

**THE INFLUENCE OF STRATEGIC LEADERSHIP ON FIRM INVENTIVE AND
INNOVATIVE PERFORMANCE**

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Strategic leaders hold different beliefs regarding how much to invest in technological innovation, and how to manage it. While certain visionary leaders have created extraordinarily innovative organizations, little evidence exists regarding the degree to which strategic leaders generally influence the production of valuable inventions and new products. We examine how much of the variation in firms' inventive (patent) and innovative (new product) performance strategic leaders explain. Based on a sample of Chief Executive Officers (CEOs) and Chief Scientific Officers (CSOs) who managed 27 large biopharmaceutical companies, from 1984 through 2004, we find that strategic leaders explain between 38% and 43% of the variation in inventive performance across firms, and that CEOs explain more of this variation than do CSOs. Stable firm characteristics are responsible for 27% of the variation in firms' inventive performance. By contrast, 51% of the variation in innovative performance is attributable to firm differences, and CEOs and CSOs explain less than 4% of this. Finally, we show that CEOs and CSOs strongly influence the degree to which a firm derives inventive advantage from internal and external knowledge diversity.

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1.0 INTRODUCTION

1.1 Motivation and Contribution

A firm's ability to continually produce relevant inventions, and convert them into marketable products, has a profound effect on its competitiveness and the pathways toward future success that are open to it (Geroski, Van Reenan, & Machin, 1993; Teece, Pisano, & Shuen, 1997). Accordingly, strategy scholars have sought to explain why some firms are better inventors or innovators than others (Ahuja & Lampert, 2001; Katila & Ahuja, 2002; Katila & Shane, 2005; Taylor & Greve, 2006). Empirical research has identified resource differences, particularly the diversity of a firm's and its partners' knowledge (Miller, Fern, & Cardinal, 2007; Phelps, 2010; Sampson, 2007; Srivastava & Gnyawali, 2011; Taylor & Greve, 2006), and the structure of intra- and inter-firm networks (Ahuja, 2000; Tortoriello & Krackhardt, 2010; Tsai, 2001; Tsai & Ghoshal, 1998) as among the critical drivers of a firm's inventive and innovative capabilities.

Management scholars also recognize executive commitment to innovation as essential to a firm's ability to sustain it (Berger, Dutta, Raffel, & Samuel, 2009; Ireland & Hitt, 2005; O'Connor, 2008). Strategic leaders who shape their companies to become extraordinary innovators are lauded in the popular press and practitioner journals (Ernst & Chfobot-Mason, 2011; Skarzynski & Gibson, 2008). Moreover, some studies find that executive pay is tied to inventive and innovative success (Balkin, Markman, & Gomez-Mejia, 2000; Makri, Lane, & Gomez-Mejia, 2006). Empirical studies, however, rarely link strategic leaders to fine-grained measures of inventive or innovative performance (Yadav, Prabhu, & Chandy, 2007). Instead, scholarly work tends to focus on leadership in teams, and on project outcomes rather than firm

level innovative performance (Elkins & Keller, 2003; Hoffman & Hegarty, 1993; Wu, Levitas, & Priem, 2005).

Hence, it is not clear *how much* the average strategic leader (C-level executive) affects her firm's inventive or innovative success. The lack of evidence is troubling, given a predominant view that strategic leaders are the ultimate shepherds of firms' capacities to invent and to innovate. In this study, we investigate how much variation in inventive and innovative performance is attributable to a firm's Chief Executive Officer (CEO) and Chief Scientific Officer¹ (CSO), as compared to enduring firm differences. We also determine whether strategic leaders significantly influence the inventive benefit firms derive from internal and external knowledge diversity.

We chose the biopharmaceutical industry to study these issues, as both invention and product innovation are central to the financial well being of these firms (Gambardella, 1992, 1995). In this context, we limit our attention to large firms, where the role and challenges of executives are more comparable. We use hierarchical linear modeling (HLM) to assess their influence, which, in contrast to ANOVA or dummy variables, allows us to use all available data without aggregating, while adjusting for the lack of independence that arises in clustered data. Since our mixed model accounts for randomness effect, it avoids inappropriately incorporating the influence of chance on measured effect variances, which has been a challenge with variance decomposition analysis (Brush & Bromiley, 1997; Mackey, 2008). By treating strategic leaders as a random factor, we increase the generalizability of our findings, and by estimating mixed models, we are able to separate the average effect of strategic leaders on inventive and innovative outcomes from the influence they have in individual firms.

¹ CSO refers to the highest executive level position related to technology and R&D. In addition to CSO, firms use other titles for this position, such as Chief Technology Officer, Vice President of R&D, Executive Director of R&D, President of Research Lab, Senior Executive of Research, or Vice President of Science & Technology.

We make several contributions to research on innovation. First, we find that strategic leaders matter tremendously to a firm's inventive success. CEOs and CSOs explain almost twice as much of the variation in inventive success as do stable firm attributes, implying that the vision and strategic direction provided by these executives influences inventive performance more than what resources or routines a firm has accumulated. This finding ought to motivate greater attention to strategic leaders in research on invention. Second, CEOs have a larger effect than CSOs on invention success. We believe this reflects greater variation in how firms define the CSO's role, and the tendency for CSO discretion to be constrained by the CEO. This finding highlights the CEO-CSO relationship as an area in which firms might seek inventive advantage.

Third, we find that CEOs and CSOs significantly, and to roughly equal degrees, influence how much inventive benefit firms derive from knowledge diversity. Whereas the average leader has a relatively modest effect on the relationship between knowledge diversity and inventive success, leaders at the upper bound harness the creative forces of diversity for tremendous inventive advantage. Determining what sets them apart is an important avenue for future research. Fourth, we find that strategic leaders influence innovation performance much less than do stable firm effects, suggesting that differences amongst leaders matter less when formal processes and routines affect outcomes, or when problems can be managed through well-defined structures. Overall, our results suggest that research on invention (e.g. patent outcomes) ought to account for the influence of strategic leaders more than it has, but that the focus on firm characteristics to understand differences in innovative (new product) performance is well placed.

2.0 THEORY AND HYPOTHESES

Following Hambrick (1981), we refer to strategic leaders as the upper-level executives whose decisions and actions significantly impact their organization. Their role, function, and the types of decisions they make differ significantly from those of team leaders and middle managers (Hart & Quinn, 1993). While most middle management leadership effectiveness is measured on the basis of group productivity or group satisfaction (Elkins & Keller, 2003), effectiveness of the upper-level executives must be related to overall corporate performance, or the achievement of major strategic priorities. In high technology and science driven industries, sustaining superior inventive and innovative performance, by generating a continuous stream of valuable ideas and patentable knowledge and converting them into novel products, are important strategic priorities (Ahuja & Lampert, 2001; Katila & Shane, 2005). Yet, there is little systematic evidence on whether strategic leaders are in fact responsible for differences in firms' inventive or innovative performance.

We propose strategic leaders, specifically the CEO and CSO, should explain much of the variation in firms' inventive performance, but less of the innovative differential. For similar reasons, we also hypothesize that strategic leaders will exert a greater influence on inventive performance than will stable firm factors, but that the reverse will hold for innovation performance. We also expect strategic leaders to have a significant effect on the inventive benefit firms derive from internal and external knowledge diversity.

2.1 When Do Strategic Leaders Matter Most?

The terms invention and innovation are sometimes used interchangeably, but they involve distinctive processes (Ahuja & Lampert, 2001; Katila & Shane, 2005). Whereas invention

produces novel ideas, innovation converts them into commercially viable products (Amabile & Khaire, 2008; Hansen & Birkinshaw, 2007; Schumpeter, 1934). The creative insights and serendipitous discoveries – the happy accidents researchers stumble upon while in pursuit of solutions to known problems, are a central feature of invention (Meyers, 2007), leading some to describe it as a process that cannot be controlled. Amabile and Khaire (2008; p. 102) put it this way, “One doesn’t manage creativity. Creativity is something one manages *for*.” For example, to create the preconditions for invention, Skarzynski and Gibson (2008) urge leaders to create time for reflection and experimentation, maximize diversity of thinking, and foster connection and conversation.

By contrast, innovation, the process of converting ideas into viable new products, is managed and structured so as to eliminate anomalies and unplanned variation (Nelson & Winter, 1982). Most companies use some type of stage gate process to break development into a pre-specified series of activities and assessment criteria, in an effort to de-risk and reliably execute innovation (Cooper, 2001). Tasks are usually well structured, and milestones provide clear objectives (Macher & Boerner, 2012; Sosa, 2009). While strategic leaders may have an important role to play in developing gates and metrics, once these processes are established, their purpose is to eliminate idiosyncratic influences on how decisions are made, and on the way the process unfolds (March, 1991; March & Simon, 1958; Winter, 1986). Thus, innovation largely occurs through standard operating routines, a central component of organizational memory, designed to produce the same decisions regardless of who is managing the process (Eisenhardt & Tabrizi, 1995; Huber, 1991; Pentland & Reuter, 1994; Walsh & Ungson, 1991).

These fundamental differences between invention and innovation suggest strategic leaders may affect them to varying degrees and by distinctive means. We expect strategic

leaders to have greater influence during invention, when problems are ill structured and formal procedures are inadequate to guide decision making and coordination.

For instance, as a firm's chief strategist, the CEO is responsible for crafting a vision² that is robust to innumerable uncertainties and future events that may undermine the firm's current competitive strategy. A clear vision allows for consistency in direction without dictating the path a firm takes to get there; it provides common focal points to guide firm-wide decisions, enabling greater internal and external consistency amongst them (Hart & Quinn, 1993; Ireland & Hitt, 2005). With respect to invention, Mumford, Bedell-Avers, & Hunter (2008) maintain that a firm's vision or mission serves several critical functions, including helping to define the goal of creative efforts, providing direction without being too restrictive, establishing guidelines for the selection and allocation of resources, and defining the scope of potential solution paths. Thus, by articulating objectives that guide discovery, strategic leaders can have an important influence on invention.

Leaders' actions also convey the kinds of behaviors they value and wish to encourage. Those who display transformational behaviors encourage others to engage in creative processes, heightening their alertness to inventive opportunities (Jung, Wu, & Chow, 2008; Scott & Bruce, 1994; Waldman & Bass, 1991). However, most firms hire strategic leaders for their execution abilities, not for their discovery skills and CEOs with the insight and commitment to cultivate organizational capabilities for invention are rare (Dyer, Gregersen, & Christensen, 2011; O'Connor, Leifer, Paulson, & Peters, 2008). The analytical and execution skills so central to resource allocation decisions and reliable product development activities are taught in MBA

² We use the term vision to refer broadly to high level strategic objective or intent or articulation of what a firm is and strives to become. In some firms, this meaning is captured in a codified vision or mission statement. In others, certain aspects of the strategic leaders' vision may be communicated through particular mandates – such as an emphasis on specific mega-trends (water scarcity, security, etc.)

programs and more widely held amongst strategic leaders (Dyer et al., 2011). Moreover, strategic leaders often find it difficult to commit to activities with the degree of uncertainty, failure rates, and ill defined time frames which characterize invention (Martin, 2009; O'Connor, et. al. 2008). Quarterly financial performance, for which strategic leaders are rewarded, is more securely augmented by investing in established businesses and managing incremental product extensions. The vision and strategic direction provided by strategic leaders are less crucial guides during the relatively predictable and controlled stage gate development process (Cooper, 2001; Nagji & Tuff, 2012; O'Connor et al., 2008). Indeed, because routines are rooted in shared tacit knowledge, they are difficult to modify directly and generally slow to change (Cohen & Bacdayan, 1994; Nelson & Winter, 1982; Pentland & Rueter, 1994). In firms with well established product development processes, leadership is primarily invoked to circumvent routine processes, such as to support a disruptive or breakthrough invention (Burgelman, 1994; O'Connor, et al., 2008). Collectively, these arguments suggest the following hypotheses:

Hypothesis 1a: More of the variation in firms' inventive performance is attributable to differences in strategic leaders than is the variation in firms' innovative performance.

