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Innovation in Motion: Organizational Shifts between Exploration and Exploitation – a Longitudinal Study from the Medical Devices Industry

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Abstract

Innovation in Motion: Organizational Shifts between Exploration and Exploitation – a Longitudinal Study from the Medical Devices Industry

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This dissertation examines how firm engage in innovation through exploration and exploitation by focusing attention on the timing and triggers for shifting between these two innovation modes. In Schumpeterian environments, rapid exploitation of innovations is essential to innovation success and firm performance. Therefore, timing is a crucial strategic choice that can determine firms' gains from innovation activities. Understanding how incumbents and startups time their movements between modes of innovation will give us a better understanding of the evolution of technology, and how timing of firms' innovation activities may influence innovation trajectories in Schumpeterian environments.

To better understand the drivers and timing decisions of these firms, this dissertation investigates incumbents and startups timing their shifts between modes of innovation, a crucial part of successful innovation development and performance. Chapter one reviews the relevant literature on technological change and evolution, exploration and exploitation, and complementary assets. Chapter two investigates incumbents and startups that have already entered via exploitation within a product domain and when they choose

to cycle to exploration. Chapter three examines when firms shift from exploration to exploitation, a necessary step to generate resources for future innovations and current operations. If firms exploit too quickly, they run the risk of not extending the value of their core exploratory innovations. If the firm waits too long to exploit, it faces significant competitive risks from substitute innovations.

The empirical analysis of the dissertation is based on a sample of over 83,000 medical device product introductions drawn from the population of all medical device submissions to the US Food and Drug Administration (FDA), over 30 years (1990-2020) using robust research designs. In sum, the dissertation seeks to advance our understanding of the timing and triggers of when firms move between modes of innovation, key in accounting for how firms navigate innovation trajectories and changing technologies in the modern dynamic economy.

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INTRODUCTION

Innovations are central to firm performance, particularly so for Schumpeterian environments, where rapid innovation advances are captured by those who can exploit them in relatively short periods of time (Nelson & Winter, 1982; Schumpeter, 1934). Traditionally, incumbents have been characterized as maladaptive to technological change (Hill & Rothaermel, 2003; Polidoro & Yang, 2021), allowing them to be outperformed by smaller firms' exploratory innovations that alter existing domain trajectories (Rosenkopf & Nerkar, 2001). Recently, however, scholars have provided evidence that innovation trajectories are shaped concurrently by incumbents and startups' exploratory activities across domains (Agarwal, Audretsch, & Sarkar, 2007; Giustiziero, Kaul, & Wu, 2019). Given that both types of firms explore, it stands that incumbents and startups may orchestrate around each other's exploration and exploitation activities as well. Yet, insights into the timing and triggers for transitions between both types of innovation remain scarce (Benner & Tushman, 2002) – let alone whether incumbents and startups manage these transitions similarly or in distinctive patterns. How firms balance between exploration and exploitation is crucial to firm success (March, 1991), and clarity on the timing and triggers of these shifts may increase our understanding of how firms balance these modes of innovation. Against this backdrop, this dissertation studies how incumbent and startups choreograph their exploration and exploitation activities across product domains.

Understanding the triggers and timing of shifts, of innovation activities by the firm, holds the potential to better explicate organizations tradeoff determinations in pursuing each mode of innovation. Balancing these two activities has been identified as essential for firms to succeed (March, 1991; Siggelkow, 2003). A stream of research on ambidexterity, simultaneous exploiting existing capabilities and pursuing new opportunities (Raisch et al., 2009), has emphasized that the tradeoffs between exploration and exploitation need not be intractable. Though, scholars researching ambidexterity note the challenges in pursuing both objectives within the firm (He & Wong, 2004; Tushman & O'Reilly, 1996). As all successful explorations' efforts can eventually become exploitative innovations, how and when firms choose to change focus matters in understanding how they may pursue both. While the extant literature suggests incumbents exploit and startups explore as a pattern of innovation, that may not always be the case. Indeed, startups strive to achieve incumbency, and meeting competitive pressures successfully requires timing as well. Thus, the difficulty in balancing the two activities, how to respond to rivals in successfully exploring, and a dearth of information about how firms address these tensions is what makes this an important research question.

After the literature review and identifying the relevant research opportunities, I begin with a focus on startups in chapter two, where I study firms' decisions of when to explore vs. exploit. Prior work had highlighted startups as sources of exploration, yet interestingly, an important body of research has highlighted the difficulties the extent to which startups may profit from the innovations they create (Ahuja et al., 2013; Clarkson & Toh, 2010). In addition, the innovation literature has long been aware of the considerable uncertainty exploration entails, and a consistent theme in research on startups is the significant uncertainty they face too (Polidoro & Yang, 2021). These findings suggest that relative to incumbents, startups may explore, but it is not always the case they will do so.

Given the degree of uncertainty they face and lack of complementary assets, startups may be induced to participate instead first in exploitation (Lampert, Kim, & Polidoro, 2020; Teece, 1986). Specifically, prior research suggests that new, exploratory product innovation domains may be driven by startups (Polidoro & Yang, 2021; Rosenkopf & Nerkar, 2001; Shane, 2001), while incumbents tend to exploit (Levinthal, 1997). However, startups face a dilemma in terms of when to exploit and when to explore, as incumbents are motivated to engage as well. Successful product innovation is a combination of a technological solution as well as institutional capabilities. Depending on the domain, the sequence of when to exploit and the move to more exploratory products, or a different domain is not immediately clear. In other words, it is not obvious if startups begin at exploration and move to exploitation or vice versa in a product domain. Innovation is fraught with uncertainty, in particular uncertainty related to support from key external actors that shape innovation trajectories (Garud & Rappa, 1994; Nelson & Winter, 1982; Polidoro, 2020). By engaging in exploitation, they may gain such acceptance and develop institutional experience in the process that could be used for more exploratory innovations. Thus, incumbents, with significant institutional experience would be at an advantage where the technological search could be paired with the complementary value of institutional experience. Thus, this study proposes that startups, relative to incumbents delay their ability to shift from exploitative product innovations to the exploratory areas they are thought to dominant. Some important contingencies on this main effect are the firm's regulator capabilities, and the firm's technological diversity in the product domain. These contingencies mitigate these main effects respectively.

In chapter three, the second empirical paper investigates the timing and triggers for firms to shift from exploration to exploitation. The sequencing of each mode is important for balancing between the two activities (March, 1991; Rothaermel & Deeds, 2004). When firms choose to exploit could signal a convergence of a technology domain or entice rivals to enter as the technology in the domain may have been legitimated through competition and continued acceptance by relevant external actors. I argue in this paper that exploratory product families or groups in a domain tend guide firms' decisions whether to exploit or not. If firms exploit early, they lose the opportunity to deter imitation through differentiation for example. If the firm delays excessively to exploit, it faces rivals potentially producing substitute innovations (Polidoro & Toh, 2011) consistent with Schumpeterian destruction. Firms with broader exploration product families in a domain are likelier to shift to exploitation more often. This tradeoff decision is mitigated by rival's entry or when the firm is a startup, while exacerbated when the firm's design capabilities are weaker in the focal product domain.

The empirical analysis uses all medical device product introduction by over 800 firms, in the US between 1990 and 2020. This setting is ideal for several reasons. First, with over 83,000 products across all 19 FDA-determined medical groups, this is an innovation intensive research setting, one that comprises various product domains. Second, this setting instantiates the notion of Schumpeterian environments, as both startups and incumbents play an important role in creating new medical devices. Third, mirroring the insight that outside parties play an important role in innovation, especially in mitigating uncertainty, innovations in the medical device industry are subject to regulatory oversight and new products need to obtain U.S. Food and Drug Administration (FDA) approval before market introduction. Fourth, this setting enables observation of innovations with distinct degrees of novelty, as new products are subject to different regulatory review and approval processes, depending on their degree of novelty. Specifically, innovations in this setting range from exploratory products, that is *senso strictu* new products for which the FDA requires a product market application (PMA) to exploitative products whose underlying technology or product is similar to one already approved by the FDA and which requires a different regulatory review and approval process through a 510K submission. Importantly, not only does this setting enables observation of innovations with varying degrees of novelty, but also such distinctions are made by the regulatory agency with authority in the domain. Fifth, I am able to observe fine grained levels of innovation in products submitted by the firms, the order they enter, how long they took to be approved, and position within the domain. This allows for observation of what commitment level firms may make in addition to domain entry. Lastly, this industry illustrates the highly technologically dynamic and uncertain nature of innovations. Although the FDA plays a crucial role in mitigating uncertainty before the introduction of a new medical device, uncertainty remains even after such regulatory oversight requiring the FDA in certain cases to recall products that have already been granted approval and introduced into the market.

In sum, this dissertation advances our understanding of how incumbents and startups in Schumpeterian environments, and transitions between exploration and exploitation. It points to startups pursuing both exploratory innovation and exploitative innovations, though due to uncertainties and lacking complementary assets not necessarily beginning with exploration or transitioning to it as expected. It suggests an asymmetric effect in complementary asset accumulation regarding institutional and social acceptance of novel innovations, a necessary step for commercialization. Regarding firms' decisions of when to exploit, the dissertation showcases that incumbents' exploratory product base and rival behavior influence the decision of when to fend off potential disruption to an exploitation trajectory vs. ensuring utilizing of successful exploratory efforts. It also advances our understanding of the role of external actors and firm timing decisions for when to submit more uncertain innovations versus exploiting an existing innovation.

The dissertation proposal is organized as follows. First, I review the literature relevant to technological change and evolution, exploration and exploitation, and complementary assets. Second, I expound upon the theory and hypotheses development as well as data, methods, results and discussion for the second chapter. Third, I elaborate on the theory, hypotheses development, data, methods, results, and discussion for the third chapter. Lastly, I provide an overview conclusion of my findings of the dissertation.

CHAPTER I: LITERATURE REVIEW

In this section, I review the core concepts and literature that combined inform my dissertation. The dissertation is focused on firms timing and triggers of shifts between exploration and exploitation. Namely, I start the literature review with a focus on technological change and drivers of shifts in innovation. Then I move on to the literature on how organizations balance exploration and exploitation and the role of temporality in managing the modes of innovation. Finally, I examine how complementary assets change the timing of firm adaptation to technological disruption.

Technological change and evolution

Patterns of technological change and evolution

Patterns of technological change and evolution remains an important theme in organizational scholarship, strategy research, and the literature on entrepreneurship. Managing innovation in the face of technological change is a key question of firm performance and sustainable competitive advantage in strategy (Nelson, 1991; Teece et al., 1997). While technological change poses real dangers for firms, it is an important factor in how innovation advances. Specifically, technological change via evolutionary models of innovation and punctuated equilibrium (Dosi, 1982; Tushman & Anderson, 1986)

This perspective, which will be the focus of this dissertation, is that innovation and technological change is driven by the internal capabilities, and activities of the firm through technological regimes that evolve over time (Dosi, 1982; Nelson & Winter, 1982). This perspective has been what could be characterized as a "supply side" dynamic, where the technological trajectories maybe a function of the individual firm level capabilities chosen over time (Helfat, 1996). There is also a complementary "demand side" view of the perspective, whereby technological evolution and change is a firm response to customer needs, but it relates to the supply in that much of the accounting for firm difficulties in adapting to these needs is due to supply side factors such as stock of resources and capabilities, path dependent nature of organizational behavior, and the role of routines, regular, consistent patterns of action by organizations (Nelson & Winter, 1982), guiding firm action (Adner & Levinthal, 2001; Christensen 1997; von Hippel, 1988).

In this dissertation, I draw on the technological change and evolution literature that notes technological change happens in paradigms and regimes which themselves are situated in broader social and institutional systems. Dosi (1982) posits that technological change could be viewed as a path dependent process as a technological paradigm or "means of inquiry" that affects which problems are examined, the potential solution set to those problems, and which firms solve them. This framework draws on Kuhn's (1970) framework about the evolution of science and paradigms. This lineage of ideas is consistent in Tushman and Anderson's (1986) view of technological discontinuities and the environment, where technology evolves as the interaction of individuals, and path dependent choices of firms. This leads to incremental changes in innovation until the period of discontinuous disruptive change, followed by evolution to a dominant design. Scholars note that technological change requires context and does not occur otherwise (Dosi, 1982; Rosenkopf & Tushman, 1998).

There are several important features of the technological regime framework for understanding technological change and evolution. Technological development can be viewed as a function of what a given firm perceives, or an opportunity structure (Cohen & Levinthal, 1990; Dosi, 1982; Nelson & Winter, 1982), the alternatives (Sahal, 1985), and the market conditions facing the firm (Christensen, 1997). Nelson and Winter (1982) use Schumpeter's distinction between Mark 1 (Schumpeter, 1934) and Mark 2 (Schumpeter, 1950) periods of innovation to suggest that technological regimes start from entrepreneurial insights, however over time with accumulation of knowledge embedded in routines and a pattern of incremental changes occurring, the incumbents start to gain advantage through process innovations and economics of scale, and eventually weeding out inefficient firms through competitive pressures (Breschi, Malerba, & Orsenigo, 2000). Consistent with this view of technological change are the technology cycle models (Abernathy & Clark, 1985; Anderson & Tushman, 1990; Dokko et al., 2012) where the evolution pattern is a punctuated equilibrium model (Kuhn, 1970); largely of incremental change over time that is suddenly disrupted by technological discontinuities, rare, and not predictable. The discontinuity is supposed to be an exogenous shock, originating from outside the technological regime and surrounding environment. The shock marks the start of an 'era of ferment' where many technological alternatives will compete to dominate, and eventually the emergence of a dominant design will bring the period of incremental change again until the cycle repeats. Many of the discontinuous change studies in prior literature focus on the devaluation of core upstream knowledge held by incumbents. For example, Dosi's (1984) study on semi-conductors, Mitchell's (1989) on medical diagnostics, and Rothaermel (2001) studying biopharmaceutical alliance formation, all identified an upstream exogenous shock to the core knowledge of incumbents. These studies are examples of how innovation affects the technology regime and life cycle. Tushman and Anderson's (1986) key observation was that competence destroying discontinuities are what ruin incumbents, which is consistent with Henderson and Clark's (1990) idea that architectural innovations (innovations changing the interdependencies of other parts) would also destroy incumbents core knowledge. These ideas focus on incumbents' rigidities, lack of understanding of new innovations, and challenges in capability reconfiguration as important factors for how innovation operates in the technological regime view of technological change and evolution (Lavie, 2006).

In the case of technological evolution, it is important to understand the context in which radical and incremental innovations takes place. Discontinuities are problematic for incumbents because they fundamentally affect whether the firm can survive and adapt (Christensen & Bower, 1996; Henderson & Clark, 1990; Tushman & Anderson, 1986). Theoretically, they also offer a chance for incumbents to revise their strategies in an industry. For example, alliance structures have been known to change post discontinuity, as a means of incumbents adapting to radical change (Arora & Gambardella, 1990). However, the literature notes that incumbents often lose their edge post discontinuous technological change (Abernathy & Utterback, 1978; Christensen & Bower, 1996; Henderson & Clark, 1990). As discontinuities mark a "sharp price-performance improvement over existing technologies" (Tushman & Anderson, 1986, p. 441), they often make the older technology simply not viable in the new paradigm. Benner and Tripsas (2012) found this effect when digital photography replaced film, Taylor and Helfat (2009) posited the same when electronic calculators replaced mechanical ones. Though the theory posits that discontinuity exogenously emerges from outside the technological regime, interestingly, at times a technological discontinuity is an existing technology from a different market. Levinthal (1998) found that wireless communications were the common source of several new discontinuities in other industries.

Across all these views, there is an acknowledgement that innovations and technological change can be products or processes. Klepper and Simons (1997) found that when product and process innovations peaked differed in the US automotive industry in early 20th century. Filson (2001) found however, different patterns of early versus late product and process innovations, including in the automotive industry. In this dissertation, I focus on product innovations in the technological change and evolution tradition.

The types of firms engaged in innovation during technological change and evolution is very important as well, namely incumbents and startups. There have been some studies which do not distinguish how firm strategies may differ on firm type in the face of technological change and discontinuity. If the new technology were competency destroying (Tushman & Anderson, 1986), an architectural one (Henderson & Clark, 1990), or governed by firm response to customer demand (Christensen & Bower, 1996), then incumbents and startups would not be expected to behave similarly. Schumpeterian competition, the interaction between incumbents and startups, builds on the idea of "creative destruction" (Schumpeter, 1934); and has focused precisely on such competition between the two. The new entrant through innovations makes the incumbents capabilities obsolete, threatening the incumbent's survival and competitive advantage (Agarwal &

Gort, 1996; Hill & Rothaermel, 2003; Rothaermel, 2003). The incumbent response is entry barrier creation and work to first mover advantage through pre-emptive innovations themselves (Agarwal & Gort, 2001; Aghion et al., 2009; Lieberman, 1989). Indeed, several studies suggest that startups or new entrants introduce the radical new technologies into an industry, and incumbents face the prospect of competence destruction, though at times incumbents introduce innovations that are competence enhancing themselves.

Implications for organizational adaptation and evolution

The patterns of innovation occurring at the technology level have organizational implications as well. Organizations, boundedly rational, and using their existing perspective (Dosi, 1982) to problem solve for technology solutions, will engage in local search; looking in areas adjacent to current knowledge and capabilities, to find these innovations (Helfat, 1994; Nelson & Winter, 1982). The knowledge they have, and subsequently gain through activity in local search, are encoding into organizational cognition via routines (Zollo & Winter, 2002). Routines, enacted encoding of knowledge, organizations gain from search and innovation, are meant to increase efficiency and draw on elements of tacit knowledge, and can facilitate exploitation (Nelson & Winter, 1982). This basis for search is why there are longer periods of incremental refinement. However, when shifts between the long period of incremental refinement and a discontinuity, ‘technical advance so significant that no change in old technology could compete’ (Tushman & Anderson, 1986, p. 441), take place, there are significant consequences for organizations as well. Recalling that the value and structure of routines are based on using experiential knowledge and interdependencies between components of knowledge to speedily enact organizations goals, a disruption due to technological discontinuity causes several issues. First, the underlying knowledge encoded in the routines may itself be outdated. Second, the tacit knowledge and interdependencies between components needed to use the routine will be obsolete (Zollo & Singh, 1997). Moreover, articulating and finding out how to recombine or deconstruct such information is difficult, resource intensive, and may not be amenable to the new paradigm. Third, pressures exist for a firm to continue using 'what works' even in the face of new information in the environment (Leonard-Barton, 1992; Levinthal & March, 1993). These challenges are so prevalent, there is a considerable body of work investigating the failure of incumbent firms in the face of technological change (Afuah, 2001; Agarwal & Audretsch, 2001; Gilbert, 2005; Helfat & Lieberman, 2002). However, there are examples of when firms engage in both exploration and exploitation and draw on routines in order to do so. As firm capabilities are based on resource manipulation (Helfat et al., 2007; Teece et al., 2007) firms better able to mobilize their resources in response to the discontinuity should perform better. Exploration and exploitation activities are based on these organizational routines, often recombining into new ones to bypass the path dependent problems of exploitation bias in firms, and competency traps due to success (Christensen & Bower, 1996; Henderson & Clark, 1990). Winter (2003) noted the existence of a higher order routine that can be used for changes to existing operating routines. Zollo and Winter (2002) conjectured that knowledge through experience accumulation was how these changes in routines took place. He and Wong (2004) showed that firms with specific search routines maintained higher variation in performance in their exploratory strategy, requiring changes in routines, thus changes in exploration paths.

Firm heterogeneity in successful adaptation to the technological regime during change is another organizational implication of innovation at the technology level. One source of variety is overcoming dangers of local search. One solution would be to ally with other firms so as to share new knowledge (Narajan & Mitchell, 1998). Another is to rely on firm resources such as status, Podolny (1993) found that higher status firms' products were better received. Abernathy and Clark (1985) had suggested that redeploying an existing technology in new domains may create niches which would help avoid competency trap in focal domain. Levinthal (1998) draws on an evolutionary idea of technological speciation theory where new technology lines arise from existing technological domains of a firm. By watching the demand side of technological change firms may apply their existing abilities in a new domain, thereby adapting to the novel context without changing the underlying resources and capabilities (Adner & Levinthal, 2002). Of course, differing firm types do not adapt uniformly to these change pressures.

Incumbents and startups vary in their adaptive capabilities. Incumbents face several disadvantages in the face of technological change. There are dangers to competences (Tushman & Anderson, 1986), destroying existing profits (Lavie, 2006), and uncertainty about future success which combined with inertia and potential commitments makes investment in new technology difficult (Hill & Rothaermel, 2003). Christensen's (1997) foundational work noted the "innovator's dilemma" regarding self-disruption where incumbents do not change to new technology until the risk has arrived. Management may have resistance to change in the environment (Burgelman, 1994), suppliers, and customer have preferences (Christensen, 1997). While incumbents face challenges, startups face material hurdles as well. Startups may create novel innovations, but the opportunity to capture the full value from them is more limited, and risks of knowledge spillovers maybe greater (Agarwal, Audretsch, & Sarkar, 2010).

Product innovation and technological evolution

Products play a key role in the evolution of innovations. The technology cycle encompasses both product and process innovation (Klepper, 1996) studies have noted the importance of products in the life cycle (Agarwal & Audretsch, 2001; Klepper, 1997; Utterback & Abernathy, 1975). Major product changes are thought to originate from outside the focal industry and are started by new entrants (Agarwal et al., 2007).

Products are important downstream components of technological change. As noted before, often the disruption is to the core knowledge embedded in routines of incumbents which governs the types of product innovations that are made. Thus, understanding the nature of product evolution is important. For products, during a technological cycle, the initial conditions would be low market volumes, and high technological variety among the producers. The product innovation would not be well understood by any of the players, the performance criteria are often vague. The uncertainty and differences in the performance requirements for the product in the market mean that initially smaller firms and new entrants may have an opportunity to gain share, however, strong external experience to facilitate adoption and respond to technical issues is also important. These differences are what account for how technologies ultimately evolve, through the products.

