Article

Formulation of a Success Model in Pharmaceutical R&D: Efficient Innovation Model

SAGE Open
January-March 2014: 1–9

DOI: 10.1177/2158244014527986
sgo.sagepub.com

Hyunju Rachel Kim[1]

Abstract

Recently, pharmaceutical R&D has been demanded to increase productivity in terms of time efficiency and innovation as well. There have been discontinuous challenges coming up in this industry, such as globalized R&D competition, stricter regulation, lengthy process of clinical trials, and so on. Considering external changes, high competition, and discontinuities in the industry, it is a good time to redefine the concept of success in pharmaceutical R&D. Thus, this article attempts to formulate a new success model in pharmaceutical R&D, through contextualizing the industry's success factors.

Keywords

industry sector management, management, social sciences, development management, decision science, operations management, business administration and business economics, economic science, industrial organization, neuroscience, behavioral sciences

Introduction

The pharmaceutical industry faces many challenges including low productivity (Enyinda, 2008; Hirschler, 2011), declining approval rates from the Food and Drug Administration (FDA) (Hirschler, 2011), and R&D over-expenditures (DiMasi, Hansen, & Grabowski, 2003; Scherer, 2011). There were debates on how to analyze the R&D expenditures or what is its impact on policy makers in Congress (DiMasi, Hansen, & Grabowski, 2008; Light, 2008; Light & Warburton, 2005).

This article takes a new approach to these issues. This article proposes a best managerial model as a solution to R&D managers who need to generate innovative treatments and get FDA approvals. Now more than ever, R&D managers need a new managerial model for overcoming challenges that often result in managerial defeats and lay-offs. Focusing on improving success and efficient innovation is the best way to overcome these industry issues.

This article formulates "Efficient Innovation Model (EIM)" which redefines the concept of success in pharmaceutical industry. According to the model, firms' R&D strategies and R&D managerial capabilities comprise the key constructs that bring about efficient innovation. Outsourcing, collaboration, and offshoring R&D strategies are understood as significant ways toward efficient innovation. R&D managerial capabilities are defined by managerial openness and strategic cognition; managerial openness consists of the openness to new technology, openness to networking, and openness to information sharing.

In addition to suggesting the EIM, this article builds edifice of optimal managerial capabilities by identifying the constructs of optimal managerial capabilities and examining them in relationship with R&D strategies in the context of industrial logic. It appears that managerial capabilities play a significant role in constituting EIM in identifying industrial logic, conducting R&D strategies, and achieving innovation in a most efficient way. For instance, EIM in pharmaceuticals is seamlessly sealed by this article's constructs of managerial capabilities.

EIM diverges from conventional Ansoff's Success Hypothesis. Ansoff broadly hypothesized the relationships among triplet—industrial turbulence level, strategies, and matching managerial capabilities (Ansoff, 1987a, 1987b; Ansoff & McDonnell, 1990). Industrial turbulence levels were quantified by the degree and speed of change and discontinuity. However, this view lacks in a definition and constructs of managerial capabilities as well as strategies in the context of success. The EIM connects managerial capabilities with their strategies to create success.

This article contributes to managerial capabilities literature by highlighting that managers are ultimately responsible for identifying industrial success models and success factors, conducting strategies, and gaining innovation. It builds managerial capabilities constructs through contextualizing industrial logic and strategies; it further specifies constructs and solidifies their interplay. This approach is more specific at reflecting management than *dynamic capabilities* (Teece, Pisano, & Shuen, 1997). Dynamic capabilities are illustrated as the managerial capabilities that are able to utilize internal and external resources in changing ways: networking, technology, collaboration, learning vehicle, and so on.

[1]Alliant International University, San Diego, CA, USA

Corresponding Author:
Hyunju Rachel Kim, School of Management, Alliant International University, 10455 Pomerado Rd., #15, San Diego, CA 92131, USA.
Email: dr.kim.rachel@gmail.com

This article emphasizes on the interplay between a firm's exercised strategic behavior (outsourcing, collaboration, and offshoring) and managerial strategic cognition and suggests there is significance between the two (Kim, 2012). Furthermore, it develops managerial capabilities into strategic cognition and managerial openness to networking, technology, and information sharing toward innovation. This is a more industrial-specific and practice-grasping approach to strategic cognitive algorithms than abstract ones: *strategic link* (Morrow, 2001), *strategic relevance* (Ponzi, 2002), *strategic business link* (Broadbent, 1998; Zack, 1999), *givens* (March & Simon, 1958), *sense-making* (Weick, 1995), *interpretive schemes* (Daft & Weick, 1984), and *dominant logic* (Prahalad & Bettis, 1986). Strategic cognition is important as it provides intra-relationships between managerial capabilities and inter-relationships with strategies implementation and achieving innovation (Kim, 2012).

Conducting R&D collaboration strategies (domestic and/or offshore) is understood as efficient innovation strategy that requires management's high level of strategic cognition and openness. The collaboration strategy is involved with multi-step operations that managers make new patterns of decisions through. This perspective contrasts with organizational rigidity where management repeats historical patterns of R&D procurement reflecting ingrained repertoires (Simon, 1947), search rules (Cyert & March, 1963), operating procedures (Allison, 1971), and routines (Nelson & Winter, 1982).

