways that their firms act ambidextrously, which are discussed below in more detail.

Patenting

Firms identify different reasons for patenting their drugs and their reasons appear to vary by firm size. For executives from the smaller firms I interviewed, patenting activities are limited in scope and scale. A Vice President at one of the smaller firms I interviewed stated that their patents are limited to those issued to their co-founder and

when they decide to pursue a new product, it draws from patents developed by the co-founder. I searched the USPTO online patent search engine (<http://patft.uspto.gov/netahtml/PTO/search-bool.html>) and I found one patent granted to this firm and 21 patents granted to its parent company. The inventor listed on each patent was the co-founder of the firm. The CEO of another small firm also stated that their scope of patenting activities is limited. They decide to patent a compound "...if it builds on a core competency."

An executive of the largest company I interviewed stated that the reason they patent compounds is to protect their intellectual property. However, there are exceptions. This executive made the distinction between protecting intellectual property through patenting and protecting "company proprietary information" internally. There is some information that the company deems proprietary and wants to keep confidential. If the company is uncertain whether another company is using the same formula, they are likely to protect the technology internally. Otherwise, patenting proprietary information would release that information to competitors, thereby ruining the firm's competitive advantage.

The rationale to pursue patents that exploit existing competencies in smaller firm is limited resources to pursue a wide range of activities. Firms do not have the funding to pursue radically different chemical compounds, especially given the recent economic downturn in which funding for discovery activities has virtually disappeared. Alternatively, one of the largest firms in my sample is less constrained by resources and expertise and the primary criterion was for deciding whether to patent was propriety information.

These results for large and small firms, based on interviews with a limited number of firms, suggest a scope condition for the positive effects of the interaction between exploration and exploitation on success as stated in Hypothesis 4a. The scope condition is that pursuing both exploration and exploitation is more difficult for small firms due to fewer resources to pursue a wide range of innovation activities. Additional support for this scope condition is provided by March (1991), who contends that pursuing exploration and exploitation simultaneously, and the quantitative analysis in this study. As reported above in the regression model for large and small firms predicting patenting (Table 5-2), the interaction between exploration and exploitation is significantly associated with patenting in large firms, but not in small firms. Regression models also show that for large firms the ambidexterity interaction is a statistically significant predictor at each innovation stage. For small firms, the ambidexterity interaction is a statistically significant predictor at one innovation stage, products in clinical trials (Table 5-10).

Drug Development (Clinical Trials and Commercialization)

Biotechnology firms face myriad impediments to product development. But, the broad principles guiding decisions about whether to pursue a product are market potential and unmet medical needs. According to the CEO of one small company in my sample, the decision about which products to develop is straightforward. When deciding which products to develop, firms “[l]ook for unmet medical needs. How do you fit into the market place? How does your drug fit into the panoply of drugs? Figure out whether the

product fits a niche; what we are doing is different and complementary. It's pretty straightforward." The decision is clear-cut because the drug development process is expensive and the difference between firm success and failure can hinge on the success of one product, especially for small companies.

An executive in a larger company succinctly put their criteria for evaluating whether to pursue a product. She stated that the criteria are "the size of the market of a potential drug" and "the unmet medical need." These criteria are revisited by the firm constantly throughout each stage of innovation when evaluating a particular drug and deciding among alternative candidate chemical compounds. Still, market considerations are not the only criteria. Safety is another consideration. The same executive continues, "And then once you've gotten over, it's the market and an unmet medical need; then it's a matter of, you've got the product that is going to be safe and efficacious in the clinic."

Of course, the science behind the drug is the critical factor for deciding whether a drug is safe and efficacious in clinic trials. There are many scientific criteria for evaluating a drug's effectiveness and safety. Whether a drug is infused slowly or rapidly into the blood stream can determine its effectiveness. Other considerations are the dosage of the drug, whether infusion of a drug leads to necrosis (i.e., kills living tissues or leads to infection as it enters the body), the drug's rate of absorption into the blood stream, unanticipated side effects, and harmful interactions with other drugs. Difficulties with respect to conducting clinical trials identified by a CEO I interviewed include complying with regulatory agencies, especially when compliance procedures vary by country; recruiting patients; selecting cities for trials; public perception of trials and

drugs; and securing funding from investors who perceive biotechnology as a risky business.