A key step in technological change and evolution for products is the emergence of a dominant design. The dominant design outcome after variations among different producers are made and the selector (Nelson & Winter, 1982) chooses what is successful, leading to a period of common understanding about the main idea of the innovation. Dominant design reduces uncertainties for innovating firms, which allows for investment in equipment that may be specialized. Embedded in this idea is an ordered step between innovations and design improvements which are the deciding factor in acceptance by the market. A dominant design also allows design and need choices to be combined with preferences of the eventual customers, a necessary step for products (Clark, 1985). For example, Utterback and Suarez (1995) found that dominant designs emerged across several industries, such as automotive, transistors, and TVs. Other scholars have found this phenomenon as well, Murmann (2003) in synthetic dyes, typesetter (Tripsas, 1997), flight simulation (Rosenkopf & Tushman, 1998). They also showed that following these design emergences, products were then incrementally improved using technological based on the design (Stuart & Podolny, 1996).

Part of the importance of products in these technological cycles is that firm innovation is guided by path dependent choices in these frameworks. Per Nelson & Winter (1982), there is endogenous learning by doing and vicarious learning from relevant others (Ingram & Baum, 1997) whereby firms develop their capabilities. As firms develop innovations, their basis to do so is contingent on path dependent decisions made. Indeed, as incumbents become more experienced in a focal domain, they 'become more vulnerable to their environments' (Levinthal & March, 1993; p. 102), and risk entering a competency trap (Levitt & March, 1988). Due to routines which become more efficient at the focal innovation activity, the underlying core knowledge will exhibit core rigidities (Leonard-Barton, 1992) even in the face of a clear environmental need to change. Several scholars have demonstrated how firms' innovation activities, through local search, without adjusting to explore (more distant investigation) can lead to poorer innovation outcomes (Helfat, 1994; Martin & Mitchell, 1998; Rosenkopf & Nerkar, 2001). Even though dominant design reduces uncertainties in the new technological regime, if the incumbents prior experience is not suitable for change, they are worse off than those attempting to adapt *de novo* (Christensen et al., 1998). On balance, the role of products and the challenges firms face in adapting them to technological change and evolution is part of the broader challenge firms face in technological change as it is not only a function of technical parameters. There are institutional and social factors which make technological change particularly difficult as well.

Social context of technological evolution

Technical capabilities and factors are often thought insufficient in accounting for the evolution of innovation during technological change. An assumption about the technological change and evolution pattern described is often that the broader social and institutional system it is embedded within is relatively unchanging. Though period of incremental changes can be somewhat abstracting away the role of institutional factors, and even the exogenous shocks which break inertia are thought to be disruptive to technological ability, both must account for the institutional influences that govern what ends up as “acceptable”. Technological paradigms and regimes do not just show what is included, there is a “powerful exclusion effect” as well (Dosi, 1982, p152). Moreover, as the technological know-how is less specified during periods of technological change, institutional and social forces (which already operate as the selection device) may have more influence (Dosi, 1982). The paradigm does not just say what to look at, it also influences what to ignore. In articulating their descriptions about the nature of radical innovations, Abernathy & Utterback (1978) have an example of how regulatory constraints in auto emissions can be thought of as another performance dimension to be solved by the engineer and how that may lead to more innovative designs. However, the regulatory requirements are not generated by the focal firm. The determination of the dominant design is not a function necessarily of the best technical solution either. Utterback and Suarez (1993) note that the design is a function of prior product varieties and interactions with environment. Anderson and Tushman (1990) suggest that not always the most technologically forward design would be chosen. From an organization ecological perspective, social processes are important for technological emergence. As the number of firms increase (density), the legitimation determination process for the population begins, and with increased resources, an eventual understanding is achieved (Hannan & Freeman, 1977; Wade, Swaminathan, & Saxon, 1998). Tushman and Rosenkopf (1992) offer a techno-socio order model, whereby technological evolution co-evolves with social interactions. Though variation, selection, and retention per the evolutionary perspective is thought to play out in the technical domain, it is the social and political processes in the technological communities making the innovations which determine a dominant design, and thus the most technically proficient design may not be chosen (Nelson & Winter, 1982). This perspective is similar to the socio-cognitive model for organizational cognition (Weick, 1979). If reality is selectively perceived and cognitively organized and interpersonally negotiated, then technology as an abstract function would be more susceptible to these forces. This view suggest technology is a combination of beliefs, artifact, and evaluation routines (Garud & Rappa, 1994). The knowledge is what is cognitively known, though how it is achieved is through a 'search heuristic' (Nelson & Winter, 1982) by the firms. Van de Ven & Garud (1993) build on this idea by suggesting technological selection is based on rules and regulations, resource endowments, and the firm's technical abilities. Garud and Rappa (1994) homed in on the criticality of evaluation routines for selection of new technologies. Given that beliefs underlie the understanding institutional actors have about a technological, the institutional environment will become crucial to what gets chosen. Rosenkopf and Tushman (1998) illustrate how technology and networks of standards committees, help one type of flight simulator come to dominate the market. As participants in the institutional environment, technological change is co-evolving phenomenon between the technology and its environment (Rosenkopf & Tushman, 1993; Van de Yen & Garud, 1993).

Novel innovations present several difficulties for those responsible to make ex ante evaluations regarding their value. New technologies even after a dominant design form, are only part of the story. Often new technologies are made up of smaller sub parts which are not delineated in the dominant design and have several interacting parts (Tushman &

Rosenkopf, 1992). Indeed, dominant design has been characterized as a high-level architecture with stable core pieces (Henderson & Clark, 1990), but differing subsystems and components (Murmann & Frenken, 2006). As a dominant design can also be thought of as an agreement about the socio technical order (Tushman & Rosenkopf, 1992), the integration of the additional components is not automatically determined, indeed several technological alternatives may exist for them. To be clear, there are material coordination requirements post discontinuous technological change, and the systems that do so are themselves embedded in a social system. For example, technical standards often guide the components in an innovation and how standardization processes unfold is a marked non-technical process (Garud & Kumaraswamy, 1993; O'Mahoney & West, 2005). Recall, that technological evaluation is a combination of beliefs and routines, there is a process of institutionalization, potentially a dominant design of the external environment vis a vis the technology that must take place as well. Once the evaluative routines are more commonly accepted then the ability to evaluate the technology is possible. However, practices of testing and norms do not evolve *sui generis*, but often are embedded themselves in prior states (Constant, 1987; Jagenberg, 1983). Dosi (1982) acknowledge this linkage between ex ante ambiguity and technology in pointing out how technological trajectories are often based on the innovator's beliefs about what is possible. Though they have potential alternative paths in mind, the uncertainty around any innovation for success means that different innovators will choose different paths (Anderson & Tushman, 1990).

Institutional actors themselves have several considerations for determining the best way to select innovations post technological change. On a cognitive level, Weick (1990) notes that new technologies are often very complex and abstract. As such, the ability to ground a basis for evaluation is difficult ex ante. Next, there is often debate about the appropriate criteria for performance when a new technology arrives, or even what are all the functionality options present. Then, the amount of information available about a new technology maybe both limited and quite overwhelming as innovators gather knowledge about the technology (Garud & Rappa, 1994). Thinking about the technology cycle as being embedded in a series of communities, there is a socially determinant interaction process for technological progress. Scholars have shown that even during incremental change, there is still a great deal of debate among subgroups about a technology (Dokko & Rosenkopf, 2010; Simcoe, 2007). As institutional actors will be drawing on path dependent evaluative routines based on different knowledge bases, they are subject to the same bias and challenges as the focal firm. Indeed, in some instances, these actors face more challenges as they must sort through a series of different technological solutions in an attempt to make sense of it (Polidoro, 2020). Indeed, challenges to learning, development of competency traps, and role of errors can make ex ante evaluation of novel technologies quite difficult. Not only is evaluation of the technology difficult, but the different firm types presenting to these entities.

Different types of firms are thought to have differing interactions with these non-technical requirements. Specifically, incumbents and startups navigate the institutional and social processes of technological change differently. Arend (1999) suggests that incumbents face short term pressures to perform from external entities like shareholders, and thus they do not always account for institutional and social pressures in their technological developments. Mitchell & Singh (1996) however suggest incumbents benefit from previous relationships with users, financial entities, or governmental actors and these provide information about the environment even after change and thereby facilitate adaptation to it. Indeed, (Stieglitz & Heine, 2007) note that experience with regulatory issues gives incumbents material complementary assets they can use to commercialize future innovations.

External actor influences on innovation and technological change are a large body of work and includes more than formal institutional actors. Some prior work has noted the role of interorganizational interactions that drive technological innovation, for example allying with competitors (Ahuja, 2000; Gulati, 1995), or participation in the coordination groups like standards (Anderson & Tushman, 1990). In later work, the role of science and third-party certification became included as an influencing factor on technological evolution and which technologies persist (Polidoro, 2013). In addition, other important evaluators include financial analysts. For example, Benner and Ranganathan (2012) showed how analyst pressures influence incumbent innovation strategy for investments in new technologies. Benner & Ranganathan (2013) also demonstrated how investor beliefs lead to diverging reactions to technological change. These non-technical factors of technological change suggests that firms must adapt to the risks or be eliminated.

Summary analysis

In this section I reviewed the existing work on technological change and evolution. The literature notes several important themes. One is that technological change occurs due to somewhat exogenous change that is not easily predictable among firms engaged in boundedly rational search for solutions to problems (Cyert & March, 1963; Simon, 1962; Levinthal, 1997). To discern what the problems and solutions are in the first place, these technologies firms pursue are contained in technological regimes or ways of seeing that have important inclusion and exclusionary criteria (Dosi, 1982; Nelson & Winter, 1982).

Firms vary in their capabilities and adaptability due to routines, path dependency and absorptive capacity to modify and extend their innovation activities to match a given solution (Adner & Levinthal, 2001; Cohen & Levinthal, 1990). Technological solutions are not just a product of technical capability but are embedded within a broader social and institutional structure that must approve and accept the offered set of options for an innovation (Anderson & Tushman, 1990; Dosi, 1982; Tushman & Rosenkopf, 1992). These external considerations are an important influencer on the success of firms solving a problem, and the technological trajectory changing.

Firms face several challenges in adapting to technological change. Existing customers and pressures exist to focus attention on existing technology and routines. Radical innovations or novel exploration requires distant search which is not easy for the firm to engage in, and even when so engaged, incorporating it into the broader firm's products is also difficult (Levinthal, 1997).

The literature begins to note differences in firm type for these broadly agreed upon points as well. Schumpeterian view of competition is between the incumbent and the new entrant, thought to be the source of disruptive change which upends the existing technological regime (Agarwal et al., 2007; Schumpeter, 1938). Startups with their relatively flexible structure and lack of path dependent investments should adapt readily to the environment and bring about the technological changes that disrupt incumbents.

While the literature notes the importance of external pressures on technological evolution, and firm differences in type to account for how innovation evolves, some topics remain less explored. The first is the timing of these disruptions. The second is how each type of firm would adapt to the institutional or external pressures. While the literature notes time as a central construct, the timing part is less precise. Technologies are invented, through the process of interaction among producers and evaluators and the market, the dominant design emerges, and the iterative process takes place (Hill & Rothaermel, 2003; Utterbeck & Abernathy, 1975). What triggers each of these points in the cycle, and how long until the next piece is often invoked directly are the less clear points in the literature. The role of incumbents and startups in the cycle are clearly delineated, but with the concurrent view of innovation where both produce novel innovations, it is not clear when the destruction to a focal technology takes place, or why it is one type of firm or the other who engages in it. There are some allusions to the role of the institutional environment in potentially selecting one form of technology over another (Tushman & Rosenkopf, 1992), but once more the drivers of these selections and when they would take place is not specified. The role of time is crucial in the technologies evolution because firms are engaged in a process that is reliant in part on what took place before. The sequencing of innovation is an implicit key factor in accounting for novel and incremental innovations. The dominant design element for example cannot take place without technological variation that follows a disruptive innovation. The sequence of steps is completely reliant on a timeline for the process to unfold. Since incumbents and startups could in theory be part of novel innovations, understanding their respective triggers for when to move from one type of innovation mode to the other is central to understanding broader shifts between exploration and exploitation in innovation.

Exploration and Exploitation

The exploration and exploitation literature is keenly relevant to this dissertation research on the timing of when firms shift between each mode of innovation. In this stream of literature, innovation activities are divided into each type and are defined in opposition to one another. Indeed, a central question in this literature is how firms balance seemingly opposite activities and each have a path dependent tendency to reinforce continued use of that type of innovation (Piao & Zajac, 2016). In this section, I review the literature with a focus on the challenges of balancing these activities. I note the role of routines and path dependency as key mechanisms for accounting for these shifting challenges. Then I briefly discuss the core concepts in the literature regarding ways firms have balanced the two activities such as structural and temporal sequencing. Last, I focus on the differences between incumbents and startups in these dynamics, particularly relevant as firm type differences may well account for differences in timing on the innovation activities.

Pursuit of firm innovation

Exploration and exploitation are central innovations activities that must be balanced carefully for firms to continually innovate successfully. In March's (1991) seminal work on exploration and exploitation there is a core tension or "two gestalts" of organizational behavior that co-exist (Tushman & O'Reilly, 1996). Exploration is conceptualized as involving experimentation, searching, and inducement of variation to find new strategies to meet problems (Holmqvist, 2004). Whereas exploitation, improves efficiency and productivity through refinement, reduction in variance, and improvements in execution (Levinthal & March, 1993; March, 1991).

A foundational point in March's (1991) framework is the presence of tradeoffs between exploration and exploitation for organizations. These are due to resource constraints, inertia, and divergent goal outcomes borne from the assumptions in the framework. A firm must decide how to allocate its scarce resources (Barney, 1991), and thereby face a tradeoff in the return on those allocations. A crucial tradeoff is short-term success for longer term viability through exploration and potential opportunities. Focusing on the short term provides gains but runs the risk of obsolescence in the longer run (Holmqvist, 2004; Leonard-Barton, 1992).

Viewed from the adaptation literature perspective, another tradeoff is the stability of the current environment for flexibility to respond to changes (Lewin, Long, & Carroll, 1999). If one focuses on maintaining stability, responding to environmental threats becomes difficult (Hannan & Freeman, 1977), focus on exploration and no gains from such an investment could be made (Sorensen & Stuart, 2000). Looking at the opposing outcomes of each activities gives another view on this tension. March (1991, p. 73) refers to returns from exploration as "less certain, more remote in time, and more distant from locus of action". Yet, if no discovery investments are made, future success cannot be insured. Another challenge from this tension is the presence of path dependence when deploying each activity (Levinthal & March, 1993). Exploiting leads to further refinements, which makes change more difficult, whereas experience with exploration suggests more exploring is easier, and thus recouping discovery investments becomes more challenging. Despite these challenges, there is a need for both.

Many scholars have characterized these differences in other ways. Argyris and Schon (1978) offer a single vs. double loop learning model; while Burns and Stalker (1961) suggest mechanistic vs. organic structures as operant, or as radical vs. incremental product innovations (Rothaermel & Deeds, 2004). Underpinning both activities is a behavioral model of bounded rationality (Cyert & March, 1963), where problemistic search is the means through which firms develop these experiences and knowledge to solve the innovation problem (Posen & Levinthal, 2012). For innovation, exploration can be through of as search, risk taking, and experimentation processes, and exploitation draws on refinement and incremental improvements (Greve, 2007; March, 1991). Both types of activities can be simultaneous or iterative, but as the knowledge base in part draws on what happened (Cohen & Levinthal, 1990), path dependencies can occur (Peng et al., 2008).

Exploration and exploitation can be viewed through the routines that govern each type of activity as well. In this perspective, organizations gain experience and knowledge from the environment, and encode them within routines to be reenacted repeatedly and drive behavior changes in the organization (Argote, 1999). Exploratory routines are designed for search and novel solutions to problems, whereas exploitation-based routines draw on existing knowledge to reduce costs (Sorenson, 2003). Indeed, scholars note the importance of these routines for product innovation specifically, for example product development (He & Wong, 2004; Nerkar & Roberts, 2004).

A large and growing body of work exists to examine exploration and exploitation. The idea of exploration and exploitation has been widely examined in organizational learning (Levinthal & March, 1993; March, 1991) and firm adaptation (Eisenhardt & Brown, 1997). It has been examined in phenomena relevant to strategic management such as alliances (Lavie & Rosenkopf, 2006; Rothaermel, 2001; Rothaermel & Deeds, 2004), the role of managers (Beckman, 2006), and of particular interest in this dissertation--product innovation (Danneels, 2002; Greve, 2007; He & Wong, 2004; Jansen et al., 2006). These questions have also been investigated across many levels of analysis, for example individual (Gibson & Birkinshaw, 2004), organizational (Greve, 2007; Nerkar, 2003), and inter-organizational (Lavie & Rosenkopf, 2006; Rothaermel, 2001) levels. Such a broad body of work has led to some differences in assumptions.

There are several perspectives on how to characterize exploration and exploitation. The first is the extent to which organizations pursue it simultaneously or sequentially. The punctuated equilibrium view (Burgelman, 2002) suggest that temporal differentiation is the main factor. By switching activities over time, the firm on balance is engaged in both activities. Noting March's point that adaptation requires both activities for success, firms must pursue them both. Thus, the simultaneous pursuit of both exploration and exploitation via differentiated subunits or individuals that are integrated in various ways (O'Reilly & Tushman, 2008). These subunits are differentiated to the task of either exploration or exploitation. Scholars also work to get clarification on the concepts themselves. How narrow should refinement of knowledge be used in this framework (Gupta et al., 2006). He and Wong (2004) suggested exploitation does involve some knowledge production, but Vermeulen and Barkema (2001) say only the use of pre-existing knowledge would count. As knowledge is multi-dimensional, learning from either activity must start to be part of the others conceptual space (Li, Vanhaverbeke & Schoemakers, 2008). These conceptual views draw on different mechanisms, and whether the organization drives them, or environmental exogenous factors force the issue is still an open question in the literature.

In this dissertation, I draw on the view of exploration and exploitation existing on a continuum and drawing on March's (1991) definitions and conceptualizations. I follow the view of exploration and exploitation as existing on a continuum, i.e., they are more function of degree as opposed to type. For example, research on alliances and new knowledge production suggest R&D alliances are exploratory while marketing and production knowledge focused alliances as exploitation based (Lavie & Rosenkopf, 2006; Rothaermel & Deeds, 2004). New knowledge can only be acquired if the current knowledge base facilitates it (Cohen & Levinthal, 1990). After exploration, the application of the new information is exploitation of it (Rothaermel & Deeds, 2004). Looking within the organization, Gupta et al., (2006) noted that even within the firm these activities are being pursued in part by both types of units.

Push to exploit, need to explore

While the need for exploration is well documented, there are several pressures for firms to exploit as well. Exploitation is a constrained set of activities that increases efficiency and improves execution using known knowledge and capabilities of the firm (Levinthal & March, 1993; March, 1991). Firms often face immediate performance pressures and as existing knowledge provides more predictable returns, there is a tendency towards exploitation more generally. Guiding firms' activities in each of these innovation modes are routines, repeatedly enacted encodings of knowledge in the firm that are used to create innovations and represent firm level cognition from the experiences of individuals within the organization (Nelson & Winter, 1982). There is also a feedback loop whereby as firms develop better capabilities in a market, technology, or strategy, the experience and response from environment makes it more likely for that action set to be repeated. These repeated actions promote more use, and thus a self-reinforcing cycle continues.

Successful exploitation can actually create several challenges for firms. Past experiences which lead to success influence firm evolution in complex ways. Certainly, prior experiences lead to learning (Argote et al., 1990), or more status (Podolny, 1993), but on the other hand, can shift a firm's focus from a changing environment. This persistence due to success can lead to a "competency trap" (Levinthal & March, 1993), whereby firms ignore information in the environment and are susceptible to change. Indeed, at times firms continued even after it is rational to change due to this phenomenon (Audia et al., 2000; Weick, 1993). As there are path dependencies with exploitation, when or, how soon after experiences occur can heavily influence the evolution of the firm and this negative outcome (Kim & Rhee, 2009). Rhee and Kim (2015) investigate the role of timing for the development of these traps and find that historical and social aspiration levels influence whether they stay in the traps. Part of the reason why these traps occur is the encoding of the routines. By drawing on experiential knowledge, the practices, routines repeated are at the expense of alternative ways of doing the same tasks (Miller, 1994). If there were changes in the environment, this opportunity to learn would be foregone. This danger is particularly high when the environment is changing (Levinthal, 1992). In the case of innovation, existing technological regimes (Dosi, 1982; Henderson & Clark, 1990) make change difficult. From a performance feedback perspective, change occurs only if the relevant aspiration level is not achieved; this is the basis for problemistic search (Cyert & March, 1963; Greve, 2003). However, if existing actions are successful, this trigger does not occur, thereby leading to a trap due to competency. However, not all the constraints on firm shifting from exploitation are internally based.

There are several externally based factors which tend firms to exploit as well. First, the underlying processes of search, path dependencies, routines, and firm incentives to performance exist for several external entities relevant for the firm to succeed. Indeed, the dynamics of firm- outside entity interactions are a crucial part of technological change, and innovation writ large (Benner & Ranganathan, 2012; Polidoro, 2020; Theeke et al., 2017). Theeke et al., (2017) found that brokerage companies tended not to get as much coverage when they produced novel technologies, as coverage is central to capital flowing to firms, thus a bias in innovation towards knowledge already known to analysts. Benner and Ranganathan (2012) found that financial analysts tend to discount firms that produced innovations outside of their core technological operations, the key finding is that while the technology was successful, the analysts were not sure how to assess it given the combined innovation regimes. Polidoro (2020) found that regulators routines influenced how easily they were able to evaluate firms novel drug innovations. This difficulty in evaluation lead to material time consequence delays which are financially costly to firms, and indeed can cause competitive disadvantage. Benner and Ranganathan (2013) showed how firms had to invest additional resources to placate financial analysts as well as investors while pursing innovations necessary for continued success in the industry.

