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From Invention to Innovation: Toward Developing an Integrated Innovation Model for Biotech Firms*

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A review of extant literature reveals various theories on innovation, including technology push, market pull, and an organizational approach. All of these theories have been criticized for their lack of integration and inapplicability to today's competitive environment. An integrated view of innovation has emerged that synthesizes the variables in previous approaches. However, the application of this view has been restricted to investigating the innovation processes within the computer and manufacturing industries, whereas the biotechnology industry has been ignored. This is despite biotech managers' well-acknowledged thirst for innovation and the ability of biotech to shape the way we live. The present article contributes to the literature by applying an integrated approach to the biotech industry, thereby extending understanding of innovation management beyond the traditional field of inquiry. An integrated approach is of particular relevance to biotech companies, given the complexities of managing the industry's long development cycle and intense collaborative activities. In-depth interviews with eight organizations in Maryland formed the basis for an investigation into the challenges of managing the innovation process in biotechnology firms. The findings revealed that biotech entrepreneurs are ill prepared to lead their organizations through several transformations necessary along the product life cycle because of their fixation on a technology-push approach and lack of an understanding of integrated innovation. These leaders also lack the commercialization knowledge necessary to push products to markets, resulting in avoidable delays and loss of productivity. The existing research has dispelled myths associated with biotech. Specifically, it suggests biotech entrepreneurs cannot rely solely on inventions but must invest in a timely application of knowledge to organizational and market forces to take full advantage of the innovation potential associated with the industry. This article presents a conceptual framework for applying the integrated innovation model to biotech firms and makes the case for incorporating market-oriented mechanisms, building and using appropriate organizational capabilities, developing effective collaborations, and creating parallel interactions as major elements in a general strategy toward the success and improved efficiency of biotech companies. The limitations of current research are discussed, and avenues are highlighted for much-needed future research into the biotech industry.

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Introduction

During the past two decades biotechnology has emerged as a vital global industry associated with a sustained flow of innovations and tools for dramatically improving human health and quality of life worldwide (Gans and Stern, 2004). Until the early 1980s, the prevailing belief was that no new company could compete with the pharmaceutical industry giants because of the enormous costs of developing a research and development (R&D) infrastructure (Gassmann, Reepmeyer, and Zedwitz, 2004). Biotech firms not only challenged the traditional pharmaceutical companies as the discoverers and developers of new products but also built credibility in novel areas such as cell biology, molecular genetics, and drug delivery. Various authors have endorsed the economic significance of the biotech industry in today's economy because of its immense potential for growth (Baker, 2003). Despite this optimism, tensions in managing growth and innovation have gained attention as biotech companies have matured. Recent research by Accenture (2004) and Babson College, shows that almost 50% of pharmaceutical and biotech executives believe that companies in their sector become less innovative as they grow. Characteristics unique to the biotech industry have also led Baker (2003) to express doubt that these companies can balance the need to grow with the urgency to innovate, suggesting that biotech faces organizational challenges as its products move down the pipeline. This article seeks to identify some of these key challenges. To set the stage for this discussion, consideration must be given to the uniqueness of the industry.

BIOGRAPHICAL SKETCHES

Dr. Shaista E. Khilji is assistant professor of human and organizational studies at George Washington University in Washington, D.C. Her research interests focus on the interface between organizational issues, such as culture, diversity, globalization, strategy and growth, and innovation and new product development. She has published in *International Journal of Human Resource Management* and *International Journal of Cross Cultural Management*.

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What Makes Biotech Firms Unique?

Biotechnology companies operate amid uncertainty and rapid change. They face the increasing cost of R&D, global competition, and a lack of critical mass that interferes with the benefits of economies of scale. Researchers (Baker, 2003; Baker, 2004; Fuchs and Krauss, 2003) have argued that biotech firms are unique for at least three reasons. First, because they are strongly science based, more nimble, and less risk averse than pharmaceutical companies, innovation within these firms is far more radical than in other industries (Gans and Stern, 2004; Powell, Koput, and Smith-Doerr, 1996). Second, biotech companies represent tacit knowledge. The generation and economic exploitation of knowledge thus requires intense science-based interactions (Fuchs and Krauss, 2003). Alliances with other biotech firms, university research centers, and pharmaceutical companies are the norm in the industry, providing biotech with faster access to capital and knowledge, enabling companies to react more quickly and flexibly to new developments, and offering better protection of intellectual property rights (Liebeskind et al., 1995). Finally, the timeline between establishing the company (i.e., initial investment) and return (i.e., product availability in the market) is long. On average, the entire biotech process, from scientific discovery to commercialization, can take up to 15 years (MdBio, 2003) (Figure 1). This reality exposes entrepreneurs to a plethora of critical and time-sensitive decisions. For example, how can the company attract capital and collaborations without a tangible product in the early stages of its life cycle? Once the invention is in hand, who can the company partner with for manufacturing, design, and marketing—especially since most small biotech companies do not possess all the necessary competencies to make their discoveries available to end consumers? Gassman et al. (2004) cites a report by Reuters that demonstrated the unfortunate outcome of these decisions for many companies, including a 90% failure rate among biotech firms. Thus, despite common belief that biotech industry has transformed itself into a dynamic source of innovation, not all companies share in the success. Their plight adds urgency to the investigation of the challenges these companies face.