This article begins by providing a general background of the pharmaceutical industry including industrial logic, the importance of R&D, as well as current industry challenges. Next, it discusses the current success models and an industrial success factor involved in them, followed by an illustration of the most preferred strategies for achieving efficient innovation. Finally, the article demonstrates the significance of R&D management capabilities regarding industrial logic, strategies, and the EIM.

Missing Link: R&D Management Capabilities

To understand pharmaceutical industry's logic, it is critical to understand the significance of R&D and its managerial capabilities. It is not easy, however, to have a holistic view of R&D by using annual financial performance reports as a yardstick. R&D has not brought short-term outcomes related to investments. In addition, even when analyzing R&D's long-term outcomes, it is hard to articulate R&D function by relating econometric data such as market value. For example, past studies in R&D spending announcements and positive share-price reactions (Chan, Martin, & Kensinger, 1990; Doukas & Switzer, 1992) suggested that R&D expenditure does not ensure consistent long-term contribution to shareholder value (Chauvin & Hirschey, 1993).

Therefore, rather than relying on econometric analyses, it is critical to focus on the industrial success—innovative treatments or products. Besides, it should be achieved in a fast and confidential manner to earn patents, all necessary components of staying ahead of competitors in this industry. Hence, managerial capabilities play an essential role at identifying industrial characteristic opportunities that include the early detection of potential from raw data, such as a new technology or a new regulation, and making sense out of that raw data. Understanding industrial logic is crucial to formulating success models and conducting R&D strategies is imperative for innovation. In this way, management capabilities function at the core of R&D and its innovation activities.

Pharmaceutical Industry Overview

To understand R&D significance, it is necessary to have a general understanding of the R&D processes in the pharmaceutical industry. The following section aims to address reports on R&D management's role as a determining factor of a company's success. This background research serves as the foundation for attaining an industrial logic.

Importance of R&D in Pharmaceuticals

R&D is at the core of the pharmaceutical industry in terms of generating patents and exclusive rights over time. This legal rewarding system is linked to monetary rewards, such as retention of profits and preventing competitors from catching up or copying information knowledge. Under this structure, the well-known blockbuster model drugs appeared in the 1980s targeting mass markets with a focus on prevalent cardiovascular or metabolic diseases such as hypertension, peptic ulcers, and lipid metabolism disorders. Good examples of these drugs are enalapril, ramipril, cimetidine, ranitidine, and atorvastatin (Lipitor). Lipitor was only the sixth HMG-CoA reductase inhibitor entering the market for the treatment of lipid metabolism disorders and provided over $10 billion in annual sales (Nickisch, Greuel, & Bode-Greuel, 2009).

Current Challenges of Pharmaceutical Industry

Regulation, patents, and globalized competitors. Pharmaceutical industry has faced stricter regulations for the last 10 years. Compared with other major markets that regulate drug prices directly or indirectly, drug prices in the U.S. pharmaceutical market were largely unregulated. Since 2002, increasing numbers of pharmaceutical patents have been expiring; consequently, domestic companies producing generic drugs are posing greater threats to "big pharma." Pharmaceutical price controls in the United States also began with the passage of the Medicare Modernization Act (MMA) in 2003. Furthermore, R&D in pharmaceutical

companies has been fast growing in India, Brazil, and Asia—especially China (Howells, 2008). They may take advantage of this situation by sharing information about products with expired patents and improving manufacturing capabilities. However, globalization notwithstanding, the United States still specializes in searching for new treatments and new drugs.

Declining productivity. The pharmaceutical industry has been experiencing low productivity mostly stemming from extensive requirements in clinical trials (requirements understood as an exchange for possible exclusivities and returns on R&D investments). According to pharmaceutical industry representatives, the current pricing structure is necessary both to cover the high fixed costs of R&D operations and to maintain R&D investment for the future (Abbott & Vernon, 2007). However, within a decade, productivity got worse in terms of the success ratio of clinical trials and commercialization. In 1995, only 1 in 5,000 compounds made it all the way through the maze of clinical trials and approvals to the market (Studt & Cassidy, 1995). More recently (1992-1999), however, successful models have changed and only 10% of drugs entering development reach the market, with only 20% of marketed drugs recovering their investment. The entire drug development process is very lengthy—8 to 12 years—and extremely costly—$802 million (DiMasi et al., 2003) to $868 million (Adams & Brantner, 2006) for each new drug. Furthermore, additional drugs with total annual sales of $170 billion will lose their patents by 2015 (Nickisch et al., 2009).

Formulation of EIM

Current Success Models

Research into existing products and their markets helps conceptualize what constitutes success in the pharmaceutical industry. To conceptualize what constitutes success in this industry, existing products and their markets were investigated. Broadly, there are three types of products in the current market. The first type is a producer-driven for branded products, the second is a buyer-driven model for quality generics for high-end markets, and the third is generics for low-end markets (Haakonsson, 2009). Branded products are known as blockbuster models, which are the most preferred success model by pharmaceutical companies as they provide a monopoly period by granting a patent and market exclusivity. On the other hand, "specialty pharma" approaches have also been successful since they differentiate markets and products from *Big Pharma's* main interest in the mass market (Nickisch et al., 2009). These specialty pharma approaches were based on the diversification of products and marketing in the pharmaceutical industry and each company's unique capabilities.