The dangers of engaging in excessive exploitation only are many. While returns to exploitation are more certain, longer-term viability of the firm requires exploration. Experience experimenting develops search and experimentation capabilities (Levinthal & March, 1981), necessary for general internal variety and more heterogenous sources of knowledge (Kim & Rhee, 2009). Focusing on exploitation makes firms unable to find new sources of innovation and adapting to a changed environment is central to firm survival (Schumpeter, 1950). The challenge is that many actions are exploitative in a way, in that on a dimension of performance it is chosen so as to improve that dimension (Adner & Levinthal, 2008). Thus, a need for exploration is paramount.

Exploration provides several benefits for firms. Given the pace of change in the environment, firm ability to adapt to changing needs is clear on its face. Scholars have long identified environmental change as central to firm success (Child, 1972; Hannan & Freeman, 1984; Sorenson & Stuart, 2000; Suarez & Oliva, 2005). March (1991) noted that firm's likely success is not only the mean but the variance in expected performance. While exploration is the riskier of the two activities, it is critical for competition among a number of firms, as it accounts for the variance in performance (Levinthal & March, 1993; Uotila, 2017). In terms of routines that govern exploration, routines design for change can facilitate search itself (Winter, 2003). By facilitating search, new knowledge and resources maybe found which can change the resource and knowledge base of the firm. Indeed, a greater knowledge pool, increases the changes of producing a profitable new knowledge combination (Katila, 2002; Katila & Ahuja, 2002). In terms of innovation and product development, scholars have shown how product routines help firms with change (Karim & Mitchell, 2000). In contrast to exploitation-based routines which draw on tacit knowledge, exploration routines are more modular, relying on articulated knowledge to promote search, given an externally based change in the environment, organizations with such routines can adapt through such routines through recombination. However, exploration is not without its drawbacks as well.

Exploration poses some risks for firms as well. First, excessive exploration means that firms never recoup the investment costs borne out to find the innovation in the first place (Levinthal & March, 1993). If firms keep changing and recombining knowledge, a key outcome of search in innovations—failure, another reinforcing dynamic can take place. Failures, lead to problemistic search, which may lead to more failures, and then iterate back to search for a solution. As new technologies are replaced by others, firms may not develop competences need to leverage them to produce resources to continue or even for more exploration. As returns from an innovation or technology are due partly to the experience, neither bad innovations nor good ones can be separated as all will initially appear poorly performing while new. From a behavioral theory perspective, if aspirations level change, downwards, but are then adjusted back upwards this can lead to an optimism that is ill founded. Such a distortion in the learning dynamic is also self-destructive as the firm does not adapt effectively by matching its actions to the environmental need (Levinthal & March, 1993). A balanced attention to both types of activities is what is required.

While a balanced focus on both activities is required, it is exceedingly difficult for firms to do so. Organizations appear to have challenges in making these tradeoffs. As exploration and exploitation are based on different organizational capabilities and routines (Nerkar & Roberts, 2004; Peng et al., 2008); they may just specialize in either. Regarding technology changes, exploitation reduces the incentives to pursue new opportunities, and may reduce the firm's ability to do so. Per the learning perspective, each activity involves a self-reinforcing dynamic which induces imbalances and can actually accelerate the respective activities (Levinthal & March, 1993). Some work has noted how different types of firms struggle with this dilemma. For example, Reinganum (1989) notes that incumbents may not wish to explore so as not to make their own products obsolete.

Attempts to balance exploration and exploitation

Balancing exploration and exploitation is necessary for firm success. While strategy scholars have debated over how firms balance these two activities, and its influence on performance, they agree on its importance. Two of the most prominent views on balancing these activities are ambidexterity (simultaneously balancing), and a punctuated equilibrium view (temporal transition) (Kang & Kim, 2020; Raisch & Birkinshaw, 2008; Raisch & Tushman, 2016; Tushman & O'Reilly, 1996). The temporal separation is based on shifting markedly from one activity to the other and is based on a punctuated equilibrium theory of exploration and exploitation (Burgelman, 2002;

Romanelli & Tushman, 1994). Firms would engage in one activity and then alternative over time to the other (Nickerson, Nickerson, & Zenger, 2002). These periods of focus would be in the respective activity, and then require a "discontinuous jump" to the other (Mudambi & Swift, 2014; Swift, 2016). However, there is a large body of work suggesting empirical support for the ambidexterity view that firms have a competitive advantage through simultaneous support of exploration and exploitation, particularly in more uncertain settings common in technological intensive environments (Cao, Gedajlovic, & Zhang, 2009; Gibson & Birkinshaw, 2004).

There are several literature streams which have found a need to balance at the firm level important. Studies in these streams contend that firm level balancing is necessary for firm survival and success (Gibson & Birkinshaw, 2004; He & Wong, 2004; Jansen et al., 2006). The technological change innovation literature draws a comparison to a related theme—incremental vs. radical innovations (Abernathy & Clark, 1985; Tushman & Anderson, 1986). Tushman and Smith (2002) described incremental innovation as meeting customer needs for example. Other scholars focused on the importance of having both capabilities present for innovation. Ancona et al., (2001) suggested dynamic capabilities were based on both types of innovation. From an organizational adaptation view, managing current state and change creates an equivalent dilemma for firms (Kim & Rhee, 2015; Tushman & Romanelli, 1985). Tushman and O'Reilly (1996) discussed how successful organizations can align activities with evolutionary change, but also pursue exploration or "radical transformation" when there was "revolutionary change". Siggelkow and Levinthal (2003) suggested sequencing changes in organizational structure is a way to both explore and exploit. In summary, too much change is a problem for firms, whereas too much stability may lead to inertia (Huy, 2002; Levinthal & March, 1993).

While the need for balancing these activities is clear, how firms should do so is much less obvious (Adler et al., 2009). Among others, the literature has identified three broad ways in which firms can address the conflicting demands of exploration and exploitation—structural, temporal, and contextual separations. The structural ambidextrous organization divides exploration and exploitation into different units. The exploitation units are more centralized and integrated so as to leverage the knowledge and efficiencies associated with the activities. The unit maybe a larger share of the organization's overall production focus. The exploratory units are more decentralized and loosely coupled as tight integration does not facilitate the variation and open search goals of a novel unit. The value comes from how the organization coordinates the series of outcomes and activities that each of these unit types produces for the firm. The role of managers is central often in such setups as they serve as the linking function within the organization. In the more stringent designs, explorations have been examined as occurring outside the firm altogether for example through corporate venture capital investments (Ahuja, Lampert, & Tandon, 2008). Temporal separation is about cycling between the activities over time. The assumption is that the integration mechanisms, managers, are carefully choreographing efforts across the different types of activities as firms shift from one to the other. The balance comes from an overall view of innovation, not at one point in time. The challenges with temporal are different from structural, but are challenges, nonetheless. As opposed to coordination difficulties, the ability to shift between modes of innovation and back is central to a successful execution of this tactic. The third way is through domain separation, which contends that both activities can occur at the same time but in different domains. The value of a domain perspective is that the structures supporting it and the resource allocation constraints are not in conflict in such a view (Lavie, 2006). One challenge of this perspective is to clearly delineate domains across research contexts so as to make the difference clear with the structural perspective.

Despite the clear need for it, balancing the activities proves challenging for firms to maintain. One such reason is the nature of resource availability. Given constraints in resources, investment in one activity means resources not available for the other. Some studies, such as Levinthal and Wu (2010) note that resources maybe scale free and non-scale free. Such a distinction means that how firms allocate them could imply different constraints for exploration and exploitation (Kang & Kim, 2020). Balancing is difficult also because of the differences in learning process in each mode of innovation activity (Benner & Tushman, 2003; Eisenhardt & Martin, 2000). Each activity draws on different routines, processes and interdependencies (Smith & Tushman, 2005). These challenges for compounded for different types of firms as well. In particular, smaller firms lack the experience, routines, and infrastructure to manage both activities simultaneously (Ebben & Johnson, 2005). Simsek et al., (2009) noted this paucity of work on small firms and suggests strategic outcomes may differ for smaller firms pursuing ambidexterity.

Thus, a core question remains regarding balancing between exploration and exploitation—what is an appropriate amount or mixture of the two? Though exploration and exploitation are tradeoffs, each proves necessary to the firm’s survival. Exploitation activities provide resources to operate the firm as well as provide basis for exploration investment choices. Some scholars suggest this is a "reinforcing" relationship (Eisenhardt & Brown, 1997; Rothaermel & Deeds, 2004). Attempts at qualifying the nature of the relationship, are they inversely related (Park et al., 2002), or not particularly related (Jansen et al., 2006), or just positively (Katila & Ahuja, 2002) thus suggesting mixed and conflicting findings. There is also the question of intentionality or deliberateness. Do firms respond to external threats or changes in the environment or make a point of engaging in these activities to start? Some scholars have attempted to investigate this through looking at managers' actions (Gibson & Birkinshaw, 2004), however, others find that without organizational structures and routines to coordinate actions these efforts may not prove fruitful (O'Reilly & Tushman, 2008). What is the role of entities beyond the firm in managing these activities within the firm? Lavie, Kang, and Rosenkopf (2011) found that domain balancing through alliances reduced the constraints of routine conflicts and integration challenges by having different activities across different alliances; however, the extent to which firms should allocate across these domains is still another question. For all of the aforementioned ways of dealing with the dual requirements, the dynamism aspect is also largely unknown. Indeed, balancing appropriately would be the first step, maintaining such a balancing over time is another step entirely.

Summary analysis

In this section, I reviewed the studies examining exploration and exploitation. The literature thus far still has a significant open question regarding how firms should balance the two innovation activities, and what are some consistent tactics firms may employ. The role of time in affecting the two activities and the interaction between them in firms is also an important concept. Consistent with prior innovation research, the conceptualization of time here is the combination of clock and event-based time. Specifically, time as a "non-spatial continuum in which events occur in apparently irreversible succession from past through present to future" (Ancona et al., 2001). Event time demonstrates that time exists in relation to important occurrences or events, and firms react to these environmental changes (Hernes, 2017; Hoskisson, Cannella, Tihanyi & Faraci, 2004). Many of the studies focused on balancing between exploration and exploitation suggest that the resources underlying each activity make the tradeoff necessary zero sum. To summarize, existing literature suggests firms can go outside their boundaries to offset the tradeoff problem (Lavie & Rosenkopf, 2006), they can have structural sub-units that also avoid the changes in internal routines for each (Taylor & Helfat, 2009), or the temporal considerations are between domains in the firm (Siggelkow & Levinthal, 2003; Tushman & Romanelli, 1985).

Many of the studies in exploration and exploitation tend to focus on a single product line comparison. Namely, the firm is producing one domain in exploitation and another in exploration. The shifts that are examined have to do with the production process writ large as opposed to firms moving multiple product domains at different times. These studies also tend to focus on internal constraints that firms face in moving from one mode of innovation to the other. The role of path dependency, routines, and absorptive capacity is central in many of these studies. Firms typically break from the loop of each mode of innovation by getting around each of these mechanisms that reinforce the respective behaviors. For example, to address the limitations of routines that are refined for exploitation, firms may draw on search routines that explicitly search widely (Aggarwal, Posen, & Workiewicz, 2017). To avoid the limitations of the knowledge base of any one firm, they may partner with another firm to access that pocket of recombination potential.

Where the literature is somewhat less clear is in two areas, the timing of these activities, and the nature or type of firm engaged in each. Less explored are the differences among types of firms in regard to exploration and exploitation. Schumpeterian view of innovation and technological change suggests that incumbent firms would favor exploitation and startups, or smaller firms may be more facile with novel or radical innovations (Kaul et al., 2019; Schumpeter, 1934). This perspective brings up the possibility that these tradeoffs may operate differently for these types of firms than the literature has largely suggested thus far. For example, the structural and domain separation recommended for balancing these activities may require infrastructure, processes, and resources that are not readily apparent for resource constraint startup firms. As such, even if they favor exploration, how will shifts to exploitation to leverage these innovations take place? If incumbents possess the means to leverage existing knowledge and products but tend to inertia, do they face greater pressures to fall into the competency traps than the literature currently states? These questions are important because they suggest that balancing these activities may not behave uniformly across firms and therefore how innovation and technology trajectories progress may be different than currently theorized. Moreover, given that innovations and technology regimes firms pursue are situated in a social system and institutional environment where acceptance by external actors is a necessary step in the process, the ability to manage these factors would compound the asymmetric effects the current understanding of exploration and exploitation forces would generate. To be specific, startups that produce innovations but are not able to get them accepted suggests that novel innovations would not be available. Moreover, incumbents would succeed but then fall prey to radical innovations and disruptions which make future innovations impossible to generate as their resources are drained. Therefore, a better understanding of how different types of firms face these tradeoffs is important to our understanding of how innovation trajectories progress.

The second area open for investigation is a key challenge in the exploration and exploitation literature for firms in the role of time. Time is central to the learning process, and firm heterogeneity in structures, capabilities, and resources would exacerbate this baseline effect of time and ability to pursue exploration or exploitation. In addition, the firm's ability to draw inferences from experiences, apply new knowledge or pursue new knowledge would be a function of time. Even after acquiring knowledge, research suggests such knowledge may become obsolete or simply decay over time as well (Argote, 2013). Given the nature of exploration and exploitation this last point is a real consideration that merits some consideration. On a foundational level, knowing when to shift from one activity to the other is still not well understood for firms. Does it vary mostly with internal dynamics and capabilities or is it a reactionary function of what is occurring in the environment. Do firms shift once and then react only after other firms act? March (1991) suggests that as the number of competitors increases the role of variance matters more than the mean in terms of increasing performance in the environment, thus knowing when to engage in activities is crucial as this accounts for both variances, and on which side of the variance curve a given firm would find itself.

Complementary Assets

Much of literature on innovation has focused on factors that shape organizations abilities to create value and innovations. There is another important stream that focuses on what shapes organizations abilities to capture value from the innovations they do create. Thus, complementary assets is a relevant literature to this dissertation research on shifts between exploration and exploitation among incumbents and startups. In this stream of literature, complementary assets are resources and capabilities that are thought to shield incumbents from the gale of destruction (Hill & Rothaermel, 2003; Tripsas, 1997). Moreover, startups are thought to face challenges in developing them which can make commercialization of innovations difficult (Lampert, Kim, & Polidoro, 2020). In this section, I briefly review the literature on complementary assets with a focus on the delaying aspect as it relates to adaptability. I first highlight how they operate as a buffering agent from the travails of technological change. Then I discuss how management of the external environment is a crucial aspect of complementary assets. I highlight core concepts in the literature, and lastly note the role complementary assets play in firms' willingness to pursue more novel innovations or less. The differences in these willingness levels being relevant for when firms may shift from one type to another, and the assets themselves a potential trigger in doing so.

Profiting from innovation: the role of complementary assets

A foundational idea about firm innovation is in Teece's widely cited article (1986) about the role of complementary assets and how firms capture value from innovations. Teece notes that those which innovate new products may not always profit from them and indeed often commercializing firms are not the same as the ones who made the innovation in the first place. In Teece's framework, the role of the appropriability regime, intellectual property, and industry architecture as well as presence of dominant design were all important factors in a firm's ability to leverage the innovation made (Teece, 1986). However, he notes that appropriability regimes may be weaker or stronger exogenously or deliberately in some instances if it favors a firm (Teece & Pisano, 2007). I follow Teece's framework in how to conceptualize complementary assets. Namely, by looking at an innovation as the basis for analysis, firms differ in their knowledge, resources, and capabilities (Amit & Schoemaker, 1993; Barney, 1991; Peteraf & Bergen, 2003), and innovations require technological knowledge as well as market information. Moreover, the information is partly tacit and partly not, thus the role of capabilities or assets becomes central to a firm's ability to leverage the innovation. For example, in Teece's framework, marketing, competitive manufacturing, and sales support are all important complementary assets which are specialized. The nature of these assets is generic, specialized, or co-specialized. Generic are thought to be readily available on a market and though valuable the strategic leverage would be limited (Barney, 1991; Rothaermel & Hill, 2005). Specialized assets are characterized by a unilateral dependence between innovation and the complementary asset. Whereas co-specialization means there is a bilateral dependence

(Teece, 1986). To illustrate, if the firm had after-market service facilities but they were only functional for the innovation, this would be mutual dependence.

Complementary assets are identified as important but have been characterized several ways across literatures. An early stream of work based at University of California Berkeley emphasized the structure of the firm (boundaries, and control of complementary assets) as the relevant trait for successful technological commercialized (Teece, 1986). This framework was referred to as "Profiting from Innovation" (PFI) framework, and it attempted to address what accounted for lack of returns from innovation for innovators. Teece's framework, emphasized the role of "downstream market related factors" such a manufacturing, distribution, brand name, or other technologies that supported the focal innovation. The idea being without such assets, the full value of the innovation may not be realized to customers and allowed a supplier or other participant in the value chain of activities to develop a criticality for the innovator and thus lose value in the sharing of the profits. Therefore, availability of complementary assets is imperative for commercialization of innovations (Gans & Stern, 2003). There have been a multitude of papers examining how important complementary assets are. Mitchell (1989) found that sales and service capabilities of firms allowed firms to enter new fields of medical imaging sooner than it otherwise would have, Tripsas (1997) showed that manufacturing capabilities and type font sets offset the competence destroying innovations incumbents faced, while Roy and Cohen (2017) showed that firm with greater downstream complementary assets, had better information about demand during technological change and thus were product leaders in their innovations. Some scholars have even argued that firm specific assets that may exist beyond the firm's boundaries, such as networks can be assets. Inter-firm networks have been shown to increase learning opportunities, increase resource flows, and facilitate firm response to technological changes (Gulati, 1998; Gulati, Nohria, & Zaheer, 2000; Hagedoorn & Duysters, 2002). Thus, these networks can be a source of complementary advantage through their relational rents (Dyer & Singh, 1998) which are tied to the individual firms.

The value of complementary assets is embedded in the heterogeneity among firms' capabilities and resources. Complementary assets, particularly the specialized ones are built over long periods of time, are subject to time diseconomies (Dierickx & Cool, 1989), and a function of path dependent choices made by the firm (Helfat, 1994; Nelson & Winter, 1982). Thus, they are idiosyncratic to the firm, and very difficult to imitate for competitors, thereby being a source of competitive advantage (Barney, 1991). Per Teece's (1986) view, complementary assets increase the value of the technological innovations of the firm. The complementary assets themselves are often not rendered inert by technological change itself and thus insulated from the "gale of creative destruction" (Christensen & Bower, 1996; Schumpeter, 1934). With these assets, firms reduce the advantage of being first to market. The assets also influence firm boundary decisions, indeed Teece identifies when vertically integrated downstream assets allow for material appropriation of value by the innovation. In addition, these assets facilitate gaining Schumpeterian rents because of the barriers to imitation. Per the resource base view, a key finding by Dierickx and Cool (1989) was precisely the interconnectedness of the assets that makes imitation difficult. As these differences get utilized over time, they influence the trajectory of choices and outcomes each firm experiences through its stock of complementary assets, thereby compounding the value of these capabilities to produce complementary assets.

The central value of complementary assets is their ability to facilitate firm adaptation and survival in the face of technological evolution and change. An property they possess is that they are not readily available on the open market, and even those that would be are often quickly internalized to avoid transaction and bargaining problems with the relevant party (Pisano & Teece, 2007; Williamson, 1985). Complementary assets are thought to offer incumbent firms time to adapt their products and routines when technologies are shifting (Mitchell, 1989; Tripsas, 1997; Wu et al., 2014). Thus, during periods of technological change, complementary assets can be a buffering agent to the new technology regime that has disrupted the existing technological capabilities of incumbent firms (Rothaermel, 2001; Tripsas, 1997). The complementary assets also are valuable across differing appropriability regimes. When appropriability is strong, they support the firm's competitive position, but where they are very valuable is when appropriability is weak. As they are difficult to imitate, firms able to leverage these assets can capture more value even if the underlying innovations are widely available to competitors (Cohen et al., 2000). Scholars have investigated complementary asset's ability to help firms in several contexts. Silverman (1999) showed how the relatedness of complementary assets to an adjacent industry increased likelihood of incumbent diversification to that segment. Others have examined how firm's innovation trajectories are shaped by complementary assets to leverage their value (Nerkar & Roberts, 2004). Among others, Dushnitsky and Lenox (2005) identified complementary assets as a reason for alliance formation. Regarding technological disruptions, Rothaermel (2001) found that incumbents leverage complementary assets in alliances performed better post disruption. Wu and colleagues (2014) demonstrated that complementary assets influence firm response to technological change on two levels, first by buffering the immediate consequences of change, and second in influencing how firms view where their adaptive resource allocations should be made.

One important type of complementary asset is the firm's ability to manage external influences. Incumbents are thought to possess complementary assets, which can be an aid during technological change and discontinuous innovation, however this can vary with the institutional environment as well. For example, Fuentelsaz et al., (2015) found a diminished value for complementary assets in strong institutional environments, and by extension a stronger value for them in weaker institutional environments. Danneels (2004) suggests that marketing competence for example is needed for innovation development. Von Hippel (1988) notes the importance of understanding users to help firms address demand uncertainties for products. Another importance complementary asset is experience with regulatory environment and institutional actors more broadly. Technological evolution involves processes of adaptation and selection (Levinthal, 1991; 1997). Firm adaptation to change as necessary has long been examined (Henderson & Clark, 1990; Nelson & Winter, 1982); the importance of selection is relevant as well. In particular, as selection is often by institutional actors that determine the long-term viability of an innovation (Nelson & Winter, 1982), firms must adapt to this reality as well. Namely, firms with complementary assets that support its innovations through the social system and institutional environment that technological change and firms are situated in are better off.