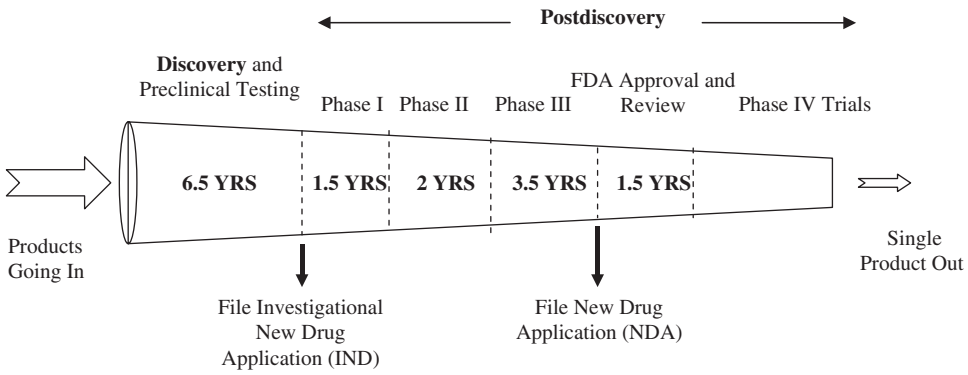


Figure 1. A Typical Drug Approval Process in Biotech

The existing literature on biotech lacks sufficient discussion of specific management challenges facing individual firms. Similarly, information on technology and innovation management (TIM) appears to lack consistent definitions and sometimes confuses industry types. Because the primary objective of this research is to study the management of innovation in the biotech industry, the authors adopted a grounded-theory approach. The main research questions included the following: (1) How is innovation understood and applied within biotech firms? (2) What challenges do biotech firms face as their products move down the pipeline? (3) How can these challenges be addressed to take full advantage of the potential discoveries?

Building on the work of previous scholars in the field of TIM, this research is aimed at a broader understanding of the innovation process in biotechnology firms. A thorough examination of the wide body of literature on biotech and on TIM has helped identify gaps and discrepancies in theory and industry application, which were used to develop a discussion of biotech innovation, and to recommend ways to manage the innovation process.

Biotech Literature: The Current Innovation Model

Innovation is the mainstay for small biotech firms; rapid innovation activities allow them to focus on niche markets (Chin, 2004). Attempts to describe biotech innovation have viewed it in terms of sequential stages of product development over an expansive and long period (Delois and Beamish, 2004; Meyer and Howe, 1997). Figure 2 illustrates one such typical model (MdBio, 2003). It indicates five

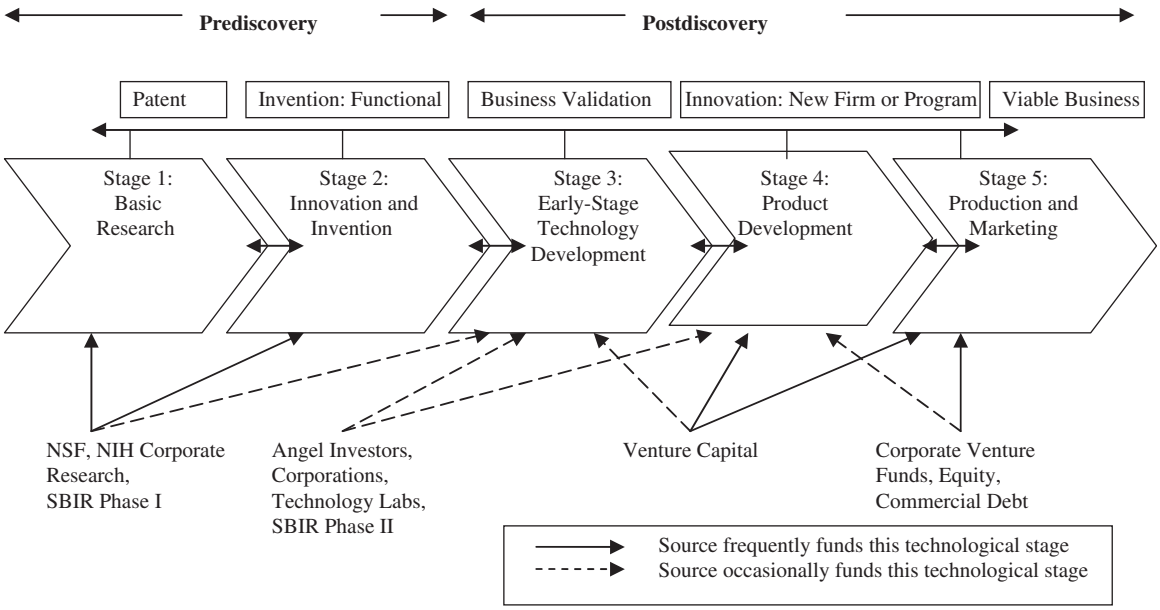


Figure 2. The Sequential Model of Innovation and Commercialization

different stages in product development and availability: basic research, innovation and invention, early-stage technology development, product development, and production and marketing. An important feature of the model, when viewed with Figure 1, is first that it outlines various important activities in its life cycle (e.g., patent, U.S. Federal Drug Administration [FDA] approval, clinical trials, product design, production, and marketing); second, it directly refers to at least two critical functions—R&D and funding and financing—and indirectly indicating a third one, the use of collaborations to keep companies funded and active in research. By pointing out a split between the prediscovery stages (i.e., stages 1 and 2) and the postdiscovery stages (i.e., stages 3 to 5) in terms of patent and invention and building a viable business, this model also highlights the relevance of different functions at each of these stages. For example, the importance of basic research looms large in the early stages of development and diminishes during later stages. During the prediscovery stages, or stages of invention, most available funds are dedicated to R&D activities. Absence of a commercial product at this stage, however, undermines efforts to attract private investors for ongoing research and development. The bulk of such funding in the United States is thus offered by the government through the National Science Foundation or National Institutes of Health. Postdiscovery (i.e., stages 4 and 5 in Figure 2), when a tangible commercial product becomes available, the chances of securing financing from venture capitalists, angel investors, and corporate venture funds are higher. At the same time, biotech firms are under immense economic pressure during these stages to exploit their technological knowledge in the marketplace, so they can compensate for the necessary initial investment, first phases of significant losses, and continuing investments in R&D. Figure 2 illustrates how business competencies become valuable and dominate the postdiscovery phases—that is, from the time an invention becomes available. To develop a viable business and to generate profits, resources and activities must then be directed toward commercializing the new product.