According to Kambhammettu (2007), "specialty pharma" approach can be categorized as follows:

- *Niche therapeutic area/orphan disease concentrators* focus on specific therapeutic segments such as ophthalmology, specific tumor types, and other rare but serious diseases. Examples are Genzyme, Alcan, and Actelion.
- *Portfolio adapters* pursue the products de-prioritized by *big pharma* and increase sales volume by means of additional development investments and intensive marketing. Shire and King Pharmaceuticals are in this type.
- *Licensing experts* license early and late stage development candidates and complete development toward approval. Helsinn Pharma is an example of this type.
- *Drug delivery experts* reformulate existing molecules to enhance their therapeutic application. Nektar and Elan apply this approach.
- *Specialty generic* companies develop their own branded generics by reformulating existing products. Barr and Watson use this approach.

From a R&D managerial perspective, the most preferred success models are either blockbuster models or orphan disease concentrate models. Blockbuster models target mass markets by focusing on prevalent cardiovascular or metabolic diseases with a bigger population of patients, such as diabetes or high cholesterol, while orphan disease concentrators target smaller populations of patients. However, both success models must contain innovative knowledge of treatments to concretely achieve any form of new valuable intellectual property, licensing, patents, and market exclusivity. As such, current FDA regulation legally rewards innovative treatments with the award of patent, market exclusivity, and FDA approval time reduction.

As predicted a decade ago, patents and market exclusivity of currently successful models are expiring; in 2011, Pfizer lost a $10-billion-a-year revenue from Lipitor due to patent expiration. Furthermore, the failure of clinical trials to replace Lipitor made Pfizer's CEO call for a reinvention. Merck discontinued one of two major clinical trials of a blood thinner that caused dangerous amounts of bleeding in some patients. The industry faces more of these types of challenges and thus, R&D management needs urgent solutions.

New Model of Innovation Management

The best way of overcoming these industrial challenges is to build efficient R&D to produce innovative products and keep more products in the pipeline. Pharmaceutical R&D management needs a new model of innovation management for enabling innovation and efficiency. However, these are conflicting ideas in management theory. Efficiency

management is characterized as a linear process that focuses on reducing costs and time. On the other hand, innovation management is typically referred to as a chaotic process in terms of nonlinear relationship between actions and outcomes over time (Cheng & Van de Ven, 1996), making it a complex adaptive system (Trochim, Cabrera, Milstein, Gallagher, & Leischow, 2006). In this respect, pharmaceutical R&D management should go beyond what most management theories define in terms of efficiency and innovation—a call to think outside the box.

EIM

Efficient innovation is an industrial and managerial success model that pharmaceutical R&D pursues. The most determinant success factor of R&D management is to discover an innovative treatment or an innovative way of treatment faster than a competitor discovers it. Without efficient innovation, the firm cannot claim any exclusive right over other competitors—a basic rule and necessity in the pharmaceutical industry. In the pharmaceutical industry, competition is highly globalized and new technologies are quickly emerging.

To have efficient innovation, companies must pursue various collaborations and networks, rather than solely building internal capabilities within companies themselves. Hence, the first way to create efficient innovation is allowing R&D management to utilize collaboration, outsourcing, and mergers and acquisitions (M&A) strategies to actively search for materials and skills that might be crucial for gaining potentially new drug candidates before competitors. Powell (1998) observed that in addition to managing inter-organizational networking, the capability of managing R&D collaboration strategy is a key driver of organizational and knowledge management.

The second way to pursue efficient innovation is with strategic decision making that translates into cost reduction. According to DiMasi (2002), the earlier a decision is made, the less out-of-pocket drug discovery and development costs a company incurs in the future. Reducing phase times by 41.3% or increasing the clinical success rate from 30.4% to 31.7% would yield a $200 million cost reduction. Though this study highlighted the importance of decision making by R&D managers, there was no direct study to connect R&D managers with strategic cognition in relation to strategic behavior (collaboration or offshoring; firms' strategic behavior) and innovation (success).

The pharmaceutical industry achieves success by new drug development, which must contain an innovative component—new or better treatments in the market. Under this industrial logic, a firm legally achieves market exclusivity when FDA approves a new treatment; however, conceptually, a firm's R&D achieves this through new knowledge creation. Hence, conceptually, drug development is a process of generating innovative knowledge where R&D management pursues the creation of new drugs through the refinement of existing materials into therapeutically more effective drugs. Essentially, pharmaceutical R&D needs to address both refining the concepts and efficiently identifying innovative knowledge for new drug creation (Elmquist & Segrestin, 2007). Drug discovery and development processes necessitate a high level of managerial openness as well as strategic cognition that enable management to stay focused on collective and cumulative knowledge processes. Hence, the EIM is determined by firms' strategic behavior and high level of managerial capabilities, strategic cognition, and managerial openness.

The Most Preferred Pharmaceutical R&D Strategies

Following an understanding of the EIM, it is important to discuss current R&D strategies. The two most preferred R&D collaboration strategies are outsourcing and offshoring. Outsourcing strategy has been historically important in United States and offshoring R&D strategy has been globalized, which remains understudied regarding efficient innovation and relationship with managerial capabilities.