Hypothesis 1b: More of the variation in firms' inventive performance is attributable to strategic leaders than is attributable to stable firm characteristics.

Hypothesis 1c: More of the variation in firms' innovative performance is attributable to stable firm characteristics than is attributable to strategic leaders.

These hypotheses are based on differences in how individuals in a leadership role affect invention and innovation. Next, we investigate whether there is a categorical difference between the CEO and the CSO role, which may limit their influence on invention and innovation.

2.2 Do CEOs or CSOs Have the Greater Influence on Invention and Innovation?

The specific role and the power base that strategic leaders possess delimit their abilities to shape organizational activities and outcomes in distinctive ways (Finkelstein, 1992; Medcof, 2008). For example, leaders with higher power bases will be more influential in determining the organizational direction and hence its future. Further, the higher power base such as technical expertise for CSO will allow her to gain credibility to better deal with strategic innovation choices and may significantly influence the organizational performance in this area (Finkelstein, 1992). Thus, in order to anticipate their relative influence on inventive and innovative performance, we examine how the formal roles of CEOs and CSOs are typically defined, and discuss the differences in their power bases.

Glick (2011) identifies six kinds of roles that CEOs fulfill: strategic, operational, informational, interpersonal, decisional, and diplomatic. CEOs spend most of their time in the strategic role, which includes acting as vision setter and strategist, as well as innovator, transformer, planner, coordinator, and creator and maintainer of culture (Glick, 2011). As a vision setter, CEOs create and articulate a compelling sense of identity and core mission for the organization, and provide ways to effectively realize long-term goals (Hart & Quinn, 1993). In most firms, the CEO has sole or primary responsibility for crafting and communicating a vision and strategic intent (Hambrick & Mason, 1984; Nadler & Heilpern, 1998). Montgomery (2008; p. 54) argues that the central role of a CEO is to be the ‘steward of a living strategy that defines

what the firm is and what the firm will become'. Related to this role, Glick (2011) documented that CEOs also establish and maintain relevant culture, coordinate plans and actions to achieve strategic long-term goals, initiate and conduct necessary change according to the external environment changes, and provide directions for the next innovation efforts.

Unlike the CEO's responsibilities that encompass the overall strategy of the organization, the CSO's responsibilities include more specifically overseeing the development of existing technologies and facilitating the assimilation and development of new technologies to enable the firm's strategic intent. The formal role description for a CSO ranges from merely managing the R&D function, to devising a technology strategy that enables the firm's competitive and corporate strategies, to contributing to the development of a firm's overarching competitive strategy and charting a technology direction in order to sustain the firm's advantage (Uttal, Kantrow, Linden, & Stock, 1992). Usually though, the CSO focuses less on the daily management of the R&D organization, and more on the development of future technologies that are aligned with the CEO's vision and the firm's strategic intent. CEOs also tend to be highly involved in these activities, but their focus is generally limited to activities that shape the strategic direction of the firm, such as technology strategy development, high level project prioritization, and overall R&D budgeting (Roberts, 2001).

Whereas a CEO's power base stems from his position at the apex of the organizational hierarchy, CSOs often derive power from their scientific or technological expertise (Medcof, 2008). This expertise may be used to inform strategic decision making and become the source of the CSO's credibility amongst other C-level leaders. However, given their hierarchical power relationship, the decision making style of the CEO may constrain a CSO's discretion to use her power. According to Arendt, Priem, & Ndofor (2005), CEOs who tend to make decisions in

isolation may ask CSOs for information but limit their input to strategic decision making. Even less influence will be expected if the CEO happens to have sufficient expertise in related technical matters (Medcof, 2008). Uttal et al. (1992) argue that CSOs often have less influence in practice than their power base affords because they employ a leadership style that is incompatible with the CEO's style. On the other hand, some CEOs actively involve their top management team in decision-making and will tend to involve CSOs and to consider R&D issues alongside other strategic decisions. CSOs in this context have greater influence on invention. Thus, relative to the CEO role, there appears to be more variance in how the CSO role is defined across firms and greater constraints on CSOs' abilities to execute the strategic aspects of their roles – which are especially central to invention.

We expect that, more than any other role-based mandate, it is the creation and dissemination of a widely understood vision and strategic intent vision which unleashes inventive energies. A CEO's vision creates clear, though broad, boundaries around the classes of problems and opportunities she considers to be strategically relevant³ (Montgomery, 2008), which in turn act as a filter, directing employees' attention to certain problems and opportunities and away from others (Ocasio, 1997; Yadav et al., 2007). By consistently demonstrating that discoveries in a particular domain are valued, a clearly articulated and consistently enacted vision reduces the personal risk researchers incur by following up fortuitous discoveries with relatively uncertain outcomes (Dyer et al., 2011; Meyers, 2007; Nagji & Tuff, 2012). Having a good sense of these boundaries encourages researchers to actively attend to 'happy accidents'

³ For example, Bhardwaj, Camillus, & Hounshell (2006) describe how leaders at DuPont fostered invention by providing broad parameters to guide entrepreneurial search in new technology domains. In particular, researchers were given a value-based reason for their discovery efforts, such as to address an anticipated market shortage or perceived inferiority in existing materials, or to use idle plant capacity. These acted as high level criteria for selecting some paths and discarding others, without which the researcher would have little basis for navigating the fuzzy front end (Bhardwaj, Camillus, & Hounshell, 2006).

and can suggest strategically relevant problems that might be solved by serendipitously discerned solutions (Berger et al., 2009; Meyers, 2007; Bhardwaj, Camillus, & Hounshell, 2006). In turn, this increases the likelihood that inventive activity throughout the firm yields a critical mass of novel ideas in the prescribed domains. Firms with more inventive ideas to choose from in a particular domain have a better chance of producing truly valuable inventions.

As CEOs hold greater decision making power and exert more influence over the corporate vision and strategic direction, and these roles are especially central to invention, where problems are ill-structured and serendipitous discoveries more likely. We expect:

Hypothesis 2a: CEOs explain more of the variation in firms' inventive performance than do CSOs.

On the other hand, CSOs may have a greater role to play in shaping the procedures used to guide product development, and their expertise ought to weigh heavily on decisions regarding which inventions are selected for further development. Accordingly, we expect:

Hypothesis 2b: CSOs explain more of the variation in firms' innovative performance than do CEOs.

2.3 How Do Strategic Leaders Affect Invention? Extracting Value from Knowledge

Diversity

We proposed that strategic leaders influence inventive performance more than they affect innovative performance. Next, we examine whether CEOs and CSOs significantly influence the degree to which firms derive inventive benefit from knowledge diversity.

Benefits of Knowledge Diversity. Diversity is a predominant explanation for the creativity that fuels invention (Amabile, 1997; Amabile & Khaire, 2008), and technological knowledge diversity, in particular, has been linked to firms' inventive capabilities (Lahiri, 2010; Miller et al., 2007; Phelps, 2010; Sampson, 2007; Srivastava & Gnyawali, 2011; Zhou & Li, 2012). This diversity enables firms to transfer solutions across domains, enhances their capacity to solve tough problems, and improves solutions by surmounting local search (Fleming, 2001; Hargadon & Sutton, 1997; Jeppesen & Lakhani, 2010). Also, knowledge diversity enables firms to identify, evaluate, and exploit discoveries from a greater variety of external sources (Cohen & Levinthal, 1990; Fabrizio, 2009; Gambardella, 1992).

It has been argued that a moderate level of knowledge diversity produces the best inventive performance (Henderson & Cockburn, 1996; Lahiri, 2010; Sampson, 2007; Vasudeva & Anand, 2011). Firms that invent in more domains tend to encompass greater technological distance, and while this expands latent recombinative opportunities, it can also negatively affect a firm's ability to integrate knowledge (Gilsing, Nooteboom, Vanhaverbeke, Duysters, & van den Oord, 2008; Phelps, 2010; Zhou & Li, 2012). Nevertheless, individual firms might derive very different inventive benefits from a given level of diversity, according to differences in their strategic leadership.

As the diversity of technological knowledge increases, its management becomes complex and informal means of coordination are necessary (Leiponen & Helfat, 2010). In particular, we argue that by cultivating a common language with which to understand a firm's direction, and instilling shared values to minimize cultural distances amongst organizational units, CEOs and CSOs can build bridges across disparate domains and enable firms to derive greater benefit from internal and external knowledge diversity.

CEO Influence: As a vision setter, the CEO cultivates a sense of identity and commitment to the firm's objectives (Hart & Quinn, 1993). By articulating a clear and consistent vision, CEOs can reduce conflict and facilitate communication, enabling a firm to extract greater benefit from its knowledge diversity. Shared goals mitigate social categorization processes that discourage information sharing (Bunderson & Sutcliffe, 2002), and encourage commitment, facilitating the integration of diverse perspectives (Pinto, Pinto & Prescott, 1993). A shared corporate vision provides clear direction regarding what to work on, is essential for quickly resolving conflicts (Holland, Gaston, & Gomes, 2000), and helps to cultivate common understanding of complex problems amongst diverse constituencies (Mumford, Scott, Gaddis, & Strange, 2002; Shalley & Gilson, 2004). Firms that develop collaborative orientations internally are better placed to see similar opportunities in their external partnerships (Berger et al., 2009; Linden, 2010).

CSO Influence: One of the key roles of the CSO is to provide a technical vision that is tightly coupled to the company's vision, or strategic intent (O'Connor et al., 2008; Smith, 2007). As a leader, the CSO is expected to set a direction for scientists' and engineers' efforts to discover the technologies that will fuel the firm's future growth. As part of the top management team, the CSO works with middle management, such as the R&D manager, to establish

commitment and motivate the implementation of key decisions (Raes, Heijltjes, Glunk, & Roe, 2011). In this capacity, the CSO conveys and reinforces the CEO's vision for the firm, and therefore is directly responsible for cultivating a base of common knowledge and shared values that facilitate collaboration across diverse domains (Medcof, 2008).

A CSO is usually a leading scientist or researcher who has management talent and is willing to create a more effective environment for other researchers to flourish. In this capacity, the CSO can create a culture that encourages networking and fosters open collaborations among scientists (Smith, 2007). Their technical background provides CSOs with expert power, a basis for influencing strategic decisions, and legitimacy with the firm's scientists (Finkelstein, 1992). CSOs are often expected to foster knowledge flows amongst organizational units and the assimilation of knowledge from strategic partners (Hartley, 2011).

Hence, we expect CSOs and CEOs to influence the relationship between internal and external knowledge diversity and inventive performance, i.e. to explain a substantial amount of the variation in how much inventive benefit firms derive from internal and external knowledge diversity:

Hypothesis 3: Strategic leaders significantly influence the inventive benefit firms derive from internal and external knowledge diversity.

3.0 METHODS

3.1 Research Setting

We examine the influence of strategic leaders on firms' inventive and innovative performance in 27 large biopharmaceutical manufacturers, over 20 years. We felt it was important to limit our attention to firms of comparable size, since leadership challenges, and the relevant tools for resolving them, vary with the span of control. As leaders have less direct control over many activities in large firms, this context provides a more conservative test of our arguments. The biopharmaceutical industry is ideal. Product innovation drives profits and requires the engagement of researchers with a highly diverse set of skills (Arora & Gambardella, 1994; Brusoni, Criscuolo, & Geuna, 2005; Henderson, 1994). Patents are widely used to protect inventions and bilateral R&D alliances are extensively formed (Bierly & Chakrabarti, 1996; Mansfield, 1961; Roijakkers & Hagedoorn, 2006).