Although the model described here exposes the relevance of important stages, features, and functions of biotech innovation, it seems to isolate internal activities and to separate them from external market forces. In fact, biotech companies rely heavily on external agencies for competitive advantage (Owen-Smith and Powell, 2004). A review of the TIM literature here illustrates the need for a more integrated approach to studying innovation.

TIM Literature: Toward an Integrated Innovation Approach

Technology push and market pull, the early innovation models of the 1950s and 1960s, proposed a unitary progression of phases in the development of products (similar to what is shown in Figure 2). The former focused on technology with no concern for market forces (Lippitt, Watson, and Westly, 1958), whereas the latter considered the market the primary source of innovative ideas, assigning R&D a merely reactive role (Clark, 1979). As the complexities of the innovation process became apparent, the organizational approach emerged, revealing innovation as a continuous process of events and emphasizing the importance of functionality within the business environment. Research revolved around identifying significant structural parameters of organizations, including concepts of centralization, formalization, size, and organization goals (Edwards, 2000; Johnson et al., 2001; Meyer and Mugge, 2001). Conflicting empirical results led to further confusion, however.

An emerging body of literature in the late 1980s suggested an integrated approach, reflecting the synthesis of both technology-push and structural parameters in the organization. Under this approach, the innovation process is viewed as the interplay of the organization's structural functions toward knowledge creation. Knowledge—transferred from R&D to manufacturing, marketing, and service through internal linkages—moves inside and outside the organization through external linkages. Initiation of the innovation process thus depends on three main sources: (1) organizational capabilities; (2) scientific and technological developments; and (3) the marketplace. The main writings to trigger this new body of literature are by Van de Ven and Rogers (1988) and Pettigrew (1985). Rothwell's (1994) integrated view is composed of interacting and interdependent stages of a complex network of intra- and extra-organizational linkages, which connect the firm both internally within functions and to the broader scientific and technological community and the marketplace. This view appears to be appropriate to the biotech industry because of its use of tacit knowledge and interdependencies with the external agencies, which force companies to

draw on necessary organizational, technological and scientific, and market resources to innovate.

The present research study was developed with the integrated approach led by Rothwell (1994), Pettigrew (1985), and Van de Ven and Rogers (1988) in mind. As Figures 1 and 2 indicate, the evolution of innovation from an idea to a marketable product in the biotech industry is multifunctional and involves intense collaboration. Funding is essential to carry through various stages of R&D, and the ability to increase development speed is an important factor in determining a company's competitiveness. For these reasons, this study argues that the sequential stage model presented in biotech literature (Figures 1 and 2) is inappropriate because it neither highlights the interplay of various functions nor considers the critical role of the marketplace in the identification of market niche for innovative products, as has been explained by the integrated approach.

The literature on TIM has defined innovation in many ways. For the present article, innovation refers to a new idea or concept generated by R&D (henceforth referred to as invention), which is transformed into a socially usable product. Successful innovation requires changes in organizational processes and conversion of an idea into a commercial product that is designed, manufactured, and adopted by users (Verloop, 2004). The distinction between *invention* and *innovation* is important because according to the integrated approach, an invention is converted to successful innovation only through parallel, directed interactions among organizational, scientific, and market aspects. Invention thus is one step, and innovation is a whole business process that creates change from invention, development, design, and production to marketing.

Research Design and Sample

This exploratory study of innovation in the biotech industry was conducted in the state of Maryland for three reasons. First, surveys place Maryland among the top six regions in the United States (Bond, 2004; DeVol et al., 2004). Second, Maryland is home to successful biotech firms, such as MedImmune and Human Genome, which serve as models to young biotech firms around the world. Third, Maryland is a convenient location for interviews because of its proximity to the first two authors.

In-depth, semistructured interviews were used to collect data. The semistructured format allowed conversations to be directed toward the chosen theme of this study and left respondents free to openly express their views. In-depth interviews offered the research team the flexibility to probe and highlight organizational and other contextual issues that would have remained hidden had a questionnaire survey been used.

Data Collection and Analysis

Interviews were conducted at the macrolevel with organizations that deal directly with improving the quality of the business environment for biotech in Maryland and at the microlevel with specific biotech firms for an inside perspective on company-specific issues. Three interviewees ABC, XYZ, and ED, were contacted for macrolevel interviews. The former two are nonprofit organizations. ABC in particular offers a variety of programs (e.g., business development, manufacturing incentive, workforce development programs) to advance the commercial development of bioscience in Maryland. XYZ is a regional cooperative marketing organization to promote the District of Columbia, Northern Virginia, and suburban Maryland as an ideal place for locating or expanding a business. Industry specialist ED has more than 20 years of experience in the local biotech industry. ED has founded and managed two small biotech firms and has knowledge of how biotech industry operates. These interviews were aimed at including a broader perspective on the state of biotech firms in the region. Respondents were asked to share their views on the role of collaborations for the development of biotech, the status of biotech firms in this region, economic policies, incentives, initiatives, the main actors, and causes of high failure rates among biotech firms.