R&D Outsourcing Strategy

Since the late 1970s, the pharmaceutical industry has had challenges and changes relating to the entry of biotechnology and biopharmaceutical firms (Powell, Koput, & Smith-Doerr, 1996; Shan, Walker, & Kogut, 1994; Walsh, 1995). From a knowledge perspective, these changes have been associated with new knowledge areas such as cell and molecular biology, pharmacology, physiology in the pharmaceutical industry (McKelvey, 1995; Orsenigo, 1989; Valle & Gambardella, 1993). The traditional pharmaceutical industry, mostly driven by chemistry, got involved in new and flexible companies called new biotechnology-based firms (NBFs). This industrial discontinuity caused large pharmaceutical firms to seek partnerships with these NBFs to adapt to new industrial change and increase opportunities. In this way, large generalist pharmaceutical firms have found outsourcing useful. Through these interactive partnerships and contracts, the NBFs have also found advantages in managing the high costs of development and marketing, since specialist contract research organizations (CROs) centered especially on clinical trial and testing work (Howells, Gagliardi, & Malik, 2008). For this reason, outsourcing has brought mutual benefits to both parties. Specifically, it stimulated many knowledge spillover effects near pharmaceutical R&D outsourcing sites.

Outsourcing strategies were what pharmaceutical companies had developed to deal with these new entrants, which were equipped with new knowledge and organizational flexibility. Hence, the previously dominant

pharmaceutical companies have been more flexible and faster via external collaboration with NBFs (Pisano, 1994; Pisano, Shan, & Teece, 1988). There have been three tendencies regarding outsourcing strategies. The first is that companies are outsourcing what they do not consider their core business areas (Howells et al., 2008). A second recent tendency among the producers of branded pharmaceuticals is that they focus on similar areas of competence. Finally, there is a shift in R&D strategy to externalize their research activities by buying upcoming biotech companies, which may have a new product in their laboratory but not the financial power or distribution systems to market it (Haakonsson, 2009).

Overall, outsourcing strategies have boosted innovation through interaction with NBFs (Orsenigo, Pammolli, & Riccaboni, 2001). In addition, there is a reduction on development time and cost benefits when using outsourcing strategies (Howells et al., 2008).

Offshoring R&D Strategy

The Agreement on Trade Related Aspects of Intellectural Property Rights (TRIPS) of the World Trade Organization (WTO) officially globalized the pharmaceutical industry (Haakonsson, 2009), and offshoring R&D became a mainstream practice. According to a study by Chacar and Lieberman (2003), U.S. pharmaceutical companies' international acquisitions and establishment of foreign research laboratories are reaping benefits in drug discovery by globalizing their R&D networks. Globalized R&D showed innovative output: the annual number of "new chemical entities" (NCEs) approved by the U.S. FDA and the annual number of U.S. patents granted increased significantly. Offshoring R&D attempts to overcome excessive centralization or bureaucratic diseconomies of R&D (Williamson, 1991). This includes the rapid expansion of economies in China, India, and Brazil, coupled with the desire to get closer to consumers in relation to R&D activity.

Despite the many supply-led claims of R&D globalization, the demand side strongly correlates with the expansion of foreign R&D. Many multi-national companies are not only facing ever-shorter development cycles; however, they are simultaneously confronting wider geographical spans of their R&D establishments.

Constructs of R&D Management Capability

As previously described, R&D collaboration strategies, outsourcing, and offshoring R&D are the most preferred strategies in pursuit of efficient innovation. These strategies involve coordinating and combining external and internal R&D resources, which are known as innovation capabilities (Coombs & Metcalfe, 2002). In this view, innovative managerial capability is essential in successfully conducting R&D collaboration strategies. R&D managerial capabilities are strategic cognition and managerial openness, where managerial openness consists of the openness to new technology, openness to networking, and openness to information sharing. These are the keys to implementing, optimizing, and making the most of outsourcing and offshoring R&D strategies.

Strategic cognition is one of the innovative R&D managerial capabilities of visualizing the potential that a new treatment can offer to patients and its potential impact on the market. Without a high level of strategic cognition, managers may not be willing to take risks in leveraging current resources for the future (see Ansoff, 1965, p. 181). Strategic cognition helps envision the potential of a new treatment, aggressively exploiting internal resources as well as exploring external resources. In the process of drug development, a certain level of resource deficiency always occurs, which is overcome by R&D collaboration strategies that explore external resources. Thus, innovation is achieved through the capability of implementation (Coombs & Metcalfe, 2002) and targeted by managers and by their strategic decisions (Bessant & Francis, 2005). At this point, strategic cognition becomes significant for pursuing innovation in more efficient ways than competitors do.

The significance of strategic cognition becomes evident in the context of the managerial implementation of R&D collaboration strategies. The managerial capability of conducting R&D collaboration strategy is a key to knowledge management (Powell, 1998). The high level of managerial strategic cognition and exercised strategies are linked to innovation (Kim, 2012). In implementing R&D collaboration strategies and exploring external knowledge through them, managers' capabilities extend beyond the concept of operational management that prioritizes efficiency and short-term economic outcomes (Ackoff, 1990, p. 523; Ansoff, 1965, pp. 5-6).

Managerial openness to new technologies—another construct of managerial capabilities—is managerial perception and practice toward new technologies. It gains significance by understanding the impact of new technologies in pharmaceutical industry. New technologies evidently are an industrial characteristic factor that caused industrial shift by allowing NBFs in pharmaceutical history. New technology ushered NBFs' successful entry (Darby & Zucker, 1997) and drove incumbent pharmaceuticals to collaborate with them (Howells et al., 2008; Orsenigo, Pammolli, Riccaboni, Bonaccorsi, & Turchetti, 1997). In a recent study, managerial openness to new technologies is linked to innovation (Kim, 2012), highlighting its importance in efficient innovation.