Invention (drug discovery) is quite different from innovation (drug development), and success in each stage is demarcated by externally validated outcomes (Arora, Gambardella, Magazzini, & Pammolli, 2009). Drug discovery consists of target selection and validation, lead finding and optimization, and animal testing (Sosa, 2009). Inventive success produces patents; we focus on those awarded by the U.S. Patent and Trademark Office (USPTO). Drug development is comprised of phase I, II, III human clinical trials, in which firms assess the efficacy and safety of their candidate compounds. Innovative success follows closely regulated human clinical trials and produces new drug approvals (NDAs); we focus on those awarded by the Food and Drug Administration (FDA).

3.2 Sample

The data for our analysis consists of a panel of 591 firm year observations, for 27 of the largest public biopharmaceutical firms (SICs 2833 through 2836) operating in the US. We obtained consolidated financial data for 32 large biopharmaceutical firms from the 2007 Compustat database, but were unable to find complete information on CEOs and CSOs for 5 of them. We followed the 27 firms for which we had complete data, from 1984 to 2004. In total, these firms employed 87 CEOs and 88 CSOs during this time, with a range of 2 to 7 executives per firm. The average tenure of CEOs and CSO was 7 and 7.2 years, respectively. CEO and CSO eras are largely distinctive, meaning turnover in one usually did not coincide with turnover at the other level. When, during a focal CEO or CSO era, there was turnover at the other level, it was generally at least two years after the focal CEO or CSO era began.

Our sample of firms represents 67% of total biopharmaceutical product sales and 58% of total R&D expenditures in this industry during our analysis period. Also during this time, the FDA approved 1,058 new drugs of which 643 approvals belong to these firms. The U.S. Patent and Trademark Office (USPTO) granted a total of 54,998 patents in 64 of the patent classes in which biopharmaceutical firms receive patents; of these 33,831 were granted to these firms. All patents granted in 64 classes received 349,487 citations; our sample firms' patents received 180,388 citations. The alliances formed by our sample represent 39% of the total 41,057 alliances in this industry.

3.3 Data

CEO and CSO data were obtained from news articles published in the LexisNexis Business database and complemented with data from Corporate Yellow Book, Mergent Online,

Compact Disclosure, Annual Reports and 10Ks. These sources provided full coverage of leadership changes during the study period. Financial data were pulled from Compustat. We obtained patent data from the U.S. Patent and Trademark Office (USPTO) database, Cassis. According to the concordance between the U.S. Patent Classification (USPC) System and the Standard Industrial Code (SIC) System⁴, 64 three digit classes correspond most closely to biopharmaceutical inventions. Defining a finite but broad universe of possible patent classes in which our focal firms can invent in increases the degree to which our patent-based measures of knowledge comparable differences across firms (Benner & Waldfogel, 2008).

To identify each firm's external partners, we drew on alliance data from Recombination Capital (Recap) Inc., a comprehensive source of biopharmaceutical alliances. This data focuses specifically on R&D alliances. In assembling the data on new drug approvals (NDAs), we followed an approach used by Cardinal (2001) and Yeoh and Roth (1999), counting a biopharmaceutical product as being a new drug approval (NDA) if it constitutes a novel chemical composition, according to the U.S. FDA classification scheme⁵.

Alliances, patenting, and drug approvals can occur at the subsidiary level. We aggregated alliance and patent data to the parent level in three steps: First, we constructed family trees of the 27 firms using the Corporate Affiliations database compiled by the LexisNexis Business Data Group. Second, using these family trees, we assigned subsidiary alliances to the corporate parent. Third, we aggregated patent data to the parent level. With this

⁴ The concordance links US patent classes with 55 unique Standard Industrial Codes (SICs) System and is available on the website: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/brochure.htm#Patent_Data.

⁵ Category 1 is for a *new molecular entity (NME)*, which has not previously been offered to the U.S. market. The other categories are: 2) *New derivative*: a chemical that has been derived from an active ingredient that is already been marketed. 3) *New formulation*: a new dosage form or new formulation of active ingredient already in the market. 4) *New combination*: a drug that contains two or more compounds, the combination of which has not been marketed together. 5) *Already marketed drug product but a new manufacturer*: a product that duplicates another firm's already marketed drug. 6) *Already marketed drug product, but a new use*: a new use for a drug product already marketed by a different firm. 7) *Drug already legally marketed without an approved NDA*. 8) *OTC switch*: approval for the over the counter sale.

firm level patent and alliance data, we set up 20 annual matrices for each firm. These included a row for each of the 64 patent classes, and columns to indicate how many patents in each class the focal firm, and each alliance partner, was granted in that year. We used these matrices to compute the internal and external knowledge diversity measures.

3.4 Variables

3.4.1 Dependent Variables

Inventive performance: New chemical entities (NCEs) that have pharmacological potential are patented and this concludes invention (Sosa, 2009). The number of citations a patent receives is a widely used measure of a patented technology's impact on subsequent inventions (Fleming, 2001; Fleming, Mingo, & Chen, 2007; Yayavaram & Ahuja, 2008). Once a patent is granted, it will be cited if it is relevant to subsequent patents, as firms' lawyers and patent examiners seek to demonstrate that their inventions constitute novel, useful, non-obvious departures from prior inventions and from knowledge already in the public domain (Alcacer, Gittelman, & Sampat, 2009). Through this process, patents that are viewed as relevant prior art for a greater number of subsequent inventions will receive more citations. Patent citations has been widely used an indication of inventions' techno-economic usefulness (Fleming et al., 2007; Yayavaram & Ahuja, 2008) and their economic value (e.g. Hall, Jaffe, & Trajtenberg, 2005; Harhoff, Scherer, & Vopel, 2003; Trajtenberg, 1990; van Zeebroeck, 2011).

We constructed annual measures of inventive performance by summing all citations (excluding self-citations) to the patents granted in a particular year, in the subsequent 3 years, so that each patent has the same opportunity to be cited⁶. We use a 3 year window because patent

⁶ We ran our analyses including self-citations and the results are consistent with those reported in this paper.

citations peak one year after the patent grant date, and 3 years allows us to account for any short term fluctuations in total citations received (Mehta, Rysman, & Simcoe, 2010). Mehta and colleagues (2010), show empirically that a patent's "citation clock" does not start until it is issued, and we therefore use the granting date rather than application date in determining citations.

Innovative performance : Innovation begins once a company submits and receives approval on an Investigational New Drug application. If a drug candidate successfully completes all three clinical testing phases, including having its manufacturing processes comply with industry Good Manufacturing Practice, a company can submit a New Drug Application (NDA) to formally request the FDA consider it for marketing approval. Receipt of an NDA approval means a firm can market its product. We measured a firm's innovative output as the count of new drug approvals (NDAs) a firm received in a year. The innovative NDA counts exclude generic drug approvals, as they are not considered novel and do not proceed through the same development stages.

3.4.2 Independent Variables

We created knowledge diversity measures using patent classes to indicate technology domains, and track a firm's distribution of patents into classes according to their application date (Sampson, 2007; Phelps, 2010; Strumsky, Lobo, & van der Leeuw, 2012). Firms manage research programs in therapeutic or anatomical areas rather than patent classes (Henderson & Cockburn, 1996). However, to sustain these programs, they invest in scientists, laboratory facilities and partnerships in order to develop certain kinds of knowledge, such as peptide chemistry. Such a firm would likely generate more patents in the corresponding class, 930 –

Peptide or Protein Sequence. While 3 digit patent classes are coarse and aggregate a lot of variation amongst technology domains, they capture important differences in knowledge (Sampson, 2007; Strumsky et al., 2012).

All independent variables are lagged by one year. The lags inherent in the patent approval process make it unlikely that our dependent variable reflects the patents used to construct the IKD and EKD measures. Both IKD and EKD are based on patents *applied for* in time t, whereas citations are to patents *granted* in time t. The average patent approval time for biopharma is between 3 and 4 years

http://www.uspto.gov/web/offices/com/annual/2009/oai_05_wlt_04.html).

Internal Knowledge Diversity (IKD): IKD represents the distribution of patents a firm has across all 64 biopharmaceutical classes. Following Hall (2002), it was measured using a nonbiased inverse Herfindahl Index (HHI) as: $IKD_i = 1 - \left[\frac{N_i * HHI_i - 1}{N_i - 1} \right]$ where $HHI_i = \sum_{k=1}^k \left[\frac{N_{ik}}{N_i} \right]^2$ i = focal firm; k=patent classes; N_{ik} = number of patents in class k by the focal firm i; and N_i = total number of patents in all classes by the focal firm i. As with the traditional Herfindahl, the index rises with the number of patent classes a firm invents in and the equality of its efforts across classes, and ranges from 0 to 1. However, Hall's measure adjusts for the size of the patent portfolio to eliminate scale effects.

External Knowledge Diversity (EKD): We measured EKD by estimating the angular separation between a firm and each of its partners' patent portfolios (Jaffe, 1986). We adjust for the fact that partners with larger portfolios will affect the EKD measure more, by dividing each firm's number of patents, in a class k, by the highest number of patents held by the firm or its partners in class k. This provides us with a proportion which reflects the degree to which each partner contributes knowledge of a particular domain, relative to the focal firm and relative to the

other partners. We then used this formula to calculate external knowledge diversity (as distance, or the amount of non-overlapping knowledge) between a firm and each of its partners' patent

portfolios: $\mathbf{EKD}_{ij} = 1 - \frac{S_i'S_j}{\sqrt{S_i'S_i}\sqrt{S_j'S_j}}$ where $i \neq j$; i = focal firm; j = partner firms;

S_i = vector of adjusted number of patents granted to focal firm; and

S_j = vector of adjusted number of patents granted to focal firm's partners

The vectors represent portfolios, $S_i = (S_i^1 \dots S_i^k)$, where S_i^k is the adjusted number of patents granted to firm, i , in class k . Most firms have more than one partner, and we calculate this measure for each partner paired with the focal firm and then take the simple average. If firms do not patent, then the vectors contain all 0 values and the EKD measure is equal to 1 (Sampson, 2007). To avoid an undefined result, where the denominator is equal to 0, we set the value of the fractional term to 0. This 0 is then subtracted from 1, leading to a value of 1 for EKD. EKD values range from 0 to 1, with 1 being the maximum.

CEO and CSO Eras: CEO and CSO eras refer to the years during which a particular individual occupied this role. To create these eras, each CEO and CSO in each firm was given a unique number for the years they were in office. For example, the CEO of Merck was coded 1 from 1984 onward until he was replaced. The next CEO was then coded 2 from the year he/she replaced the previous CEO onward. Once he/she was replaced, the following CEO was coded as 3, and so on. This coding allows us to capture the reign of each CEO and CSO, and to compare their effects across the entire pool of executives in our sample firms.

3.4.3 Control Variables

We controlled for firm characteristics that might influence inventive and innovative performance. **Firm age:** Firms tend to emphasize relatively incremental invention and

innovation as they age and acquire more rigid structures that mediate their engagement with the environment (Sorensen & Stuart, 2000). We measured age as the number of years since founding. **Firm size:** Larger firms can often attract the best talent and invest in superior facilities. However, they also tend to be risk averse and slow to act. We measured size as the logarithm of annual sales revenue in US dollars. **Firm Patent Stock:** Firms that have received many patents might have superior R&D capabilities, and they also have greater opportunity to be cited. We alternately included a count of all patents a firm was issued in time t , and in the previous three years to control for this. The results were invariant to which count we included. **Partner Patent Stock:** Partners that have been granted more patents might have superior inventive capabilities, so we also included a patent count for all of the focal firm's partners in the last three years.