As this was an exploratory study and the scope was limited, a total of five companies in different stages of development—mainly postinvention—were chosen (Table 1). In line with the aim of the study—to highlight challenges facing biotech—founders and chief executive officers (CEOs), who were also scientists in all cases, were interviewed because they are familiar with the complexities of managing inside and outside the laboratory environment. Direct contact was established with each CEO via a formal letter or a telephone call to describe the objective of the study and to request an appointment with the CEO and the founder. Interviews of 45 to 75 minutes were conducted during early 2004 by a team of researchers, including the first two authors.

Interviewers began by asking respondents to explain what *innovation* meant to them and to name a

Table 1. The Sample Biotech Companies

Company Code	Total Number of Employees[a]	Focus	Age (Years)	Stage[b]
GNM	15 (9)	Research-based	3	Past Stage 2: A recent innovation
AVN	55	Research-based	4	Past Stage 2: A recent innovation
KG	52	Manufacturer and supplier (Multi-product)	23	Passed through 1–5 at least once: Established player; holds several patents
VX	36 (31)	Research-based	4	Stage 3: Early phase trials
BO	13 (10)	Research-based	6	Past Stage 2: A recent innovation

[a] Number in parentheses is number of employees in R&D.
[b] See Figure 2.

specific innovation at each of their organizations. Follow-up questions on these innovations were related to networking techniques, funding strategies, regulatory approvals, and other environment and organizational factors. This interview technique caused respondents to narrow their focus to one key element. Moreover, because this innovation was discussed in detail, it broadened each respondent's horizon of thinking to include several dimensions that had been selected, thus highlighting specific issues and challenges associated with managing innovation.

Two-person teams conducted the interviews to facilitate open discussion. All interviews were taped, and both interviewers took notes. Since the interviews were semistructured, main categories for the study's analysis (e.g., innovation, challenges, collaboration) were predetermined. Raw data were also tabulated for an effective analysis (Perreault and Leigh, 1989). To improve the quality of data and their reliability, two raters were used (Krippendorff, 1980). The first two authors read the transcripts several times and tabulated responses independently to develop meaningful categories such as "Company GNM defines innovation as" and "Company GNM faces these challenges." Both decided to select quotes from the transcripts as supporting evidence for each challenge; some of these quotes are included in the next section of the article. With two independently developed tables in hand, discussions were held to evaluate convergence among raters. The reliability, measured in terms of the percentage of the authors' agreement (Perreault and Leigh, 1989) was found to be 99%. This reliability can be attributed to clearly predetermined concepts, the nature of the data, and the motivation and skill of the judges. Discussions were held further to review raw and tabulated data in light of the existing literature. The outcome is presented in the next section.

The sample organizations employed between 13 and 55 employees, with an average of 34. Although the age of the companies ranged between 3 and 23 years, all but one was established within the last 3 to 6 years. KG was the oldest organization, at 23 years, and the only firm generating profits. This exception was welcome because it implied that KG was a multiproduct company and had gone through the entire life cycle at least once. KG's personnel offered experienced insight into the key issues being discussed. All other companies had one invention in hand and were past stage 2 (Figure 2; Table 1). This sample was therefore suited to understanding organizational challenges that biotech companies may face after invention (Accenture, 2004; Baker, 2003).

Results

Interviews from this exploratory study reveal a paradoxical situation for small biotech companies. In the following section, each paradox is discussed separately.

Paradox 1: The Harsh Reality—Innovation Is Worth What the Market Is Willing to Pay

Although innovation is vital for survival in a rapidly changing business climate and regarded as a critical differentiator between companies, it is an overused term that does not necessarily mean the same thing to everyone (Verloop, 2004). During the initial stage of the current study, the researchers wondered what innovation really means to biotech firms. The interviewers began by asking respondents in the biotech firms what they understood by innovation. Although interviewees described innovation as a "light bulb or breakthrough" moment, they agreed it was not instant but evolved over a period of time. The innovation period was referred to as an exciting time because it provided companies with a tangible and marketable product, thereby improving chances of raising capital to fund late-stage activities, including clinical trials,

manufacturing, sales, and marketing (Figure 2). It was considered to be an important stage in the life cycle of the company but also a nerve-wracking period because market mechanisms—which often determined the net value of their invention—were beyond companies' control. An interviewee at VX remarked, "Despite everything, innovation is really worth what someone is willing to pay for." This reality was a surprise to respondents, who referred to it as a "rude awakening" and said it added to their stress by exposing them to challenges of a new kind. In the words of the CEO of GNM, "We had our major discovery a few months ago. Now a conundrum we are grappling with is how to exploit it; how do we publicize and sell that information?"

Discovery is indeed the first big step toward progress. It may also be the first reality check for biotech management, given their complete reliance on the scientific ability of their teams in the first stages of development. As the interviews show, a lack of business acumen and marketplace knowledge can lead to time lags that hurt the competitiveness of an innovation.

