

What Management Strategies Can a Pharmaceutical Company Implement to Sustain Innovation?

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The discovery and development of life-saving drugs have been central to improving health worldwide. However, the state of pharmaceutical innovation has been recently challenged due to falling industry outputs, with breakthrough therapies remaining elusive for many companies. Sustaining drug innovations is a top priority for pharmaceutical executives. The research examines existing literature to explore patterns and trends in managing the sustainability of drug innovations in the pharmaceutical industry. An initial survey of articles on general, non-pharmaceutical industry specific strategies for sustaining innovation provides a definition for sustained product innovation. Strategic themes such as organizational structure and culture, a firm's ability to adapt to changes, the role of

knowledge and technology management as well as alliances and networks among firms are discussed. A brief history of strategic innovation in the pharmaceutical sector provides context in building a way to frame practitioner and researcher thinking around levers of management strategies that can be used to understand

and sustain drug innovations at the firm level. Findings reveal that pharmaceutical companies which adapt their organizational culture, knowledge and technology levers to the cycles of scientific advances within the constraints of their regulatory and market

environments are most likely to succeed. These levers of management strategies seem to be affected by the firm's absorptive capacity and its ability to form strategic alliances with other organizations.

What management levers can pharmaceutical executives use to frame their thinking around sustaining drug innovations in their companies?

Keywords: Pharmaceutical Innovation, Management Strategies, Sustained Innovation, Biopharmaceutical, R&D, Strategic Alliances.

Pharmaceutical innovation has played an important role in medical progress and public health. Throughout history, new drug discoveries such as antibiotics, antihistamines, cholesterol-lowering statin drugs, anti-human immunodeficiency virus (HIV), and anti-cancer therapies have all contributed significantly in prolonging human life expectancy and improving the quality of life globally (Daemrich & Bowden, 2005).

Despite a long history of innovation and growth in the 1950s to 1990s, the pharmaceutical industry has been experiencing stagnant growth and a decelerating pace of innovation since the turn of the new millennium (Munos, 2009). Between 2000 and 2014, the branded pharmaceutical industry lost most of its customers to generics due to an innovation crisis, patent expirations, escalating research and development (R&D) costs, and the narrowly-targeted drugs it now produces. The increasing cost of developing new drugs reduced the spread of research (Mullard, 2014), with R&D costs estimated to be as much as \$2.9 billion (DiMasi, Grabowski, & Hansen, 2016). In 2015, an uptick in pharmaceutical innovation was observed for the first time after many years, with 51 drug approvals from the U.S. Food and Drug Administration alone. Thirty-nine companies contributed to that success, with eight gaining multiple approvals (Munos, 2016). There were some clear front runners in the list of innovation contributors, while others lagged behind.

An examination of drug approvals in the last five to ten years among biopharmaceuticals showed that the top three companies with the highest number of drugs approved were the same. The bottom three companies were also the same. Moreover, a handful of companies that have traditionally been seen as “mid-sized” were gaining their way to the top.

These observations naturally led to the initial research question. What strategies do successful companies implement to promote and subsequently sustain drug innovations over time? The flip side of this question is to ask what strategies unsuccessful companies are implementing that result in a failure to sustain drug innovations in the long-term.

The intent of this literature review is to identify thematic threads in the innovation literature that would help build a conceptual framework for management strategies that practitioners can use to sustain innovation in pharmaceutical companies. These thematic threads shall be referred to as “management levers” such as knowledge, technology, and organizational culture, among others. The management of these levers and the appropriate choice of organizational alliances are postulated to help stimulate and subsequently sustain drug innovations.

Methodology

A multi-phase, iterative, and progressively directed query was conducted in the University of South Florida (USF) Libraries, JSTOR.ORG, Google Scholar and Amazon.com’s Book Department for literature covering management strategies to sustain pharmaceutical innovation. Search keywords included pharmaceutical innovation strategies, pharmaceutical innovation and growth, sustainable innovation for managers, sustained innovation and measures of sustained innovation. A review of 300 abstracts initially resulted in the download and summary of 30 articles, including books, which were relevant to the topic of interest in this literature survey. Examination of those articles led to the discovery of 39 additional articles. Review of the manuscript further led to 15 more articles, making the total 84.

Literature Summary

To comprehensively address the research question, our literature findings are grouped into three categories: (1) general strategies for sustained innovation across industries, (2) a history of strategic innovation in the pharmaceutical industry, and (3) a discussion of management levers to sustain pharmaceutical innovation. Figure 1 depicts why each category is relevant to the research question.

General Strategies for Sustained Innovation

General, non-pharmaceutical industry specific innovation literature (Scott & Bruce, 1994; Knott, 2003; Rogers, 2003; Dyer, Gregersen & Christensen, 2011) provides us with a good understanding of the innovative organization and how innovation diffuses over a social system. However, the same literature does not give us a clear path as to how organizations can sustain product innovations over time. A search of strategies for sustaining product innovations necessitates a clear definition of the concept. The simplest operational definition is given by Dougherty & Hardy (1996) who defined sustained product innovation as the generation of multiple new products, strategically necessary over time, with a reasonable rate of commercial success. We shall use this definition as our basis for understanding the strategies for sustaining pharmaceutical product innovations.

Organizational Structures & Cultures: Organizing for Sustained Innovation

A key theme that emerged is how companies organize their people, cultures, structures, and processes to manage combinations of technological, knowledge, and physical/financial resources to develop the

General strategies for sustained innovation	History of pharmaceutical innovation	Management levers to sustain pharmaceutical innovation
<ul style="list-style-type: none"> • Introduces concept of innovation and its diffusion • Defines sustained product innovation • Provides context for, themes and examples of innovation strategies from non-pharma industries 	<ul style="list-style-type: none"> • Illustrates how pharma industry innovated over time as adaptation to cycles of scientific advances • Describes strategic pathways and collaborations among large pharma and smaller biotech firms 	<ul style="list-style-type: none"> • Synthesizes key themes of strategies for managing sustainability of pharma innovation • Provides framework for understanding management strategies in sustaining drug innovations

Figure 1. Relevance of Literature Findings to Research Question

capacity for sustained innovation. This capacity is underpinned by the companies' ability to adapt to changes in their internal and external environments, their absorptive capacity for new technology, and knowledge flows as well as their strategic connections with other organizations.