Network Knowledge Diversity: Firms that work with partners who are themselves very different from each other might find this increases both the opportunities and challenges associated with exploiting external knowledge diversity for invention and innovation. We controlled for differences amongst a firm's partners' knowledge (excluding the firm):

$$NKD_i = \frac{[\sum_h \{\sum_j d_{hj}\}]}{\frac{m_i * (m_i - 1)}{2}} \quad \text{Equation (1)}$$

$$d_{hj} = 1 - \frac{S_h' S_j}{\sqrt{S_h' S_h} \sqrt{S_j' S_j}}$$

where i = focal firm; h = partner firms; j = partner firms; m = number of partners

S_h = vector of number of patents granted to focal firm's partners;

S_j = vector of number of patents granted to focal firm's partners

The index h in Equation (1) is over particular partners and j indexes over all partners excluding the focal firm. The second summation (over h) corrects for double counting because when a particular firm sums over all potential partners we need to exclude that particular firm from all other summations. When calculating the average NKD for firm i , we use the term $\frac{m_i*(m_i-1)}{2}$. This captures the number of potential relationships among the firm's partners. To illustrate, when a focal firm has 1 partner, there can be no NKD measure. When a firm has 2 partners, there is only the distance between the two. When a firm has 3 partners, there can be a distance between (1) \rightarrow (2), (1) \rightarrow (3), and (2) \rightarrow (3). Thus, this relationship can be described as: $\sum_{i=1}^m m = \frac{m(m-1)}{2}$ where m represents the number of partners.

Network size or degree centrality is the number of active alliances a firm has in each year (Freeman, 1979). Firms with more alliance partners have access to a larger volume of knowledge and receive more news about developments in the industry, which could positively influence their inventive and innovative abilities (Ahuja, 2000). At the same time, a meta-analysis of knowledge transfer found evidence that large numbers of partners can make it more difficult to manage the associated diversity (Van Wijk, Jansen, & Lyles, 2008). **Network efficiency:** Is the degree to which a firm's partners connect it to different actors in the network (Burt, 1992). A firm that is positioned in an efficient ego network receives more unique information from each partner, which might augment its ability to create useful inventions. We used UCINET to calculate a cohesion-based measure of network efficiency for each firm (Borgatti, Everett, & Freeman, 2002).

R&D expenditure: Investment in R&D reflects a firm's efforts to invent and innovate. We measured this as the logarithm of annual R&D expenditures in US dollars. **Slack Resources:** Firms with more slack have the leeway to explore and thus might avoid the obsolescence or

senescence phenomenon (Sorensen & Stuart 2000). We used current assets divided by current liabilities as our control for slack resources (Singh, 1986). ***Partner Experience:*** Prior experience with a partner improves collaboration (Reuer, Zollo, & Singh, 2002). We determined whether a partner had allied with the focal firm at any time in the preceding years and if it had designated these as established partners. We then calculated partner experience as the ratio of established partners in year t to the total partners in year t. ***Time effect:*** were introduced into the model as year dummy variables to control for industry time specific effects. The year of 1984 was taken as the base year.

4.0 ANALYSIS AND RESULTS

We tested the hypotheses using a 3-level mixed effect Poisson regression with inventive and innovative performance as dependent variables. This hierarchical linear model does not require balanced data and is suitable for discrete dependent variables. In our data, observations at each year are nested within CEO and CSO eras, and those eras are nested within firms. In the mixed effect model, we specify time as the level-1 variable, leader's era as the level-2 variable, and firm as the level-3 variable. This accommodates the clustered characteristic of longitudinal data, the positively skewed nature of count data, and the nested aspect of annual inventive and innovative performance, within leaders' eras.

To test Hypotheses 1a, 1b, and 1c, we examine how much of the variation in observed inventive and innovative performance is explained by CEOs and CSOs, as compared to stable firm characteristics. This requires models that represent how variation in inventive and innovative performance is allocated across the three different levels. To investigate this variance allocation in hierarchical linear models, we estimate the following set of equations:

At level-1, we modeled inventive / innovative performance as a function of the intercept estimate, a leader's mean performance:

$$\ln Y_{ijk} = \beta_{0jk}$$

where Y_{ijk} is the inventive / innovative performance of year i during the era of leader j in firm k ; β_{0jk} is the intercept, and $[\exp(\beta_{0jk})]$ is the mean inventive / innovative performance during the era of leader j in firm k .

At level 2, the leader's era model, we defined each mean performance for leader j in firm k , β_{0jk} , as an outcome varying randomly around the firm's mean performance:

$$\beta_{0jk} = \gamma_{00k} + r_{0jk}$$

where γ_{00k} is the mean inventive / innovative performance in firm k; r_{0jk} is a random “leader effect”, i.e. the deviation of mean performance for leader j in firm k from the firm k’s mean performance.

Lastly, the level-3 model represents the variability of inventive / innovative performance among firms. The firm’s mean performance, γ_{00k} , vary randomly around a grand mean:

$$\gamma_{00k} = \pi_{000} + u_{00k}$$

where π_{000} is the grand mean; u_{00k} is a random “firm effect”, i.e. the deviation of firm k’s mean performance from the grand mean performance.

This three-level set of equations separates the total variance in the inventive / innovative performance, Y_{ijk} , into variance at each level: among year within leader era (level 1); among leaders within firm (level 2); and among firms (level 3). This partition allows estimation of variance associated with each level of analysis. We obtained the variance of leader and firm from the base model regressions, and calculate the variance of year (level -1) as $\pi^2/3$. We then added up all variances for each level and calculated the proportion of variance of each level (level effect) as a percentage of the total variance (Snijders & Bosker, 1999).

This also provides the basis for testing Hypothesis 2, in conjunction with an additional model estimated using CEO – CSO cohorts (described below), to separate their individual contributions to inventive / innovative performance from any combined effect they may have.

To test Hypothesis 3, that leaders affect inventive performance by influencing the benefit firms derive from knowledge diversity, we expanded the base model to include predictor variables that may explain the variability in each level. Specifically, we included internal and external knowledge diversity in the model, and estimated fixed and random effects to capture

their influence on inventive performance. Whereas the fixed effects capture the average influence of IKD and EKD on inventive success, the random effects captures variation in the degree to which firms derived inventive benefits from their knowledge diversity. The random effects are allowed to vary over the reign of different leaders. This allows us to test whether there is significant variance in the utility firms get from their knowledge diversity, across CEO/CSO eras. A general model for a three level mixed effects Poisson model takes the following form.

The level 1 (time) model is:

$$\ln Y_{ijk} = \beta_{0jk} + \sum_{p=1}^P \beta_{pjk} X_{pijk}$$

where Y_{ijk} is the dependent variable in year i during leader's era j , of firm k ; β_{0jk} is the intercept of leader era j in firm k ; X_{1ijk} is the level of knowledge diversity that predicts Y_{ijk} and β_{1jk} is the regression coefficient, which captures the inventive utility a firm derives from knowledge diversity, for era j in firm k ; X_{2ijk} , refers to the control variables and β_{2ijk} are the corresponding regression coefficients. The coefficients β_{0jk} and β_{1jk} are allowed to vary randomly over leaders and firms, but are not predicted by leader- or firm-level variables.

The level 2 (leaders' era) model is

$$\beta_{0jk} = \gamma_{00k} + r_{0jk}$$

$$\beta_{1jk} = \gamma_{10k} + r_{1jk}$$

$$\beta_{pjk} = \gamma_{p0k} \quad \text{for } p = 2, \dots, P$$

where γ_{00k} is the intercept of firm k ; γ_{10k} is the mean inventive utility firm k derives from its knowledge diversity; r_{0jk} and r_{1jk} are level 2 random effects that represent the deviation of

leader jk 's mean from the firm mean. It is assumed that the variability among leaders within each of the K firms is the same.

The model of level 3 or firm level is

$$\gamma_{00k} = \pi_{000} + u_{00k}$$

$$\gamma_{10k} = \pi_{100}$$

$$\gamma_{p0k} = \pi_{p00} \text{ for } p = 2, \dots, P$$

where π_{000} is the grand mean; π_{000} is the overall mean of knowledge diversity utility rate; u_{00k} is the deviation of firm k 's mean from the grand mean.

Tables 1a and 1b provide the summary statistics of the standardized variables and the correlations among the variables. Tables 2a and 2b present the results of the mixed effect regression with inventive performance as the dependent variable for CEO and CSO eras, respectively. Models 1 and 6 are the base models that include only a random intercept of level-2 leader id and level-3 firm id. In Models 2 and 7, we added control variables along with random intercepts for leaders and firms. Models 3 and 8 are the models that include control variables, IKD, and generate a random coefficient for IKD. Models 4 and 9 are similar to Models 3 and 8 but include EKD. We then include both diversity variables in Model 5 for CEOs and in Model 10 for CSOs. Tables 3a and 3b report the random effects of CEO-CSO cohort analysis for both inventive and innovative performance. Tables 4a and 4b present the results of the mixed effect regression for innovative performance during both CEO and CSO eras. We started with Models 1 and 5 as the base models and progressively added control variables and independent variables.

Insert Tables 1a, 1b, 2a, 2b, 3a, 3b, 4a, 4b about here

Hypothesis 1a predicts that strategic leaders will have a lesser impact on innovative performance than on inventive performance. We investigated this by comparing the random parameters generated for invention (Tables 2a and 2b) with those generated by comparable models that take innovation output as the dependent variable (Tables 4a and 4b). Using the base Models 1 and 6 in Tables 2a and 2b, we examined the 95% confidence interval for the variance of the random-effect parameters. If the intervals do not include zero, we can conclude that the value represents the amount of variance that resides within a level. The intervals around the CEO and the CSO intercepts exclude 0, and indicate CEOs and CSOs explain significant variance in inventive performance. Using the base Models 1 and 5 in Tables 4a and 4b, we found similar results for the variance in innovative performance, but with much smaller magnitude.

We then calculated firm and leader effects by taking the percentage of each variable's variance over total variance. We calculate leader effects on the variability of inventive and innovation performance by taking the percentage of CEO or CSO variance over total variance. We find that stable firm factors account for around 27% of the proportion of variance in firms' inventive performance; CEO and CSO effects account for 38.4% and 42.9%, respectively. (Note, these percentages add up to more than 100% because there is some overlap amongst the CEO and CSO eras.) We found that the firm effects accounted for around 51% in innovative performance, while CEOs and CSOs accounted for 3.3% and 3.6% of the variance in innovation, respectively, significantly less than the results of leader effects on inventive performance.

In support of Hypothesis 1a, these comparisons suggest that CEOs and CSOs account for a substantial influence on inventive performance (between 38 and 43%), but far less for influencing innovative performance (less than 4%). Our calculations also show that leaders

account for more of the variation in inventive performance (between 38 and 43%), than do stable firm effects (27%), in support of Hypothesis 1b. Conversely, and in support of Hypothesis 1c, stable firm effects account for 51% of the variation in innovative performance, where strategic leaders account for less than 4%.

To test Hypotheses 2a and 2b, whether CEOs or CSOs explain more of the variation in inventive and innovative performance across firms, we developed a three-level model similar to the previous approach, but with level-2 variable as the combined CEO and CSO era. Each CEO and CSO pair, in each firm, was coded uniquely to represent the period of reign of both leaders in their current position. Changes in either of the paired leaders will change the code.