Besides market expectations and scientific criteria that influence decisions about whether to pursue drugs, there are tremendous path-dependent forces that influence the product development process. Path dependence is to the notion that "...what happened at an earlier point in time will affect the possible outcomes of a sequence of events occurring at a later point in time" (Sewell 1996:262-263). Path dependence occurs in biotechnology because the procedures followed in drug development process are stipulated by the regulatory environment, which is prescribed by the FDA. If a drug fails to meet the prescribed standards of safety or yields an expected outcome, clinical trials are discontinued. The decision to stop pursuing a drug in clinical trials due to drug ineffectiveness can be difficult. The decision can be difficult because of the amount of time and resources invested in R&D and clinical trials up to that point in time. The costs associated with clinical trials, combined with stringent FDA regulations, generate extraordinary path-dependent forces. As one executive explains,

Once you get locked in by the FDA, once you go to trials, you can make some tweaks but the core product cannot change.... You are locked in. That's why you have to make wise decisions. You can't afford to pursue unsuccessful clinical trials. I have seen companies pursue drugs that they know will fail because they are locked in and they just hope for the best; hope something good happens.

Even though the decision to terminate a product can be difficult, everyone I interviewed agreed that it is best to terminate a drug that is producing poor results. According to the informants, the decision to discontinue unsuccessful clinical trials was easier for larger firms. Large firms have more resources and larger product portfolios to

help overcome mistakes. A Vice President at a smaller-sized firm points out that it is better to stop pursuing an ineffective drug, because it can lead to additional costs down the road. Either the FDA will not approve the drug or, if the drug gets approved but has harmful side effects, it may have to be recalled in the future, costing the firm millions of dollars. “At some point you have to come up with a rational decision and say, ‘I’ve spent 50 million dollars already, it’s going to cost me \$300 million more to fix the problem and in the end it’s going to take me an awful long time to recoup that cost.’ It’s just not worth it to do that.” This Vice President indicates that it is best to make the “go, no-go decision” early in the process to reduce potential costs. Although he unequivocally supports ending ineffective clinical trials, he discusses the decision in terms of financial cost. His discussion includes hypothetical dollar amounts and the decision-making criteria include a drug’s ‘cost’ and ‘worth.’

Larger firms have more resources to absorb the costs of failure compared with small firms. When I asked an executive of a large firm about the “go, no-go decision” mentioned above, she acknowledged that the cost might be part of the rationale for small firms, but she provided a different perspective on failed drugs. She highlighted the importance learning from mistakes and moving on to other products.

Our decisions [about whether to discontinue pursuit of a drug] are always science and data based and not driven by emotion or desire or ‘it’s got to work, it’s got to work!’ [I]f your molecule is pretty toxic or the biological activity isn’t what you thought it would be, you have to cut your losses. But, behind [the failed drug] there are a whole lot of other promising molecules.... Cutting of the losses doesn’t mean you always stop and put things away. It could be an opportunity to out-license. It could be that there’s a backup molecule that we’ll then move forward; or, there’s a different approach on that disease area. So it’s not as

though everything is lost, and we always learn something from the failures, as much as you learn from the successes.

The overarching theme of the comments from this executive, and a broad aim of the company's product development activities, is scientific progress, separate from minimizing costs or failures. She expressed confidence in her company's drug portfolio and the potential of alternatives that are waiting to be developed. She also suggested that a less effective drug might be usefully pursued by another company. She seemed to privileged good science, and learning from mistakes, over costs and short-term profit. This approach to dealing with failure, which may very well contribute to the long-term financial success of the company, can only be afforded by firms with sufficient financial resources in the first place. Although the emphasis of science over cost and emotion could be viewed as a socially desirable response to an interview question, and certainly the bottom line has to be considered a primary criterion for decisions about drug development, this executive additionally seemed to value science and positive contributions to society as decision-making criteria.

Several of the informants I interviewed affirmed that the boundaries between each stage are relatively arbitrary and permeable. One Vice President mentions that her firm is constantly thinking ahead in the innovation process as well as providing feedback to those at earlier stages.

The lines between discovery, product development, and commercialization are dividing lines that are pretty gray because the later stages of activities are taking what they've learned and sending that information back to the early stages of discovery and development including what's important in the market or a patient population in any particular therapeutic area we're working on. And then each

group is also reaching back to know what's coming so that when it gets there, you're ready for it and you're not thinking about it now for the first time.