In a study of large, mature organizations (average age 96 years), Dougherty & Hardy (1996) contended that a more lasting approach to developing organization-wide capability for sustained innovation is by changing the underlying configuration of power, from a personal network base to an organizational system base. For mature organizations to develop the capacity for sustained innovation, they must successfully make innovation-to-organization connections in three key areas:

- Resource availability for new products
- Collaborative structures and processes (both internal and external) to solve problems creatively and connect innovations with existing businesses
- Incorporation of innovation as a meaningful component of the organization's strategy

Collaborative structures and processes can include those that firms establish with their supplier networks. Jean and colleagues' (2014) study demonstrated that supplier involvement in the co-design process has an inverted U-shaped relationship with product innovation in emerging markets. The findings implied that supplier involvement in product co-design with their customers can be beneficial for suppliers, through knowledge sharing and creation. However, to sustain the positive impact of knowledge sharing on product innovation, the study also suggested that firms need to craft governance mechanisms, including knowledge protection and trust building, in the product innovation process.

Drawing on an in-depth study of innovation practices and journeys at 3M corporation, Garud and

colleagues (2011) identified how combinations of practices afford organizational actors multiple and flexible avenues to achieve product innovations. These combinations of practices included manifest structure (e.g., products, patents, and platforms), relational processes (e.g., interactions between people within and across platforms and businesses), temporal dynamics (e.g., moments of serendipity enabled by organizational guidelines allowing employees to spend 15% of their time exploring innovative projects), and regulative guidelines (e.g., annual goals include a 30% stretch objective) that are activated at various stages of an innovation journey. Furthermore, practices were facilitated by innovation narratives which served as anchors linking the company's past, present, and future. The 3M study highlighted the interplay between structural and cultural aspects of an organization associated with innovation.

Adaptation to Internal and External Changes

Another key to a company's success is control of its internal environment and the ability to respond to changes in its external environment. Hall & Vredenburg (2003) asserted that sustainable development innovation is a strategy that incorporates market-driven innovation, and the additional constraints of social and environmental pressures. In 2009, General Electric (GE) responded to the pressures of emerging markets while attempting to accelerate organic growth by creating what's now called "reverse innovation." GE's companies had traditionally developed great products at home, and then distributed them worldwide, with some adaptations to local conditions. With reverse innovation, GE did exactly the opposite. Two products it highlighted at the time--a \$1,000 handheld electrocardiogram device and a portable, PC-based ultrasound machine that sells for as little as \$15,000--were developed for rural India and rural China, respectively. They were considered "revolutionary" not just because of

their small size and low price, but also because they were originally developed for markets in emerging economies, and then sold in the United States where they pioneered new uses for such machines (Immet, Govindarajan & Trimble, 2009). Hoonsopon & Ruenrom (2012) further supported the assertion that firms must continuously respond to changing external factors such as demand uncertainty, competition, and technological turbulence to maintain competitive advantage and sustain their business in the long run.

Many studies have suggested that adapting to changes with leadership flexibility gives firms a greater chance at sustaining innovative performance. Flexibility and adaptability are related elements that characterize what has been referred to in literature as an ambidextrous organization--one that is able to find an appropriate balance between explorative and exploitative innovation strategies. Exploration refers to firm behaviors characterized by search, discovery, experimentation, risk taking, and innovation; while exploitation implies firm behaviors characterized by refinement, implementation, efficiency, production, and selection (March, 1991; Cheng & Van de Ven, 1996). Tushman and O'Reilly (1996) contended that "To remain successful over long periods, managers and organizations must be ambidextrous--able to implement both incremental and revolutionary change." He and Wong (2004) tested this ambidexterity concept within the context of technological innovation. They provided empirical evidence consistent with the ambidexterity hypothesis by showing that (1) the interaction between explorative and exploitative innovation strategies in relation to a company's technological resources is positively related to sales growth rate, and (2) the relative imbalance between explorative and exploitative innovation strategies is negatively related to sales growth rate.

The Role of Knowledge Management

A focal point in the innovation literature's discussion of exploration and exploitation strategies, as they relate to innovation, is the management of knowledge. Nonaka & Takeuchi (1995) stated that the organization that wishes to cope dynamically with the changing environment needs to create information and knowledge, not merely process them efficiently. The organization recreates itself by destroying the existing knowledge system, and then innovating new ways of thinking and doing things. Similarly, Leonard-Barton (1995) introduced the concept of "the whole system of knowledge management" as a

core capability comprising of managerial activities and systems bound up with technological competitive advantage that serves as a source of sustained innovation. More specifically, Leonard-Barton distinguished between four interdependent dimensions of core capability. The first two of these dimensions are characterized as "dynamic knowledge reservoirs:" (1) the knowledge and skills of employees and (2) the physical technical systems, which are also seen to embody the tacit knowledge of current and past employees. The remaining two are characterized as "knowledge-control or -channeling mechanisms:" (3) the managerial systems of education, rewards and incentives; and (4) the values and norms of the organization, which are seen to determine what kinds of knowledge and knowledge- building activities are encouraged.

Innovation processes can, according to Pavitt (2005) and others, be divided into three main sub-processes: (1) the production of knowledge (exploration), (2) the transformation of knowledge into working artifacts (development), and (3) the matching of these artifacts to the needs and demands of the market (exploitation). These sub-processes are not necessarily linearly aligned, but in most concrete cases, they are strongly inter-linked and overlapping. Within the context of the knowledge-intensive pharmaceutical industry, the unique process by which a pharma company transforms scientific knowledge (biochemistry, pharmacology, genomics, etc.) into working artifacts in the production of drugs plays a role in sustaining drug innovations.