Paradox 2: Performing a Balancing Act—Forming Alliances without Revealing Trade Secrets

The respondents in the sample talked about their continual efforts at establishing collaborations around the globe. The GNM founder remarked, "Although we are a small company, every day—yes, every single day—we try to form alliances. When I am not on the phone with the venture capitalist, I am trying to see who we can potentially collaborate with." Therein lay a paradox. On one hand, interviewees realized that to survive in a competitive environment when they lacked in-house complementary competencies, they had to seek out collaborations with other companies. The founder of VX said, "We are not developing something that is out there. This is cutting-edge stuff. You want as much leverage and protection [as you can get] going forward. But we also realize we don't hold all the pieces, so we have to collaborate with other players out there."

On the other hand, biotech is an industry of closely guarded scientific discoveries and patented information. Interviews indicated that forming alliances is not a straightforward process. During the pre-invention stage, collaborations are difficult to establish because of the absence of a tangible product and a high failure rate among small biotech firms that causes other firms to adopt a cautious approach. Postdiscovery, biotech firms face a new challenge as the CEO of GNM explained. "When we did not have an innovation, the dilemma was how to sell just an idea. Now that we do (have a product)—we are in this netherworld of having an incredible discovery that you want to talk about (for leverage or out of excitement) but can't tell all about because its value lies in the secret; and if you told it you have lost it."

Despite a lot of collaborative effort at a certain level, the very nature of biotech and intellectual property legalities requires that trade secrets be protected up to a certain stage. This paradox makes forming alliances more difficult than has been mentioned in the literature. The following discussion outlines other challenges associated with alliances.

Paradox 3: The Secret of Maintaining Alliances—Just Because It Doesn't Work Doesn't Mean It Is Dead

The strategic benefits of alliances are alluring, but the recipe for successful alliance can never be fully written. Collaboration involves two or more distinct companies with different goals that quite possibly conflict. Interviews revealed companies had to constantly readjust their expectations and at times live with floundering alliances. The CEO of VX, which collaborates with a research institute, pointed out, "As we mature into conducting trials, we are discovering new differences. They are academics and we are industry people. We have timelines, and they don't understand that. Whenever we miss a deadline, we have a burn rate of half a million dollars a month. It kills a small company like us."

One would expect floundering alliances to fall apart, but interviews revealed that biotech may be unique in this respect. The CEO of AVN explained, "You know it is a bad relationship, but continuing to work together is in everyone's interest. They are a small company and we supply a fair amount of their resources. We need their technology because without it, we would have to start from scratch and invent something new ourselves. Neither of us also wants the public exposure of having to go out there and say the alliance is no longer existent because that would look bad. So we try to find ways to make it work." Despite many potential problems, fruitful collaborations exist. Respondents believed these were the result of a high level of commitment and mutual trust among all parties.

The interviews reveal that biotech firms engage in intense collaborative agreements even in the initial stages of product development. Conflicting interests

and inexperience at managing collaborations interferes with some companies' ability to benefit from these alliances, however.

Paradox 4: Moving Ahead from Invention to Innovation

As biotech companies proceed through various stages, they naturally are faced with new realities. All but one company in the sample were found to be ill equipped to deal with these challenges. The respondent from AVN explained, "How do you prioritize your projects? How do you evaluate markets and how do you realize strategic fit? How do you make these decisions? Really, I don't have the answers." The interview respondent at ABC reaffirmed this dilemma, citing the "scientists' inability to move beyond the initial stage of innovation" as the biggest challenge facing biotech firms today.

KG, which has multiple products and is the only well-established and profitable company in the sample, was atypical. Interviews revealed something else unique: Over the years, KG had been streamlining organizational mechanisms, including processes, to develop a holistic view of projects and products and to align them with strategic goals and objectives. This effort improved visibility and control over time and resources. The CEO at KG commented, "One thing we have learned over the years is that how things happen is most important. I believe organizational process is crucial. Good companies learn to do things and let the right processes become ingrained in their culture."

The interviews showed that smaller biotech companies were neither aware of organizational processes as an integral part of innovation management nor had developed appropriate capabilities. These companies were struggling for a suitable course of action after invention.

Paradox 5: In the Blind Spot—Commercializing Inventions

Biotech may be based on pure science, but innovation management is not. The overall success of an invention requires distinct but complementary strategies and skills as well as parallel interactions among technological, market, and organizational knowledge bases (Pettigrew, 1985; Rothwell, 1994; Van de Ven and Rogers, 1988). Together, these lead to breakthrough discoveries, provide insights into viable means of serving the market needs, improve chances of FDA approvals, and ensure a significant financial return.

The interviews indicate that small biotech firms—frequently formed by scientists around the fruits of their basic research—are more easily guided to breakthrough discoveries because of mastery of scientific and technological knowledge, which is their core competency. Both organizational and market knowledge are lacking, however. When it comes to translating inventions to innovations, firms neither possess the knowledge to commercialize nor realize the urgency of grasping market dynamics to speed up the process. The respondent at ABC remarked, "There is a difference between developing a product and developing a business. Once you get past a certain point you need people who know how to develop a product and find a market, build infrastructure, and attract investment. Not a lot of biotech firms realize that."

The dichotomy between commercialization and R&D activities becomes more pronounced during later stages of product development, when the need to understand the marketplace is far more acute. Although biotech managers, a majority of whom are scientists, hope to drive their ideas to market success, they often ignore the very basics of transforming their discoveries into commercially viable products.

Paradox 6: Which Way Forward—Too Much Control, or Too Little of It?