Openness to networking and openness to information sharing are the two other important constructs of managerial capabilities that gain significance by understanding the drug discovery and development process. The work of Elmquist and Segrestin (2007) showed that the drug discovery process is more of a creative process

wherein new concepts and knowledge are continually generated. While doing so, R&D management functions as knowledge interpreters and innovative *knowledge generators*. Drug discovery and development processes necessitate a managerial openness that enables management to stay focused on collective and cumulative knowledge process, as well as strategic cognition.

Managerial openness to networking is highly related to innovation. In the process of innovation, R&D managers both individually and organizationally expand the boundary of knowledge. Thus, the innovative knowledge is strategically accumulated, expanded, and generated by R&D management via communication. During the process of developing and introducing innovation, R&D communication networks are significant at the inter- and intra-firm levels (Tushman, 1979). In a knowledge expansion or organizational learning process, a common code of communication and coordinated search procedure are important (Teece et al., 1997). As the prior studies addressed the importance of networks, accordingly, managerial openness to networking is critical in sharing and expanding knowledge. It includes networking with R&D staffs, with other department managers (over R&D), within firms, and between firms (i.e., with R&D managers at other firms). According to Powell et al.'s (1996) study on inter-organizational collaboration in biotechnology, firms embedded in benefit-rich networks are likely to have greater innovative performance as well.

Managerial openness to information sharing is highly related to innovation. Early studies showed that information sharing between and within organizations was one of the critical factors for organizational creativity (Clitheroe, Stokols, & Zmuidzinas, 1998; Ford, 1996; Woodman, Sawyer, & Griffin, 1993). Furthermore, recently, the R&D networks are considered a flow of information (Whelan, Teigland, Donnellan, & Golden, 2010). R&D professionals use three external information sources: personal contacts, Internet sources, and academic publications (Whelan et al., 2010). Conclusively, it is critical for R&D managers to have high level of openness to networking and information sharing to increase innovation.

Strategic cognition and openness—cognitive flexibility—are the main attributes of strategic managers. Both these attributes represent two aspects of strategic thinking—metacognition (the process of thinking about thinking) and leadership (Industrial College of the Armed Forces, 2001). Strategic managers are like strategic leaders as they lead organizations toward the targeted positions in the market, achieve the organization's goals, and help shape future norms and rules in the industry (Kang & Afuah, 2010). From this perspective, strategic managers tend to be more creative and are referred to as *map makers* rather than *map users* (Mintzberg, Ahlstrand, & Lampel, 1998, pp. 159-160). The strategic cognition is referred to as *long-term planning* (Pascale, 1999), *high level of conceptualization* (Industrial College of the Armed Forces, 2001), and the *intuition of bringing all together of knowledge and experience* (Mintzberg et al., 1998).

In implementing R&D collaboration strategies and pursuing innovation, both strategic cognition and managerial openness play significant roles. Strategic cognition and managerial openness are vital since R&D managers aggressively exploit external sources for innovative opportunities. Day (1994) observed that managers' mental models provide a shared ideology that enables collective interpretation of market reality, and thus these models play a key role in managerial decisions about capability enhancement and renewal. When managers interpret the market situation as an opportunity rather than a threat, their cognitive flexibility is engaged and they tend to more aggressively invest resources in new strategic initiatives (Dutton & Jackson, 1987; White, Varadarajan, & Dacin, 2003).

R&D is essentially a constant, lengthy discovery process toward creation (Elmquist & Segrestin, 2007). Managerial openness becomes critical in the drug discovery and development process that consists of multi-steps with diverse experts. During pharmaceutical R&D management's pursuit of innovation, there are multi-interim steps toward newness that require managerial openness. Therefore, when managers pursue innovation, innovative treatments or products, they strategically position themselves toward innovative knowledge and potential opportunities for innovative knowledge generation.

Managerial openness can be measured by the perceptions and practice of R&D managers regarding networking and information sharing. This involves interaction with others in a social context called *participative openness* (Senge, 1992). Information sharing is more delicate than networking in this industry, which tends to pursue confidentiality of appropriated knowledge. This is close to Senge's *reflective openness* that contains a cerebral response to the ideas of others but does not involve direct social interaction with others.

By contextualizing industrial logic and industrial success models, this study formulates EIM that optimizes efficient innovation with R&D strategies and managerial capabilities. EIM situates R&D managerial capabilities at the core of it and demonstrates the significance of optimal R&D management capabilities. The R&D managerial capabilities; openness to information sharing, networking, and new technology; and strategic cognition, are essential to pursuing innovation and strategizing decision making to exploit internal/external resources (Kim, 2012). Pharmaceutical companies need to develop and grow these R&D management capabilities in pursuit of innovation.

Conclusion

This article formulated an EIM to redefine industrial success and achieve efficient innovation. The EIM strengthens innovative managerial capabilities and actively

deploys R&D strategies by identifying industrial turbulence factors and overcoming resource deficiencies. By using the EIM, R&D managers are better able to perform efficient innovation, to achieve industrial success, and to address the pharmaceutical industry's current challenges including declining productivity and globalized competition.