The Role of Technology Management

Another important focal point in sustaining innovation is the organization's management of technological resources. Nelson (1959) considered that firms that diversify their technological base are likely to benefit from new technological possibilities. Since many innovations are designed to solve unrelated problems, companies that are more diversified profit more from their own research activities because they capture more of the social benefits of their innovations.

Technological diversification allows companies to obtain a higher cross-fertilization between different, although related technologies (Grandstand, 1998; Suzuki & Kodama, 2004), and gains from unrelated technologies that take place in the firm. For example, cross class analysis of patent applications by Canon and Takeda from 1960s to 1990s revealed that interactive histories of their main business domain with other technological trajectories have

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helped facilitate persistent innovation at the firm level. Canon diversified its technology by mostly exploring their core technology concerning the “camera.” Their diverse technology base consisting of four major core technologies--camera, digital processing, electro-photographic, and semiconductor manufacturing technologies--made Canon able to diversify their business domain into copiers, printers, semiconductor manufacturing and so on. Takeda, on the other hand, imported genetic engineering, protein engineering and genome informatics technologies. Then those technologies were fused with core technologies such as organic synthesis and fermentation. It brought Takeda technology diversification at product level and persistent innovative entry to a variety of medicines for many symptoms (Suzuki & Kodama, 2004).

Garcia-Vega’s (2006) econometric analysis based on panel data of 544 European firms from 1995 to 2000 provided empirical evidence that both R&D intensity and patents, measures of innovative performance, increase with the degree of technological diversification of the firm. Possible explanations include the resultant spillovers from other (related) technological fields that a firm can receive when it diversifies its technology. The Canon and Takeda examples demonstrated this phenomenon. Moreover, diversification can reduce the risk from technological investments and creates incentives to spend more on R&D.

A 2012 McKinsey survey ... found that companies who collaborated deeply with suppliers grew twice faster than their peers.

The Role of Networks and Alliances

An integral part to the management of knowledge and technology resources while adapting to evolving business environments is a firm’s working relationships with their suppliers and customers. There is a growing body of evidence that customer relationships and supplier involvement can positively influence firm performance (Singh & Power, 2009). A number of survey type cross-sectional studies show that collaboration has a positive impact on the financial performance of firms (Vickery et al., 2003; Wisner, 2003; Johnston et al., 2004). In addition, comparative studies show that firms in supply chains with high levels of collaboration have greater competitive advantage than those in less collaborative supply chains (Themistocleous et al., 2004; Myhr & Spekman, 2005).

When developing collaborations with suppliers, firms have a wide range of options to choose from. These range from the formal, codified and contractual relationships to informal, mutual relationships (Kaufman et al., 2000; Weber et al., 2000). These

include partnerships, alliances, joint ventures, franchises, license agreements, contractual relationships, outsourcing agreements, service agreements, administered agreements, hierarchical relations, equity investments, cooperative agreements, R&D consortia, cartels, subcontractor networks, industry standard groups, action sets, and market relations (Bowersox et al., 2003; Golobic et al., 2003; Todeva & Knoke, 2005).

Supplier collaboration is seen as the joint development of capabilities by both the customer and supplier for the purposes of reduced cost, process improvements, and innovation in products or services (Noor, et al., 2013). A 2012 McKinsey survey of more than 100 large global companies on supplier collaboration practices found that companies who collaborated deeply with suppliers grew twice faster than their peers. Benefits of collaboration also accrue to the suppliers. Their business is more stable, they become more cost competitive, and they can then deploy these capabilities to win more business externally. In a 2010 survey of the auto industry, suppliers that gave Toyota and BMW the highest cost reductions also rated the two companies as their best customers (Noor, et al., 2013). This demonstrates the mutual benefits of long-term collaborations.

On the other hand, developing demand-side (customer) collaboration has unique challenges in that the reality for most firms is that the “customer” is often

a channel in a distribution system charged with the task of navigating a path to the ultimate user of a product (Singh & Power, 2009). Developing relationships with channel partners becomes a potential source of strategic advantage when they work with a supplier to find consumers and end users (Bowersox, 1990). Developing relationships with customers can therefore involve not just collaborating with the users of products, but also with those intermediaries providing access to consumers (Singh & Power, 2009). This is especially applicable to the pharmaceutical firm whose ultimate consumers are patients, but have to work through channels such as physicians, drug distributors, supply chain partners, and various R&D collaborators.

A summary of the key findings from literature on general (non-pharmaceutical industry specific) strategies for sustaining product innovations is shown in Table 1 on the following pages.

Pharmaceutical Industry: A History of Strategic Innovation

Pharmaceutical firms have adapted their drug development and innovation strategies to the cycles in

Table 1. General Strategies for Sustaining Innovation: Summary of Relevant Findings

Key Strategic Focus	Key Findings	Author, Year of Publication
Organizational culture (people, leadership, structures, processes, social networks, and communication channels)	Organizational structure, culture and climate are the top underlying characteristics for organizational innovativeness. These are followed by leadership and management style that support innovation, organizational support to change, creative human capital, and learning orientation and knowledge management.	Uzkurt, Kumar, & En-sari (2013)
	Innovators can be distinguished from non-innovators via five special skills (innovator's DNA).	Dyer, Gregersen, & Christensen (2011)
	Flexible leadership increases likelihood for success in implementing innovative products and processes.	Rosing, Frese, & Bausch (2011)
	Recognition of elements of serendipity facilitate intellectual discovery and inventions.	Taleb (2010)
	Heterogeneity stimulates innovation and growth. The underlying logic is that heterogeneity fuels diffusion; diffusion erodes leaders' shares; the loss of shares stimulates innovation, which in turn fuels new diffusion.	Knott (2003)
	Diffusion of innovation is determined by perceived attributes of innovations, type of innovation-decision, communication channels, nature of the social system, and the extent of change agents' promotion efforts.	Rogers (2003)
	Increased uncertainty and diversity encourage the adoption of innovations.	Gallo (2011)
	Most innovations result from a conscious, purposeful search of opportunities within the company and the industry as well as the larger social and intellectual environment.	Drucker (1985)
	A more lasting approach to sustained innovation is by changing the underlying configuration of power, from a personal network base to an organizational system base. Incorporate innovation as a meaningful component of the organization's strategy.	Dougherty & Hardy (1996)
	Combinations of practices involving interplay of people, organizational structures, relational processes, temporal dynamics and regulative guidelines need to be activated at appropriate stages of the innovation journey. Innovation narratives reinforce these practices.	Garud, et al. (2011)