Regardless of industry type, control must exist, or there is no organization at all. Another dilemma facing biotech companies during the postdiscovery stage is who exercises control and how much of it. This question makes good sense in the context in which these companies operate. First, these companies depend on venture capitalists and government agencies for funds. Second, lack of complementary skills pushes companies to form new alliances that do not necessarily run smoothly. Founders of biotech firms tend to tighten their grips in an effort to exercise greater control but are forced to seek out financing and collaborations for sustenance, which in essence takes away the control they want to retain. This situation was described by the VX founder, as that company was conducting clinical trials in collaboration with a number of firms at the time of the interviews. "I believe control is very important in this business and I exercise it to keep the company going. Although right now we have no choice but to collaborate . . . Going forward, I want to do as much activity as I can in-house."

From a different perspective, the respondent ED believed, not giving up control at this stage was a critical mistake these scientists made. In his words, "A smart scientist will step back very early in the process and let venture capitalists run the company, who have done it before. Scientists should realize that it is better to own 10% of a very large company than 100% of nothing. However, it is a tough lesson. They have nurtured the company from a very early age, and it is hard to give up control."

Organizational growth is a complex phenomenon that requires new and effective control mechanisms to balance the needs for delegation and centralization. This balance is of particular importance to biotech. Biotech managers find achieving the right balance difficult. This critical issue hinders the speed of biotech development and has created a Red Queen Effect, a situation in which companies put considerable effort into expanding their businesses, only to find themselves working harder and harder to maintain the status quo (Wells, Coady, and Inge, 2003).

Discussion and Implications for Management

How Is Innovation Understood and Applied at Biotech Firms?

Because biotech firms are known as the source of innovation, researchers began by asking respondents what innovation meant to them and how it was applied in their organizations. Interviews clearly revealed a narrow understanding of innovation. Although it was referred to as the outcome of several years of scientific research, innovation was nonetheless treated as an isolated event. It was also evident that respondents were unaware of the distinction between invention (i.e., breakthrough scientific discovery) and innovation (i.e., a socially usable and marketable product). Previously, innovation was described as a series of interrelated and complex activities that ought to be undertaken simultaneously; and for every invention to transform into innovation the effective interplay of three main sources is important: scientific developments, organizational capabilities, and the marketplace. An understanding of the latter two, in particular, appeared to be missing in the sample. Postinvention, respondents were found to be grappling with marketplace dynamics and admitted to being suddenly hit by market realities. Additionally, firms did not realize the need to simultaneously adapt organizational mechanisms as inventions moved down the pipeline. These examples illustrate a fixation on the technology-push innovation model, described as a traditional approach in the literature. The interviews also indicate that since the mainstay of biotech companies is scientific discovery, or invention, efforts directed at developing external linkages are weak and haphazard. A complete focus on scientific developments thus may prevent companies from pursuing an integrated approach, which requires an effective synthesis of internal and external parameters in the organization and successful interactions of the aforementioned sources.

What Other Challenges Do Biotech Firms Face as Products Move down the Pipeline?

The overall importance of alliances suggests that working jointly is a crucially beneficial mechanism for biotech, which a majority of firms do recognize. Efforts to establish alliances are fraught with difficulties, however. Earlier on in the life cycle, due to the confidential nature of the scientific work, biotech companies may be unable to spark the interest of prospective partners in their idea. Interviews also revealed that it would be incorrect to assume that fully formed collaborations are fully functional. Alliances do not necessarily bring in synergistic benefits to both partners. Earning mutual trust and respect is not easy, given the differing, sometimes incompatible, goals of the partners involved. Fear of earning bad publicity deters companies from breaking up alliances, however.

Scientists-turned-entrepreneurs also lack commercialization knowledge, and are ill prepared to convert invention into innovation, resulting in avoidable delays. The desire to retain control in moving products down the pipeline, despite the lack of well-developed in-house complementary skills, also seems to further hold back the advancement of biotech products. Statements, such as "Control is very important" and the notion that that if you want something done right, you have got to do it yourself are indicative of this desire (see Paradox 6).

The current study, in its search of key challenges facing biotech, has also been able to bring some industry-specific realities to the forefront, identifying and dispelling myths. First, although cooperation may be the norm in biotech and the number of alliances may be growing exponentially, forming and maintaining these alliances is not easy, nor are these alliances necessarily fruitful. Recent research by Accenture (2004) indicates that despite increasing attention, executives in pharmaceutical companies of all

sizes are also not getting the benefits from alliances that they seek. The growth in the number of alliances therefore must be interpreted with caution. Second, biotech is generally believed to be an exciting industry with immense innovation capabilities. Wrong again—not all biotech companies have necessarily incorporated a holistic understanding of innovation that goes hand in hand with managing the innovation process effectively in an integrated manner and developing new products speedily. This may be the primary reason why so many promising inventions in research laboratories fail to see the light of the day. Most significantly, the rosy picture eloquently presented in the literature does not depict real challenges faced by small biotech firms. Researchers need to look beyond impressive overall industry facts to explore critical issues. The recent biotech revolution may have great potential, but it is still in its early growth phase. Oliver (2003) argued that sorting out the winners is just as tough as in the modern industrial or information ages, when hundreds of railroads, car companies, and software firms competed with one another. Few survived. The research described in this article shows that biotech cannot rely solely on invention but must invest in a timely application of knowledge to organizational and market forces. Dedicated leaders with vision, commitment, strong management teams, and effective business plans will determine the winners.