This same Vice President provides further detail into how her firm uses criteria from future stages to influence innovation at early stages. She says that if her company is considering a number of different antibodies for development, they will select the ones with the best properties. All things being equal, out of those antibodies with the best properties, the development department will evaluate potential drug candidates according to the firm's ability to manufacture them, put them into a stable form, and whether the drug has to be delivered in a particular way for a target population.

The Vice President of another company also comments how criteria for success at a later stage influence products at an earlier stage. He oversees development at his company and describes how the marketing team influences the clinical development program.

Now the marketing team is going to tell me, I can sell your product if you give me these answers. Or, my drug is going to compete with another drug that's possibly on the market. And I know what that other drug is and what that drug is capable of doing.... [W]hen they go out and sell the drug they have to be able to compete against that product and say we are better than this drug because I can demonstrate that through my clinical program. Now, if I can't measure that or figure out how to do that, the marketing team is going to come back to me and say, 'I don't care what you're doing, you can get all the approvals you want and you can spend 800 million dollars in the approval process, but in the end, because of what you're giving me, I can't compete against the competition. Or, I can't provide the information I know the doctors are going to be asking for.' So, marketing has an important say in the clinical development program because ultimately you want to be able to give them the answers you need to sell your product.

For the purposes of this study, the main point of the preceding discussion is that the stages of innovation are not necessarily distinct or occur in isolation. There is a

certain degree of fluidity between each stage as companies make efforts to be forward looking and anticipate the challenges that may arise in the future. Thus, the results from these interviews highlight another predictor of success across the stages of innovation that is not captured in this study's quantitative analysis – the ability to anticipate obstacles in subsequent innovation stages.

Are Exploration and Exploitation Subjective?

Initially, the informants I interviewed definitively stated that their firms engage in exploitation or incremental innovation activities, with one exception who characterized his firm's products as radical innovation. Then, as the interviews progressed and the respondents discussed their firms' innovation activities in greater depth, each interviewee revealed a more nuanced view of innovation strategies in their companies. Upon closer examination, each firm not only exhibits a more complicated view of innovation activities than was initially acknowledged, each firm engages in innovation activities that depend on the respondent's point of view.

One of the informants, the CEO I interviewed, began the interview by stating that his firm's product portfolio is quite innovative. The company focuses on "next generation" drug candidates. Their drugs contain new technology and their company is one of the first to test the new technology in clinical trials. The company's technology represents radical innovation relative to the entire industry. But, because they are a smaller company, they have relatively few products in trials and their products coalesce around a single technology and therapeutic area. Their products are fairly homogenous,

representing slight within-product variation, and they operate in a narrow market niche. Even though the company exhibits novel products relative to the environment, each new product tested in clinical trials represents a high level of exploitation relative to the firm's existing products. Whether the firm is viewed as a radical innovator, then, depends on the point of view. At first blush, from the point of view of the environment, the firm's product development strategy was identified by its CEO as radical innovation. But, with respect to the firm's existing products, the firm engages in incremental innovation. This firm's product portfolio provides an example of how innovation, whether it is viewed as incremental (exploitative) or radical (exploratory), depends on one's point of view.

The Vice President of a larger firm in the sample responded to the question of whether her firm engages in incremental or radical change by saying that her firm's innovation strategy is characterized by incremental change. Regarding her firm's product development activities, she states, "It's more of a building upon the lessons that we've learned either within a therapeutic area or that others have learned, or that we learn through the literature or through partners on what we do." After further reflection, however, she identifies some ways the development process may include radical change. For example, the equipment used in the development process may change radically, even if the product does not. "Maybe there are radical changes in technology, whether its equipment technology or something that aids our work that we'll take a look at and adapt to our studies." A lab engineer at a large pharmaceutical company, made a similar point about innovation including changes in the equipment used in the clinical development or manufacturing process. Even in a place like a manufacturing facility, where the product

cannot be changed, radically new equipment could be used to improve the reliability of the process. The engineer also points out the possibility that clinical trials could be tested at a new factory or plant with new equipment, rather than being tested at an existing plant with existing equipment. He mentions that the inverse could also occur. If a drug was being phased out, his firm would consider the possibility of recruiting drugs for manufacturing from other companies, so the firm could make use of existing facilities and expertise. These comments about exploiting existing product knowledge while exploring new equipment or development or manufacturing processes represent one type of ambidexterity: exploiting drug content while exploring new development processes.