scientific and medical advances over time. Galambos and Sturchio (1998) noted the following transitions that forced pharmaceutical firms to develop new capabilities:

- Scientific developments and the gradual acceptance of the germ theory of disease at the turn of the 20th century, followed by the chemo-therapeutic revolution--the predominance of chemical compounds in treating disease--in the 1930s and 1940s provided opportunities for innovation. Synthetic organic chemistry and soil microbiology led to the discovery and

production of antibiotics including streptomycin (Merck), chlortetracycline (Lederle), chloramphenicol (Parke-Davis) and tetracycline (Pfizer). In the 1940s and 1950s, advances in virology provided another set of new opportunities for entrepreneurship. This scientific advancement was followed shortly by a new wave of breakthroughs in the development of additional antibiotics, hormones, anti-depressants, anti-psychotics, anti-allergy drugs, and new vaccines that provided the basis for a new style of targeted pharmaceutical research and development.

Adaptation to business environment changes, organizational flexibility	Sustainable innovation strategy incorporates market-driven innovation, and the additional constraints of social and environmental pressures.	Hall & Vredenburg (2003)
	Firms must continuously respond to demand uncertainty, competition and technological turbulence to maintain competitive advantage and sustain their businesses in the long run.	Hoonsopon & Ruenrom (2012)
	Both structural and cultural changes are required to facilitate firm- and system-level sustainability.	Laukkanen & Patala (2014)
	Empirical example of “reverse innovation” as a response to changes in business environment.	Immelt, Govindarajan, & Trimble (2009)
	To remain successful over long periods, managers and organizations must be ambidextrous--able to implement both incremental and revolutionary change.	Tushman & O'Reilly (1996)
	Organizational ambidexterity--finding balance between explorative and exploitative innovation strategies--increases likelihood of sustained innovations.	Cheng & Van de Ven (1996); March (1991)
	Empirical evidence showing the interaction between explorative and exploitative innovation strategies in relation to a company's technological resources is positively related to innovative performance.	He & Wong (2004)
Knowledge Management	The organization recreates itself by destroying the existing knowledge system, and then innovating new ways of thinking and doing things.	Nonaka & Takeuchi (1995)
	Whole “system of knowledge management” is a core capability comprised of managerial activities and systems bound up with technological competitive advantage that serves as a sustainable source of innovation.	Leonard-Barton (1995)
	Innovation processes consist of interlinked and overlapping sub-processes involving the production of knowledge and its transformation into working artifacts that meet market demands.	Pavitt (2005)
Technology Management	Technological diversification allows companies to obtain a higher cross-fertilization between different, yet related technologies as well as gains from unrelated technologies.	Grandstand (1998)
	Technological diversification prevents negative lock-in effect in one particular technology, and sustains firm evolution and business renovation.	Suzuki & Kodama (2004)
	Empirical evidence shows that innovative performance increases with degree of firm's technological diversification.	Garcia-Vega (2006)
Role of Networks and Alliances	Customer relationships and supplier involvement can positively influence firm performance.	Singh & Power (2009)
	Supplier collaboration, defined as the joint development of capabilities by both the customer and supplier for the purposes of reduced cost, process improvements, and innovation in products or services, results in mutual benefits for both customers and suppliers.	Noor, et al. (2013)
	When developing supplier collaborations, companies have a wide range of options including formal, codified, and contractual relationships to informal, mutual relationships.	Kaufman et al. (2000); Weber et al. (2000)

- The period between 1930 and 1960 saw the institution of safety regulations in the U.S. and Europe in the wake of the 1937 sulfanilamide incident and the thalidomide tragedy in the late 1950s. These incidents, which resulted in deaths and congenital malformations, led to the expansion of laws that strengthened the authority of regulatory agencies, and required pharmaceutical companies to comply with comprehensive pre-market requirements for drug safety and efficacy.
- During the biotech revolution in the 1970s to 1980s, large pharmaceutical companies adopted one of two strategic pathways into biotechnology. The first strategy involved developing highly specific expertise and then generalizing it across a range of different therapeutic categories. The second strategic alternative included acquiring and building upon general capabilities very early in the process of establishing licensing, research, and equity relationships with biotech enterprises. By the early 1990s, all of the large corporations were found to have extended their traditional networks by establishing new types of contractual ties with biotech firms (Galambos & Sturchio, 1998).

Synthesizing from the works of Galambos & Sturchio (1998), Daemmrich & Bowden (2005) and Munos (2009, 2016), key milestones in the recent history of pharmaceutical innovation shown below in Figure 2 demonstrate how innovations in the in-

dustry were interwoven with advances in biological sciences, medicine, and regulations.