Furthermore, the EIM empowers R&D management to pursue innovative knowledge by strategically exploring external knowledge. This managerial view addresses industrial issues, innovative knowledge creation/expansion, and strategies in a dynamic way that contains multi-variables. This provides a better approach to innovation than the conventional way of only looking at the two dimensions of inputs and outcomes.

In management theory, managerial capabilities, business models, and industrial logics are mutually interconnected; business models are the interpretation of management hypothesis about customers, markets, and the best way of the firm to meet their needs (Teece, 2010). In Teece's definition, a business model is organized around the hypothesis of what customers want or what management thinks they want; therefore, the unit of analysis in a business model is its value proposal. Industrial logics and business models are closely related as these anticipations are formed from within a manager's mind-set, which stem from their reading of the industry's dominant logic. In short, managers create the business models by interpreting the industry's dominant logic. Furthermore, there is an implicit association between business models and strategy, as strategy refers to the choice of business models through which the firm will compete in a marketplace (Casadesus-Masanell & Ricart, 2010, p. 196).

The main contribution of this article is shedding light on the important relationship between managerial capabilities, strategies, and innovation (an industrial success model). Firms achieve innovation through a focus on strategic behavior and developing innovative managerial capabilities, specifically strategic cognition and managerial openness (Kim, 2012). The underlying premise behind the EIM is that managers are at the core of every decision-making and strategic behavior. When managers possess high level of openness to new information, new technologies, and networking, then, they tend to identify industrial turbulence factors and industrial success models. On the other hand, when managers possess high levels of strategic cognition, they facilitate long-term planning for strategic goals and are willing to make strategic decisions about resource utilization or deficiency, such as collaboration strategies. In addition, this article contributes to current management literature by building constructs of managerial capabilities (Kim, 2012). Dynamic capabilities did not specify constructs, though illustrated as "the ability to integrate, adapt, and configurate internal and external resources" (Teece et al., 1997, p. 516). This research demonstrates the importance of managerial practitioners to emphasize core capabilities to achieve innovation.

In today's current market, pharmaceutical R&D needs optimal managerial capabilities to evaluate current moves in the marketplace, formulate success models, and create competitive strategies to take preemptive actions in the fast-changing global environment. In other words, companies will achieve efficient innovation when they focus on developing high levels of strategic cognition and managerial openness. Hence, this article offers internal locus view of innovation that pharmaceutical R&D needs to efficiently generate.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research and/or authorship of this article.

Reference

Abbott, T. A., & Vernon, J. A. (2007). The cost of U.S. pharmaceutical price regulation: A financial simulation model of R&D decisions. *Managerial and Decision Economics, 28*, 293-306. doi:10.1002/mde.1342

Ackoff, R. L. (1990). Redesigning the future. *Systems Practice, 3*, 521-524.

Adams, C. P., & Brantner, V. V. (2006). Estimating the cost of new drug development: Is it really $802 million? *Health Affairs, 25*, 420-428. doi:10.1377/hlthaff.25.2.420

Allison, G. (1971). *The essence of decision: Explaining the Cuban missile crisis*. Boston, MA: Little Brown.

Ansoff, H. I. (1965). *Corporate strategy*. New York, NY: McGraw-Hill.

Ansoff, H. I. (1987a). The emerging paradigm of strategic behavior. *Strategic Management Journal, 8*, 501-515.

Ansoff, H. I. (1987b). Strategic management of technology. *Journal of Business Strategy, 7*(3), 28-39.

Ansoff, I., & McDonnell, E. (1990). *Implanting strategic management*. New York, NY: Prentice Hall.

Bessant, J., & Francis, D. (2005). Targeting innovation and implications for capability development. *Technovation, 25*, 171-183. doi:10.1016/j.technovation.2004.03.004

Broadbent, M. (1998). The phenomenon of knowledge management: What does it mean to the information profession? *Information Outlook, 2*(5), 23-35.

Casadesus-Masanell, R., & Ricart, J. E. (2010). From strategy to business models and onto tactics. *Long Range Planning, 43*, 196-215. doi:10.1016/j.lrp.2010.01.004

Chacar, A. S., & Lieberman, M. B. (2003). Organizing for technological innovation in the U.S. pharmaceutical industry. *Advances in Strategic Management, 20*, 299-322. doi:10.1016/S0742-3322(03)20011-5

Chan, S. H., Martin, J., & Kensinger, J. (1990). Corporate research and development expenditures and share value. *Journal of Financial Economics, 26*, 255-276. doi:10.1016/0304-405X(90)90005-K

Chauvin, K. W., & Hirschey, M. (1993). Advertising, R&D expenditures and the market value of the firm. *Financial Management, 22*, 128-140. doi:10.2307/3665583

Cheng, Y. T., & Van de Ven, A. H. (1996). Learning the innovation journey: Order out of chaos. *Organization Science, 7*, 593-614. doi:10.1287/orsc.7.6.593

Clitheroe, H. C., Stokols, D., & Zmuidzinas, M. (1998). Conceptualizing the context of environment and behavior. *Journal of Environmental Psychology, 18*, 103-112. doi:10.1006/jevp.1998.0091

Coombs, R., & Metcalfe, S. (2002). Innovation in pharmaceuticals: Perspectives on the co-ordination, combination and creation of capabilities. *Technology Analysis & Strategic Management, 14*, 261-271. doi:10.1080/09537320220000210 4

Cyert, R. M., & March, J. G. (1963). *A behavioral theory of the firm*. Englewood Cliffs, NJ: Prentice Hall.