We reported the random effect parameters of CEO-CSO cohort analysis in Tables 3a and 3b. The base models included only the random effects of the level 2 combined CEO-CSO id and the level 3 firm id. We then added categorical predictor variables CEO and CSO to the base model to estimate the proportion reduction in variance. We calculated the proportion of variance explained by each of the leaders using the following formula:

$$\frac{V_{\text{CEOCSO (base)}} - V_{\text{CEOCSO (CEO or CSO predictor)}}}{V_{\text{CEOCSO (base)}}$$

The estimated proportion of variance in inventive performance explained by CEO was 0.208 (4.27-3.38 / 4.27). The estimated proportion of variance in inventive performance explained by CSO was 0.164 (4.27-3.57 / 4.27). That is, 20.8% of the variance in inventive performance was accounted for by CEO, and 16.4% of variance in inventive performance was accounted for by CSO. These percentages underestimate to some degree the total influence of a level because variation that is jointly explained by a CEO-CSO pair is excluded. We did the same analysis for innovative performance and found the estimated portion of variance in innovative performance accounted for by CEO and CSO were 3.6% and 21.4% respectively.

The analysis used to test Hypotheses 1b and 1c provided a comparison based on variation among individuals within a C-level leader group, whereas the CEO-CSO cohort analysis showed a comparison across the two leadership roles. Hence, this second analysis suggests that CEOs as a class of leader ultimately have a stronger influence on inventive performance, even though more of the variation being explained in inventive performance corresponds to differences among CSOs. This suggests that individual differences mattered more at the CSO level, while a greater proportion of CEOs' influence was prescribed by their role.

On the contrary, the CEO-CSO cohort analysis for innovative performance showed quite the reverse results from the inventive performance cohort analysis. This analysis indicates that the CSOs have the stronger influence on innovative performance than that of the CEOs. Together, these results provide support for Hypotheses 2a and 2b.

Hypothesis 3 specifically predicts that both CEO and CSO positively affect the utility a firm can derive from knowledge diversity for inventive performance. To test this hypothesis we ran Models 3 and 4 (for CEOs) as well as Models 8 and 9 (for CSOs), which include random effects for internal and external knowledge diversity. If CEOs and CSOs influence the utility of these diversities, the random-effects diversity parameters should show a range of variation that does not include 0. As reported in Tables 2a and 2b, neither the intervals for IKD nor EKD included zero, confirming Hypothesis 3.

Consistent with Hypothesis 3, strategic leaders influence inventive success by affecting how much benefit firms derive from IKD and EKD. However, this did not tell us how large their influence is; we get a sense of this graphically. Specifically, we plot the average effect of IKD and EKD on inventive success, and then the upper and lower bounds on that relationship, as determined by the CEO or the CSO. The range of CEO and CSO effects on the relationship

between IKD, EKD, and inventive performance are illustrated in Figures 1 and 2. They show that the most effective leaders deviate substantially from the least effective leaders. CEOs and CSOs at the upper bound guide their firms to derive much greater benefit from internal knowledge diversity, and to a lesser degree external knowledge diversity, than the average strategic leader. Note that the figures truncate the predicted maximum value of inventive performance for IKD.

Insert figure 1 and 2 about here

5.0 DISCUSSION

This study offers several contributions to the literature on innovation and leadership. We go beyond prior work by considering both invention and innovation, including the CSO as well as the CEO, and investigating the degree to which strategic leaders explain variation in how much benefit firms derive from diverse internal and external knowledge. While our analytical method prevents us from offering causal explanations for what we found, prior work offers a great deal of insight regarding the likely mechanisms underlying this pattern of results. What has not been made clear by previous research is the degree to which strategic leaders explain differences in firms' innovative performance.

How Much Do Strategic Leaders Matter, for Invention and Innovation? Not only are firm level studies of strategic leaders' influence on invention rare, the literature offers mixed views of whether and how much we should expect them to affect firms' inventive and innovative performance (Amabile & Khaire, 2008; Yadav et al., 2007). Given the central role that innovation plays in sustaining firm vitality, we might expect a firm's top executives to care deeply that it excels in this activity. In fact, strategic leaders appear to recognize the mandate to cultivate their firms' innovation capabilities, but find it difficult to execute (Amabile & Kramer, 2012; Criswell & Martin, 2007; Martin, 2009).

One barrier is cognitive. The tendency to filter information and appraise opportunities in conformance with extant beliefs constrains leaders' capacity to embrace new ways of competing and innovating (Benner & Tripsas, 2012; Leonard-Barton, 1992; Tripsas & Gavetti, 2000).

Another is situational. Leaders face numerous demands on their time and attention, leaving little room for reflection and fresh perspective (Hambrick, Finkelstein, & Mooney, 2005).

The literature also presents conflicting views on the role of top executives versus mid-level managers. CEOs are charged with establishing a direction for the firm and possess more power than other managers (Nadler & Heilpern, 1998; Hambrick & Mason, 1984). Through their communications and symbolic and substantive actions, strategic leaders affect what information other members of the firm pay attention to, and how they interpret it (Yadav et al., 2007). However, some authors contend that mid-level managers, who champion ideas (Burgelman, 1986, 1994) and directly confront early signals of environmental shifts (Christensen, 1997; Grove, 1996), are the driving force behind innovation. CEOs are often portrayed as affecting innovation indirectly, such as by supporting individuals and project teams (Montoya-Weiss & Calantone 1994). In light of these mixed perspectives, it seems important to ascertain how much strategic leaders actually affect key outcomes of invention and innovation.

We find that strategic leaders, specifically CEOs and CSOs, each contribute importantly to inventive success. Between 20.8% and 38.4% of the variation in inventive performance (patent citations) across firms is attributable to the CEO, and between 16.4% and 42.9% reflects the CSO. Surprisingly, strategic leadership explains only about 3% of the variation amongst firms' innovative performance (new drug approvals).

Further research is needed to isolate the reasons for this difference, but two possibilities seem likely. First, whereas all pharmaceutical firms compete to produce NDAs, there are notable differences in their leaders' visions for how to get to there, particularly in what kinds of research to support. Whereas some pharmaceutical CEOs and CSOs have sought to foster a science-driven approach to research and target fundamental breakthroughs, others have pursued more incremental and focused research (Galambos & Vagelos, 2004; Fagan & Beer, 1999; Rodengen, 1999). This variation might correspond to distinctive patenting outcomes.

Second, invention and innovation differ in important ways, and invention may offer more room for strategic leaders to matter. Case studies of pharmaceutical firms reveal vast differences in how individual leaders have managed drug discovery within and across firms (Henderson, 1994; Henderson & Cockburn, 1994; Pisano, 2006; Thomke & Nimgade, 2008). Drug development, on the other hand, is highly regulated and, once a firm has selected which drug candidates to push forward into clinical trials, affords less room for managers to affect outcomes. Beyond the idiosyncratic features of drug discovery and development, we think invention is precisely the kind of activity for which strategic leaders' influence matters most.

While academic research fails to consistently distinguish the two, invention and innovation comprise distinct processes and benefit from different management approaches (Cooper, 2001; Roberts, 2007; Schumpeter, 1943). Invention refers to idea generation and early stage discovery, which is characterized by ill structured problems and unpredictable choices. Firms strive to increase variation during this stage, to raise the likelihood of discovering something truly novel and useful. Innovation, by contrast, is managed in well defined stages, to increase the reliability with which firms achieve specific goals. Key tasks tend to be analytical, and leaders influence outcomes by selecting which projects to fund.

Mark Fishman, president of Novartis Institutes for BioMedical Research puts it this way: "The leader's job is to map out the stages of innovation and recognize the different processes, skill sets, and technology support that each requires. For instance, efficiency-minded management has no place in the discovery phase... you must accept that the discovery phase in pharmaceutical innovation is inherently muddleheaded. Efficient models make good sense for the middle and end stages of the innovation process, when the game has moved from discovery to control and reliability" (Amabile & Khaire, 2008, p. 104).

Formal processes offer less guidance to invention, few clear or measurable outcomes can be specified, and many paths are indistinguishable ex ante. These qualities make it particularly ripe for leadership influence. It is here where softer skills, intuition and experience, and especially a CEO's ability to craft a compelling vision ought to matter most (Bhardwaj et al., 2006). By defining the direction in which a firm will move, a strategic leader's vision provides some of the structure missing in early stage discovery (Berger et al., 2009). Authors speculate that the capacity to articulate a compelling vision is the primary reason transformational leadership behaviors correlate positively with exploration and creativity (Friedrich, Vessey, Schuelke, Ruark, & Mumford, 2010; Mumford et al., 2002). Reiter-Palmon and Ilies (2004) argue that, although leaders may not devise the solutions, they must engage in the generative process by offering meaning and direction, which helps to define problems and conceptualize solutions.

Leader versus Firm Effects. We also found that strategic leaders have a stronger influence on firms' inventive performance than stable firm factors, where they accounted for over 38% of the variation in firms' success and firm effects explain 27%. By contrast, 51% of the variation in innovation outcomes was attributable to the firm and less than 4% to the firm's leaders. This suggests firm resources matter less for invention than how strategic leaders manage the resources at their disposal; the reverse holds for innovation. To affect invention, strategic leaders must shape the process of discovery; to influence innovation, strategic leaders must manage the accumulation of key resources, such as technology, talent, facilities, procedures, and culture.

Strategic Leader Influence on Benefits from Knowledge Diversity. We also find that some of CEOs' and CSOs' influence on invention is attributable to their ability to leverage

internal and external knowledge diversity. Research has generated relatively consistent findings on how leaders can affect creativity and their firms' inventive success, and much of it seems relevant to managing and benefitting from diversity. Key insights include the need to manage intrinsic motivation by creating a work environment that appreciates novelty and risk, challenges employees and supports collaboration, is open to diverse perspectives, and manages conflict constructively (Amabile & Khaire, 2008; Amabile & Kramer, 2012). Leaders that communicate a clear and consistent vision for their organization, and convey their expectations regarding goals and missions for innovation are more likely to succeed in this regard (Berger et al., 2009; Mumford et al., 2002; Friedrich et al., 2010; Shalley & Gilson, 2004).

Empirical Contribution. We measured annually the firms' inventive and innovative success across different leaders' eras within firm and across firms over 20 years of observations, thus our data exhibit hierarchical, or nested, data structures. These data structures present several issues for analysis including the interdependence of observations and the cross-level nature of the data. Because repeated observation within leader's era tend to be more homogeneous than if observations were randomly sampled from a larger population, observations based on these environments are not fully independent. Thus in our hierarchical data, the assumption of independence for OLS regression and most analytic techniques is certainly violated and may produce unreasonably small standard errors (Raudenbush & Bryk, 2002). To deal with the cross-level nature of the data, we can aggregate or disaggregate data and analyze them at the higher- or the lower-level units. However, disaggregating the data may increase interdependency of the variables, while the aggregating approach may disregard potentially meaningful lower-level variations in outcome measure (Raudenbush & Bryk, 2002). Further, ordinary regressions and analysis of variance prevent us from disentangling level effects on the outcome of interest.

Adopting a multi-level analytical perspective overcomes these problems. Our 3-level mixed effect Poisson regression explicitly models each year observation-, leader's era- and firm-level residuals, therefore recognizing the partial interdependence of each year observation within the same era and firm. The total variance in our dependent variable is decomposed into within-era variance, between-era within-firm variance and between-firm variance, and those sources of variation are studied simultaneously. Therefore, unlike traditional ANOVA for the decomposition of variance, the analysis accurately models the true relationship between the independent variables and the dependent variables. Our approach essentially examined lower-level and higher-level variance in the outcome measures, while maintaining the appropriate level of analysis, thus the analysis accurately model the true relationship between the independent variables and the dependent variables.