Management Levers for Sustaining Pharmaceutical Innovation

The brief history of biopharmaceutical innovation and our review of general innovation concepts provide us with the context for framing our understanding of management strategies to sustain drug innovations. Biotech and pharmaceutical companies have adapted to changes in evolving scientific knowledge and technological development in order to produce innovative drugs through the decades. Such adaptation was not uniform among companies--some were successful; others failed. Many companies disappeared, or became absorbed by mergers and acquisitions (M&A). Amid a flurry of M&A activities, alliances among big pharmaceutical companies and smaller biotech firms as well as networks with academic institutions, government, health care professional and patient communities became a key feature in the emerging biopharmaceutical and life science ecosystem. The appropriate mix of alliances and networks is important in the acquisition of new scientific knowledge and technology streams that are foundational to the production of innovative drugs. Studies argue that firms need to acquire external knowledge to innovate, with absorptive capacity determining the magnitude of innovation performance (Jeon et al., 2015).

Characteristics of the Industry

The pharmaceutical industry has some unique characteristics. First, the innovation process in the

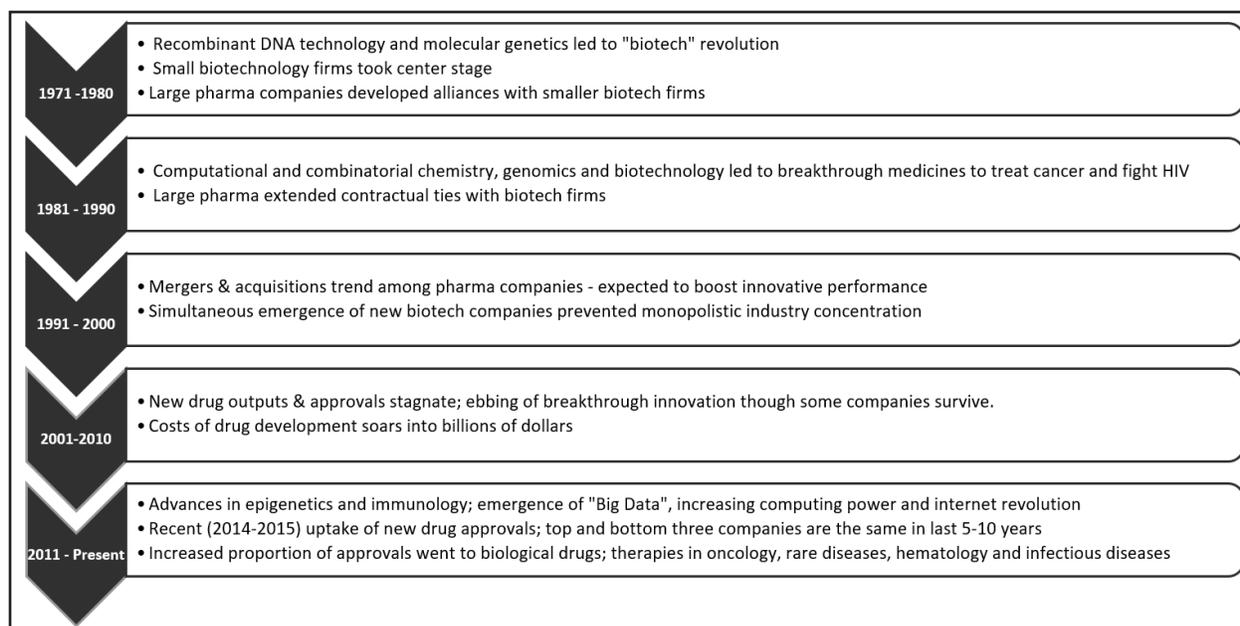


Figure 2. Key Milestones in Recent History of Pharmaceutical Strategic Innovation

pharmaceutical industry is sequentially marked by six different stages of innovation of a new drug: discovery, pre-clinical, clinical trial phases 1, 2, 3, and pending approval from a regulatory agency for market authorization. This process takes an average of 12 years for a drug to travel from the research lab to the patient. Second, pharmaceutical companies have to comply with specific regulations to prove the safety and efficacy of drug products. Third, there is a complex set of intellectual property laws, especially in the U.S. which is the biggest market for innovative drugs. Patents protect the intellectual property rights of innovator companies from copycat versions of their drugs for 20 years after they are invented (Berry & Martin, 2008; Grabowski, 2011; Owens, 2015). However, this is a bitter pill for pharmaceutical companies to swallow because it can take 8 to 12 years after invention to accumulate enough data to get past the approval of regulatory agencies. On top of these unique characteristics, the industry must contend with varying pricing and payment schemes across the globe depending on who pays for the drugs.

The recent (2000–2014) declines in pharmaceutical industry productivity have been blamed on four factors (Thong & Lotta, 2015):

1. Increasingly tough scientific barriers have emerged as more difficult diseases have been tackled. The low-hanging fruit has

been plucked, and the industry now must bet on new bioscience technologies to find better medicines.

2. Innovation in big pharma R&D organizations has declined as their scale, complexity, and consequent bureaucracy have increased.
3. Regulatory agencies are imposing higher hurdles for efficacy, safety, and quality--new technologies and innovative treatment approaches also mean many unknowns and new risks.
4. Healthcare payers have set higher requirements for cost-effectiveness--a new medicine selling at a high, patent-protected price will not be reimbursed if it is only marginally better than an old, off-patent medicine selling at a much lower price.

So, how should pharmaceutical leaders think about returning to a path of innovation and sustaining it? What management levers do they have and how are these levers related to each other? The concept map in Figure 3 illustrates how pharmaceutical executives might frame possible relationships between a firm's management levers (knowledge management, technology management, and organizational culture), its absorptive capacity, and its alliances and networks with the goal of sustaining innovation.