Daft, R. L., & Weick, K. E. (1984). Toward a model of organizations as interpretation systems. *Academy of Management Review, 9*, 284-295.

Darby, M. R., & Zucker, L. G. (1997). Present at the biotechnological revolution: Transformation of technological identity for a large incumbent pharmaceutical firm. *Research Policy, 26*, 429-446.

Day, G. S. (1994). The capabilities of market-driven organizations. *Journal of Marketing, 58*(4), 37-52. doi:10.2307/1251915

DiMasi, J. A. (2002). The value of improving the productivity of the drug development process: Faster times and better decisions. *Pharmacoeconomics, 20*(Suppl. 3), 1-10. doi:10.2165/00019053-200220003-00001

DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: New estimates of drug development costs. *Journal of Health Economics, 22*, 151-185. doi:10.1016/S0167-6296(02)00126-1

DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2008). Misleading congress about drug development: Reply. *Journal of Health Politics, Policy and Law, 33*, 319-324. doi:10.1215/03616878-2007-063

Doukas, J., & Switzer L. N. (1992). The stock market's valuation of R&D spending and market concentration. *Journal of Economics & Business, 44*, 95-114. doi:10.1016/0148-6195(92)90009-Y

Dutton, J., & Jackson, S. (1987). Categorizing strategic issues: Links to organizational action. *Academy of Management Review, 12*, 76-90.

Elmquist, M., & Segrestin, B. (2007). Towards a new logic for front-end management: From drug discovery to drug design in pharmaceutical R&D. *Creativity and Innovation Management, 16*, 106-120. doi:10.1111/j.1467-8691

Enyinda, C. I. (2008). *Modeling risk management in the pharmaceutical industry: Global supply chain logistics using analytic hierarchy process model* (Doctoral dissertation). North Dakota State University of Agriculture and Applied Science, Fargo.

Ford, C. M. (1996). A theory of individual creative action in multiple social domains. *Academy of Management Review, 21*, 1112-1142.

Haakonsson, S. J. (2009). The changing governance structures of the global pharmaceutical value chain. *Competition & Change, 13*, 75-95. doi:10.1179/102452909X390574

Hirschler, B. (2011, March 11). Analysis: Big Pharma strips down broken R&D engine. *Reuters*. Retrieved from http://www.reuters.com/article/2011/05/11/us-summit-rd-idUSTRE74A3JA20110511

Howells, J. (2008). New directions in R&D: Current and prospective challenges. *R&D Management, 38*, 241-252. doi:10.1111/j.1467-9310.2008.00519.x

Howells, J., Gagliardi, D., & Malik, K. (2008). The growth and management of R&D outsourcing: Evidence from UK pharmaceuticals. *R&D Management, 38*, 205-219. doi:10.1111/j.1467-9310.2008.00508.x

Industrial College of the Armed Forces. (2001). *Strategic leadership and decision-making*. Retrieved from http://www.au.af.mil/au/awc/awcgate/ndu/strat-ldr-dm/cont.html

Kambhammettu, S. (2007). *Evolving paradigms in the specialty industry*. Frost & Sullivan Market Insight. Retrieved from http://www.frost.com/prod/servlet/market-insight-top.pag?docid=103268702

Kang, J., & Afuah, A. (2010). Profiting from innovations: The role of new game strategies in the case of Lipitor of the U.S. pharmaceutical industry. *R&D Management, 40*, 124-137. doi:10.1111/j.1467-9310.2010.00597.x

Kim, H. R. (2012). *Openness and strategic aggressiveness as R&D management capabilities in the context of biopharmaceutical industry* (Doctoral dissertation). Alliant International University, San Diego, CA.

Light, D. W. (2008). Reply to DiMasi, Hansen, and Grabowski. *Journal of Health Politics, Policy and Law, 33*, 325-327. doi:10.1215/03616878-2007-064

Light, D. W., & Warburton, R. N. (2005). Setting the record straight in the reply by DiMasi, Hansen and Grabowski. *Journal of Health Economics, 24*, 1045-1048. doi:10.1016/j.jhealeco.2005.07.003

March, J., & Simon, H. (1958). *Organizations*. New York, NY: Wiley.

McKelvey, M. (1995). *Evolutionary innovation: The business of biotechnology*. Oxford, UK: Oxford University Press.

Mintzberg, H., Ahlstrand, B. W., & Lampel, J. (1998). *Strategy safari: The complete guide through the wilds of strategic management*. London, England: Financial Times.

Morrow, N. M. (2001). Knowledge management: An introduction. *Annual Review of Information Science and Technology, 35*, 381-422.

Nelson, R. R., & Winter, S. G. (1982). *An evolutionary theory of economic change*. Cambridge, MA: Belknap Press.

Nickisch, K. J., Greuel, J. M., & Bode-Greuel, K. M. (2009). How can pharmaceutical and biotechnology companies maintain a high profitability? *Journal of Commercial Biotechnology, 15*, 309-323. doi:10.1057/jcb.2009.3

Orsenigo, L. (1989). *The emergence of biotechnology*. London, England: Pinter.