Indeed, Polidoro (2020) found that FDA approval times for drugs increased in the face of multiple technologies but were reduced when new technologies in the same domain as the focal one were present. Firms better able to navigate through such a regulatory process are likelier to gain market share and acceptance by these gatekeeping entities.

Acquisition and change in complementary assets

The literature on complementary assets has often focused on their value, but how they originated is important as well. Many studies note the importance of transaction costs for specialized assets (Pisano, 1990), or R&D capabilities as means of utilizing technological change in accounting for complementary assets, but how they started are less clear. Arora and Ceccagnoli (2006) demonstrate that commercialization strategies vary with costs of building complementary assets, but the origin of those strategies is not a focus of the study. More broadly, firms are shaped by their capabilities endowment at a given point in time, thus their ability to develop complementary assets are similarly constrained.

Part of the challenge maybe that the role of complementary assets varies with the innovation cycle stage as well. Pre-dominant design the value of complementary assets are much lower, firm rivalry and performance of the underlying technology are more important dimensions. As a dominant design emerges, the appropriation phase of innovation is more central, and the nature of the complementary assets become crucial (Gans, Hsu, & Stern, 2002). For example, generic assets maybe available more widely and do not involve significant redeployment costs. Specialized assets which take time to build and are not easily reversible for another use may become more valuable. The value of understanding when complementary assets are developed is important as they influenced the types of innovations the firm maybe willing to pursue. For example, Shane (2001) finds that more specialized complementary assets available increase the chance of firms attempting to exploit a given technology. Whereas Ceccagnoli et al., (2010) show that acquiring externally generated technology is less likely for firms that have more cospecialized downstream assets. These studies suggest that firm's willingness to exploit innovations is tied to their complementary assets, and by proxy the likelihood of exploration would be affected. Therefore, understanding when these path-dependent, difficult to change, but important assets begin their evolution is important.

Given that technologies are always evolving, firms must adapt as well. Per Teece (2007), industry intellectual property protections may not be sufficient for the firm to leverage. In some cases, the protections are strong, and the innovation is difficult to imitate and so the firm is protected, but often the protections are weak, and co-specialized assets are required. When technological change has occurred, the use of these specialized assets can affect the very boundaries of the firm. The value chain may be disrupted, and what should be internal and what is no longer needed will influence the value of the assets accumulated already. For example, Teece (2007) suggests the R&D investments could be adapted to account for the presence or lack of intellectual property protections, or to coincide with the co-specialized assets the firm has already accumulated. This is a shifting in the firm's innovation search to leverage its existing R&D complementary assets. Another adaptation need is demand changes due to technological change. Tushman and Anderson (1986) refer to forecast demand challenges and the differences in firms' ability to execute that task. Firms with complementary assets about customers, their needs, and manufacturers that support them are likelier to adapt better to technological changes (Morgan, Vorhies, & Mason, 2009; Pavitt, 1991; Roy & Cohen, 2017).

There has been work looking at how complementary assets do change within firms. Teece's original framework focused on the value of complementary assets, but given the changing environment and uncertainty, there are persisting concerns firms face. Polidoro and Toh (2011) show that firms must consider the substitute threat to a firm's innovations, and not just the imitative danger to innovations for firms with specific resources and capabilities. Even if a firm's technological solution were to become dominant, and accepted by outside parties, that substitute uncertainty for a firm will always remain, thereby making a static view of complementary assets in complete in our understanding of how they influence firms value capture from innovations, and so a more dynamic view of how they may behave is needed (Lampert, Kim, & Polidoro, 2020). Scholars drawing on the "technology commercialization strategies" literature suggest that appropriability regime will dictate if contracting or internally developing complementary assets is the dynamic choice (Gans, Hsu, & Stern, 2002). If the protections are strong, then whomever made the innovation needs to deal with whichever firm has complementary assets. However, once again this is more of a single period view of the use of complementary assets. Hsu, Wakeman, and Simon (2013) note that innovations often exist in a trajectory and that innovators should view the opportunity to learn about how to develop these assets themselves should be added to our understanding of how complementary assets influence technological change. Some work has examined changes in complementary assets but has focused on other firms as opposed to the focal innovating firm; for example, Jacobides, Knudsen, and Augier (2006) look at how firms may change their competitive positioning by degrading rivals' complementary assets.

Assuming the complementary assets are in place, there is great firm heterogeneity in how they are utilized. Resource heterogeneity, path dependency, and firm ability to modify or recombine these resources into new resources is a key driver of firm competitive advantage and differences (Barney, 1991; Cohen & Levinthal, 1990; Nelson & Winter, 1972; Zollo & Winter, 2002). Given that complementary assets are valuable largely in the presence of other resources, this heterogeneity is compounded. Since firm ability to adapt to technological changes is a function of their complementary assets (Hill & Rothaermel, 2003), then differences among how they deploy these assets should be expected as well. These differences are tied to a foundational property of complementary assets. Innovations needing co-specialized assets owned by the firm are more likely to be made internally as the firm would want to avoid opportunistic behavior. Therefore, multiple firms with differing complementary asset stockpiles based on resource investment allocations made many periods before the focal innovation exists, would be expected to have different outcomes in the current competition for primacy (March, 1991).

It is not just heterogeneity among firms broadly, different types of firms have access to complementary assets in different ways. As a technology matures in an industry, the use of specialized assets means that incumbents would be favored, and entry would prove difficult and this likely crowds out new entrants. Regardless of resource base, lack of opportunity or experience to participate in the domain means that complementary asset deployment or development would be reduced for later entrants. New firms or startups may be thought to be sources of novel innovations, but they often lack the specialized and co-specialized assets internally to leverage these innovations (Rothaermel, 2001). Indeed, even smaller incumbents face challenges as the resource allocation choice is consequently in terms of on the margin improving the technology of building assets to commercialize whatever is being developed. Looking once again at the technological commercialization strategy literature (Gans & Stern, 2003; Teece, 1986) determining the mode of commercialization differs for smaller firms and incumbents because incumbents may already possess complementary assets. These assets may not be developed in the focal industry, but they exist none the less.

Complementary asset access differences: Incumbents and startups

Complementary assets are a key aspect of how organizations can commercialize the innovations they produce in Schumpeterian environments, without which the innovator may not profit from the innovation. While complementary assets are thought to advantage all firms that possess them, this is especially true for incumbents in the technological domain or industry. Prior research in technology commercialization, shows that industry incumbents that own complementary assets can garner some benefit from a technological innovation even if their own technological capabilities are weaker, and the intellectual property protections are weaker (Gans & Stern, 2003; Teece, 1986). Indeed, if complementary assets can maintain value in the next technological regime, entrants face a material constraint in developing their own in time to garner value from the innovations in that domain, thus favoring incumbents. There is a consideration for incumbents however too, as they are path dependent investments. Thus, complementary assets can also bias the firm's choices of where else to search and invest. Incumbents are likelier to pursue technological trajectories that are in align with their existing assets, regardless of what the environment maybe signaling. How much these choices differ from those more attune to the technological edge, and market needs will vary with production capabilities, complementary assets of the firm, and competitor action (Wu, Wan, & Levinthal, 2014).

Much of the literature on technological change and complementary assets has startups as sources of innovation but not necessarily the complementary assets to commercialize them. As performance in a new technological domain is contingent on a viable commercialization strategy this would put startups at a material disadvantage. Startups are thought to have significant technical capabilities. As they are not bound by routines, inertia, or path dependent investments that incumbents face, they can focus their expertise on the technological domain. Creation of new products often draws on these capabilities (Helfat & Raubitscheck, 2000), but how startups can extract value is less clear. Gans et al., (2002) argue that technology startups will actually ally with an incumbent when complementary assets are costly to acquire. Since complementary assets are time intensive, specific, and difficult to transfer, this situation should be frequent. For startups preferring to commercialize without incumbent involvement, they face challenges. As they are new, they face higher risks of failing, and need to develop routines for the technological processes and products. Therefore, any shift in focus to development of complementary assets, could compound risks in the original technological efforts, thereby devaluing their own asset accumulation (Hsu, Wakeman, & Simon, 2013). Firms operating in innovation driven environments face significant uncertainties about several issues---upstream inputs, competition, new entrants, downstream partners, and technological viability. Uncertainty in the Schumpeterian environment is characterized by these uncertainties, and how firms must balance their ability to appropriate value against building value at all is a challenge (Lampert, Kim, & Polidoro, 2020). Since development of specialized assets is more valuable in stable environments, smaller firms attempting to do so in such uncertain environments run a material risk. If flexibility were a necessary trait, then resource constrained firms would do well to see how to maintain it when facing well-resourced competitors. There are some instances where entrants maybe able to build some complementary assets. If generic complementary assets are important to commercialize a new technology, then new entrants are incentivized to build their own complementary assets and can access them via the market (Rothaermel & Hill, 2005; Teece, 1986).

Complementary assets matter for firm value appropriation for both radical and incremental innovations. For novel innovations that have the potential to disrupt, if they are indeed started by smaller firms, there is an opportunity to develop specialized complementary assets over time given that the entrant faces the same tradeoffs for each subsequent incremental innovation based on the focal novel choice. Therefore, it may be expected to see new entrants' partner or enter into an alliance with an incumbent initially and then slowing develop their own capabilities over time (Hsu, Wakeman, & Simon, 2013). Incumbents innovating in any domain face significant uncertainty in value of their investments due to radical innovation introduction possibilities from new entrants, as such, it must consider how to deploy complementary assets to avoid displacement from new entrants, a material finding in technological change and adaptation literature (Henderson & Clark, 1990; Lampert, Kim, & Polidoro, 2020; Suarez & Utterback, 1995). A key element of these analyses is the role of the domain where per categorization literature (Grodal, Gotsopoulos, & Suarez, 2015; Kennedy & Fiss, 2013), the socio-cognitive elements that go into deciding which products belong together and which are distinct are important. The domains decide what products and technologies are competing, and also which areas to develop complementary assets within.

Summary analysis

The discussion above notes the importance of commercialization strategies and capabilities for firms want to appropriate value from innovations. Some key questions that arise from the literature are about the role of time, and how startups and incumbents differ in their development of these complementary assets. Wernerfelt (1984) noted complementary assets can aid in new product market entry; however, startups are thought to be the source of novel innovations and least likely to possess these assets. Klepper and Simons (2000) identify the role of complementary assets in accounting for entry and survival patterns of firms over an industry life cycle, but the role of incumbents and startups in this time cycle matter is also important. The entities that possess the assets maybe different from those that possess the innovation. What happens if incumbents have some technological capabilities as well?

Summary

In the literature review portion of the dissertation, I summarized the current state of understanding in three distinct literatures related to shifts between exploration and exploitation—technological change and evolution, balancing exploration and exploitation, and complementary assets. In table 1.1 below is a synopsis of key concepts across the literatures.

See Table 1.1 page 130

All three literatures are crucially important to understanding how firms differ in their type and how these differences may account for when they choose to engage in one more of innovation or the other, and what potentially drives shifts or changes in those modes. Yet, each literature focuses on a different aspect of this question. The studies on technological change and evolution are at the technology and product level for the most part, and thus the heterogeneity among firms and adaption capabilities are less central. The balancing of exploration and exploitation discusses the need for firms to engage in both types of activities and notes the material challenges facing them in doing so. However, this literature tends to examine either one product domain at a time in making these claims or views the temporal dimension between domains. The complementary assets literature focuses on firm heterogeneity, showcasing how firms may survive technological change without experiencing the 'gale of destruction' to the firm itself. However, in this perspective, while time is implicitly important in that the assets are built over time and cannot be quickly assembled, how firms time their moves between modes of innovation is less clear.

Taken together there are some promising inquiries to be made given these pockets of the literature that merit exploring. First, how does the type of firm influence the development of complementary assets, and subsequently its deployment in use or defense of each innovation mode? Second, what is the timing aspect of each of these innovation types, is it based on the internal dynamics of a given firm, or does it rely in part on the external pressures that maybe coming due to technological change, or competitive pressures from rivals that threaten to induce technological change and disrupt a focal firm's innovation trajectory? Third, how does the firm manage these competing pressures over time given that there are often many product lines operating at the same time? Thus, all together these questions offer a wonderful opportunity to examine in the dissertation. In the next two chapters, I first will look at how startups and incumbents differ systematically in when they pursue exploration, and the role that complementary assets play in accounting for these differences. Indeed, the plasticity that may facilitate startup adaptability in technical skills, maybe a liability on the institutional navigation and commercialization success side. I then examine when firms are shifting to exploitation, and how the exploratory product portfolio and depth maybe a driver of when to shift. The decision to start a completely new product group or invest in novel but nearer innovations, gets precisely at this dueling tension of harvesting today vs. planting for tomorrow. By investigating these questions, this dissertation seeks to advance our understanding of important issues about the timing of technology innovation development, and how entrepreneurship is influenced by institutional environment factors as highlighted in the literature review above.

CHAPTER II: WHEN IS A GOOD TIME? FIRM INNOVATION IN EXPLORATION AND EXPLOITATION

Abstract

In Schumpeterian environments, exploratory innovation advances are captured by those who can exploit them in relatively short periods of time. In this dynamic between exploration and exploitation, scholars have found incumbents and startups' to concurrently shape a domain's innovation activities trajectories. Yet, less is known about the timing and triggers for transitions between exploration and exploitation types of innovation, specifically as to whether these transitions unfold similarly or in distinctive patterns for incumbents and startups. I seek to address this question by drawing on the literatures of exploration and exploitation as well as complementary assets. I argue incumbents, with regulatory capabilities and technological diversity would be at an advantage relative to startups in transitioning to more exploratory innovations, in a product domain. My analysis is based on over 30,000 product introductions across all 19 FDA-determined medical groups, representing product introductions of over 650 medical device firms in the US between 1990 and 2020. This study advances our understanding of how incumbents and startups use complementary assets in transitioning between exploration and exploitation in Schumpeterian environments. Further, I extend our understanding of how complementary asset development within firms, may differ for incumbents and startups and thus strategies for shifting between modes of innovation.

INTRODUCTION

Managing the pace of innovations is crucial to firm success. Particularly in Schumpeterian environments where innovation is thought to be rapid and value captured by those who can exploit in a timely manner (Nelson & Winter, 1982; Schumpeter, 1934). The characterization of firms during technological change finds incumbents maladaptive to innovation, and often out maneuvered by purportedly by more nimble, smaller new entrants that product disruptive innovations that can fundamentally change the entire technological trajectory in the domain (Polidoro & Yang, 2021; Rosenkopf & Nerkar, 2001). This is part of the creative destruction process during technological change and evolution. Literature notes, incumbents may respond through developing of complementary assets to buffer or reduce the hazard of complete destruction. Recently, scholars have noticed that both incumbents and new entrants actually are producing novel innovations, referred to as a "creative construction" process (Giustiziero et al., 2019). A key feature of this model of concurrent innovation trajectories is that both types of firms must be pursuing dual activities of finding new innovations and refining existing ones, exploration and exploitation. The literature on exploration and exploitation has long noted the challenges firms face in engaging in these activities are in tension with one another (March, 1991). Yet, an important underexplored area is the timing of the transitions between these modes of innovation. Moreover, it is not known how incumbents and startups may differ in these patterns of transition or timing.

Exploitation provides the basis for firm resources and innovation, but exploration is necessary for longer term firm survival and competitive advantage. Determining when firms are able to shift between these modes of innovation is crucial to understanding how they manage their innovation trajectories. This is particularly true for startups as they are thought to be the engines of innovation in a domain (Agarwal et al., 2007). This conflict in expectations brings us to the research question—how do startups differ systematically from incumbents in their decisions to shift to exploratory products? Specifically, for those that have entered in exploitation, when do they shift to exploratory products. In this chapter of the dissertation, I argue that while inertial forces should apply to both startups and incumbents, startups face additional more externally borne hurdles. Namely, due to greater uncertainty about the merits of their innovations, product failures (when they occur), and broader questions about the viability of the firm. Therefore, startups should take longer to shift to exploration. There are several important contingencies for the main effect. The firm's regulator capabilities in the product domain, and its technological diversity in the product domain attenuate this delay in time to shift to exploration.

This study aims to make several contributions. First, it advances our understanding of the challenges firms face in switching between modes of innovation. Specifically, the study identifies inter-temporality within a domain as a potential mechanism from the perspective of firms, especially startups. Next, the study furthers our understanding of complementary assets. Though prior work notes startups disadvantage in development of them, I highlight an asymmetric effect in institutional and social support systems necessary for innovation commercialization. This study also contributes to our understanding of Schumpeterian environments. Prior work suggests incumbents are maladaptive and startups are nimble; however, this study suggests that startups may not be as nimble as previously thought. Relative to incumbents, startups maybe exposed to more externally based rigidities, and this uncertainty reduces degrees of freedom for startups.

THEORY AND HYPOTHESES DEVELOPMENT

Exploration and exploitation

Innovation success for firms requires balancing two distinct but contrasting innovation activities by the firm—exploration and exploitation (March, 1991). Exploration is characterized by experimenting, searching, and generating new knowledge for the firm to develop future opportunities. While exploitation is characterized by a constrained scope of activities, focus on efficiency, and optimize execution using existing knowledge and capabilities (Levinthal & March, 1993; March, 1991). As firms face immediate performance pressures, and existing knowledge facilitates more reliable returns, firms are thought to have a tendency towards exploitation (Leonard-Barton, 1992). One consequence of this exploitation tendency is the "competency trap" whereby firms execute efficiently in existing operations but can be disrupted through innovations by rivals. Underlying firm activities in each innovation mode are routines, repeatedly enacted encodings of organizational knowledge that firms use to create innovations and are repositories of firm cognition (Nelson & Winter, 1982). Exploitation and exploration both are executed through these routines, and recombing the existing routines into new ones is a way to overcome the "competency trap" and path dependent risks of exploitation bias in firms (Christensen & Bower, 1996; Henderson & Clark, 1990). Indeed, Winter's (2003) "higher order routine" could be used for creation and changes in firm search patterns and action. Another study by Zollo and Winter (2002) suggests learning through knowledge and experience accumulates over time and the results are changes in the routines. He and Wong (2004) found that firms with search specific routines experienced higher variation in performance as part of their exploratory strategy, due to changes to routines (and thus exploration outcomes). These studies point to a central premise in the literature, these seemingly opposing tensions are typically viewed as occurring within the firm, and thus a function of internal properties of the firm. However, scholars have noted how firm use of exploration and exploitation may be affected by factors beyond the firm's boundaries.

Firm exploration and exploitation have been known to be influenced by the external environment the firm is situated within. Indeed, scholars have noted several aspects of the external environment such as collaborations with other firms (Rosenkopf & Nerkar, 2001), and opportunities for new knowledge (Cohen & Levinthal, 1990) as factors changing or shifting the focus onto each mode of innovation. Benner and Tushman (2003) argue that firm processes adjust for one level of dynamism in the environment and is influenced during tech change, suggesting several contingencies remain to be examined for exploration and exploitation processes. Uotila, Maula, Keil, and Zahra (2009) examine industry level factors like R&D intensity, finding a U-shaped relationship between exploration and performance. Lee, Lee, and Lee (2003) look at "power users" in a market, to see the impact on firm exploration and exploitation. Their study examined the role of network externalities in accounting for asymmetric effects of each innovation mode for improving firm growth with power users in the PC industry influencing the network structure. One particularly crucial external environment factor are rival firms that influence both explorations, potentially in legitimating a new technology or product area, and exploitation through market pressures. Specifically, rivals' innovation activities may alter the tradeoffs a focal firm faces in its exploration and exploitation activities.

Complementary assets

The value of complementary assets is their ability to facilitate firm adaptation and survival in the face of technological evolution and change (Teece, 1986; 2007). Thus, during periods of technological change, complementary assets can be a buffering agent to the new technology regime that has disrupted the existing technological capabilities of incumbent firms (Rothaermel, 2001; Tripsas, 1997). Complementary assets are often invoked as specialized manufacturing, distribution, marketing, or services (Mitchell, 1989; Rothaermel & Hill, 2005; Teece, 1986; 1988). One important type of complementary asset is the firm's ability to manage external influences. While incumbents are thought to possess complementary assets, which can be an aid during technological change and discontinuous innovation, however this can vary with the institutional environment as well. For example, Fuentelsaz, Garrido, and Maicas, (2015) found a diminished value for complementary assets in strong institutional environments, and by extension a stronger value for them in weaker institutional environments. Danneels (2004) suggest that marketing competence is needed for innovation development. Von Hippel (1988) notes the importance of understanding users to help firms address demand uncertainties for products. Of particular importance as a specialized complementary asset in managing external influences is experience navigating the institutional environment, and having knowledge of regulatory processes (Teece, 1986). Technological evolution involves processes of adaptation and selection (Levinthal, 1991; 1997). Firm adaptation to change has long been examined (Henderson & Clark, 1990; Nelson & Winter, 1982); but the importance of selection is relevant as well. In particular, as selection is often by institutional actors that determine the long-term viability of an innovation (Nelson & Winter, 1982), firms must incorporate this factor as well. Namely, firms with complementary assets that support its innovations through the social system and institutional environment that technological change and firms are situated in are better off. Indeed, Polidoro (2020) found that FDA approval times for drugs increased in the face of multiple technologies but was reduced when new technologies in the same domain as the focal one was present due in part to regulators' familiarity with applicant firms' submissions. Firms better able to navigate their products through a regulatory process are likelier to gain market share and acceptance by these external evaluators.

One source of heterogeneity in firm use of complementary assets is that different types of firms have access to complementary assets, namely incumbents and startups. As a technology matures in an industry, the use of specialized complementary assets means that incumbents would be favored, and entry would prove difficult and this likely crowds out new entrants. New firms or startups may be thought to be sources of novel innovations, but they often lack the specialized and co-specialized assets internally to commercialize these innovations (Rothaermel, 2001). Indeed, even smaller incumbents face challenges in the resource allocation tradeoffs to build assets to commercialize technologies.