As discussed in preceding chapters, ambidexterity includes the practice of using one drug to treat to treat multiple diseases. A number of people I interviewed mentioned that this is a common occurrence in product development. Companies often use one drug to treat multiple indications, usually with a broad therapeutic area like oncology. For instance, a drug used to breast cancer initially may also be tested in clinical trials to treat ovarian or prostate cancer. But a drug can crossover to be tested in other therapeutic areas. One Vice President of product development stated,

There may be a target for your drug that's expressed in multiple cancer types. So you may initially commercialize your product in breast cancer and then later on you'll commercialize it for other cancers – whatever, prostate cancer or other types, but that's within the same disease area. But, we also have lots of examples where there's a target and that mechanism of action is important in more than one disease pathway that crosses therapeutic areas. So, both of those situations occur and we particularly like them in development because all of the work that we do to be able to manufacture a product can then be used by more than one therapeutic area. So, the same amount of work, but two applications.

Another way to view incremental or radical innovation involves the time scale under investigation. One Vice President referred to time as lens through which to view the scope of change. She notes that what is considered incremental change over the short-term might be radical change when observed over a longer period of time. “[O]ne might take a block of activities that might take five or seven years to get to a certain place and, if you look at where you were and where you are seven years later, that may be a radical change.”

The responses to the question of whether their firms employed incremental (exploitation) or radical (exploration) innovation strategies reveal that these characterizations of innovation are not discrete categories. Their responses draw attention to additional ways that ambidexterity can occur. First, the scope of innovation depends on the reference point. The firm can innovate relative to its existing products or the environment. Second, even though the drug may not change in clinical trials or manufacturing, the equipment or the transformational processes used to develop the drug can represent radical innovation. Third, firms can recombine existing knowledge of the drug with new therapeutic areas. Fourth, varying time scales can influence the scope of innovation activities. That is, firms may participate in exploitation in the short-term, but the aggregation of short-term innovations can product radical change in the long-term. Each type of ambidexterity allows firms to negotiate the space between exploration and exploitation.

CHAPTER 6:

DISCUSSION

The major findings of this study are threefold. First, I find broad support for the notion that the scope of learning increases the likelihood of success across the stages of innovation. Second, ambidextrous product development strategies predict success at each innovation stage, but the findings vary by firm size. Third, analysis of the interviews illustrates that whether products are viewed as exploration or exploitation depends on one's point of reference, which can include the firm or the environment and the time scale. I will discuss these findings in turn, how they relate to extant research on organizational learning and innovation, and suggest limitations of this study, which lead to avenues for future research.

Scope of Learning and Innovation

The challenges endemic to innovation are minimized to the extent that organizations learn from past experience, alliance partners, and their networks. Results from regression models support this expectation about the association between increasing the scope of learning and success at successive innovation stages. First, results show that organizational characteristics that proxy organizational learning (i.e., absorptive capacity and organizational competence measured by firm age), predict success at the first stage of innovation. Product discovery increases to the extent that firms increase their absorptive capacity. The results confirm Cohen and Levinthal's (1990) assertion that investment in

producing and assimilating knowledge through R&D increases the propensity of patenting activity. In addition, firms learn from their mistakes and become more competent, increasing the likelihood of innovation success. But, success is also constrained by structural inertia, which, combined with organizational competence, produces a nonlinear effect of firm age (Sorenson and Stuart 2000). As firm age increases, innovation success also increases. For the oldest firms, early innovation-stage success levels off and then decreases.

Results from this study regarding the subsequent stages of innovation – product development and commercialization – support extant research on complementarity among alliance partners in biotechnology. Because of high product development costs, biotechnology firms ally with partners with complementary assets. According to this view, alliances are the expression of partnerships between innovative start-ups with new products and large, resource-rich pharmaceuticals with the infrastructure to develop, market, distribute, and sell the new product (Rothaermel and Deeds 2004). Results from regression models support the complementary perspective. The effects of upstream alliances and horizontal alliances predict the success of products in development and products on the market, respectively.

Network characteristics play an important role in innovation, especially in the final stages of innovation. Powell and colleagues find that network effects such as network centrality and the total number of strategic alliances predict future alliances (Powell et al. 1990) as well as financial performance (Powell et al. 1999). Firms learn from their past alliance experiences in co-managing the innovation process. Furthermore,

broad-ranging and diverse networks allow access to greater resources, knowledge about products, and knowledge about the market; all of which encourage product success.