Limitations and Future Directions. It will be important to examine whether our results hold in other science-based industries, which face less regulated development processes and complex products. It would also be fruitful to examine whether strategic leaders have the same influence on the benefit firms derive from other types of diversity, such as functional background, demographic, and tenure differences, for innovation. It would also be useful to investigate further whether stability or changes in leadership affects this utility, as there are conflicting arguments in the literature. On the one hand, leadership stability may provide researchers with the confidence to explore and take risks. On the other hand, it may lead to inertial patterns of search and collaboration which would undermine inventive capacity.

Previous studies have shown that intensive internal research helps a firm to effectively absorb external knowledge (Cohen & Levinthal, 1990; Gambardella, 1992; Henderson & Cockburn, 1996; Lane & Lubatkin, 1998). However, openness to discoveries and innovation

opportunities outside the firm is also essential to benefitting from absorptive capacity (Volberda, 1996). It may be instructive to examine whether executives' orientation to open innovation explains firm's competence in utilizing diverse knowledge. Finally, top executives can affect the influence of knowledge diversity on invention in two different ways that complement to each other. Strategic leaders may influence how much diversity a firm accumulates, and they also shape how productively their firms utilize it. Further research could delve more deeply into how leaders affect both outcomes.

TABLES AND FIGURES

Table 1a. Descriptive Statistics and Correlations for Inventive Performance^a

	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Inventive Performance	1.000												
2. Firm Knowledge Stock	0.624	1.000											
3. Partner Knowledge Stock	0.183	0.250	1.000										
4. Network Knowledge Diversity	-0.154	-0.261	-0.479	1.000									
5. Network Size	0.263	0.650	0.253	-0.307	1.000								
6. Network Efficiency	0.223	0.301	0.156	-0.143	0.337	1.000							
7. Firm Age	0.447	0.556	0.272	-0.281	0.427	0.121	1.000						
8. Firm Size	0.473	0.620	0.206	-0.265	0.582	0.238	0.678	1.000					
9. R&D Expenses	0.474	0.674	0.230	-0.287	0.675	0.385	0.631	0.911	1.000				
10. Slack Resources	-0.253	-0.271	-0.109	0.150	-0.228	-0.001	-0.368	-0.426	-0.328	1.000			
11. Firm's Partner Experience	0.222	0.346	0.108	-0.182	0.335	0.357	0.233	0.416	0.470	-0.220	1.000		
12. Internal Knowledge Diversity	0.076	0.028	-0.050	0.023	0.051	-0.023	0.137	0.066	0.036	-0.075	0.001	1.000	
13. External Knowledge Diversity	-0.235	-0.373	-0.578	0.468	-0.380	-0.178	-0.306	-0.328	-0.371	0.152	-0.204	0.020	1.000
Mean	345.13	75.15	30.36	0.95	32.94	0.59	50.21	6.85	5.14	3.37	0.52	0.62	0.92
Std. Dev.	428.93	91.34	92.64	0.14	40.75	0.12	37.56	2.99	2.30	3.93	0.32	0.28	0.16
Min	0.00	0.00	0.00	0.00	0.00	0.00	2.00	-3.82	-1.67	0.49	0.00	0.00	0.00
Max	2167.00	403.00	804.00	1.00	204.00	0.79	154.00	10.87	9.41	43.76	0.95	1.00	1.00

^aCorrelations greater than 0.08 and less than -0.15 are statistically significant at $p < .05$

Table 1b. Descriptive Statistics and Correlations for Innovative Performance^a

	1	2	3	4	5	6	7	8	9	10	11	12	13
1. Innovative Performance	1.000												
2. Firm Knowledge Stock	0.319	1.000											
3. Partner Knowledge Stock	0.145	0.250	1.000										
4. Network Knowledge Diversity	-0.124	-0.261	-0.479	1.000									
5. Network Size	0.424	0.650	0.253	-0.307	1.000								
6. Network Efficiency	0.148	0.301	0.156	-0.143	0.337	1.000							
7. Firm Age	0.282	0.556	0.272	-0.281	0.427	0.121	1.000						
8. Firm Size	0.454	0.620	0.206	-0.265	0.582	0.238	0.678	1.000					
9. R&D Expenses	0.445	0.674	0.230	-0.287	0.675	0.385	0.631	0.911	1.000				
10. Slack Resources	-0.242	-0.271	-0.109	0.150	-0.228	-0.001	-0.368	-0.426	-0.328	1.000			
11. Firm's Partner Experience	0.190	0.346	0.108	-0.182	0.335	0.357	0.233	0.416	0.470	-0.220	1.000		
12. Internal Knowledge Diversity	0.089	0.028	-0.050	0.023	0.051	-0.023	0.137	0.066	0.036	-0.075	0.001	1.000	
13. External Knowledge Diversity	-0.194	-0.373	-0.578	0.468	-0.380	-0.178	-0.306	-0.328	-0.371	0.152	-0.204	0.020	1.000
Mean	1.663	75.15	30.36	0.95	32.94	0.59	50.21	6.85	5.14	3.37	0.52	0.62	0.92
Std. Dev.	2.713	91.34	92.64	0.14	40.75	0.12	37.56	2.99	2.30	3.93	0.32	0.28	0.16
Min	0	0.00	0.00	0.00	0.00	0.00	2.00	-3.82	-1.67	0.49	0.00	0.00	0.00
Max	24	403.00	804.00	1.00	204.00	0.79	154.00	10.87	9.41	43.76	0.95	1.00	1.00

^aCorrelations greater than 0.08 and less than -0.15 are statistically significant at $p < .05$

Table 2a. Mixed Effect Poisson Regression - The influence of Chief Executive Officer (CEO) on the relationship between knowledge diversity and inventive performance

Variables	Model 1	Model 2	Model 3	Model 4	Model 5
Fixed effects					
Year		-0.771***	-0.546***	-0.666***	-0.431***
Firm Knowledge Stock		0.633***	0.589***	0.636***	0.580***
Partner Knowledge Stock		-0.019***	-0.017***	-0.012***	-0.020***
Network Knowledge Diversity		0.014***	-0.001	0.014***	0.014***
Network Size		-0.283***	-0.396***	-0.371***	-0.515***
Network Efficiency		0.212***	0.182***	0.229***	0.182***
Firm Age		0.470***	0.729***	0.450*	0.802***
Firm size (log sales)		-0.793***	-0.914***	-0.811***	-0.985***
R&D Expenditure (log R&D)		1.159***	0.749***	1.224***	0.754***
Slack Resources		-0.074***	-0.105***	-0.059***	-0.112***
Partner Experience		0.032***	-0.006	0.020***	0.002
Internal Knowledge Diversity			1.678***		1.701***
Internal Knowledge Diversity Squared			-2.006***		-1.994***
External Knowledge Diversity				-0.244**	0.055
External Knowledge Diversity Squared				0.122***	-0.075*
Intercept	3.893 ***	4.599***	4.462***	4.586***	4.431***
Random effects (var)					
Intercept : Firm	2.57 (1.16-5.69)	0.487 (0.167-1.420)	0.580 (0.252-1.339)	0.481 (0.171-1.353)	0.626 (0.279-1.405)
Intercept : CEO	3.65 (2.44-5.47)	1.257 (0.812-1.944)	0.774 (0.482-1.242)	1.146 (0.727-1.807)	0.715 (0.057-0.184)
Internal Knowledge Diversity			3.919 (2.559-6.003)		4.187 (2.724-6.437)
External Knowledge Diversity				0.181 (0.098-0.335)	0.102 (0.057-0.184)
Wald χ^2		15026.64***	10967.41***	12680.16***	9638.98***

Significance levels: † p<0.1, * p<0.05, ** p<0.01, *** p<0.001; The 95% Confidence Intervals are in parentheses

Table 2b. Mixed Effect Poisson Regression - The influence of Chief Scientific Officer (CSO) on the relationship between knowledge diversity and inventive performance

Variables	Model 6	Model 7	Model 8	Model 9	Model 10
Fixed effects					
Year		-0.829***	-0.826***	-0.885***	-0.896***
Firm Knowledge Stock		0.575***	0.497***	0.580	0.495***
Partner Knowledge Stock		-0.010***	-0.009***	-0.001***	-0.016***
Network Knowledge Diversity		0.001	0.003	-0.029**	-0.019***
Network Size		-0.156***	-0.045***	-0.185***	-0.075***
Network Efficiency		0.130***	0.084***	0.180***	0.104***
Firm Age		0.600**	0.477**	0.447***	0.352*
Firm size (log sales)		-0.639***	-0.398***	-0.554***	-0.441***
R&D Expenditure (log R&D)		0.878***	0.537***	1.021***	0.804***
Slack Resources		-0.318***	-0.307***	-0.291***	-0.293***
Partner Experience		0.063***	0.040***	0.060***	0.050***
Internal Knowledge Diversity			1.485***		1.870***
Internal Knowledge Diversity Squared			-1.735***		-2.005***
External Knowledge Diversity				-0.194*	-0.144
External Knowledge Diversity Squared				0.125***	0.219***
Intercept	3.726**	4.493***	4.598***	4.483***	4.455***
Random effects (var)					
Intercept: Firm	2.84 (1.22-6.57)	0.409 (0.081-2.060)	0.423 (0.160-1.117)	0.369 (0.108-1.256)	0.285 (0.091-0.891)
Intercept: CSO	4.62 (3.07-6.96)	2.043 (1.322-3.158)	1.089 (0.708-1.676)	1.640 (1.065-2.527)	1.093 (0.700-1.704)
Internal Knowledge Diversity			3.672 (2.443-5.520)		4.718 (3.151-7.052)
External Knowledge Diversity				0.330 (0.162-0.672)	0.684 (0.321-1.458)
Wald χ^2		9973.49***	8393.35***	9455.91***	8082.35***

Significance levels: † p<0.1, * p<0.05, ** p<0.01, *** p<0.001; The 95% Confidence Intervals are in parentheses

Table 3a. Cohort CEO &CSO Random Effects Parameters for Inventive Performance

Random Effects Parameters (variance)	Base Model		CEO as predictor		CSO as predictor	
	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.
Firm: intercept	2.85	1.04	3.02	1.06	3.01	1.14
Cohort CEOCSO : intercept	4.27	0.67	3.38	0.55	3.57	0.58

Table 3b. Cohort CEO &CSO Random Effects Parameters for Innovative Performance

Random Effects Parameters (variance)	Base Model		CEO as predictor		CSO as predictor	
	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.
Firm: intercept	3.78	1.41	4.18	1.60	3.86	1.40
Cohort CEO-CSO : intercept	0.28	0.08	0.27	0.08	0.22	0.07

Table 4a. Mixed Effect Poisson Regression – The influence of Chief Executive Officer (CEO) on the relationship between knowledge diversity and innovative performance (NDA)