Beyond the difficulties in accumulating complementary assets from experience, startups and incumbents means of acquiring these assets are different as well. Startups are thought to have significant technical capabilities. As they are not bound by routines, organizational inertia, or path dependent investments that incumbents face, they can focus their expertise on the technological domain. New product development draws on these novel capabilities (Helfat & Raubitscheck, 2000), but how startups recoup value is not obvious. Gans et al., (2002) suggest that startups partner with an incumbent when complementary assets are prohibitive to develop. Since complementary assets are time intensive, specific, and difficult to transfer, this situation would be common for startups (Dierickx & Cool, 1989). As they are new, they face higher risks of failing, and need to develop routines for the technological processes and products. Therefore, any shift in focus to development of complementary assets, could compound risks in the original technological efforts, thereby devaluing their own asset accumulation (Hsu, Wakeman, & Simon, 2013). Firms operating in innovation driven environments face significant uncertainties about several issues---upstream inputs, competition, new entrants, downstream partners, and technological viability. Uncertainty in the Schumpeterian environment is characterized by these uncertainties, and how firms must balance their ability to appropriate value against building value at all is a challenge (Lampert, Kim, & Polidoro, 2020). Thus, startups face a different challenge from incumbents—the technical properties which aid in innovation may constrain the startups in capturing value from those same innovations.

Startup shift to exploration

Firms, incumbents and startups alike, face several incentives and pressures to stay in exploitation mode of innovation. The literature suggests firms tend to have a bias towards exploitation for several reasons. As innovation activities are governed by routines, exploitation-based activities are to refine existing processes and gain efficiencies. If they are successful, these are repeated and reinforced, thereby tending to become more rigid in the firm's routine repertoire when innovating (Leonard-Barton, 1992). Eventually, continued success can lead to cognitive inertia (Tripsas & Gavetti, 2000) and ultimately a competency trap (Levinthal & March, 1993). There are also external pressures on firms to produce in the short term from investors, financial analysts, and other institutional actors that makes the uncertainty of exploration particularly challenging (Benner & Ranganathan, 2012; Theeke et al., 2017). Still, exploration is a necessary component of the innovation cycle.

Exploration provides several benefits for firms despite the uncertainty. If exploitation were followed to the maximum with current resources and capabilities, firms would be at risk in several ways. First, the opportunity to find new ways to recombine existing resources and capabilities will be diminished. Secondly, development of any future capability requires time, and exploitation would provide a longitudinal harm in that firms after realizing they should shift would not be able to recognize gains in the next several immediate periods of time. Therefore, drawing on exploration, which may also rely on routines, per Winter (2003) "higher order" routines that facilitate recombination and change, becomes necessary. Indeed, Zollo and Winter (2002) found that learning and knowledge accumulation happens in part due to changes in the routine, and exploratory ones are most likely to change. He and Wong (2004) suggest that firms use specific search routines which may create higher variations in performance, and this variation is part of an exploratory strategy, and also changes the firms operating routines. Though exploration has many benefits, incumbents and startups do not face these inertia forces to stay in exploration or exploitation similarly.

Startups face additional hurdles beyond the routines based internal constraints that facilitate the competency traps and cognitive inertia that may challenge incumbents. Indeed, startups are often created for the focal domain, and so internally based structures and routines that hamper incumbents are often not as rigid in these younger firms which makes adaptation and change in routines easier (Ganco & Agarwal, 2009). However, the same properties that address these internally driven technical constraints, may actually compound the uncertainties that are externally borne for the startup relative to the incumbent. First, the startup faces significant uncertainty about the technological success of the product. While any firm engaged in innovation development faces uncertainty about the underlying technological solution, startups are characteristically resource constrained, and somewhat focused in their product scope (Khessina, 2003). Therefore, any one product as a function of the overall firm is significant. Startups, as new and often small firms, often do not have the experience and accumulated knowledge and coordination routines need to produce an innovation (Eisenhardt & Schoonhoven, 1990). Startups also face greater uncertainty about the merits of the technological solutions in the technological regime they operate in. Incumbents, often diversifying entrants, are engaged in local search when producing even their novel innovations, and therefore have a basis in some other solution set for the problem they are addressing (Rothaermel, 2001). As innovations are embedded in an institutional and social system, truly novel innovations face a greater hurdle in gaining acceptance from the institutional actors such as regulators empowered to ensure the safety of those using the innovations (Polidoro, 2020).

Assuming the innovation is brought to fruition successfully there is another dimension startups must face. As with any innovation, the chance for failures and subsequent harm exists. Indeed, though the best learning for a firm often occurs after a failure (Denrell, 2003; Haunschild & Sullivan, 2002; Madsen, 2009), these are significant setbacks that can destroy the confidence of regulators and the market in a product and ultimately a firm. Thus, a relatively recent young firm in the technology space is both resource constrained and reputationally at risk if their products were to fail. This issue ties into a broader concern about the general capability of the firm that any startup faces when entering the market. An innovation's performance criteria are often not fixed, and the evaluative routines of regulators are contingent on how similar or relatively similar it is to existing products (Garud & Rappa, 1994; Tushman & Rosenkopf, 1992). If the performance criteria of the product are not readily available, the institutional actors may well infer some credibility from the producer, and startups do not have this resource. The firm may have the best technical solution, but scholars have shown that not the best solution always gets chosen (Dokko et al., 2012; Dosi, 1982), and in part interaction with institutions and relevant evaluators is why.

Beyond the challenges the startups face, an additional complexity is that their remedies are relatively few as well. To reduce concerns about the technological certainty of their solution would require some attempt to deploying it, but that is precisely that challenge in the first place. Moreover, the only way to signal quality about the merits of the innovation is to apply it to the problem but depending on the context this is quite difficult. Firms may attempt to publish findings, or seek arenas to demonstrate their abilities, but incumbents come with a steady track record regarding a given product (Polidoro & Theeke, 2012). For the regulator, the combination of unknown product and unknown entity, suggests that all else equal, regulators would be more circumspect about startups products. Lastly, though startups may attempt to mitigate these issues in part through alliances or partnerships with known firms, the hazards of these arrangements are well documented in the literature (Baum, Calabrese, & Silverman, 2000), and do not mitigate the fundamental point that the startup itself is viewed as more uncertain in its ability to perform. Thus, spending more time in an exploitation phase for a given domain to gain credibility and complementary assets is a response by startups to address this challenge. For these reasons therefore,

> *H1: Startups, relative to incumbents, take longer to shift from exploitation to exploration in a given product domain.*

Firm domain capabilities and exploration

Incumbents and startups do not face these uncertainties concerns uniformly. The role of the institutional actor is important for firm decisions in choosing their mode of innovation. Regulators are the ultimately selector of successful innovations, and their approval determines if any solution goes to market at all (Nelson & Winter, 1982). A relevant factor in how firm explorations and exploitations are reviewed is that innovation in a given domain will have different technological solutions available to it. When a focal firm submits a product, depending on the amount of new knowledge and interdependencies in it, the regulator may have to update or can rely on its existing portfolio of evaluative criteria and routines to determine the products efficacy. Indeed, Levinthal and Posen (2009) note how performance criteria and the order of their importance were the underpinnings of selection.

Firms that have some prior experience with the regulator draw on two levels of advantage for their subsequent submissions. First, the regulator is familiar both with a type of technological solution that maybe utilized in future innovations. Also, the tacit knowledge developed in ascertaining how a given firm produces an innovation is constrained by time compression diseconomies (Dierickx & Cool, 1989), and thus can be developed over time. The second advantage has to do with familiarity with the regulators evaluative process on the firm side. While the regulator learns about the focal innovations and firm, the firm is learning about the regulator's idiosyncratic preferences, ways of evaluating, and what might be of focal interest to it. Though the comprehensiveness of information to be submitted would not be expected to change from innovation to innovation, how it is presented, what is emphasized, or perhaps some preemptive emphasis on areas that the firm has experienced could be utilized in a focal submission. This is the kind of experience that is leveraged across multiple domains, or even within a product domain as the regulators are often repeated events in terms of these preferences (Polidoro, 2020). Startups which often do not have these experiences upon entry, face uncertainty not just from themselves to the regulator, but also about the regulator itself. The review time a regulator takes reflects how complex an evaluation about a focal innovation is, and if there are cognitive as well as reputational concerns, this time to review could be lengthened. In essence, the firm's ability to navigate the process is being reflected in how long the regulator took to have reviewed prior products. Startups are then more likely to pursue exploration as they gain domain relevant experience with regulators. Therefore,

H2: More FDA review time experience will reduce the time of shifting from exploitation to exploration in a given product domain for startups, relative to incumbents.

Firm technological product diversity and exploration

Incumbents and startups may differ in their technological diversity as well. Maintaining different product areas, even if related, draws on multiple routines, path dependencies in knowledge development as well as higher complexities in interdependencies. Moreover, as firms increase their product areas, potentially higher order governing mechanisms such as routines maybe drawn upon (Winter, 2003). Firm's technological diversity has several potential implications for the uncertainties firms face. First, specialized firms often draw on a narrower set of routines which are less likely to be useful if a disruptive innovation is introduced into the environment by a rival entrant. Such changes could require recombination of knowledge and routines but using a narrower combination base to navigate uncertainty in the search process for a solution. There is an external consideration for firms as well if they decided to adjust their technological diversity. Narrower product scopes are clearer to evaluators in terms of what to expect innovation and solution wise in a given domain. Scholars have shown when firms differ from expectations external actors maybe be skeptical of potential success and impose more constraints on these firms (Zuckerman, 1999).

Firms face differing pressures to explore depending on their technological diversity levels. At lower levels of diversity (higher concentrated), firms can be constrained by their path dependent choices. Indeed, firms most central in a given technological solutions maybe least likely to change, despite being most likely to be affected should it occur (Christensen & Bower, 1996; Henderson & Clark, 1990). They may choose to delay shifting to new products but run the risk of disruption to their core business. Such as consequence would not just affect the initial competitive interaction, but as new innovations evaluated are on a trajectory of products, and indeed evaluators have their own routines governing how to operate (Polidoro, 2020), it could affect many subsequent innovations based on that focal design. Therefore, concentrated firms maybe worse off in attempting to gain acceptance for their solution in the marketplace. The uncertainty of disruption is particularly acute for startups as they are often resource constrained to start.

As noted before, startups face significant externally borne uncertainties in their innovation development activities. Thus, while often a single solution is a starting place, many wish to proceed to multiple products for several reasons. First, multiple products signal viability to competitors, external evaluators, and the marketplace. While incumbents may not see value in signaling through multiple products, novel firms need to demonstrate likelihood of survival. There are also learning, and experiential benefits through increasing one's product diversity which increase likelihood of success in any focal domain. Therefore, startups with higher concentration of products post exploitation entry, are likelier to take the risks needed to explore all else equal. Therefore,

H3: More technological diversity within product domains will reduce the time of shifting from exploitation to exploration in a given product domain for startups, relative to incumbents.

In figure 2.1 below is the model with all the hypotheses and predictions.

See Figure 2.1 page 152

DATA AND METHODS

Empirical setting: Medical devices industry

The empirical analysis in this dissertation is based on data about medical devices. The primary data source for both essays come from the Food & Drug Administration

(FDA). The FDA reviews all medical devices that sold and used in the United States (FDA). To submit a product for regulatory approval of a medical device, a firm must include many pieces of information about the safety, efficacy, and scope of use for the device as well as many clinical trials. While most devices may eventually get approved, the agency can always request more information if preferred. After the firm submits the application, the application goes to one of nineteen medical advisory committees that are empaneled with experts and officials to overlook the application. These committees are responsible for over one thousand product codes which the products are grouped into by function. These scientific experts then make a recommendation for final review by the FDA. Though there are significant processes and procedures to ensure consistency and safety, there is material uncertainty in the safety and efficacy of any one medical device. Beyond the focal approval, the FDA must also consider if side effects or longitudinal issues maybe relevant as well. In table 2.1 below are all the medical advisory committee groups the FDA oversees.

See Table 2.1 page 131

Regarding the FDA's own structure, it is in an environment with several constituent actors. As part of executive branch, it is ultimately overseen by Congress, and if devices that were approved prove harmful, it can and has brough intense attention on the agency and caused damage to its reputation and loss of autonomy (Olson, 2004). To reduce the chance of errors, FDA can take as much time as it deems necessary for a focal application, though there is always pressure from industry and at times constituent groups in the public if the medical need is great, to complete the approval process relatively quickly. The accumulated experience and knowledge in the scientific community within the FDA has been viewed as an organizational level cognitive process for product reviews by scholars (Bodewitz et al., 1987). As such, while generally the FDA review process for medical devices is viewed as rigorous by the scientific community (Carpenter, 2004), it has at times been thought to be subject to the same challenges as the cognitive frame of any organization (GAO, 2015).

The FDA has two primary pathways for medical device reviews. The first is a "pre-market approval" or "PMA" database for medical devices that are considered novel and require additional scrutiny. Following literature these can be viewed as exploratory or novel products (Carpenter, 2002; Mukherjee et al., 2017; Thirumalai & Sinha, 2011). The second pathway is called "510K" and are still devices that require close review. However, there are two key distinctions with the PMA pathway, the first is that these are deemed less dangerous generally. Second, the approval of the product is contingent on the firm being able to demonstrate that the functionality, technology part is largely equivalent to an already approved design on the market. This distinction makes 510Ks ideal as a form of exploitation-based product innovations. The FDA also tracks recalls for all these products within their respective domains after approval. In figure 2.2 is an example of a PMA in the FDA database, and in figure 2.3 is an example of a 510K in the FDA database.

See Figure 2.2 page 153

See Figure 2.3 page 154

Medical devices are an excellent setting to examine these questions. It is an incredibly innovation intensive context, where new knowledge is imbued in a company's products (Mitchell, 1989; Wu, 2013). The context is also about new product introductions, though there is a substantial literature on upstream examination of the industry (Katila & Ahuja, 2002; Theeke, Polidoro, & Frederickson, 2017; Wu, 2013), the opportunity to examine products gives another perspective on how firms commit to certain innovation trajectories. These products are not just downstream results of firm search efforts, they also represent market commitments by the firm that must be approved by an institutional actor, thus, they are significant strategic decisions by the firm.

See Table 2.2 page 132

See Table 2.3 page 133

In table 2.2 are the breakdowns of product counts by medical group. In table 2.3 are similar product breakdowns for PMAs and 510Ks by medical group as well.

Research design for Chapter II

In testing the predictions an empirical consideration is that the incidence of firms, incumbents and startups shifting to exploratory products, may produce innovation trajectories with systematically different technical capabilities, which would suggest the possibility of endogeneity issues related to non-random assignment (Holland, 1986). If incumbents and startups have qualitatively different technical capabilities when shifting to exploration innovations, this can result in different time rates in when they chose to make such a shift. Moreover, startups being younger, may simply be later as a function of going up the learning curve any firm would face in deciding when to explore. Furthermore, literature suggests that startups are the engine of novel innovations generally (Abernathy & Utterback, 1978; Rosenkopf & Nerkar, 2001; Tushman & Anderson, 1986). Novel innovations have more complexity, are more difficult to articulate, and may simply take longer to prepare for submission to the regulator. Therefore, to address these concerns about endogeneity, a matching strategy was implemented to match a startup and the counterfactual incumbent in a product domain. To reduce the likely differences between the two firms, the analysis will be focused on new to the firm products in an original PMA.

In this study, I focus on a subset of the product introductions that encompass exploration and exploitation and differences between incumbents and startups. This will give a starting sample of 64,813 firm-year-quarter-medical group observations from 2002-2020. The additional variables will be used for the matching design and analysis. In this study there are several firm types, those which operate in both PMAs and 510Ks and some that are operating only in either innovation type. Tables 2.4, 2.5, and 2.6 below demonstrate how they are spread across the medical groups.

See Table 2.4 page 134

See Table 2.5 page 135

See Table 2.6 page 136

Dependent variables

Time to exploration—grouped at the firm, year-quarter, medical group, level. the number of days after entry until the firm shifts to PMA or exploratory products. Following other work in this area (Wu, 2013), PMAs are thought to suggest more "breakthrough" innovations. 510K applications per the FDA must be based on existing technology or product and thus are exploitative by design.

Independent variables

Startup indicator- this is a binary measure. It is a dichotomous variable that reflects whether the firm is a startup. This is a time invariant indicator that facilitates testing the treated (1) and control group (0) design.

Firm domain capabilities – this is the number of days between product approval and introduction by the FDA. This has been used in other work analyzing FDA review (Wu, 2013). The length of time is of consequence to firms and reflects the extent to which the firm has ability to navigate the review process through differences in application submission.

Firm technological diversity – this is a Herfindahl measure and is captured at the firm - year-quarter, medical group level. The calculation process follows work in product diversification or distribution of events (Desai, 2015; Hoskisson et al., 1993; Martin & Sayrak, 2003). The data comes from the FDA medical device PMA and 510K databases.

Control variables

To reduce concerns about potential omitted variable bias, I attempted to control for several sources of potential heterogeneity across observations. First, are the organizational level differences. Organization *size*- operationalized here by logged total assets by organization by year-quarter. Size is an important factor that influences firm exploration and growth (He & Wong, 2004). I also used several controls to address product domain and FDA domain differences. First, to address baseline innovation exploratory differences across the firms, I have *focal organization PMAs* at the medical group levels. Next, to capture sample baseline differences, I also have *510K measures* at the same levels of analysis. To account for the competitive affects both direct and indirect on exploration and exploitation, I have included PMA and 510K measures for firm rivals at each level of analysis as well. I also account for medical group differences captured in group identifiers. Having heterogeneity in product categories experience has been shown to influence innovation capabilities of firms (Karim & Mitchell, 2003). Table 2.7 summarizes the constructs and their measures of all variables used in the analysis.

See Table 2.7 page 137

Model estimation

To have more confidence in the inference of the proposed hypotheses, several challenges regarding endogeneity need to be met. Being a startup, per the literature, may systematically alter how they engage in exploratory product innovations. Moreover, incumbents may draw on capabilities that are outside the focal domain in a systematic pattern as well. To address these endogeneity concerns, I leverage the richness of the data on medical device product submissions and focus analysis on the constructed matched sample. Namely, for each startup, there is a counterfactual incumbent in the same domain, after product entry at the exploitation level so as to focus analysis on the shift to exploration. Any outside domain influences would be explicitly adjusted for in the model. The matching adjusts for all the firm and product domain variation as well as when the firms enter the focal product domain in question. Based on the coarsened exact matched sample (Blackwell et al., 2009), I compare startups and incumbents in their time to first exploratory product entry. Namely, the following equation:

$$\textit{time to exploration} = \beta_s\ \textit{startupID}_i + \beta X_{it} + \theta Y + \delta V + \beta_i\ \varepsilon_{it}\ \textit{(Equation 1)}$$

In equation 1 above, β_s captures the extent to which being a startup increases the time to shift to the first exploratory product. B is a vector of coefficients for the control variables X_{it}, θ represents the coefficient for the year-quarter effects. The δ represents the firm fixed effects.

To test the moderation variables for the interactions, the variable Contingency$_{it}$ means the contingent variables—firm regulatory capabilities, and firm technological diversity respectively.

The follow equation was used:

$$time\ to\ exploration = \beta_s\ startupID_i + \beta_s\ startupID_i\ x\ \beta_{sc}\ Contingency_{it} + \beta X_{it} + \theta Y + \delta V + \beta_i\ \varepsilon_{it}\ (Equation\ 2)$$

Figure 2.4 illustrates the research design proposed.

See Figure 2.4 page 155

To model the shift to exploration, survival analysis is an appropriate analytical strategy. While there are many distribution possibilities to use in modeling this phenomenon, per prior empirical work (Carpenter, 2004), the Weibull distribution is an appropriate choice for the survival regression analysis. Indeed, this form assumes event times follow the parameter baseline distribution should hold even if the independent variables were at zero (Wooldridge, 2002). The Weibull distribution also accounts for the monotonic effect of time. Beyond the primary models, I did several robustness models tests to ensure the results held. The results were also analyzed with different specifications such as using different distributions and the results held. Figure 2.5 below shows a Kaplan Meier plot that indeed startups are shifting towards exploration later than incumbents.

See Figure 2.5 page 156

This study examines how startups and incumbents differ in their decision to shift towards exploration. I argue that startups face significant externally based rigidities which make them much less nimble than Schumpeterian view of environment would suggest. Moreover, the shift is likely delayed further by uncertainties these firm types face regarding technology, firm survival, and ability to withstand failures, a common part of innovation—particularly exploring. In figures 2.6 and 2.7, are some plots of the data the lend some support to the analysis described above.

See Figure 2.6 page 157

See Figure 2.7 page 158

RESULTS

In table 2.8 is the summary statistics and the correlation matrix for the variables. I checked the initial model for multicollinearity (Greene, 2012) and ran analyses after adjusting some of the control variables. The VIF scores were below 10, and the even more stringent value of 5 across most models (Kleinbaum et al., 1988), and thus alleviates concerns regarding collinearity.

See Table 2.8 page 138

See Table 2.9 page 139

Table 2.9 shows the survival regression analysis estimates of firm shifts towards exploration. I first run a model with only the controls, and then tested each hypothesis. Model 1 has only the controls. Model 2 tests the first hypothesis (H1) that startups shift to exploration later than incumbents. Model 3 tests H2, where the firms domain capabilities decrease the time firms shift to exploration, though this time reduction is still greater for startups. Model 4 tests H3, the focal firm's technological diversity negatively moderates time to exploration for firms. Model 5 is the fully specified model.

The H1 prediction is that startups will shift to exploration later than incumbents. Consistent with this prediction, the coefficient on the startup indicator measure is positively significant ($b = 1.323$, $p < 0.001$), indicating that as startups do shift to PMAs or exploration later than incumbents in the product domain. Such findings support H1. The H2 prediction tests the first interaction effect. Specifically, the role of firm domain capabilities reducing this delaying effect. Therefore, where more domain capabilities are present, this reduces the uncertainty facing startups in their shift towards exploration. Confirming the prediction, the results in model 3 shows a significant negative effect of the interaction of startups and firm domain capabilities ($b = -0.0042$, $p < 0.001$). Such findings support H2.