Rothaermel and Deeds (2006) find significant effects for cumulative network experience as well, but only for products in development and products on the market. Extrapolating from these studies about the competitive advantages of networks of strategic alliances, I hypothesized and found that network characteristics have a statistically significant effect at the last stage of innovation but only for small firms.

Although I find broad support for the hypotheses regarding the scope of learning and innovation, the results vary by firm size. The results for large firms confirm the scope of learning hypotheses with the exception of network characteristics at the final stage of innovation. For smaller firms, the effects of firm and alliance characteristics are inconsistent while network characteristics have conform to expectations at the final innovation stage. For small firms, at the final stage network centrality has a nonlinear (inverted-U) effect on firm sales. Support for this finding can be found in Uzzi's (1996) study of 23 entrepreneurial clothing apparel firms in New York (see also Uzzi 1997). Uzzi's sample is also composed of small firms (ranging in size from 2 to 182 employees). Uzzi's results are based on the notion of "embeddedness," measured as degree centrality, resembling the measure use in this study. Uzzi finds that firms that are highly integrated or embedded in their network are insulated from information that exists beyond their network and vulnerable to environment change (Uzzi 1997).

For smaller firms there is also a positive and significant effect of network experience measured as the total number of alliance at the final stage. However, the

variable used by Rothaermel and Deeds (2006), the cumulative number of years engaged in strategic alliances, is not significant. One possible explanation is that the dependent variables employed in their study were products in trials and products on the market, not sales growth. Nevertheless, results from regression models in my study show that when network experience is measured as the number of years engaged in strategic alliance there are significant nonlinear effects for products in trials. This result corroborates other research by Rothaermel and Deeds (2006) who find that with respect to products on the market there are decreasing returns to network experience. The findings for small firms in my study are generally consistent with prior research and confirm the hypotheses about the scope of learning at the final stage of innovation. Combined with prior research (Rothaermel and Deeds 2006; Uzzi 1996), my results for the nonlinear effects for network characteristics provide scope conditions to the scope of learning hypothesis: for small firms network characteristics have curvilinear effects (inverted U-shape) at the latter stages of innovation.

The results of my study – that the effects of firm, alliance, and network characteristics are associated with innovation success – are not novel in themselves. But, integrating these approaches into a comprehensive explanation *is* novel and provides an orienting framework for theorizing about success across the stages of innovation. This novel theoretical framework integrates existing research by highlighting the notion that learning occurs at various levels of analysis. Learning that occurs at the firm level is associated with innovation success at the early stages (Cohen and Levinthal 1990; Sorenson and Stuart 1999). Learning that take places between strategic alliance partners

increases complementary knowledge between firms and innovation success at various stages of innovation (Rothaermel and Deeds 2004). At the latter stages, innovation success is likely to result from a firm's position in the network (Powell et al. 1990, 1999) or from network experience (Rothaermel and Deeds 2006). Accordingly, my study offers a more general contribution to innovation theory. Explanations of innovation success that examine only one or two stages of innovation are incomplete. My dissertation examines various stages of innovation rather than the piecemeal approach of past research. Examining multiple innovation stages is critical for gaining a complete understanding of the entire innovation process. My results suggest a broad proposition, which, I think, provides a framework and a testable theory for examining innovation in other research settings outside of biotechnology. The proposition is that the increasing scope of learning is associated with success at subsequent stages of innovation.

One limitation of my research is the measure used for the final stage of innovation, sales growth. A more direct measure of the final stage of innovation is product performance. However, collecting this variable requires a substantial amount of additional data collection. One operationalization of product performance is market share. Market share is measured as a percent of the units sold by the focal firm divided by total units sold by competitors in the same product segment. One possible source for such data is MarketResearch.com. Depending on data coverage (i.e., whether MarketResearch.com covers a wide range of drugs on the market), data from MarketResearch.com might be supplemented by product-specific information from companies' annual reports. If data on product performance were limited or difficult to

obtain, this variable might be alternatively operationalized as product sales in dollars or units sold.

Future research could also examine in much more detail how firms learn from their strategic alliance partners and from the environment and how these factors influence learning at the final stage of innovation. Additional data on strategic alliances could include the size of the alliance partner, the type of the partner (universities, research institutes, or other biotechnology firms), success of alliance partners developing products and partners' financial performance, and whether or to what extent an alliance partner has experience developing a similar product. Additional data on the environment might include existing niche width in which firms are operating, benchmarking efforts, monitoring the environment (i.e., monitoring competitors as well as association and industry publications), and mimesis with other products in the environment.