Orsenigo, L., Pammolli, F., & Riccaboni, M. (2001). Technological change and network dynamics: Lessons from the pharmaceutical industry. *Research Policy, 30*, 485-508. doi:10.1016/S0048-7333(00)00094-9

Orsenigo, L., Pammolli, F., Riccaboni, M., Bonaccorsi, A., & Turchetti, G. (1997). The evolution of knowledge and the dynamics of an industry network. *Journal of Management and Governance, 1*, 147-175.

Pascale, R. T. (1999). Surfing at the edge of chaos. *Sloan Management Review, 40*(3), 83-94.

Pisano, G. P. (1994). Knowledge integration and the locus of learning: An empirical analysis of process development. *Strategic Management Journal, 15*, 85-100. doi:10.1002/smj.4250150907

Pisano, G. P., Shan, W., & Teece, D. J. (1988). *Joint ventures and collaboration in the biotechnology industry*. Cambridge, MA**:** Ballinger Publishing.

Ponzi, L. (2002). *The evolution and intellectual development of knowledge management* (Unpublished doctoral dissertation). Long Ireland University, Brookville, NY.

Powell, W. W. (1998). Learning from collaboration: Knowledge and networks in the biotechnology and pharmaceutical industries. *California Management Review, 40*, 228-240. doi:10.2307/41165952

Powell, W. W., Koput, K. W., & Smith-Doerr, L. (1996). Interorganizational collaboration and the locus of innovation: Networks of learning in biotechnology. *Administrative Science Quarterly, 41*, 116-145. doi:10.2307/2393988

Prahalad, C. K., & Bettis, R. A. (1986). The dominant logic: A new linkage between diversity and performance. *Strategic Management Journal, 7*, 485-501. doi:10.1002/smj.4250070602

Scherer, F. M. (2011). *R&D costs and productivity in biopharmaceuticals* (Faculty Research Working Paper Series). John F. Kennedy School of Government, Harvard University. Available from www.hks.harvard.edu

Senge, P. M. (1992). Mental models. *Strategy & Leadership, 20*, 4-44. doi:10.1108/eb054349

Shan, W., Walker, G., & Kogut, B. (1994). Interfirm cooperation and startup innovation in the biotechnology industry. *Strategic Management Journal, 15*, 387-394. doi:10.1002/smj.4250150505

Simon, H. (1947). *Administrative behavior*. London, England: MacMillan.

Studt, T., & Cassidy, R. (1995, November). The realities of drug discovery, from an insider's viewpoint. *R&D Magazine, 37*, 58-60.

Teece, D. J. (2010). Business models, business strategy and innovation. *Long Range Planning, 43*, 172-194. doi:10.1016/j.lrp.2009.07.003

Teece, D. J., Pisano, G., & Shuen, A. (1997). Dynamic capabilities and strategic management. *Strategic Management Journal, 18*, 509-533. doi:10.1002/(SICI)1097-0266(199708)18:7<509::AID-SMJ882>3.0.CO;2-Z

Trochim, W. M., Cabrera, D. A., Milstein, B., Gallagher, R. S., & Leischow, S. J. (2006). Practical challenges of systems thinking and modeling in public health. *American Journal of Public Health, 96*, 538-546. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1470516/pdf/0960538.pdf

Tushman, M. L. (1979). Managing communication networks in R&D labs. *Sloan Management Review, 20*, 37-49.

Valle, F., & Gambardella, A. (1993). "Biological" revolution and strategies for innovation in pharmaceutical companies. *R&D Management, 23*, 287-302. doi:10.1111/j.1467-9310.1993.tb00835.x

Walsh, J. P. (1995). Managerial and organizational cognition: Notes from a trip down memory lane. *Organization Science, 6*, 280-321. doi:10.1287/orsc.6.3.280

Weick, K. (1995). *Sensemaking in organizations*. Thousand Oaks, CA: Sage.

Whelan, E., Teigland, R., Donnellan, B., & Golden, W. (2010). How Internet technologies impact information flows in R&D: Reconsidering the technological gatekeeper. *R&D Management, 40*, 400-413. doi:10.1111/j.1467-9310.2010.00610.x

White, J. C., Varadarajan, P., & Dacin, P. (2003). Market situation interpretation and response: The role of cognitive style, organizational culture and information use. *Journal of Marketing, 67*, 63-79. doi:10.1509/jmkg.67.3.63.18654

Williamson, O. (1991). Comparative economic organization: The analysis of discrete structural alternatives. *Administrative Science Quarterly, 36*, 269-296. doi:10.2307/2393356

Woodman, R. W., Sawyer, J. E., & Griffin, R. W. (1993). Toward a theory of organizational creativity. *Academy of Management Review, 18*, 293-321.

Zack, M. H. (1999). Developing knowledge strategy. *California Management Review, 41*, 125-146. doi:10.2307/41166000

Author Biography

Hyunju Rachel Kim (aka Rachel Kim) is a management researcher and journal reviewer specialized in strategic management, innovation management, entrepreneurship, technology management, etc. Currently, she aspires to mentor undergraduate and graduate students, teach management courses, and add value to the academic field and biotechnology industry as a researcher and consultant based upon her prior experience of pharmacy entrepreneur as a pharmacist.