An Integrated Biotech Innovation Model

A synthesis of the critical issues highlighted in this article has resulted in a proposal for an innovation model that is appropriate for biotech firms. This model depicts the complex network of intraorganizational and interorganizational linkage and consists of parallel, interacting, and interdependent stages that support an integrated approach to managing innovation (Rothwell, 1994). Unlike the traditional technology-push model that the sample companies mostly pursue, this innovation model is developed with a view to providing direction to biotech firms in understanding how to move products and inventions along the pipeline efficiently to address organizational and management challenges.

How Can These Management Challenges Be Addressed?

Previously in this article it was suggested that the domain of biotech activities be divided into three main categories: funding and financing, R&D, and establishing and maintaining alliances whose nature will vary on the basis of a distinction between pre-invention (i.e., discovery) and postinvention stages. In addition, the discussion of Figures 1 and 2 has also highlighted important activities in the biotech products life cycle: patent acquisition, FDA and regulatory approvals, clinical trials, product design, production, and marketing. The model incorporates all of these activities, which will be expected to serve as the backdrop to three sources outlined in the integrated approach: marketplace dynamics, organizational capabilities, and scientific and technological knowledge. Together these will determine the direction of building several necessary in-house organizational competencies. For example, prior to invention, although activities may be focused on scientific aspects companies will also need to adopt a proactive approach toward understanding market dynamics, sustaining existing organizational capabilities, and building new skills and capabilities—both organizational and commercial—for use in the future. Incorporating a strong market orientation will also broaden scientists' understanding of innovation to help them deal with so-called harsh market realities. With an invention in hand, the emphasis shifts to adapting structures to new organizational capabilities, developing still newer capabilities for further growth, and sustaining flexible organizational structures that are open to modifications. In particular, commercialization activities need to be effectively used because the main issue is how to successfully sell the innovation. The business benefits need to be clearly communicated early on; parallel development of an effective collaborative interface between R&D and marketing can be useful. These activities will help transform an invention into an innovation that can satisfy the market and generate revenues and profits. At this stage, knowledge of the regulatory approval process is also required to obtain a patent. As suggested previously, involving marketing managers and legal experts, as well as training scientists in business development, will ensure a smoother transition between these distinct and interacting stages.

For establishing collaborations, the postinvention period may be easier but also exposes companies to intellectual property issues. Building and maintaining effective alliances remains a significant challenge. With integrated innovation management running through the entire life cycle, the process will result in a viable business if the innovation can proceed

smoothly through clinical tests, product designs, production, and marketing and if it can satisfy market needs. Biotech companies should identify common goals earlier and should use formalized contracts with clear-cut roles and expectations to avoid conflicts with their alliance partners. These companies should also learn to place themselves in a better strategic position with respect to gaining valuable collaborations. Gans and Stern (2004) propose an idea factory whereby small biotech firms can play established companies against each other to auction the invention and innovation to the highest bidder. This strategy requires market research and product profiling (Garnsey, 2003). Companies also need to weigh the pros and cons of alliances and learn to relinquish control whenever necessary to fully use complementary assets offered by external agencies. Chesbrough (2003) argues that this approach can lead biotech companies to developing and implementing effective innovation management strategies.

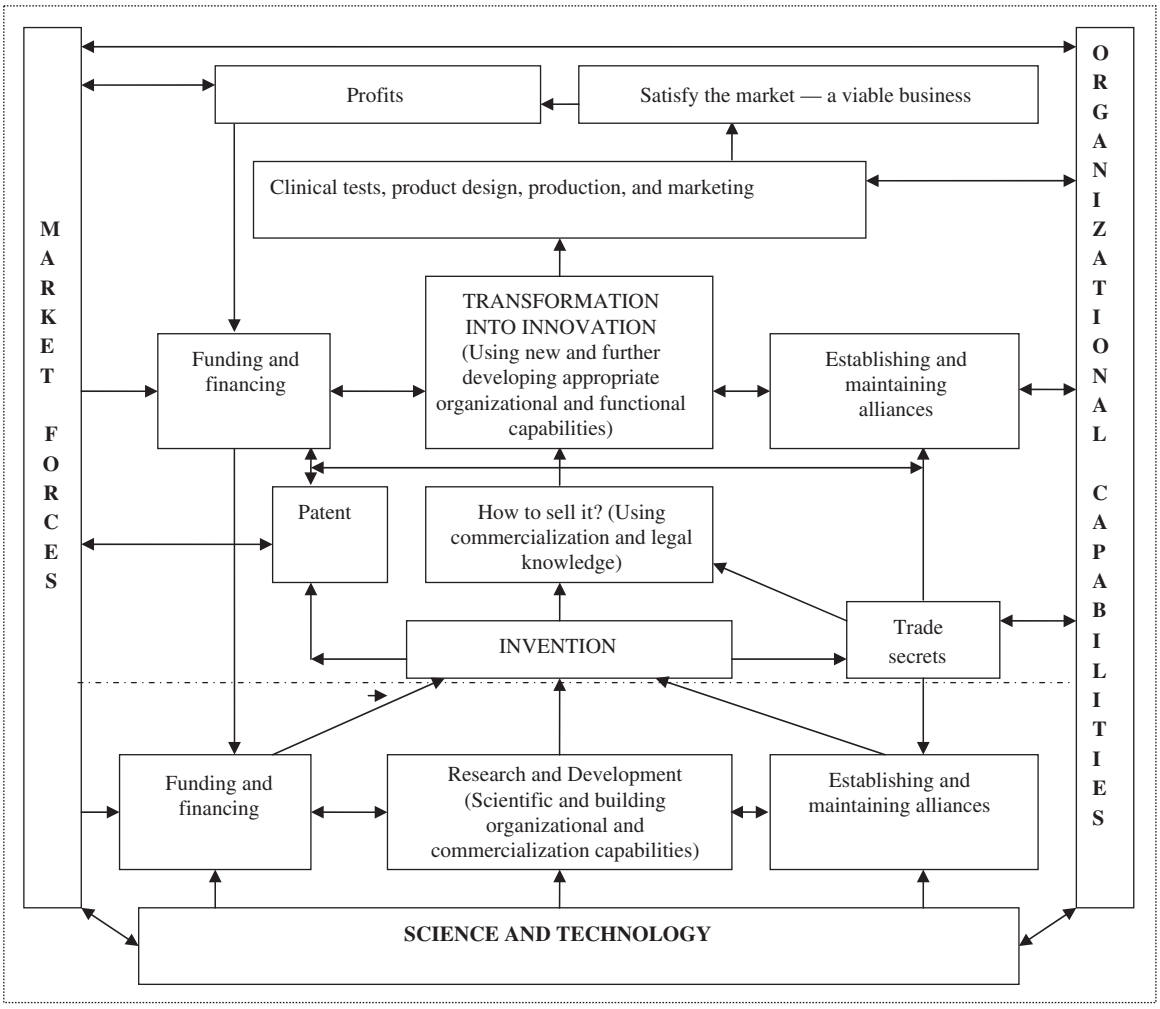
The proposed model departs from the linear and sequential models apparently used by the biotech industry. As interviews indicated, these models have made companies more vulnerable to inflexible organizational mechanisms and a general lack of understanding of the intense impact of marketplace forces, leading to poor decisions. If biotech managers understand the interplay of external and internal mechanisms—and specifically the interactivity of science and technology, organizational capabilities, and marketplace dynamics in decision making—they are likely to be in better strategic positions for long-term economic survival.