Ambidexterity

Results from regression models show that product development strategies are important at every stage of innovation, especially ambidextrous strategies. The positive effect of the ambidexterity interaction for three out of four dependent variables is consistent with my contention that firms increase their chances for success when they simultaneously pursue exploration and exploitation (Benner and Tushman 2003; Birkinshaw and Gibson 2004; Gibson and Birkinshaw 2004; Gupta et al. 2006; He and Wong 2004; Tushman and O'Reilly 1996, 2004; Tushman and Smith 2002). Furthermore, the negative effect of ambidexterity imbalance provides a point of caution

(He and Wong 2004). The balance between routine and flexibility can be elusive and firms should exercise caution about pursuing either exploration or exploitation at the expense of the other. Difficulties with finding a balance arise because resources are limited to pursue both exploration and exploitation activities simultaneously since a broad range of organizational activities are associated each and conflicting demands exist between the two. Taken together, the results of these two ambidexterity measures suggest that firms should judiciously select among alternative strategies, maintaining a balanced approach to product development to increase their chances of success.

While the concept of recombination is certainly not new with respect to the literature on innovation, my study contributes to research on multiple fronts. First, earlier literature on product development strategies provides useful accounts of recombination, but these writings are typically theoretical (Teece 2007) or anecdotal (Carroll and Hannan 1995; Hargadon 2003). In contrast, I operationalize recombination and examine the statistical effects of recombination strategies. Second, my study contributes to the literature on organizational ambidexterity by identifying recombination as an additional category or conceptualization of ambidexterity. Third, I move beyond existing accounts of ambidexterity to identifying an additional dimension, whether products are used for new applications.

The notion of recombination and innovation has been examined in other organizational contexts. For example, Stark (1996) shows that decentralized reorganization of assets and centralized management of liabilities led to new organizational forms in post-socialist Hungarian firms. Clemens (1993; 1997)

demonstrates that participation in women's groups provides women with the skills (i.e., organizational repertoires) necessary for organizing campaigns and lobbying legislators for woman suffrage. Nevertheless, there is limited quantitative research on recombination as a product development strategy and this topic deserves more attention. Future research could elaborate the antecedents and the decision-making processes that bring about recombination. These processes would be especially interesting to study in rapidly changing environments such as high technology and consumer electronics. Further research could also examine the circumstances in which recombination is most likely to be effective. For instance, results from my study illustrate that recombination is not a statistically significant predictor of products on the market for small firms or sales growth for large firms. These results raise a number of questions. What is the source of difficulty for these firms regarding successfully ambidexterity? Is the difficulty due to a dearth of internal resources or expertise or structural inertia? Is there some way alliance partners can help these firms overcome ineffective recombination efforts? Are these effects robust for firms in other industries?

Another avenue of research includes finding the appropriate balancing point between exploration and exploitation. This study shows that balancing exploration and exploitation increases the likelihood of innovation. But, theorists could study whether there is an appropriate balancing point between exploration and exploitation. Is there a specific combination of exploration and exploitation activities that produces an optimal balancing point of a maximal cost/benefit ratio? Does the balancing point differ for large and small firms, and why?

Relative Exploration and Exploitation

Are exploration and exploitation activities subjective? Analysis of interviews with informants in biopharmaceutical firms demonstrates that the answer is yes. Whether a new product is incremental (exploitative) or radical (exploratory), is subjective based on the informant's point of view. A new product might be radically different from existing products for a particular firm (exploration), but the same product – or a slight variation of the product – may already exist in the firm's environment (exploitation). Alternatively, a new product may be a radical innovation vis-à-vis the environment (exploration), but the new product may be an incremental change from existing firm products (exploitation).

The notion of the relativity of exploration and exploitation suggests a topic for future research. Can a new product be evaluated and compared relative to its proximity to a firm's and environment's existing products. A hypothesis to be explored in future research: as a result of firm-level learning and isomorphic pressures in the environment, products are likely to be more successful to the extent they build on existing products in both the firm and the environment. In other words, products are mostly likely to be successful when they maximize knowledge transferred within the firm and from the environment.