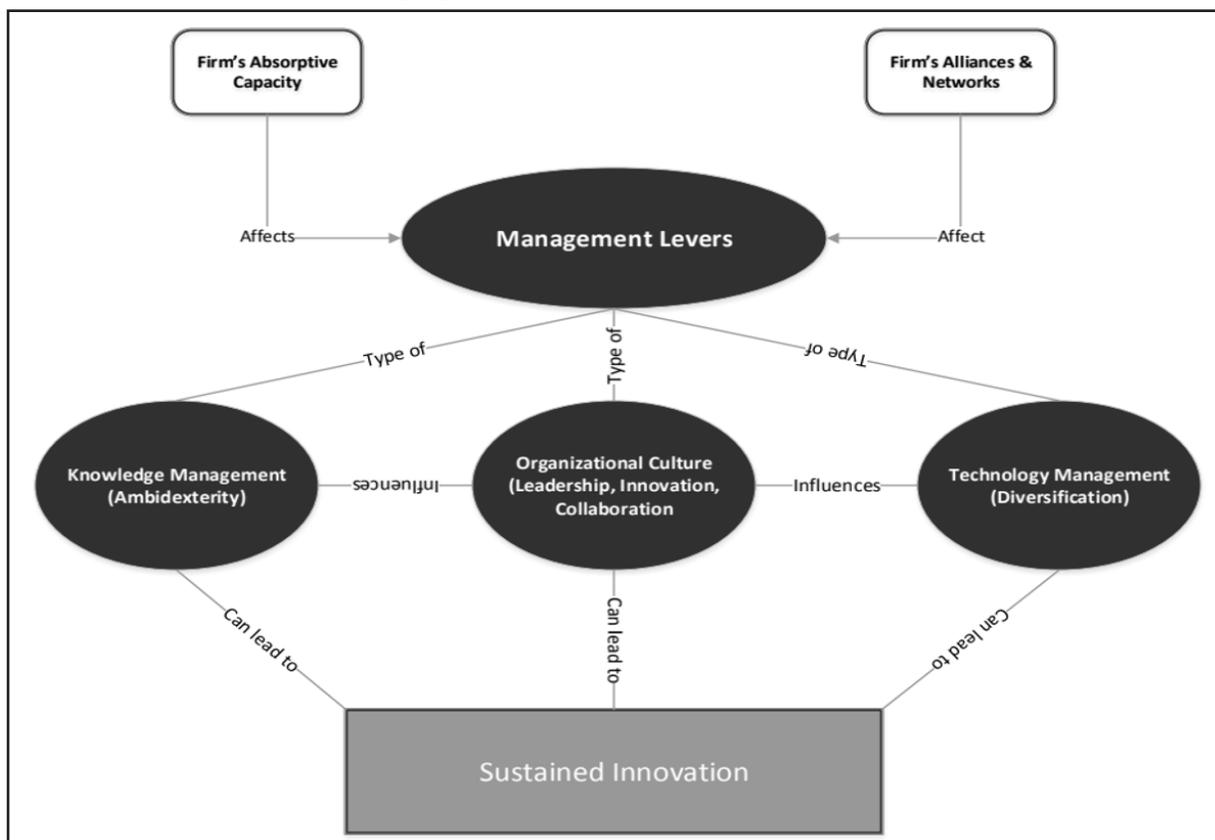


Figure 3. Concept Map: Management Levers for Sustained Pharmaceutical Innovation

Ambidexterity in Management of Knowledge

An ambidextrous organization is one that flexibly uses exploratory and exploitative activities as part of their business strategy. Exploitation strategies, such as the efficient employment of current assets and capabilities, are needed to survive in the short term. Exploration strategies, such as the development of novel capabilities, are needed in the long term. He & Wong (2004) showed direct evidence from a sample of 206 manufacturing firms of the positive effect of ambidexterity on firm performance. Their study revealed that firms that knew how to balance explorative and exploitative innovation strategies tended to positively influence their sales growth rates.

Gilsing and Nooteboom (2005) framed exploitation and exploration as parts of a “cycle of discovery” to help understand the emergence of the pharmaceutical industry. In this cycle of discovery, exploitation of existing scientific knowledge base and the exploration of developing areas of scientific progress propelled pharmaceutical innovations from a sectoral perspective. In the early 1960s, the growing body of knowledge on and experience with organic chemistry increasingly enabled firms to produce pharmaceuticals on a large-scale and in a reliable way. This period was characterized by a strong focus on incremental innovations and the exploitation of the existing knowledge base in organic chemistry.

In the 1970s and 1980s, substantial progress in physiology, pharmacology, enzymology, and cell biology created a growing understanding of biochemical and molecular roots of diseases and the effectiveness of existing drugs in curing those diseases. These new medical insights in diseases offered researchers new areas to apply and develop their skills and to diversify the development of new drugs. During this period, those pharmaceutical firms that had maintained absorptive capacity through in-house R&D and developed close relations with networks of individual scientists were able to make the transition to the biotechnological revolution.

In the late 1980s and 1990s, genetic engineering opened up completely new areas for innovation and altered the drug discovery process in profound ways. A hybrid practice was created that was built up of existing elements (organic chemistry) and new elements (genetic engineering), and that formed a topple point between exploitation and exploration: it was exploitation of the existing knowledge on the curing effects of familiar proteins, and exploration of

new processes that enabled the production of existing and new proteins.

The combination of molecular biology and genetic engineering techniques enabled firms to identify upfront clearly defined search spaces and potential targets for drug discovery. While the past period of random screening basically “discovered” drug compounds, this new rational approach was aimed at the “design” of drugs following the understanding of the biological underpinnings of diseases (Pisano, 2002). However, in the early 1990s it became increasingly clear that this fully rational approach did not deliver satisfactory results as it showed disappointing performance, incurred high costs, and provided unattractive revenue potential. The purely rational and large-scale approach was found to lack sufficient accuracy, was more costly than anticipated, and led to the development of increasingly similar drugs across pharmaceutical firms, resulting in little product performance differences and consequently lower market potential (Nightingale, 2000). As a response, firms moved away from the fully rational approach and started to introduce again some randomness into their search processes in order to be able to differentiate from competitors.

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This shift from a process of screening hundreds of compounds towards a parallel process of screening ten-thousands of compounds, generated vast amounts of data. A proper interpretation of this data then required state-of-the-art software

in the fields of database systems, data mining, data management, statistical analysis, and visualization techniques which continued on through the new millennium.