Variables	Model 1	Model 2	Model 3	Model 4
Fixed effects				
Year		-0.381**	-0.302**	-0.412**
Firm Knowledge Stock		0.132	0.032	0.112
Partner Knowledge Stock		-0.009	-0.001	-0.006
Network Knowledge Diversity		0.066	0.073	0.073
Network Size		0.067	0.011	0.074
Network Efficiency		-0.084	-0.094	-0.077
Firm Age		-0.163	-0.033	-0.155
Firm size (log sales)		0.466	0.538	0.466
R&D Expenditure (log R&D)		0.995**	0.920**	0.974**
Slack Resources		-0.703**	-0.684**	-0.709**
Partner Experience		-0.191*	-0.171*	-0.188*
Internal Knowledge Diversity			-0.130	
Internal Knowledge Diversity Squared			-0.050	
External Knowledge Diversity				-0.052
External Knowledge Diversity Squared				-0.012
Intercept	-0.914*	-0.482***	-0.473***	-0.492***
Random effects (var)				
Intercept : Firm	3.637 (1.744-7.583)	0.056 (0.000-8.047)	0	0
Intercept : CEO	0.238 (0.121-0.467)	0.291 (0.124-0.683)	0.248 (0.107- 0.513)	0.331 (0.127-0.860)
Internal Knowledge Diversity			0.172 (0.059-0.498)	
External Knowledge Diversity				0.038 (0.001-0.205)
Wald χ^2		133.96***	175.64***	131.36***

Significance levels: † p<0.1, * p<0.05, ** p<0.01, *** p<0.001 ; The 95% Confidence Intervals are in parentheses

Table 4b. Mixed Effect Poisson Regression - The influence of Chief Scientific Officer (CSO) on the relationship between knowledge diversity and innovative performance (NDA)

Variables	Model 5	Model 6	Model 7	Model 8
Fixed effects				
Year		-0.522***	-0.486***	-0.527***
Firm Knowledge Stock		0.005	-0.005	0.000
Partner Knowledge Stock		0.013	0.016	0.009
Network Knowledge Diversity		0.067	0.066	0.071
Network Size		0.278†	0.249†	0.255†
Network Efficiency		-0.062	-0.056	-0.070
Firm Age		-0.094	-0.017	-0.101
Firm size (log sales)		0.736†	0.810†	0.784†
R&D Expenditure (log R&D)		0.835**	0.788*	0.789*
Slack Resources		-0.426†	-0.349	-0.480*
Partner Experience		-0.161**	-0.156*	-0.132†
Internal Knowledge Diversity			-0.257	
Internal Knowledge Diversity Squared			0.155	
External Knowledge Diversity				-0.080
External Knowledge Diversity Squared				0.057
Intercept	-0.895*	-0.499***	-0.475**	-0.505**
Random effects (var)				
Intercept: Firm	3.838 (1.847-7.975)	0.149 (0.021-1.080)	0.204 (0.043-0.967)	0.113 (0.009-1.506)
Intercept: CSO	0.270 (0.133-0.548)	0.241 (0.096-0.606)	0.155 (0.057-0.425)	0.248 (0.089-0.681)
Internal Knowledge Diversity			0.102 (0.021-0.506)	
External Knowledge Diversity				0.049 (0.012-0.198)
Wald χ^2		126.84***	127.56***	126.93***

Significance levels: † p<0.1, * p<0.05, ** p<0.01, *** p<0.001; The 95% Confidence Intervals are in parentheses

Figure 1. The range of CEO's influence on the relationship between Knowledge Diversity and Inventive Performance

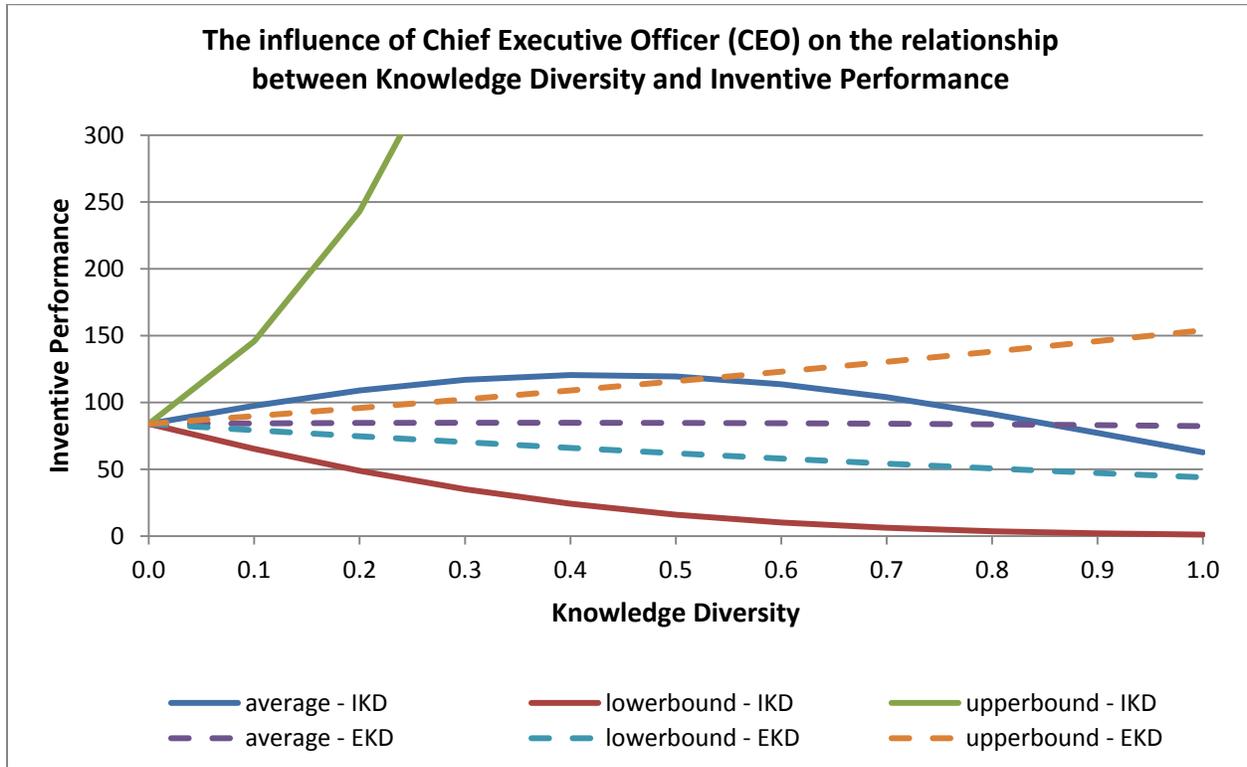
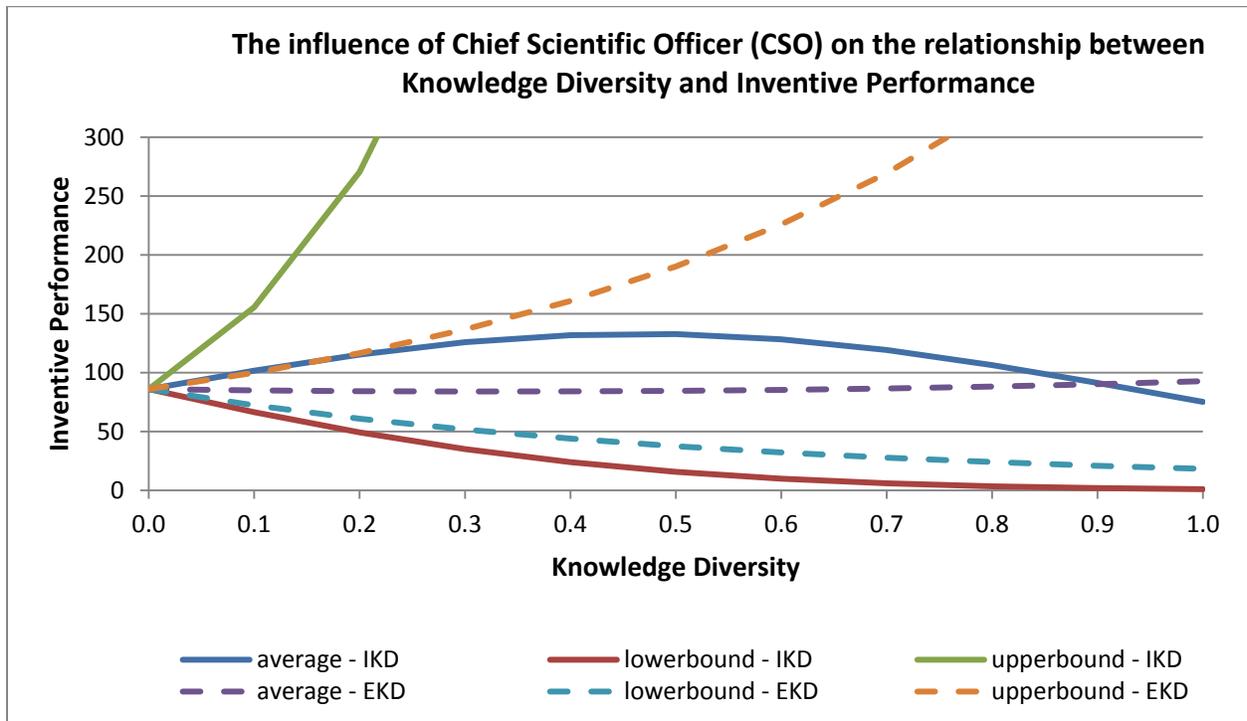


Figure 2. The range of CSO's influence on the relationship between Knowledge Diversity and Inventive Performance



APPENDIX A

The Innovation Value Chain in Pharmaceutical Industry

Besides merger and acquisition, growth in the pharmaceutical market comes from innovation (Gassmann, Reepmeyer, & von Zedtwitz, 2008). Leading pharmaceutical companies usually rely heavily on producing blockbuster drugs – a drug with at least \$ 1 billion in annual revenues- as their growth strategy. Strong first-mover advantages on launching blockbusters seem to be the driver behind this strategy. However, this strategy faces some problems recently, as they confront patent expiration and maturing drug portfolios, and the increasing power of generic drug producers. For example firm that focuses alone on these blockbusters may experience significant drops in sales once the patent of this drug expires (Gassmann et al., 2008). Within one quarter after expiration, this block buster can lose up to 80% market share (Pammolli & Riccaboni, 2007). Therefore, pharmaceutical companies have to innovate to increase the number of new product in order to sustain growth. They depend significantly on their ability to develop new drugs, and to overcome regulatory and market barriers (Agrawal, 1999).

Drug development is a complex process and high risks. Over time R&D costs increases, and any failure of a newly developed substance can cause significant losses. The high attrition rates during drug development refer to a high risks in this process. During the pre-clinical and clinical phase the probability to abandon any substance that prove to be unsafe and has no effect are high. The later the attrition, the higher the costs will be (Gassmann et al., 2008). Those aspects have tremendous impact on the level of invention and alter the competitive dynamics in this industry.

The figure below shows a typical innovation value chain of pharmaceutical firms. A team of scientists start the discovery process by finding out the primary sequence of biochemical process that leads to a disease in question. They expect that this knowledge would help them identifying an effective drug that might inhibit the process. They do thousands of experiments to discover a set of molecule targets that have promising pharmaceutical properties. Further, they do some more works to refine these targets by finding their derivatives that might show better properties. This optimization process leads to a selection of the most attractive molecule candidate. At this point, the team knows that this molecule candidate has only about a 1-in-5000 chance to be developed as a commercially effective drug.