H3 tests the second interaction effect. Looking at the focal firm's technological diversity (how concentrated its product portfolio is), the interaction effect is negative. To examine this result, as firm product domain concentration increases, the uncertainty present to the core product areas and potential loss become greater. This risk is increasingly so for startups which are facing additional uncertainties due to lack of complementary assets and experience in the domain. Therefore, the need to explore increases. Confirming my prediction, the results of model 4 show a significant negative effect on the interaction of firm technological diversity and startups ($b = -1.99$, $p < 0.001$). Such findings confirm H3. Model 5 is the fully specified model, and the results show support for the hypotheses.

Robustness analyses

To demonstrate confidence in the findings, and show robustness of the results, I ran a variety of supplemental analyses to address any potential concerns about the reported models. One concern might be that the results might be sensitive to the analytical specification, which could influence the results. Though Weibull is appropriate in this setting (Carpenter, 2004), another potentially appropriate specification is the exponential distribution. I test this in Models 6-9, and the results do not change with this distribution adjustment change. I also test the lognormal specification in models 10-12, and once again the results materially held. I also ran models using the Cox proportional hazards specification in models 13-15. For interpretation purposes a negative sign here means less likely to occur, thus in these models, startups having a negative sign is consistent with the theorizing that they shift towards exploration later than incumbents do. Tables 2.10, 2.11, and 2.12 summarize these models (6-15). As the results show robust findings, these further increases confidence in the analyses. These were all executed on the matched sample.

See Table 2.10 page 140

See Table 2.11 page 141

See Table 2.12 page 142

DISCUSSION

This study contributes to the ongoing interest in how firms manage their innovation activities, a key part of which are the tradeoffs in exploring vs. exploiting, a significant research interest of strategy (Benner & Tushman, 2003; Jansen et al., 2006; Levinthal & Posen, 2009). These studies note internally driven factors affecting the tradeoff decisions between these activities. This paper shifts the focus to when and triggers for this shift, specifically, the differences between startups and incumbents in when they move from exploitation to exploration. In Schumpeterian environments, quickly exploiting innovations is essential to innovation success and firm performance. However, without shifting to exploration at some point, long term performance is not possible. While startups may explore, they face significant uncertainties in the likelihood of success with the product. They also face challenges in commercializing the technology, as they lack the complementary assets necessary to do so. I argue that startups, relative to incumbents shift towards exploration at a later point in time. This delay in exploration has downstream consequences for exploitation, for example as the evaluator is exposed to differing technical solutions, familiarity with each firm's solution can influence acceptance or how long it takes to be approved. This effect is mitigated when firms have prior domain experience with innovations and getting them through the approval process. Firm domain capabilities reduce the uncertainties facing firms in both technological and institutional from the FDA specifically. The firm's technological diversity is also a mitigating factor. Namely, concentration of product areas spurs firms to shift to exploration sooner given the risk of disruption by competitors. The empirical analysis offers support for these hypotheses. One strategic response to the uncertainties they face is that startups may spend more time in exploitation to gain necessary complementary assets before shifting to exploration. The empirical analyses are consistent with these predictions.

Limitations

A potential limitation of this study is in the empirical focus of shifting to the first exploratory product. To simplify the analysis, and have more confidence in the inference being drawn, the study looks at the first exploratory product so as to be sure of the firm's timing minimum. However, such analysis leaves out several potential effects. For example, literature notes that first mover is not always an advantage, and indeed, perhaps the most exploration occurs for firms when the start doing the second or third product. It is also difficult to separate from the analysis the extent to which complexity of the innovation is responsible for the timing element as well. These possible considerations will require more examination in future research.

Managerial implications

This study has several implications for managers. The first is that incumbents looking to startups as sources of novel innovations may want to consider how they proceed with the negotiation for these supposedly novel products. If institutional navigation is a highly relevant factor, the role regulators play suggests that specific types of complementary assets have value and should be included in assessing the innovation's value. Moreover, managers may not want to source their most novel products externally as much since the submissions to the regulator might actually be more delayed if they did so. Second, the value of starting in exploration for startups maybe of interest to managers. Though new firms are searching for differentiation in markets, to venture capital, and other external evaluators, considering how to make a path for commercializing the results of the search for innovations could be valuable as well.

Contributions and future research

This study aims to make several contributions. First, it advances our understanding of how firms may be balancing between modes of innovation. Specifically, the study identifies inter-temporality within a domain as a potential mechanism from the perspective of firms, especially startups. While prior work has noted the importance of a 'between domain' temporal balancing, there can also be a 'within domain' effect that has important implications for the firm's overall temporal balancing strategy in sum. If startups are shifting to exploration later than incumbents in a given domain, this suggests that the novelty could be occurring later than expected. If startups are not driving the changes in exploration, where does their technological novelty get expressed? An interesting future research idea would be to see if perhaps the domain evolution changes dramatically between domains with startups present and others that do not have them. If indeed, the startups influence is delayed, there should be a nonlinear innovation submission pattern over time. Another interesting potential idea is to examine the nature of the recalls that startups and incumbents are experiencing. Though not in the scope of this study, the reasons for the recalls are in the dataset collected, and future work can begin seeing if there are systematic patterns in differences for reasons of recalls between incumbents and startups.

Another potential contribution of the study relates to complementary assets. Though prior work notes startups have a disadvantage in development of them, I focus on a specific difference in the institutional environment regarding their rates of approval. Prior work has noted that regulators faced with multiple technologies may draw on these to evaluate a novel innovation more efficiently (Polidoro, 2020), but if the firm type itself has an issue on the rate at which the innovation is being examined this is important to consider in the evolution of the technology. Indeed, the technological regime and cognitive frame surrounding it can be influenced by the uncertainty of the technology and the limitations of the parties participating in sensemaking of the value of the innovation, but there may also be a bias present here—another manifestation of the liability of newness.

Some interesting future research ideas come to mind given this possibility. The first is to see if the context can shift the assumption about startups. For example, startups are thought to potentially struggle with failures in the products if they occur. What would be the regulator response if the failures had just been occurring with incumbents, would this weaken the penalty the startup experiences in submitting its novel solutions? Also, what are some credible signals that startups may procure that level the playing field for a given domain. For example, in the exploitation-based product domains, would there be a "generics" equivalent after significant cumulative product experience at the domain level? That is to say does the age of the domain exacerbate the difference between incumbents and startups since the regulator is basing their concerns on the uncertainty present due to the technology and design capabilities of each relative firm type?

This study also makes a contribution to the understanding of how Schumpeterian environments operate. Prior work contends incumbents are maladaptive and startups are nimble. Yet this study offers that startups may not be as nimble as previously thought. Relative to incumbents, startups maybe exposed to more externally based rigidities, if this is the case, then startups are more constrained and by proxy their innovations in the radicalness maybe as well. The lack of rigidity relates to the routines being developed, the expectations of customers and investors initially being observed, and the lack of path dependent decisions to adapt to; however, there is a converse to having little history. As technology progresses in a social and institutional environment, a lack of history is a lack of observability, and all else equal significant more uncertainty that cannot be reduced via risk management. Therefore, startups may be technologically free but institutionally constrained, whereas the incumbents are somewhat of the reverse. Some interesting future directions arise out of this view of the types of firms. The first question is what happens if the startup and incumbent de-emphasize their respective identity at each stage of the product's evolution. Taking a real-world example for a moment, the BioNTech –Pfizer vaccine, is often referred to as the "Pfizer" vaccine. This is in part due to Pfizer's much broader name and simplicity in reference. However, this vaccine for Covid-19 was also among the fastest approved by the FDA. It is possible that BioNTech developed the underlying technology, and then Pfizer emphasized its identity in the product submission for approval. Granted these are vaccines under emergency circumstances, but there are other firms much more well known, and under these circumstances they took longer to be approved. The idea that firms should explicitly manage their technological and institutional components in innovation has important implications for exploration and exploitation. This tension suggests that part of the duality is not simply internal drawing on the same resources, but also external drawing on competing perceptions.

Another interesting question has to do with firms that explicitly specialize in either exploration or exploitation and never attempt to shift, how to do they interact with those that pursue both? For example, for startups that never intend to become incumbents, do they jettison the issues surrounding their perceived inexperience as they become "pure player" explorers and therefore are not expected to have worked "all the bugs" out? On the other side, what about firms that only ever exploit, wait for a product to get approved and once it is standardized, move in to gain economies of scope and scale? Would these "pure players" shift the timing considerations of firms that try to do both exploration and exploitation? The literature suggests that to be successful firms must do both, but in practice the "pure play" type of firms do exist. The timing questions examined in these studies implicitly takes the literature view of firms needing to pursue both. It is possible that innovation trajectories and technological change might evolve different if there are different types of firms each playing their part in the search for innovations.

CHAPTER III: TRIGGERS FOR SHIFTING TOWARDS EXPLOITATION AND EXPLORATION

Abstract

While firm exploration is long known to be essential to innovation success, firms tend to spend more time in exploitation. Yet, less is known about what the triggers are for when firms leave an exploitation oriented trajectory in their product development or technology, and when they pursue a more exploratory innovation. In this study, I ask what prompts firms to shift off of exploitation, and drawing on literatures in competition, exploration and exploitation and technological change, I argue firms with more exploratory product bases will pursue exploitation in a given product domain. However, rival entry and firm design capabilities make firms more likely to shift from exploitation and to pursue more exploration innovations. Startups are less likely to divert from an exploitative trajectory. I use detailed medical device data across all regulated medical device groups for over 60,000 product introductions between 2002 and 2020. This study advances our understanding of what triggers firms to shift along the continuum between exploitation and exploration modes in a technological dynamic environment within multiple product domains, a challenge firms often face.

INTRODUCTION

Firm exploration, producing radical novel innovations, is a crucial part of firms' innovation trajectories and how they maintain competitive advantages in uncertain environments (March, 1991). Exploration is inextricably tied with exploitation, refinement and use of existing knowledge and resources to harvest returns presently, though distinct, they are linked as each facilitates the existence of the other, and so both are necessary for firm adaptability to technological change, innovation, and ultimately performance. Prior work has identified many reasons for firm's facing challenges and tradeoffs balancing both activities. Firm capabilities and resources, path dependent investments, and routine evolution (Barney, 1991; Helfat, 1997) present a tendency to use what is available, particularly if it is successful in the environment, this competency trap (Levinthal & March, 1993) tends to result in an exploitation bias. Exploration is difficult for firms, though it can be achieved through strategies like search routines or use of higher order recombination routines for existing resources and capabilities to make more "long jumps" in innovation (Levinthal, 1997). While pursuing both activities is thought to make the best chance for firm success, the role of time is important in the way these activities are sequenced as well (March, 1991). Firms spend longer in exploitation as a matter of duration of time and exploitation by construction is often preceded by exploration (if the exploitation is based on firm's innovation investments). As exploitation may be longer in duration, not accounting for the rate of innovations and what triggers these firms to shift from exploration to exploitation is an important under-explored question.

Given exploitation is crucial to garner resources for firm operations and future exploration activities, better understanding firm timing of it is a crucial aspect of pursuing both innovation activities. Firms have conflicting pressures that are not clearly resolved from the literature. On the one hand, firms need to profit from exploration, extend the value of the innovations, and for the successful products, refine the core features of that innovation to deter imitation as well as provide differentiation in the market (Katila & Chen, 2008; Nelson & Winter, 1972). On the other hand, firms run serious risks from competition with substitute innovations that may induce creative destruction if exploration is pursued for too long (Hill & Rothaermel, 2003; Schumpeter, 1934). In destroying value that would be appropriated, firms lose also the opportunity to shift to exploitation to harvest their returns. Toh and Polidoro (2013) showed how certifications can be used to both illustrate potential of a field while deterring rivals from entering. Similarly, firms may want to start a new cycle of exploration, as a way to preempt loss of value from rivals launching similar products. Timing these two activities is very difficult, too long and the firm becomes disrupted, switch too early, and the value from exploration is not realized.

In this chapter of the dissertation, I seek to investigate what are the drivers for firms to manage their shifting from exploration to exploitation. Determining the sequence of each mode is critical as resource constraints are a focal challenge for firms in balancing exploration and exploitation (Lavie, 2006; March, 1991; Smith & Tushman, 2005). In addition, when firms choose to exploit may be a signal of technological convergence in the domain which can an influence the entire technological trajectory of the domain. Lastly, determining when firms choose to exploit influences the resource base for managing future innovations, a critical stabilizing response in an uncertain environment.

I argue that firms with more exploratory family product domains are more likely to shift towards exploitation. This likelihood is a function of the firm's own place along the trajectory of products in a technological frame (Wu et al., 2014). Additionally, the role of the external environment, especially rivals, provides additional pressures (Rindova et al., 2005) which can shift the relative tradeoff of entering a more uncertain domain or exploiting within the current one. Several important contingencies moderate this primary effect. Rival product entry and firm design capabilities exacerbate and mitigate this main effect. Another important factor is whether the firm is a startup, which prefer to exploit within their product families due to resource constraints and challenges in gaining acceptance of products by evaluators.

This study advances our understanding of the tradeoffs for exploration and exploitation in firms, particularly the environmental triggers firms face when deciding to shift between the two each. Furthermore, this study adds to our understanding of the nuances of competition that facilitate preemption by firms in the Schumpeterian view of innovation. The study also advances our understanding of how nuanced exploration and exploitation maybe in terms of degree of novelty and incremental development. Namely, even within relatively novel domains, firms face a tendency of bias to pursue related innovations, this suggests simply building capabilities to search distantly initially may not be sufficient for longer term success in innovation.

THEORY AND HYPOTHESES DEVELOPMENT

Pre-Market approval product families and exploitation

Exploration is crucial to long term success in innovation for firms, but it presents several material risks, as it is in direct contrast with an equally relevant part of the process- exploitation (March, 1991). Thus, tradeoffs are one of the defining characteristics of this model of innovation and technological evolution and change. As the same resources are being allocated across both types of activities, the firm must be careful about uncertainty, a core part of innovation development process. Exploration poses uncertainty in technological progress, and there is also uncertainty in terms of acceptance of the technological solution by institutional and other external actors (Polidoro, 2020; Theeke, Polidoro, & Frederickson, 2017). While these uncertainties pose significant risks for the firm, a commonly identified source of uncertainty and difficulty is the role of time. Timing is relevant to firm innovation development activities, as resources and capabilities are path dependent, the temporal ordering of decisions has a substantial impact on the sequence of what is available to the firm when (Eisenhardt & Brown, 1997). Regarding exploration and exploitation, temporal sequencing, or attempting to move back and forth over time with the same units or sub organizational domains has been offered as a way to manage these activities (Tushman & Anderson, 1986; Tushman & Romanelli, 1985). However, timing also characterizes the uncertainties in these innovation activities. Firms' exploratory product domains face multiple uncertainties, and many are related to timing (Katila & Chen, 2008). First, there is technological uncertainty that the firm's solution will be functional at all. Second, routines, interdependencies, and the knowledge base available to the firm for future exploitation are a function of what has already been chosen ex ante by the firm thus far in the evolution of the domain. If the firm has several exploratory product domains, there is both a greater pressure to use, and a larger base of resources to use for recombination. Moreover, if the firm does not leverage these opportunities, soon, they may be upended by the actions of other firms. Innovations have equifinal possible solutions (Kaplan & Tripsas, 2008; Teece, 1986). The institutional actors responsible for selecting an innovation may have performance criteria that can fluctuate, but contingent on a functional solution being found, any one given way of solving the problem would be sufficient. Therefore, firms are on the clock to ensure that their solution is out and available to the market. There is also the direct competitive effect of have more exploratory product families, domains already under investigation for exploration can signal potential viability to competitors, but they can also deter imitation as the rival has to decide how much to invest in an area that already has activity (Toh & Polidoro, 2013). Therefore,

> *H1: The greater the number of exploratory product families a focal firm has in a product domain, the more likely the focal firm engages in exploitative product innovation.*

Rival entry and exploitation shift

In considering how exploration and exploitation timing for the focal firm will operate, the role of rivals in this context is also important. Rival entry into a product domain offers a dual effect for focal firm---competitive pressures, but also a potential easing of uncertainty via institutional actors' decision making. A firm's ability to maximize returns on exploration investments maybe due in part to rival entry. Rival entry increases potential number of technological solutions. Should the alternative become the dominant design in the market, the firm is at a loss. This risk is not just for the current product, but the future iterations based on the initial design. The additional challenge is that market pressures could increase the focal firms need to differentiate and shift towards exploration earlier than it otherwise may move. Research on competition has shown that focal firm's respond to rival actions depending in part on the timing of that action. For example, a technology investment announcement may be cancelled if a technology standard is adopted (Smith, Grimm, Gannon, & Chen, 1991). The rivals' product depth maybe an indicator of their likely intensity to defend a market position. Indeed, if product domain has few players, or concentration of products in domain, competitive response can be a function of rivals' behavior, not just focal firm incentives (Powell & Brantley, 1992).

Additional rivals can offer the chance for the focal firm to learn vicariously, and potentially build a novel innovation off the investment of rivals, but they are exposed to the same risk of substitutes as the increase in rivals persists. Thus, as the number of PMA families for rivals increases, the focal firm may wish to pursue exploratory investments sooner, as the risk of disruption of their exploitative products is higher. Therefore, the timing decision would be accelerated in terms of searching for new products.

> *H2: A higher number of rival exploratory product families in a product domain, will negatively moderate the likelihood of exploitative product innovation by focal firms with more exploratory product families.*

Startups and exploitation persistence

While all firms face multiple pressures to tend towards exploitation, one key differentiation among firms is incumbency. The bias towards exploitation exists for all firms (Levinthal & March, 1993; March, 1991), but startups face a series of pressures that encourage exploitation, despite having some structural factors that suggest exploration would be preferred. Specifically, similar to incumbents, startups develop routines that can be reinforced over time (Argote, 1999; Nelson & Winter, 1982). If the firm were to continue to grow at some point even inertia could set in (Audia et al., 2000). Another factor is that external entities may expect a certain performance level from a startup as it is new. For example, industry analysts, investors, or even a regulating entity could draw inferences about the product or technology depending on the startup's degree of novelty in the domain (Theeke, Polidoro, Fredrickson, 2017). What makes this pressure particularly challenging is that startups are thought to be free or structured more for exploration.

Startups often are thought to be focused on their initial development of innovations. Unlike incumbents, they are not hampered with prior expectations, routines, or path dependencies born out of existing products (Agarwal et al., 2007). This degree of freedom should lead to startups pursuing more distant innovations that can pose a threat to incumbents (Rosenkopf & Nerkar, 2001; Schumpeter, 1934). Thus, all else equal, one would expect startups to have a lower bias towards exploitation within a product domain. Indeed, incumbent adaptation to technological change is well established phenomenon (Leonard-Barton, 1992; Tripsas & Gavetti, 2000), therefore, for competitive reasons, startups able to pursue more exploratory innovations should be likelier to succeed and eventually become an incumbent themselves. However, there are reasons for startups to tend to exploit despite these seeming structural advantages.

Startups may be facile technologically, but maybe constrained in terms of value appropriation opportunities and institutional acceptance. Relative to incumbents, startups lack complementary assets (Teece, 1986), and thus in innovation intensive environments with limited appropriability opportunities, lacking these assets is a risk to startups. Moreover, while startups could pursue radical innovation, the uncertainty surrounding technological development is particularly consequential to them. For example, a firm may have only one or two products, and so the threat of rival entry or substitution is particularly dangerous to the firm. Another constraint is simply resources. As a younger, typically smaller firm, startups face a resource constraint horizon, competing with firms that are better resourced. Assuming a particular technological trajectory has passed scrutiny and the firm is able to leverage any experience or learnings in additional products, this could produce much needed knowledge, resources, and bolster the firms changes of survival and eventually long-term success. Indeed, the additional products more incremental in nature provide two benefits, the first are the tangible aforementioned ones, the second is continuing to build credibility and capabilities to pursue innovations in that focal domain, which may support a future radical innovation change in the future. Thus, startups are likelier to want to pursue more exploitation oriented development across the PMA family or families they manage. Thus,

H3: Startups with more exploratory product families are more likely to engage in exploitative product innovation than incumbents.

Firm design capabilities and exploitation

An unavoidable part of innovation are product failures. Novel technological solutions are necessarily uncertain in their likelihood of success. Therefore, failures are both inevitable and still highly to be avoided. Failures in products create several problems for firms. First, failures demonstrate a lack of safety in the products themselves, and this by inference suggest that the design capabilities of the firm may not be up what is required. Secondly, product failures are highly salient events which often are public and then draw scrutiny from many external observers, such as investors, the public, financial analysist, and of course regulators (Barnett & Freeman, 2001; Desai, 2015). Third, failures in innovation are difficult as the complexity and uncertainty in any innovation make the causality of events difficult to ascertain (Haunschild & Sullivan, 2002).

To mitigate these concerns firms must demonstrate the safety of products to the regulator which will necessarily divert resources from the innovation process. Beyond the resources, the attention of the firm must be averted as well to address the focal problem, as they necessarily must shift focus between safety and efficiency in returning to production (Haunschild, Polidoro, & Chandler, 2015), and build a response to the regulator to meet their concerns. In addition, articulating the interdependencies and components responsible for the events may be a longer-term event that must be attended to as well. As innovations build on one another, the trajectory is necessarily stopped if a given product fails to operate as expected. Though failures often induce firm search that is more careful about the parts of how a product works, there are competing demands within the organization for accountable for the failure in the first place (Madsen, 2009), namely assigning blame which may hamper efforts to get to the right solution. Necessarily all these concerns mean that resources and attention will be less available for the firm to pursue more exploratory innovations. However, beyond the resource constraints, the uncertainties surrounding the technical abilities of the firm have just been magnified. If innovations built on prior work are not reliable, then incremental innovations would not be reliable either. Thus, the relative uncertainties of pursuing a different novel innovation product and keeping the current trajectory become closer together in terms of value to the firm. Moreover, competitive pressures from rivals and hesitancy on the part of external evaluators will dampen any value from existing portfolio of products. Therefore, firms will take steps to reassess what is known and reliable, and it is likelier that more novel technologies are easier to pursue while this reviewing exercise takes place. Therefore,

> *H4: Fewer design capabilities by a focal firm, will negatively moderate the likelihood of exploitative product innovation by firms with more exploratory product families.*

In figure 3.1 below is the model with all the hypotheses and predictions.