While there has been rich discussion of biopharmaceutical exploitation and exploration strategies in knowledge management at the sectoral (industry) level, there seems to be a paucity of case studies at the firm level. For example, does each of the top companies that have maintained drug approvals in the last 10 to 15 years exhibit a pattern of exploitation and exploration strategies seen at the industry level? Are there differences in strategies among large, medium, and small pharmaceutical and biotech companies? Further inquiry is needed to determine whether pharmaceutical organizations with ambidextrous knowledge management are more successful in promoting drug innovations than those organizations that focus solely on exploitation or exploration strategies.

Technological Diversification

An empirical study on a panel of 544 European R&D

active companies (including, but not all pharmaceuticals) from 1995 to 2000 showed that both R&D intensity and patents increased with the degree of technological diversification of the firm (Garcia-Vega, 2006). Firms which diversify their technologies tend to receive more spillovers from other related technological fields, and reduce the lock-in effect in low profitable technologies. Diversification can also reduce the risk from technological investments and creates incentives to spend more on R&D and enhance innovation.

A study by Quintana-Garcia and Benavides-Velasco (2008) of 115 international biotechnology firms with a U.S. parent during the period 1976-2002 provides strong support for the premise that a diversified technology base positively affects innovative competence. Study results demonstrated that introducing new technologies into the firm's knowledge system favors the search for complementarities and novel solutions that increase the rate of invention and avoid learning traps. This evidence supported the notion that it is valuable to create inventories of competencies to permit effective utilization of new knowledge, and positively influence the accumulation of absorptive capacity that allows the firm to predict the nature and commercial potential of technology advances and to exploit technological opportunities.

However, a high degree of technological diversification may become a source of information overload implying high coordination and communication costs. The level of such investment will be lowest when the firm uses known procedures and accumulated experience. In consequence, compared to exploitation, returns from exploration are more remote in time, distant, and uncertain. Exploitation provides efficient solutions and supports current organizational viability through near and clear returns. On the other hand, exploration improves the ability to adapt to a changing environment because it increases the variance of organizational activities (Quintana-Garcia & Benavides-Velasco, 2008). Because of the changing nature of innovation requirements embedded in technology cycles, firms must develop capabilities to balance exploration and exploitation.

Absorptive Capacity

A recent study by Jeon et al. (2015) of 98 pharmaceutical companies from 1990 to 2011 showed the importance of absorptive capacity in improving a firm's innovation performance. Using the annual count of newly granted patents as a measure of innovation

performance, and the annual R&D intensity (R&D expenditure/total sales) as a measure of absorptive capacity, their analysis indicated that the impact of absorptive capacity on acquisition and newly granted patents seemed to occur more quickly for small and medium firms. This meant that small and medium firms could obtain this effect in a relatively short time. Absorptive capacity plays an important role in external technology acquisition as it allows firms to learn different ways to create new knowledge through the acquisition of external knowledge. This absorptive capacity quickly influences external technology acquisition activity and innovation performance because firms can develop an educational process to effectively identify, assimilate, and exploit acquired knowledge. The study results illustrated how external knowledge can lead to innovation performance and how absorptive capacity mediates the achievement of that performance.

This notion of absorptive capacity as a mediator between knowledge-technology management and innovation performance is in concordance with what other authors have observed (Henderson, et al., 1999; Pisano, 2002; Gilsing & Nooteboom, 2005).

For example, firms that adopted the first molecular techniques in the early 1980s were successful in managing the subsequent transition from random to guided drug discovery. These firms had developed strong in-house R&D capabilities and nurtured close links to scientists that enabled them to build up and maintain sufficient absorptive capacity and identify relevant external knowledge.

Because of the changing nature of innovation requirements embedded in technology cycles, firms must develop capabilities to balance exploration and exploitation.

Alliances and Networks

Prior to the biotech revolution, innovation at large pharmaceutical companies was linked to complex networks of public and nonprofit institutions. The relationships most important to the pharmaceutical companies had been with individual scientists, public institutions (such as the U.S. National Institutes of Health and public health organizations) and nonprofits such as research universities (Galambos & Sturchio, 1998). Starting with the biotech revolution in the 1970s and 1980s, a growing web of biotech contractual ties added a new element to the networks that have traditionally sustained innovation in this industry. Strategic alliances between large pharmaceuticals and smaller biotech firms utilizing cooperative agreements and various networks of contractual relationships were recognized as key factors in sustaining innovation through the early 1990s.

Mergers and acquisitions (M&A) then became a prominent feature in organizational alliances in the pharmaceutical industry in the 1990s through the turn of the 21st century. An examination of the performance of 160 pharmaceutical acquisitions from 1994 to 2001 found evidence that on average, acquirers realized significant positive returns (Higgins & Rodriguez, 2006). These returns were positively correlated with prior access to information about research and development activities at target firms and a superior negotiating position. However, the M&A model became increasingly challenged towards the late 1990s and early 21st century when the industry showed signs of fatigue: skyrocketing costs, ebbing of breakthrough innovations, intense competition, and flattening sales growth were observed (Munos, 2009).

Alliances between biotech and pharmaceutical firms have continued until today. Recent (2014-2015) new drug approvals have registered an uptick after more than a decade of what seemed to be plateauing innovation and productivity. Is this uptick a foretelling of new alliances within the industry posed for major disruption? An investigation of the co-evolutionary patterns of the dynamics of technological alliances and the structure of the knowledge base in the pharmaceutical sector by Krafft, et al. (2014) in Europe, US, and Japan revealed that technological alliances represent a key resource for firms in knowledge-intensive sectors. Such alliances help firms to cope with dramatic changes in the knowledge base, marked by the introduction of discontinuities opening up new technological trajectories. The empirical results of this investigation support the existence of a life cycle in biotechnology affecting the pharmaceutical industry. The dynamics of alliances were found to depend on the phase of the biotechnology cycle, among other things.