The concept of relative innovation raises questions about whether quantitative indicators of exploration and exploitation, such as those used in this study, are valid. The best way to establish validity is to understanding the organizational and environmental

context of the products under examination. I have confidence in the validity of my analysis for the following reason: because whether a product is exploratory and exploitative in my study is determined based on existing products in the firm. The firm is the reference point. However, the same analysis could be performed by using different variables for exploration and exploitation with respect to products in the environment. Exploration could be measured as the number of drugs in clinical trials that have never been pursued in clinical trials by other biopharmaceutical firms. Exploitation could be measured as the number of drugs in clinical trials that have been pursued in clinical trials by other biopharmaceutical firms. Then, the results from the two different points of view could be compared.

CHAPTER 7:

CONCLUSION

The problem with innovation is that diverse activities are required to succeed at each stage including product discovery, product development, and product success. Each stage requires varied activities and resources that make the innovation process time consuming, expensive, and difficult to manage. The biotechnology industry is especially prone to these problems considering the large amount of time, money, and regulatory obstacles present in product development. To complicate matters once these activities are mastered, changes in the organizational environment can stipulate new “rules of the game.” Changes in the environment constitute new technology, cultural preferences, or regulatory requirements, rendering previous organizational competencies irrelevant.

Three perspectives to organizational learning address the challenges endemic to innovation and animate research on success across the stages of innovation in the biotechnology industry. Each perspective focuses on particular innovation stages, under-theorizing the entire innovation process. But taken together, these approaches suggest that learning occurs in a variety of ways – within the firm, between alliance partners, and from the entire network – to improve innovation success. I argue that increasing the scope of learning increases the likelihood of success at subsequent stages of innovation. Of course, I am painting with broad brush strokes. For instance, I contend that increasing firm competence and absorptive capacity leads to patenting activity. But, firms also pursue patents by engaging in strategic alliances. Nevertheless, these patents are shared

by partners and likely yielding fewer benefits than a solo venture. Therefore, my contention is that early-stage discovery activities are relatively easier to accomplish within the firm, without the help of alliance partners since joint ventures are often difficult to manage and fail to meet their objectives. The scope of learning argument continues by suggesting that increasing the scope of learning from the firm to the alliance, to learn or benefit from alliance partner's complementary knowledge about product development, increases the likelihood of success at the second stage of innovation, product development. Again, there are exceptions. At the intermediate stages of innovation, success occurs without the aid of alliance partners. But in the biotechnology industry where product development is so costly, my contention is that product development is relatively easier with help from alliance partners. Finally, as the scope of learning expands from alliance partner to the overall network, successfully marketing and distributing a product is made easier as a firm's overall network experience and centrality increase.

In this study I move beyond conventional explanations of innovation success in the biotechnology industry and I examine product development strategies. My results support the notion that pursuing both exploration and exploitation increases success across innovation stages. But, the findings also provide a cautionary tale: an imbalance in ambidextrous activities decreases the chances for innovation success. The positive effects of the ambidexterity interaction and the negative effects that result from an imbalance indicate that firms should not pursue ambidexterity indiscriminately. More

ambidexterity is not better unless it is accompanied by a balance of exploration and exploitation activities.

My study complements current understandings of ambidexterity and innovation by conceptualizing a related, but different, ambidexterity product development strategy – recombination. Recombination utilizes existing products or applications of products in novel ways. In the biotechnology industry, recombination takes place as a firm uses a drug with which it is familiar to treat a new disease. Recombination also takes place as a firm uses knowledge of a disease with which it is familiar to develop a new drug.

Another contribution of this study is that exploration and exploitation can be viewed subjectively. Whether a product is perceived as exploration depends on one's point of reference. The perception depends on whether one views the change to the firm or the environment. Or, whether a product is interpreted as exploitation can depend on the time scale. A few small changes during a matter of months are labeled incremental or exploitation whereas the aggregation of many changes over the course several years is labeled radical or exploration.

While the lessons for increasing innovation success espoused in this study are easily observable in theory, they are more difficult to implement. Nevertheless, they point out that successful innovation is a function of diagnosing the firm's strengths and weaknesses relative to the environment. For instance, Ciba Vision's president Glenn Bradley implicitly understood that exploring radically different eye-care products would present difficulties for the company, but *exploring* different eye-care products allowed Ciba Vision to *exploit* the market for disposable eye-care products developed by Johnson

& Johnson. Bradley's success came from knowing how to complement Ciba Vision's current expertise with a new strategy. In other words, Ciba Vision's success resulted from matching its experience in the general area of eye-care with promising new products.