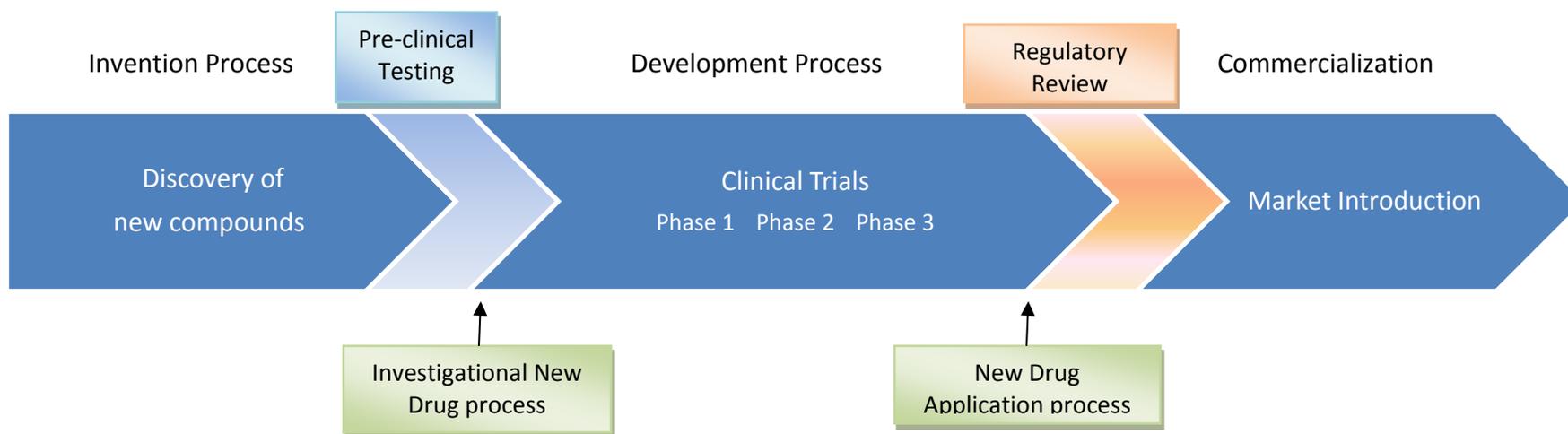
The next phase is to conduct a series of in vitro and in vivo experiment to gather more data and determine its viability for further human clinical trials. This preclinical testing provides information on the safety and potential efficacy of the candidate on inhibiting the development of a disease in question. The information will be used later to decide whether or not the candidate is good enough for further trials involving humans. There is always a chance that this molecule will never be tested in humans because the experiments may show an alarming level of toxicity or no effect in laboratory animals. However, if the results seem promising in term of its effectiveness with no toxicity concerns, the firm then submits an investigational new drug (IND) application. Once it is approved, the scientists can proceed to conduct clinical human trials.

Now, the purpose of the clinical trials is to assess the efficacy and safety of the drug candidate in human sample. Phase 1 study evaluates the safety in small sample of healthy persons, typically around 10 to 100, and may take about one year. The next, phase 2 study, assess further the safety and the efficacy of the drug at different doses in the certain patient population. The study may involve 50 to 500 patients, and the completion could take up to two years. If no

other concerns come up, the trial continues to the phase 3 to confirm further the safety and efficacy issues of the drug in the larger patient population. The phase takes longer, 2 to 4 years, to complete as it may be done in multiple trial sites, and the patients will be monitored over time for assessing the long-term safety and efficacy levels.

The firm then submits the results of the trials to a regulatory body (FDA in USA) for review. It takes about a year or even longer if the regulatory body needs clarification and further information on certain issues. If it is approved for commercialization, the regulatory body will also determine what performance and profile can be claimed for the drug.

Figure 3. Drug Development Cycle



Source: Adapted from Hansen & Birkinshaw (2007); Sosa (2009)

APPENDIX B

Case Study

CEO influence on invention at Pfizer

Edmund T. Pratt: CEO 1972- 1991

When he took charge as CEO, Mr. Pratt together with Mr. Laubach the president of Pfizer decided to pull together company's disparate research organizations to be coordinated under one centralized organization. This decision marked the company's increased focus on innovation and realized in form of Pfizer Central Research. Mr. Pratt emphasized the commitment of Pfizer to focus on R&D and realized that this commitment to pharmaceutical research will involve a long term strategy. Central Research became the centralized body for pharmaceutical, chemical, and animal health research and development.

Central Research fundamentally restructured its research organization. As a result of this effort, the company was able to focus more on new ways of drug discovery, to use extensively interdisciplinary teams and to encourage cross-pollination of ideas.

In the 1980s Pfizer was driving toward a goal to become the world's leading pharmaceutical company. Mr. Pratt continued to invest more resources in Central Research. He believed that new ideas are precious and investing on it was necessary to be innovative in this industry. He asked board approval for a long-term strategy driven by innovative research. He proposed a 20% annual increase in Central Research's budget, and expanded the central research facility to facilitate the recruitment of several hundred new scientists.

In the mid 80s Pfizer started to close the gap between R&D operations and the need for the sales and marketing group. The company moved its Central Research closer to marketing and

also streamlined its global efforts that foster close work and more effective integration among various labs in England, Japan, and France.

William C. Steere, Jr.: CEO 1991- 2000

In his tenure, William C. Steere, Jr. focused on core competencies, streamlined operations and invested more in R&D. In his quote 1997, the CEO emphasized that innovation strategy is the soul of the company not only specifically of research. He believed that Pfizer should continue built its ability to discover, and develop innovative pharmaceuticals. When many M&A occurred in the industry, the company stayed independent. When other companies cut their R&D expenses, Pfizer kept expanding its investment in R&D. This extraordinary commitment to R&D has lead investment of \$757 million in 1999 to \$2.8 billion in 1999. Further the company expanded its major research centers in the US, England and Japan to double their current capacity.

The company realized that no single company has all the good ideas. To complement its strength in R&D, Pfizer actively seeks out alliances, and also commit to become the partner of choice. During this decade Pfizer continually seeks partners that are committed to innovation. It seeks partners that enable both of them to discover and develop innovative drugs more quickly. Through these strategic networks, it has gained access to most advanced technologies available to help strengthen its scientists' works in discovery and development.

In the late 1990s and early 21st century, Pfizer reaffirmed its vision to be the number one pharmaceutical company in the world by doing its best in discovering, developing and commercializing innovative drugs through commitment to its eight core values: integrity, respect to people, consumer focus, performance, innovation, leadership, teamwork, and community.

APPENDIX C

Case study

What CEOs did to increase inventions at Merck

P. Roy Vagelos: CEO 1985-1994

In the 1980s and 1990s, Merck was one of the most research-intensive pharmaceutical firms. Over the years, Merck had introduced a number of important breakthrough drugs, and developed a great reputation for scientific excellence. To maintain this superior performance, the company continued to improve its in-house research skills and invest in its R&D activities.

Merck Research Laboratories is the centerpiece of Merck's strategic plan to provide new discoveries that enable the company to keep growing organically. Dr. Roy Vagelos lead Merck Research Laboratory from 1976 to 1984, and then lead the company as CEO from 1985 to 1994. During his tenure as the chief scientist, he revamped the research operation, modernized the labs, and increased R&D budget. He brought his experiences as an academician to develop research organization in Merck that resembles academic departments or other scientific institutions.

During his tenure as the company CEO, Dr. Vagelos had tightened Merck's focus to strengthen its leadership in developing and selling pharmaceuticals. He divested noncore businesses such as water coolers, activated carbon, alginates and bio-gums, and wound dressings divisions. He was convinced that Merck could be the best in pharmaceuticals. As the management concentrated more on pharmaceuticals, he put more pressure on the Merck Research Laboratories, the R&D engine of the company. He made certain to provide all resources the lab needs to be successful. Merck continued to pump more resources into its

research and development to stay on the cutting edge of science. By 1989, Merck spent over \$750 million a year on research and development. This spending allowed Merck to expand its R&D programs in Canada, to complete upgrading R&D facilities at Rahway, and to open the Neuroscience Research Center in England.

Dr. Vagelos emphasized that the fundamentals of Merck's R&D strategy will continue to focus on breakthrough products, especially for unmet medical needs in big market. This means that Merck will continue to rely heavily on producing blockbuster drugs – a drug with at least \$ 1 billion in annual revenues- as its growth strategy. Merck might not develop niche product, as developing this type of product is considered to be unfit with its business model.

Dr. Vagelos described his strategy for Merck for the years 1985 through 1994 were as follow:

- Focusing on the core business, i.e. developing and selling pharmaceuticals.
- Increasing innovative R&D and marketing capabilities through strategic alliances.
- Improving personnel throughout the organization. Especially in R&D area, Dr. Vagelos believes that the key to making research organization more effective and innovative is to recruit and encourage talented risk takers. Therefore he recruited more not only top grade scientists, but the ones who have entrepreneurial spirit.
- Enhancing research and development by continuously adding more resources and developing new capabilities in molecular biology and genetics.
- Improving the development of each of new discoveries for both in-house and licensed products from other firms.
- Upgrading quality in manufacturing and marketing operations.

However, insiders believed that functional excellence had increased functional barriers that made efficient cross-functional collaboration costly. Many at the company described this situation as too bureaucratic, people work in silos and tend to avoid conflict. Even though Merck try to focus, employees felt that the strategy was too generic and was not operational. At that time, the vision was unclear, and there was some confusion on the future role of research.

Raymond V. Gilmartin: CEO 1994 – 2005

As an outsider of Merck, formerly the CEO of a medical technology developer, Ray Gilmartin assumed leadership of Merck in June 1994. He was chosen for his experience in managing firm in industry characterized by intensive competition and high threat of buyers, and was viewed as a strong facilitator for integrating different functions within the company. He believed that as competition would continue to increase, therefore it is crucial for Merck to maintain a robust discovery based on excellence in research and development. He made sure that he addressed the lack of specificity and clarity around the company's strategy. Management Committee advised him to strengthen Merck's focus and to become a top-tier growth company by remaining as a research-based pharmaceutical company.

In early 1995, Gilmartin started to make some changes to create a less hierarchical organization and to foster cross-functional teams for improving product development process. Later in the middle of the year he launched the Worldwide Business Strategy Teams for the purpose of coordinating the worldwide franchise strategies for Merck products. He hoped that the teams would lead the organization in a better learning process by leveraging existing functional knowledge and developing long-term business strategies.

In line with the commitment to remain as a research-based company, Gilmartin continued to increase investment in R&D. The company spent about \$2.4 billion in 2000 and \$2.8 billion in 2001 for R&D. Although the company continued to increase the absolute size of its R&D budget, Gilmartin believed that it takes more than simply dollar amount of investment to stay on the cutting edge of science. He emphasized that research strategy, talent, and insight are the important drivers for the company's success in breakthrough research. Therefore, while rivals boosted up their R&D investment to a very high level through mergers, Merck had not followed the trend. Merck's senior management had questioned whether a vast amount of research budgeted was necessary to take advantage of the new potential of biotechnology.

Instead, Merck was pursuing 3 strategies to maintain its lead position in drug discovery: hiring the best scientists, decentralizing research, and fostering external collaboration. Hiring the top scientific talent and retaining them are crucial for Merck to keep up with the acceleration of scientific advancement. Merck developed a stock options program for its researchers in response to the intensive competition for talent.

Merck decentralized its research by investing in smaller new facilities in US, Canada, and England. The smaller labs in more places were intended to aid recruitments and improve productivity. However, this also creates the challenge of effective integration among the geographically dispersed labs.

In the past, Merck's involvement in obtaining expertise from external knowledge had been low. The structure and budgeting process were not designed to foster collaboration between internal scientists and outsiders. In order to exploit the benefits of external collaboration, Gilmartin made two internal changes in 2000. He increased the amount of dedicated budget for

external collaborations and changed the process to eliminate competition between internal and external projects. He also created special team to deal with all aspects of external collaboration. These changes helped Merck's scientists to expand their collaborative works with more potential researchers from outside, and to leverage their capabilities more effectively. While expanding external collaboration efforts, Gilmartin and Merck's senior management believed that Merck should maintain internal research programs that complement any external collaboration, collaborate on early stage research activity, and look for partners who have very specific technologies with clear scientific qualities.

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