Limitations and Directions for Future Research

Several questions that need further research emerged during this exploratory study. First, the proposed model demonstrated a complex interaction of activities influenced by three main sources, namely scientific development, organization capabilities, and the marketplace (Figure 3). This article does not allow for a more detailed investigation of these sources. Further research may therefore investigate these sources by means of case studies of firms. Each of these sources would require application of methods, models, and theories to better integrate its impact on the innovation process in biotechnology firms. Second, although the proposed model establishes interactive associations between various activities, the present study has not found evidence in sample companies to support these interactions. In addition, it focuses only on R&D, financing, and alliances as the mainstays of the biotech product development process and underemphasizes the significance of legal aspects, production, and clinical testing. Further research is needed to refine and broaden the scope of the model for a more comprehensive understanding of how companies use their innovation process to gain successful outcomes. Third, the cross-sectional nature of the study hinders its ability to establish causality between constructs and variables. A further complication is the evolution of firms in their business environment over time. For example, biotechnology firms are constantly exposed to new scientific developments that may impact their research and development efforts. In other words, they would often need to align their internal capabilities with the new technological challenges. Firms would therefore be faced with new challenges at different points of time and would need to apply different management efforts across the stages of the innovation process. This calls for a more dynamic and longitudinal view of the innovation process, taking into account a more complex set of both internal factors as well as external factors across time, to explore the relationships introduced in this study and enhance their ability to explain both the innovation successes and failures. Fourth, although biotech is unique among industries, further studies are needed to explore the integrated innovation mechanisms in other industries for cross-comparisons leading to a more complete view of antecedents of innovation across industries.

The model for biotech innovation management needs further verification and development through research in additional organizations, but even as it stands, it can serve as a useful roadmap for posing crucial research questions. The most important is this: How do organizational capabilities—understood not just as knowledge and skills systems but also as systems of management and control—change as businesses move from invention to innovation? This broad question can be further disaggregated into more detailed questions spanning the whole spectrum of leadership, organizational flexibility, and knowledge management within firms.

The biotech industry provides an important context for developing broad theories of innovation, since it is so uniquely dependent on it. Like the industry it seeks to study, biotech research is in an immature



The dotted line presents the distinction between pre-invention and postinvention stages.

Regulatory approvals are required both before and after clinical trials to grant or withdraw approved drug status.

Figure 3. The Model of Biotech Innovation Management

stage. Each of these paradoxes developed in this article offers fascinating avenues for much-needed further studies. What are the implications of an overly narrow understanding of innovation—as pure discovery—by biotech entrepreneurs? What are the most significant errors biotech managers commit while dealing with products under development? How best to manage the constantly changing alliances that biotech need to nourish to survive? How best to make the transition from scientific invention to commercial success? When to tighten and when to loosen control to maintain creativity but also to eliminate projects that lack promise and respond to inevitable commercialization? Future research directed toward exploring these questions can lead to a better understanding of this innovative yet underresearched industry.

Conclusions

This article has highlighted the challenges small biotech companies face in their search for marketable science and has suggested ways to overcome these challenges. By shedding light on the realities of the biotech industry, several myths associated with the industry have been dispelled. On the basis of the research described in this article, and on existing models for the integrated innovation approach, a new model of innovation is proposed that would be appropriate for biotech companies (Figure 3). Biotech managers are advised to use this model to guide them toward more effective decisions.

The research for this article revealed that information relating to organizational and managerial issues in

the biotech industry is scant and mostly focused on Europe, California, or Massachusetts. Maryland has been neglected in the literature, despite its prominence on the world stage. The current study contributes to filling this gap in the literature. The authors intend to build on this research, and it is hoped that these findings will intrigue other researchers to explore this topic, in terms of the industry as well as the geographic area.

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