See Figure 3.1 page 159

DATA AND METHODS

These conceptual arguments are tested on a longitudinal panel dataset of firms in the US medical devices industry from 2002-2020. The initial sample includes all publicly available submissions for medical devices in the PMA and 510K groups submitted to the FDA. The FDA also maintains a recalls database for all products that have been approved. The recalls database is also captured by medical advisory group level. Recalls are serious events for firms and of material cost when they occur. Not just for the immediate stoppage of sales and revocation of approval, but the longer-term fixes that must be made to assuage the FDA's concerns. If recalls persist, there can be spillover effects for the firm, the technological domain, and even the regulator itself if not eventually contained. The recalls database is only available beginning in the year 2002. So, for this analysis, the sample will start in that year and go to the present. Following FDA designation (Carpenter, 2002), and much of management research using medical devices (Mukherjee et al., 2017; Thirumalai & Sinha, 2011), PMAs are the novel devices and can be thought of as exploratory entries, while 510Ks are more exploitative in nature as their approval requires a predicate similar technological solution. As shifts in innovation and activity are the primary interest in the study, an appropriate sample draws on firms most active in the industry. Following prior work on firms engaged in innovation, I matched firms to Compustat and Capital IQ and Venture Xpert information, active in medical industry (Wu, 2013), and significant participants in producing products (Chatterji, 2009; Chatterji & Fabrizio 2016). The sample is made of 838 firms. These firms produce 83,685 medical devices and comprise the vast majority of activity in the industry (over 66%, Chatterji & Fabrizio 2016). This list of firms was also crossed checked against a major trade publication, Medical Device and Diagnostic (MDDI) industry and Q-MED, all major firms engaged in innovation in the industry are represented in the sample, as well as all firms that have submitted to the FDA. In table 3.1 below are the number of firms in each of the FDA medical groups, showing healthy competition across each domain and thus risk of displacement being high. In table 3.2 below are the number of PMA families across each medical group as well.

See Table 3.1 page 143

See Table 3.2 page 144

Dependent variable

Exploitation choice is a choice variable indicating whether the firm choose to enter a new PMA family or to submit a PMA within the PMA family. It is a dichotomous variable (0,1) in the focal year-quarter-product code domain.

Independent variables

Exploration span is a count variable of the number of PMA families within the medical group for the focal firm at the year-quarter level.

Startup indicator- this is a binary measure. It is a dichotomous variable that reflects whether the firm is a startup. This is a time invariant indicator [1,0].

*Rival entry***-** is calculated as count measure of PMA families in the year-quarter period by rival firms (all other firms) in a given medical group.

*Firm design capabilities—*captured at the firm-year-quarter-medical group level, is the count of the number of product failures by the firm.

Control variables

To address several potential concerns of variable bias, I controlled for several potential types of heterogeneity across observations in the sample. Organization *size-* is operationalized by the logged total assets by firm, year-quarter. I also used several controls to address FDA domain level differences. To address baseline innovation differences among firms, I have *focal organization PMAs* at the medical group levels,. I also have *510K measures* at the same level of analysis. Table 3.3 summarizes the constructs and their measures of all variables used in the analysis.

See Table 3.3 page 145

Model estimation

To estimate the influence of exploratory PMA families on likelihood of choosing to start a new innovation group or not, a panel analysis with all firms in the sample identified in chapter two during the analysis period was used. The analytical model used was linear probability models. Such models, allow for interpreting the interaction effects while keeping reliable marginal effects. Linear probability analysis is consistent with other work examining these kinds of outcomes (Theeke, Polidoro, & Fredrickson 2017). Namely, the following equations:

$$p_i = \beta_e \textit{ exploration span}_{it} + \beta X_{it} + \theta Y + \delta V + \beta_i \, \varepsilon_{it} \textit{ (Equation 1)}$$

In equation 1 above, p_i is the probability that the dependent variable will be 0 (a new PMA family, as opposed to 1, an additional PMA). β_e captures the extent to which exploration span increases the likelihood of an additional PMA. Exploration span $_{it}$ is the number of PMA families the firm is operating in the focal product domain during that time period. B is a vector of coefficients for the control variables X_{it}, θ represents the coefficient for the year-quarter effects, with Y being the year-quarter. The δ represents the firm fixed effects, and V being the firm specific identifier. $\beta_i \, \varepsilon_{it}$ captures the error terms.

To test the moderation variables for the interactions, the variable Contingency_{it} means the contingent variables—rival entry, startup identification, and firm design capabilities respectively. The follow model was used:

$$p_i = \beta_e \textit{ exploration span}_{it} + \beta_e \textit{ exploration span}_{it} \; x \; \beta_{ec} \textit{ Contingency}_{it} + \beta X_{it} + \theta Y + \delta V + \beta_i \, \varepsilon_{it} \textit{ (Equation 2)}$$

The second empirical essay in this dissertation explores how a firm's exploratory product domain families influences when it decides to pursue exploitation of its products. Theorizing about the impact of exploratory product domains highlights the effect of dueling tensions of competition in Schumpeterian environments. On the one hand, firms need to profit from explorations so as to continue operations and recoup the investments. On the other hand, continued leveraging of existing products runs the risk of being disrupted by major technological changes and being sidelined for multiple periods of future competition. The timing of when to pursue one or the other presents significant risks in either direction.

RESULTS

In table 3.4 is the summary statistics and the correlation matrix for the variables. I checked the initial model for multicollinearity (Greene, 2012) and ran analyses after adjusting the control variables. The VIF scores were mostly under 10, across models (Kleinbaum et al., 1988), and thus largely alleviating concerns regarding collinearity.

See Table 3.4 page 146

See Table 3.5 page 147

Table 3.5 shows the linear probability regression analysis estimates of firm shifts towards exploitation. I first run a model with only the controls, and then tested each hypothesis. Model 1 has only the controls. Model 2 tests the first hypothesis (H1) that more exploratory product bases (firm's PMA family count) lead to more exploitation. Model 3 tests H2, where the firms rival PMA family counts increase competitive pressure and thus less likely to engage in exploitation. Model 4 tests H3, this tests startups' being likelier to pursue exploitation within their PMA families, and positively interacts with the number of PMA families. Model 5 tests H4 about firm design capabilities and has firm recalls, and how more recalls negatively moderates with more PMA families. Model 6 is the fully specified model with all hypotheses included.

The H1 prediction is that more firm exploratory PMA families lead to more exploitation. Consistent with this prediction, the coefficient on the firm PMA family measure is positively significant ($b = 0.0224$, $p < 0.001$), indicating that as firms have more PMA families, they exploit more. Such findings support H1. The H2 prediction tests the first interaction effect. Specifically, the role of rival PMA family counts reducing this exploitation effect. Therefore, where more rival PMA families are present, this reduces the firms shift towards exploitation. Confirming the prediction, the results in model 3 shows a significant negative effect of the interaction of firm PMA families and rival PMA families ($b = -0.000013$, $p < 0.001$). Such findings support H2. H3 tests the second interaction effect. Looking at if the firm is a startup, the interaction effect is positive. To examine this result, startups face material uncertainties in pursuing more novel innovations in each domain, moreover, they face significant externally borne pressures, thus once a product trajectory is approved, they are more likely to want to exploit that innovation line, as well as gain complementary assets from learning the approval process. Therefore, the need to exploit increases. Confirming my prediction, the results of model 4 show a significant positive effect on the interaction of startups and firm PMA families ($b = 0.16$, $p< 0.001$). Such findings confirm H3. Model 5 investigates H4, the role of firm recalls. Recalls are a signal to the firm and domain evaluator that potentially the current set of routines and innovations are not based on sound design. Therefore, the typical gains from exploitation are materially diminished. Moreover, rivals maybe able to leverage the opportunity to replace the focal firm's share of the market. This risk increases as the number of PMA families increases for the firm as the base for exploitation is increasingly unreliable. Therefore, the need to shift to more exploratory products is needed. Consistent with this prediction, the results of model 5 show a negative interaction with the choice to exploit ($b = -0.00019$, $p < 0.001$). Model 6 is the fully specified model with all the hypotheses and the coefficients showing support for the hypotheses.

Robustness analyses

To demonstrate confidence in the findings, and show robustness of the results, I ran a variety of supplemental analyses to address any potential concerns about the reported models. One concern might be that the results might be sensitive to the analytical specification, which could influence the results. Though linear probability estimate is appropriate in this setting (Wooldridge, 2002), I ran several other specifications to check. I ran a logit based series of models to test this concern in models 7-11, and the results do not change materially. I also test with the probit specification for models 12-16, and once again the results largely held. I also ran models using the cloglog specification in models 17-21. There were no significant differences in the results here as well. Lastly, perhaps the construction of the dependent variable could advantage one mode over the other. As exploitation is more common, perhaps there was an issue from that. Therefore, using a different dependent variable that looked at shifts to exploration of novel domains was used in the last series of models (models 22-26). For interpretation purposes, one would expect the signs to flip as the baseline here was exploitation as opposed to shifting towards exploration, and indeed the signs for that model were consistent with the theorizing from all the other models. Tables 3.6, 3.7, 3.8, and 3.9 below summarize these models (7-26). As the results show robust findings, these further increases confidence in the analyses.

See Table 3.6 page 148

See Table 3.7 page 149

See Table 3.8 page 150

See Table 3.9 page 151

DISCUSSION

A firm's ability to successfully engage in exploitation and exploration remains a central question for innovation and strategy scholars (Kang & Kim, 2020; March, 1991). Several studies note the seeming intractability of managing both activities, and the need to follow some system for pursuing both modes of innovation, while overcoming challenges that arise with each (Levinthal & March, 1993). This paper shifts the focus to identify triggers for when firms are moving from one mode to the other. A central challenge in these environments is identifying when exploration has occurred long enough to become exploitation, or even to what degree are the activities deemed exploratory themselves based on existing knowledge or capabilities. In Schumpeterian environments where the risk of displacement by rivals or new entrants is ever present, better understanding where firm heterogeneity arises in pursuing shifts of these activities is paramount for increasing knowledge on enduring performance.

In this study, I examine the triggers for when firms stay in exploitation vs. choose to shift towards more novel explorations. I argue that firms with more exploratory bases of products will seek to continue to exploit those product areas even within the exploratory portion of the continuum in the domain. There are several important contingencies, the first being that rival expansion in the domain will increase the firm's concern about displacement or loss due to competition and thus more likely to pursue an otherwise riskier product. The role of startups is important as well, thought to be the vanguard of innovation in a domain, they are even more inclined to pursue exploitation within exploration part of the novelty continuum where possible due to the constraints they face in resource and institutional acceptance. Finally, the firm's design capabilities influence the relative tradeoff risks faced in terms of pursuing what is already known vs. shifting to another riskier product line. The empirical analyses undertaken in this study support these findings.

Limitations

One potential limitation of this study could be associated with the empirical design. Though I am able to observe all the product entries and firms participating in the industry, the question of causality is relevant. It is possible that despite fixed effects and constraining the sample of firms, some unobservable variables that drive the shift to exploitation also drove multiple exploratory product families in these domains. This concern suggests future studies to use an empirical design perhaps with a matched sample approach. Another option is to look for a shock in the industry regarding domain evolution so as to utilize a difference in difference examination of the evolution in exploitation once the domain is no longer novel. Though the sample contains many multinational firms, the focus of the context is the medical device US industry. To address this, future studies may want to include data from product approval decisions by the EU or Japan (other large medical device producing areas) to test the generalizability of the findings.

Managerial implication

This study has important managerial implications for innovation of medical devices and when to pursue fundamentally novel products or not. The existing portfolio of exploratory products has a path dependent influence on the direction of the technology and product trajectories firms pursue next. Competitors exploratory product families are not just influencing market makeup through direct competitive pressures, but they are influencing which technologies are being selected in the various product domains that the firms are competing in. Managers may wish to develop coordination routines among their product divisions to more finely time the launch and submission of their respective products so as not to bunch them together. Firms may also want to consider how to handle product recalls in their innovation development cycles. As recalls increase, it is not just the focal product at risk, but the opportunity to build on the entire trajectory of products, as entities outside the firm may have concerns about the safety and efficacy of the products.

Contributions and future research

This study aims to make several contributions. The first is that this study advances our understanding of the tradeoffs for exploration and exploitation in firms, particularly the triggers to shift trajectories. The literature has long suggested balancing activities as a means of adjusting to the needs to explore and exploit, but this study highlights that such balancing must take into account the existing portfolio of explorations and their position along the novelty continuum. Indeed, much of the work tends to group the firm's activities in a single domain (Jansen et al., 2009; Simsek, 2009), and while other studies have examined multiple domains at once (Lavie, 2011), looking at an existing exploratory base of products is closer to what a firm is balancing in practice, the trajectories, not just specific individual products. A key insight here is that timing when to explore and exploit is not just a function of the firm's internal makeup but attempting to preempt rival entry that could destroy successive opportunities to exploit.

A second contribution is a better understanding of the nuances of exploration and exploitation along a continuum of novelty. This study examines the simultaneity challenge that firms face as opposed to "pre" and "post" disruption as previously theorized. Rivals with a similar exploratory base of products, as opposed to simply more products or experience in a domain may be what drives firms to shift away from successful incremental changes and pursue more novel paths. Moreover, the nuance in moving along a continuum, is also about the dual uncertainties of the technological and competitive reactions of the firm for itself. After a product failure for example, the uncertainties between each mode of innovation may temporarily lowered.

There are several exciting potential future research opportunities from this study as well. The first is to examine the firm's regulatory capabilities. If rival entry and product failures may induce firms to make more distant innovations, perhaps external actor influence can reduce the competitive pressures stemming from both sources. For example, firms with greater product approval capabilities may take greater risks in developing a promising technological trajectory, indeed scholars have noted that discerning when to stop or continuing an innovation path is an underexplored by important aspect of innovation (Maslach, 2016). Another promising possibility is the dynamic between incumbents vs. startups, if startups lack institutional capabilities needed to navigate approvals, those that become incumbents must possess other complementary assets that facilitate exploitation. Examining the networks of startups relative to incumbents may give rise to ascertain what pattern that could be accounting for the eventual evolution from startup to incumbent.

CONCLUSION

This dissertation explores how firms move between exploration and exploitation in Schumpeterian environments, specifically as incumbents and startups. The motivation for this research originates from certain key tensions in the literature, first how do firms manage these seemingly conflicting requirements? Second, with both incumbents and startups pursuing exploration and exploitation, what are the triggers and timing differences for each in shifting between both innovation modes. Understanding these dynamics is important because it provides better insights to account for how firms determine when to invest for today vs. innovate for tomorrow. While the literature acknowledges pursuing both is crucial, how firms undertake this task is still not sufficiently understood despite its centrality to successful long term innovation success.

In looking at this question, this dissertation conceptualizes exploration and exploitation as operating along a continuum consistent with March (1991). Following that framework, the relevant literatures reviewed were exploration and exploitation, technological change, and complementary assets. In the exploration and exploitation literature, the centrality of temporal tradeoffs is longstanding, but what triggers the shift and how long does it take is less clear. In the technological change literature, the dynamic typically describing incumbents and startups have startups at an advantage during exploration. However, that literature maybe focused on the value creation advantages startups have, without fully accounting for the constraints they may face on the value appropriation side. Finally in the complementary assets literature, scholars note the importance of having complementary assets in highly uncertain environments such as

Schumpeterian ones; however, the type of assets often invoked overlook the crucial role of institutionally based processes in selection of innovation. In other words, assets that have to do with surviving not just technological change, but the understanding, preferences, or processes of the selector as well. Thus, some gaps emerged across the literature. Specifically, do incumbents and startups behave uniformly in determining when to explore and exploit, and do they respond to the same triggers when shifting?

To address these tensions, and the overarching question in the dissertation, there are two empirical essays that focus on shifts towards exploration and shifts towards exploitation. The first study suggests that startups shift to exploration later than incumbents, differently than what existing theory may suggest. Firm regulator capabilities can change the incentives of deciding when to shift towards exploration and potentially reduce the uncertainty of exploration. The role of firm technological diversity is relevant as well since it straddles the social and technological constraints firms, startups in particular, maybe facing when deciding to shift towards exploration. The interplay between incumbents, startups, and the evaluating external actor is an important piece of understanding when firms choose to explore as well as the contingencies that may exist. This study offers an alternative view to the prevailing logic that exploration is driven by young, novelty-based firms, and instead notes the centrality of the social and institutional system in technology adoption and evolution. Namely, the shift to exploration can be externally driven in part, and that firms which are freer in one aspect of innovation (no routines, prior knowledge to manage), can be constrained in another (institutional support). This dynamic matters in understanding when firms choose to explore and subsequently exploit the innovations they produce—as these activities are the basis for progress in innovation.

The second essay looks at when firms are shifting towards exploitation. Firms face a fundamental tension in continuing to pursue either exploration or exploitation. Stay too long in exploration and you do not gain any resources to continue operating as a firm. Focus on exploitation for too long, and the risk of rivals building a better product, or the development of a viable substitute grows larger. The second study suggests firms with a broader base of exploratory trajectories (PMA families) are willing to follow exploitation within the exploratory side of a domain. This main effect finding is important for theoretical and empirical reasons. Literature has long asked when exactly does exploration turn into exploitation, and when are exploitation activities a basis for future exploration? This study highlights triggers for when firms move off each path. The contingencies build on the main insight. The role of rival pressures is real for firms pursuing exploitation until they are forced to explore. The startups face additional pressures in pursuing an exploitation oriented exploration path due to their constraints in resources and institutional abilities. The firm's own design capabilities can limit the value in pursing exploitation oriented innovation, thereby changing the tradeoff for when to exploit vs. explore.

The two empirical analyses draw on a rich and complete set of data on medical device approvals by the US FDA. The data capture was the public population of medical device approvals in the United States. As the FDA is the pre-eminent evaluator of healthcare devices worldwide, this is a significant dataset. Drawing on robust multiple analyses, the empirical findings strongly support the theoretical hypotheses in each empirical essay. Looking holistically, the theory and findings of the dissertation seek to push our understanding of how firms undertake a fundamental yet seemingly in conflict set of activities necessary for innovation to progress and ultimately for firms to succeed.