As the 21st century unfolded, the confluence of increasing computing power, the Internet revolution, and “Big Data” has given pharmaceutical companies the reason to form new alliances with information technology (IT) firms that hold expertise in new emerging technologies such as artificial intelligence, machine learning, cognitive computing, and natural language processing. The previous studies on alliances do not fully explain the dynamics of these new pharmaceutical company-technology firm relationships. How will these evolving alliances impact the management of knowledge and technology resources in pharmaceutical companies? This is another area of research that might benefit pharmaceutical practitioners.

Organizational Culture: Open Innovation, Leadership, and Collaboration

Innovation literature provides empirical evidence that team leadership and change management strat-

egies such as shared commitment to organizational objectives, a non-threatening work environment, commitment to high standards of work performance, and team cooperation to develop and implement new ideas can lead to sustainable profitability (Law, 2013). The impact of organizational culture and leadership on sustained pharmaceutical innovation seems to be supported by a recent study by Munos (2016) which revealed that the top three most innovative pharmaceutical companies (based on the number of new drug approvals by the U.S. Food & Drug Administration in the last 10 years) were consistently the same organizations that had leaders who drove the vision for a transformation. Munos (2016) wrote further about these companies:

These three Big Pharma companies (Johnson & Johnson, Glaxo-SmithKline and Novartis) “did not rise to the top by luck or by buying pipelines or doing tax inversions. Their output is the result of their transformation. They each followed a different path, which reflects the vision of its leaders who made no secret about their frustration with the broken R&D model they had inherited. They did not pretend that everything is great. They set out to change what was not, and in the process created R&D models that can deliver new drugs reliably at an unprecedented pace. Luck had no part in their success, except to the extent that it favors good leaders.”

Using the same metric—the number of U.S. FDA drug approvals for each company in the last 10 years-- it was noted that the bottom three Big Pharmas were also the same: Bayer, Lilly, and Abbvie. Unfortunately, Munos stopped short of describing specific management strategies that differentiated the top companies from the bottom ones. This could be an area of opportunity for further research.

A recent case example by Thong & Lotta (2015) of the effect of organizational culture change on organizational performance was demonstrated by Orion, a smaller (3,500 employees in 2013) pharmaceutical company based in Europe. In 2007, Orion had a weak new-product pipeline, functional silos, a hierarchical management style, and an inward-looking mindset. It needed to dramatically improve its productivity and adapt to a new R&D paradigm that was sweeping across the pharmaceutical industry. In response, its R&D management team designed and implemented an organizational transformation process based on proactive culture change. Through incremental initiatives and a comprehensive reorganization, the company built a more open, collaborative, and results-oriented R&D organization able to thrive in the evolving pharmaceutical industry. The new culture emphasized openness, transpar-

ency, and enthusiasm in all R&D activities, created seamless links and alignment with the wider company and external collaborators, and engendered a focus on project productivity and results. By 2012, Orion's proprietary R&D pipeline had grown to 19 research-stage and 8 clinical-stage projects--triple the number in 2007--with an even greater increase in value, as validated by partnering agreements with Big Pharma companies.

Even before these recent studies and observations, Galambos and Sturchio's 1998 study in strategic innovation already showed that pharmaceutical firms' successful transition to biotechnology required not only scientists, but scientific leaders with diplomatic skills and links to relevant networks to build teams necessary to sustain biotech R&D over the long term. This supports the belief among many pharmaceutical innovators that while sound basic science foundation is a key element that promotes innovation, people and teams are still the main drivers of successful innovation. Indeed, a survey of 127 innovators who contributed to transformative innovations in the pharmaceutical industry revealed that the primary drivers of innovation are the people those innovators worked with as well as the institutions in which they worked (Xu & Kesselheim, 2014).

Conclusion

The literature on general, non-industry specific innovation and the history of strategic innovation in the pharmaceutical industry have provided us with patterns of thought on how to frame strategies for sustaining drug innovations at the firm level. General innovation suggests that firms with leadership that organize their cultures to adapt to internal and external changes in their environments, manage their knowledge and technology resources, and understand the role of their collaborators have a greater propensity to diffuse and sustain product innovations in the long run. The literature on pharmaceutical innovation, however, is not as unequivocal as general innovation literature. Drug innovations and productivity at the sectoral level have risen and fallen through historical cycles of discovery and scientific advancements.

The pharmaceutical industry has some peculiar characteristics--stringent regulations, long R&D process with relatively distinct phases, patent exclusivities and intellectual property issues, non-market mechanisms affecting product pricing globally--that make it particularly challenging to find a universal set of strategies to sustain innovative performance. Nonetheless, this literature survey has provided broad management levers for practitioners and academics to consider when thinking about strategies to sustain firm-level product innovations. These management levers include knowledge, technology, and organizational culture. In strategically using

these levers, it is important to remember that a firm's absorptive capacity, and its ability to form strategic networks and alliances with other organizations may impact the effectiveness of such levers. Our hypothesis is that pharmaceutical firms that possess ambidextrous management of their knowledge resources, technological diversification, and innovative and collaborative organizational cultures will likely be successful in sustaining drug innovations.

Framing the question of which management strategies can sustain pharmaceutical innovation has also led us to identify areas of research that require further inquiry. There is a lack of empirical evidence that ambidexterity in knowledge management does sustain pharma innovation. Researchers need to examine exactly what kind of exploration and exploitation strategies have led or will lead to sustained drug innovations. Another interesting area of inquiry is the topic of biopharmaceutical networks and alliances. What is the optimal model for organizational alliances and networks? How will such a model impact the management of technology and knowledge resources in pharmaceutical firms in their efforts to sustain drug innovations? These questions remain a challenge for pharmaceutical executives and offer an area of inquiry for researchers.

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Review

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Biography



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