Successful recombination comes from understanding the structure of successful (and unsuccessful) innovation. The key is to match realistic appraisals of firm competencies and weaknesses with the appropriate market niche. Firms should not reinvent the wheel. Firms should keep the successful parts of the wheel and identify ways to reinvent the unsuccessful parts.

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APPENDIX A:

INTERVIEW GUIDE

Background

1. What is your official job title?
2. How long have you worked for this firm?

Organizational Culture

3. What does your department [or organizational unit] do to foster innovation?
4. Is this department [or organizational unit] more likely to encourage radical or incremental innovation?
5. To what extent do new drugs build on existing drugs?
6. Do you ever test the same drug in multiple therapeutic areas? Or vice versa?

Innovation Stages

7. How are decisions made about which ideas to patent?
8. How are decisions made about which products to develop?
9. How are decisions made about which products should be sold?
10. At what point in the innovation process do you evaluate a product according to its likely market success?
11. What can be done, especially early in the decision-making process, to increase the likelihood of product success?
12. How often are individuals who are involved in the innovation process allowed to provide feedback to improve the product?
13. What suggestions do you have for improving the innovation process?

APPENDIX B:

DESCRIPTIVE STATISTICS

Table B-1. Means for Dependent Variables for All, Large, and Small Firms

Dependent Variable	All Firms (N=111)	Large Firms (N=55)	Small Firms (N=56)
Patents Granted	9.62	15.61*	1.69
Products in Trials	4.53	5.74*	2.93
Products on the Market	0.88	1.29*	0.34
Sales Growth	-1.07	-0.22*	-2.23

*Compared with small firms the mean difference is significant at $p < .05$ (two-tailed test)

Table B-2. Means for Independent Variables for All, Large, and Small Firms

Independent Variable	All Firms (N=111)	Large Firms (N=55)	Small Firms (N=56)
Firm Size	4.04	6.97 *	0.09
Absorptive Capacity	199.34	331.18 *	19.43
Firm Age	9.93	12.56 *	6.34
Upstream Alliances	0.83	1.15 *	0.39
Horizontal Alliances	1.74	2.30 *	0.97
Downstream Alliances	2.04	1.87 *	2.27
Network Centrality	0.01	0.02 *	0.01
Network Experience	21.67	19.06 *	25.24
Patent Self Citations	26.66	39.67 *	8.92
Patent Non-Self Citations	66.61	106.09 *	12.75
Exploration	2.28	2.26	2.32
Exploitation	0.28	0.35 *	0.18
Recombination	1.69	1.75	1.60

*The mean difference between large and small firms is significant at $p < .05$ (two-tailed test).

Variable	Mean	Std Dev	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Firm Size (standardized)	0.53	0.99	1.000												
2. Absorptive Capacity (log)	3.56	1.58	0.630	1.000											
3. Firm Age	9.93	11.06	0.792	0.716	1.000										
4. Upstream Alliances	0.83	1.28	-0.034	0.176	0.012	1.000									
5. Horizontal Alliances	1.74	2.51	0.052	0.382	0.104	0.634	1.000								
6. Downstream Alliances	2.04	3.07	-0.035	0.175	0.033	0.031	0.154	1.000							
7. Network Centrality (multiplied by 100)	1.58	2.42	0.448	0.423	0.394	0.092	0.218	0.086	1.000						
8. Network Experience (log)	1.90	1.66	-0.120	0.168	0.054	0.049	0.177	0.720	-0.030	1.000					
9. Patent Self-Citations (divided by 100)	0.27	0.92	0.421	0.313	0.411	0.105	0.033	-0.084	0.288	-0.108	1.000				
10. Patent Nonself-Citations (divided by 100)	0.67	2.20	0.491	0.377	0.477	0.036	0.056	-0.100	0.344	-0.147	0.713	1.000			
11. Exploration	2.28	2.58	-0.066	0.177	0.002	0.099	0.201	0.725	0.079	0.614	-0.074	-0.090	1.000		
12. Exploitation	0.28	0.87	0.009	0.212	0.099	0.111	0.150	0.536	0.083	0.387	-0.026	0.014	0.404	1.000	
13. Recombination	1.69	2.90	-0.075	0.215	0.027	0.157	0.221	0.628	0.063	0.546	-0.050	-0.032	0.591	0.708	1.000

*The variables Firm Age², Network Centrality², Network Experience², Ambidexterity Interaction, and Ambidexterity Imbalance are omitted from the table since they are derived from other independent variables.