Tables

Table 1.1. Literature review summary

Literature	Innovation progression	Incumbents and Startups	Uncertainty	Role of timing
Tech Change and Evolution (1)	Discontinuity / radical→ period of incremental changes	New entrants tend to drive new innovations	High following discontinuity, and it subsides	Cyclical process, though specific triggers less clear
Exploration and Exploitation (2)	Baseline is local search, and then distant search for new innovations	One view creative destruction, another creative construction; both can explore	Both thought to be uncertain, exploration more so. Startups face additional question about firm itself	Ambidexterity suggests both are done, BTOF– triggers to change, but less clear differences across firms
Complementary Assets (3)	Ensures value capture from innovations found	Incumbents buffer. Startups struggle to acquire, may start with exploitation	Mitigates uncertainty of disruptive innovation.	Time diseconomies to develop, Increases adaptation response opportunity

(1) e.g., Dosi, 1982; Garud & Rappa, 1994; Tushman & Anderson, 1986; Henderson & Clark, 1990; Abernathy & Clark, 1978
(2) e.g., March, 1991; Nelson & Winter, 1982; Levinthal & March, 1993; Rosenkopf & Nerkar, 2001; Rothaermel & Deeds, 2004;
(3) e.g., Teece, 1986; Hill & Rothaermel, 2003; Lampert, Kim, & Polidoro, 2020; Wu, Wan, & Levinthal, 2014;

Table 2.1 FDA Medical groups

TABLE 2.1 Medical Groups			
MG	MG_name	MG	MG_name
AN	Anesthesiology	NE	Neurology
CH	Clinical Chemistry	OB	Obstetrics/Gynecology
CV	Cardiovascular	OP	Ophthalmic
DE	Dental	OR	Orthopedic
EN	Ear, Nose, Throat	PA	Pathology
GU	Gastroenterology, Urology	PM	Physical Medicine
HE	Hematology	RA	Radiology
HO	General Hospital	SU	General, Plastic Surgery
IM	Immunology	TX	Clinical Toxicology
MI	Microbiology		

Table 2.2 Medical group product counts

TABLE 2.2 Medical Group Product Counts		
MG	**MG_name**	**Product_Count**
AN	*Anesthesiology*	1811
CH	*Clinical Chemistry*	4026
CV	*Cardiovascular*	26647
DE	*Dental*	3021
EN	*Ear, Nose, Throat*	1209
GU	*Gastroenterology, Urology*	4084
HE	*Hematology*	665
HO	*General Hospital*	3550
IM	*Immunology*	1862
MI	*Microbiology*	4086
NE	*Neurology*	3258
OB	*Obstetrics/Gynecology*	1164
OP	*Ophthalmic*	6492
OR	*Orthopedic*	9689
PA	*Pathology*	806
PM	*Physical Medicine*	306
RA	*Radiology*	4656
SU	*General, Plastic Surgery*	5631
TX	*Clinical Toxicology*	722

Table 2.3 Medical group product counts—PMAs and 510Ks

TABLE 2.3 Medical Group Product Counts—PMAs and 510Ks			
MG	**MG_name**	**PMAs**	**510Ks**
AN	*Anesthesiology*	284	1527
CH	*Clinical Chemistry*	1011	3015
CV	*Cardiovascular*	22031	4616
DE	*Dental*	244	2777
EN	*Ear, Nose, Throat*	821	388
GU	*Gastroenterology, Urology*	1898	2186
HE	*Hematology*	13	652
HO	*General Hospital*	665	2885
IM	*Immunology*	743	1119
MI	*Microbiology*	2408	1678
NE	*Neurology*	2001	1257
OB	*Obstetrics/Gynecology*	520	644
OP	*Ophthalmic*	5736	756
OR	*Orthopedic*	1875	7814
PA	*Pathology*	730	76
PM	*Physical Medicine*	38	268
RA	*Radiology*	399	4257
SU	*General, Plastic Surgery*	2317	3314
TX	*Clinical Toxicology*	37	685

Table 2.4 Medical group product counts—incumbents and startups

TABLE 2.4 Medical Group Product Counts—Incumbents and Startups			
MG	**MG_name**	**Incumbent**	**Startup**
AN	*Anesthesiology*	1606	205
CH	*Clinical Chemistry*	3491	535
CV	*Cardiovascular*	25022	1625
DE	*Dental*	2786	235
EN	*Ear, Nose, Throat*	1027	182
GU	*Gastroenterology, Urology*	3455	629
HE	*Hematology*	639	26
HO	*General Hospital*	3335	215
IM	*Immunology*	1721	141
MI	*Microbiology*	3841	245
NE	*Neurology*	2864	394
OB	*Obstetrics/Gynecology*	944	220
OP	*Ophthalmic*	5546	946
OR	*Orthopedic*	7792	1897
PA	*Pathology*	746	60
PM	*Physical Medicine*	289	17
RA	*Radiology*	4223	433
SU	*General, Plastic Surgery*	4889	742
TX	*Clinical Toxicology*	570	152

Table 2.5 Medical group product counts—mixed and pure type firms

TABLE 2.5 Medical Group Product Counts—Mixed and Pure Type Firms			
MG	**MG_name**	**MixFirm**	**PureFirm**
AN	*Anesthesiology*	738	1073
CH	*Clinical Chemistry*	2656	1370
CV	*Cardiovascular*	24530	2117
DE	*Dental*	766	2255
EN	*Ear, Nose, Throat*	824	385
GU	*Gastroenterology, Urology*	3022	1062
HE	*Hematology*	327	338
HO	*General Hospital*	*1677*	*1873*
IM	*Immunology*	*1302*	*560*
MI	*Microbiology*	*3429*	*657*
NE	*Neurology*	*2714*	*544*
OB	*Obstetrics/Gynecology*	774	390
OP	*Ophthalmic*	5863	629
OR	*Orthopedic*	6846	2843
PA	*Pathology*	693	113
PM	*Physical Medicine*	76	230
RA	*Radiology*	2330	2326
SU	*General, Plastic Surgery*	3868	1763
TX	*Clinical Toxicology*	362	360

Table 2.6 Medical group product counts—mixed and pure type firms in PMAs and 510Ks

TABLE 2.6 Medical Group Product Counts—Mixed and Pure Type Firms in PMAs and 510Ks

MG	MG_name	PMAs		510Ks	
		MixFirm	PureFirm	MixFirm	PureFirm
AN	*Anesthesiology*	162	122	576	951
CH	*Clinical Chemistry*	966	45	1690	1325
CV	*Cardiovascular*	21323	708	3207	1409
DE	*Dental*	202	42	564	2213
EN	*Ear, Nose, Throat*	561	260	263	125
GU	*Gastroenterology, Urology*	1571	327	1451	735
HE	*Hematology*	8	5	319	333
HO	*General Hospital*	479	186	1198	1687
IM	*Immunology*	740	3	562	557
MI	*Microbiology*	2353	55	1076	602
NE	*Neurology*	1925	76	789	468
OB	*Obstetrics/Gynecology*	388	132	386	258
OP	*Ophthalmic*	5215	521	648	108
OR	*Orthopedic*	1794	81	5052	2762
PA	*Pathology*	633	97	60	16
PM	*Physical Medicine*	37	1	39	229
RA	*Radiology*	321	78	2009	2248
SU	*General, Plastic Surgery*	2109	208	1759	1555
TX	*Clinical Toxicology*	37	0	325	360

Table 2.7 Summary of measures for Chapter II

TABLE 2.7 Summary of measures in Chapter 2

Constructs	Variable	Measure
Dependent variable		
Time to Exploration Shift	Time count in firm focal domain	The number of days between entry into exploitation until first exploratory product
Independent variables		
Startup Indicator	Startup group ID	Binary variable set to one if the firm is a startup, otherwise zero if incumbent
Firm regulatory capabilities	firm -medical group review time	Review time in days for prior products by the firm in the medical group
Firms Technology Diversity	Firm -medical group HHI	Herfindahl measure of approved products for the firm medical group
Control variables		
Firm capabilities	Firm size	Amount of firm total assets
Firm technological capabilities	Firm R&D	Amount spent on firm R&D activities
Firm medical group PMA experience	Firm medical group PMA submissions	The number of firm product domain PMAs approved
Firm medical group 510K experience	Firm medical group 510K submissions	The number of firm product domain 510Ks approved
Rival medical group PMA experience	Rival medical group PMA submissions	The number of firm medical group PMAs approved
Rival medical group 510K experience	Rival medical group 510K submissions	The number of firm medical group 510Ks approved

Table 2.8 Descriptive statistics for Chapter II

TABLE 2.8 Descriptive Statistics

	Variable	Mean	SD	Min	Max	1	2	3	4	5	6	7	8	9	10	11
1	Time to Exploration	780.58	1277.36	0.00	8413.00	1.00										
2	Startup_ID	0.11	0.31	0.00	1.00	0.17	1.00									
3	Firm domain capabilities	104.95	122.56	0.00	2926.00	0.19	0.04	1.00								
4	Firm tech diversity	0.35	0.30	0.00	1.00	0.35	0.10	0.09	1.00							
5	Firm focal exploitation (510ks)	5.01	9.05	0.00	83.00	-0.08	-0.10	0.10	-0.20	1.00						
6	Firm focal related exploration (PMAs)	40.40	109.81	0.00	661.00	-0.37	-0.10	-0.22	-0.67	0.30	1.00					
7	Firm nonfocal domain exploration (PMAs)	32.70	103.92	0.00	810.00	0.11	-0.08	-0.05	0.25	-0.18	0.04	1.00				
8	Firm nonfocal domain exploitation (510ks)	10.28	19.34	0.00	134.00	-0.04	-0.14	-0.02	-0.03	0.14	0.28	0.56	1.00			
9	Rival focal exploration (PMAs)	231.79	387.27	0.00	1512.00	-0.22	-0.07	-0.20	-0.52	0.03	0.55	-0.26	-0.20	1.00		
10	Rival focal exploitation (510ks)	255.68	149.43	0.00	627.00	0.01	-0.02	0.04	-0.30	0.55	0.29	-0.34	-0.14	0.43	1.00	
11	Firm Size (Logged)	10.98	1.99	1.50	15.01	-0.10	-0.32	-0.10	-0.21	0.19	0.32	0.38	0.47	0.08	0.08	1.00

Table 2.9 Survival model (Weibull) firms' shift to exploration

TABLE 2.9

Weibull Accelerated Event Time Regression Analysis (Shift to Exploration--Startups and Incumbents)

	(Survival Model- Weibull) [a]				
VARIABLES	DV= Time to PMA				
	(1)	(2)	(3)	(4)	(5)
Startup_ID (H1)		1.323***	0.480*	1.993***	2.942***
		(0.155)	(0.261)	(0.242)	(0.260)
Startup_ID_X_Regulatory capabilities (H2)			-0.00422***		-0.00484***
			(0.00120)		(0.00107)
Startup_ID_X_Tech diversity (H3)				-1.998***	-0.00935***
				(0.343)	(0.00109)
Regulatory capabilities			0.00536***		0.00774***
			(0.000931)		(0.00105)
Tech diversity				1.033***	1.081***
				(0.289)	(0.298)
Firm focal exploitation (510ks)	-0.0126***	-0.0201***	-0.00410**	-0.0172***	-0.0192***
	(0.00225)	(0.00206)	(0.00202)	(0.00232)	(0.00233)
Firm focal related exploration (PMAs)	-0.00163***	-0.00146***	-0.000481***	-0.00141***	-0.00120***
	(0.000110)	(0.000110)	(8.71e-05)	(0.000138)	(0.000143)
Firm nonfocal domain exploration (PMAs)	-0.000918*	-0.00326***	0.00132**	-0.00314***	0.00160*
	(0.000504)	(0.000651)	(0.000557)	(0.000801)	(0.000912)
Firm nonfocal domain exploitation (510ks)	-0.00995***	-0.00564***	-0.00333**	-0.00561***	-0.00233
	(0.00152)	(0.00165)	(0.00145)	(0.00215)	(0.00246)
Rival focal exploration (PMAs)	-0.000242***	-0.000170*	-0.000918***	1.26e-05	-0.000875***
	(8.59e-05)	(9.32e-05)	(0.000131)	(9.83e-05)	(0.000107)
Rival focal exploitation (510ks)	4.30e-05	0.000966***	0.000254	0.000399	0.000176
	(0.000283)	(0.000330)	(0.000382)	(0.000375)	(0.000410)
Firm Size (Logged)	-0.154***	0.125**	-0.0510	0.124	-0.0815
	(0.0358)	(0.0574)	(0.0550)	(0.0775)	(0.0790)
Observations	6404	6404	6166	6,105	6,105

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

Table 2.10 Survival model (Exponential) firms' shift to exploration

TABLE 2.10
Robustness Check Survival Regression Analysis (Shift to Exploration--Startups and Incumbents)

	(Exponential) [a]			
	DV= Time to PMA			
	(6)	(7)	(8)	(9)
Startup_ID (H1)	1.880***	1.121***	2.839***	4.369***
	(0.183)	(0.287)	(0.304)	(0.240)
Startup_ID_X_Regulatory capabilities (H2)		-0.0239***		-0.0143***
		(0.00193)		(0.00190)
Startup_ID_X_Tech diversity (H3)			-2.622***	-3.146***
			(0.461)	(0.570)
Regulatory capabilities		0.0274***		0.0146***
		(0.00173)		(0.00177)
Tech diversity			1.774***	1.925***
			(0.456)	(0.528)
Firm focal exploitation	-0.0149***	-0.0126***	-0.00994***	-0.00677***
	(0.00207)	(0.00226)	(0.00253)	(0.00172)
Firm focal related exploration	-0.000893***	-0.000758***	-0.000742***	-0.00120***
	(8.97e-05)	(9.37e-05)	(0.000112)	(0.000135)
Firm nonfocal domain exploration	-0.00340***	-0.00107**	-0.00289***	0.000480
	(0.000455)	(0.000444)	(0.000598)	(0.000483)
Firm nonfocal domain exploitation	-0.00711***	-0.00390***	-0.00593***	-0.00305**
	(0.00123)	(0.000831)	(0.00169)	(0.00133)
Rival focal exploration	0.000105	0.000154	0.000247**	2.98e-05
	(8.62e-05)	(0.000107)	(9.66e-05)	(9.72e-05)
Rival focal exploitation	0.00126***	0.00207***	0.000571	0.000653**
	(0.000329)	(0.000425)	(0.000376)	(0.000284)
Firm Size (Logged)	0.232***	0.0383	0.239***	0.0521
	(0.0408)	(0.0430)	(0.0606)	(0.0526)
Observations	6135	6135	6135	6105

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

Table 2.11 Survival model (Lognormal) firms' shift to exploration

TABLE 2.11

Robustness Check Survival Regression Analysis (Shift to Exploration--Startups and Incumbents)

	(Lognormal) [a]		
	DV= Time to Exploration		
	(10)	(11)	(12)
Startup_ID (H1)	1.923***	1.394***	2.958***
	(0.0498)	(0.0452)	(0.0554)
Firm domain capabilities		-0.000477***	
		(9.40e-05)	
Startup_ID_X_Firm domain capabilities (H2)		0.000619***	
		(0.000152)	
Firm tech diversity			2.579***
			(0.0722)
Startup_ID_X_Firm tech diversity (H3)			-2.622***
			(0.461)
Firm focal exploitation	-0.00453***	-0.00560***	-0.00157*
	(0.000946)	(0.000619)	(0.000864)
Firm focal related exploration	-0.000357***	-0.000388***	-0.000231***
	(4.82e-05)	(3.16e-05)	(4.42e-05)
Firm nonfocal domain exploration	-0.00327***	-0.00120***	-0.00250***
	(0.000146)	(0.000104)	(0.000135)
Firm nonfocal domain exploitation	-0.00610***	-0.00261***	-0.00282***
	(0.000431)	(0.000287)	(0.000402)
Rival focal exploration	0.000505***	0.000435***	0.000669***
	(3.22e-05)	(2.49e-05)	(3.00e-05)
Rival focal exploitation	0.000194**	0.00106***	-0.000118
	(8.75e-05)	(8.15e-05)	(8.38e-05)
Firm Size (Logged)	0.219***	0.0486***	0.239***
	(0.0105)	(0.00844)	(0.00957)
Observations	6393	6163	6393

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

Table 2.12 Survival estimations (Cox) firms' shift to exploration

TABLE 2.12
Robustness Check Cox Regression Analysis (Shift to Exploration--Startups and Incumbents)

	(stcox) [a]		
	DV= Time to Exploration		
	(13)	(14)	(15)
Startup_ID (H1)	-1.637***	-1.333***	-2.392***
	(0.144)	(0.192)	(0.250)
Firm domain capabilities		0.000831***	
		(0.000286)	
Startup_ID_X_Firm domain capabilities (H2)		-0.000753*	
		(0.000452)	
Firm tech diversity			-1.493***
			(0.337)
Startup_ID_X_Firm tech diversity (H3)			1.743***
			(0.346)
Firm focal exploitation	0.00222**	0.00318***	-0.000362
	(0.00101)	(0.000872)	(0.00115)
Firm focal related exploration	0.000195***	0.000195***	0.000125***
	(4.02e-05)	(3.72e-05)	(4.67e-05)
Firm nonfocal domain exploration	0.00181***	0.000460***	0.00150***
	(0.000245)	(0.000178)	(0.000288)
Firm nonfocal domain exploitation	0.00485***	0.00219***	0.00382***
	(0.000544)	(0.000426)	(0.000719)
Rival focal exploration	0.000122**	6.62e-05	4.53e-05
	(5.17e-05)	(5.89e-05)	(5.74e-05)
Rival focal exploitation	-4.88e-05	-0.000433**	0.000277
	(0.000213)	(0.000215)	(0.000237)
Firm Size (Logged)	-0.161***	-0.0279	-0.186***
	(0.0232)	(0.0192)	(0.0302)
Observations	6393	6163	6391

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

Table 3.1 Medical group – number of firms

TABLE 3.1 Medical Group Number of Firms		
MG	**MG_name**	**Number of Firms**
AN	*Anesthesiology*	131
CH	*Clinical Chemistry*	120
CV	*Cardiovascular*	209
DE	*Dental*	122
EN	*Ear, Nose, Throat*	62
GU	*Gastroenterology, Urology*	168
HE	*Hematology*	64
HO	*General Hospital*	180
IM	*Immunology*	77
MI	*Microbiology*	74
NE	*Neurology*	125
OB	*Obstetrics/Gynecology*	91
OP	*Ophthalmic*	164
OR	*Orthopedic*	156
PA	*Pathology*	31
PM	*Physical Medicine*	65
RA	*Radiology*	151
SU	*General, Plastic Surgery*	237
TX	*Clinical Toxicology*	52

Table 3.2 Medical group – number of PMA families

TABLE 3.2 Medical Group PMA Family Counts		
MG	**MG_name**	**PMA_Family_Count**
AN	*Anesthesiology*	20
CH	*Clinical Chemistry*	33
CV	*Cardiovascular*	386
DE	*Dental*	16
EN	*Ear, Nose, Throat*	19
GU	*Gastroenterology, Urology*	70
HE	*Hematology*	2
HO	*General Hospital*	29
IM	*Immunology*	48
MI	*Microbiology*	140
NE	*Neurology*	34
OB	*Obstetrics/Gynecology*	39
OP	*Ophthalmic*	373
OR	*Orthopedic*	102
PA	*Pathology*	55
PM	*Physical Medicine*	9
RA	*Radiology*	54
SU	*General, Plastic Surgery*	114
TX	*Clinical Toxicology*	8

Table 3.3 Summary of measures for Chapter III

TABLE 3.3. Summary of measures in Chapter 3

Constructs	Variable	Measure
Dependent variable		
Exploitation choice	New PMA family entry / PMA supplement entry	choice variable set to 0 if new PMA family is selected, 1 if PMA supplement is chosen
Independent variables		
Exploration span	PMA families	The number of PMA families in product domain
Rival span	PMA families	The number of PMA families by rivals in product domain
StartupID	indicator variable	binary (1 if startup, 0 if not)
Firms design capabilities	Firm -medical group failures	The number of product failures by the firm in the medical group
Control variables		
Firm capabilities	Firm size	Amount of firm total assets
Firm technological capabilities	Firm R&D	Amount spent on firm R&D activities
Firm product domain PMA experience	Firm product code PMA submissions	The number of firm product domain PMAs approved
Firm product domain 510K experience	Firm product code 510K submissions	The number of firm product domain 510Ks approved
Firm medical group PMA experience	Firm medical group PMA submissions	The number of firm medical group PMAs approved
Firm medical group 510K experience	Firm medical group 510K submissions	The number of firm medical group 510Ks approved

Table 3.4 Descriptive statistics for Chapter III

	Variable	Mean	SD	Min	Max	1	2	3	4	5	6	7	8	9	10
	TABLE 3.4 Descriptive StatisticsSummary Statistics														
1	Exploitation_Choice	0.84	0.36	0.00	1.00	1.00									
2	Firm PMA Family Count	6.84	9.95	0.00	34.50	-0.26	1.00								
3	Startup_ID	0.11	0.31	0.00	1.00	0.05	-0.14	1.00							
4	Rival PMA Family Count	314.52	324.94	0.00	1088.00	-0.16	0.68	-0.11	1.00						
5	Firm Recall Count	2.37	10.01	0.00	232.00	-0.07	0.23	-0.04	0.25	1.00					
6	Firm focal exploitation (510ks)	5.01	9.05	0.00	83.00	-0.26	0.65	-0.13	0.39	0.20	1.00				
7	Firm focal related exploration (PMAs)	40.40	109.81	0.00	661.00	-0.27	0.95	-0.13	0.60	0.20	0.65	1.00			
8	Firm nonfocal domain exploration (PMAs)	32.70	103.92	0.00	810.00	0.08	-0.06	-0.10	-0.33	-0.09	-0.10	0.02	1.00		
9	Firm nonfocal domain exploitation (510ks)	10.28	19.34	0.00	134.00	-0.09	0.24	-0.16	-0.14	-0.06	0.23	0.32	0.60	1.00	
10	Firm Size (Logged)	6.12	1.74	0.00	9.22	-0.09	0.33	-0.29	0.15	0.07	0.30	0.31	0.32	0.50	1.00

Table 3.5 OLS estimations effects of PMA families on Exploitation Choice

TABLE 3.5
OLS Regression Analysis (Shift to Exploitation)

VARIABLES	(OLS) [a] DV= ExploitationChoice					
	(1)	(2)	(3)	(4)	(5)	(6)
FirmPMAFamilyCount (H1)		0.0113***	0.0224***	0.0114***	0.0128***	0.0224***
		(0.00118)	(0.00264)	(0.00118)	(0.00118)	(0.00266)
FirmPMAFamilyCount_X_RivalPMAFamilyCount (H2)			-1.35e-05***			-1.19e-05***
			(2.58e-06)			(2.58e-06)
FirmPMAFamilyCount_X_Startup_ID (H3)				0.159**		0.168**
				(0.0644)		(0.0657)
FirmPMAFamilyCount_X_FirmRecallCount (H4)					-0.000245***	-0.000224***
					(3.77e-05)	(3.73e-05)
RivalPMAFamilyCount			0.000315***			0.000304***
			(4.30e-05)			(4.33e-05)
Startup_ID				0.219***		0.243***
				(0.0526)		(0.0527)
Firm Recall Count					0.00338***	0.00296***
					(0.000696)	(0.000689)
Firm focal exploitation (510ks)	-0.00536***	-0.00618***	-0.00641***	-0.00620***	-0.00624***	-0.00639***
	(0.000517)	(0.000513)	(0.000520)	(0.000513)	(0.000531)	(0.000539)
Firm focal related exploration (PMAs)	1.71e-06	-0.000440***	-0.000466***	0.000439***	-0.000442***	-0.000463***
	(3.90e-05)	(6.61e-05)	(6.70e-05)	(6.61e-05)	(6.57e-05)	(6.67e-05)
Firm nonfocal domain exploration (PMAs)	0.000317***	0.000380***	0.000412***	0.000385***	0.000396***	0.000432***
	(3.08e-05)	(3.19e-05)	(3.25e-05)	(3.19e-05)	(3.20e-05)	(3.27e-05)
Firm nonfocal domain exploitation (510ks)	0.00183***	0.00171***	0.00182***	0.00169***	0.00192***	0.00196***
	(0.000245)	(0.000246)	(0.000246)	(0.000246)	(0.000249)	(0.000249)
Firm Size (Logged)	-0.0266***	-0.0211***	-0.0263***	-0.0226***	-0.0196***	-0.0250***
	(0.00674)	(0.00668)	(0.00701)	(0.00670)	(0.00669)	(0.00704)
Observations [c]	22376	22376	22376	22376	22376	22376

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

c. firm, domain, and time fixed effects

Table 3.6 Logit estimations effects of PMA families on Exploitation Choice

TABLE 3.6

Robustness Check Regression Analysis (Shift to Exploitation)

	(Logit) [a]				
	DV= ExploitationChoice				
	(7)	(8)	(9)	(10)	(11)
FirmPMAFamilyCount (H1)	0.108***	0.150***	0.108***	0.136***	0.146***
	(0.00673)	(0.0182)	(0.00673)	(0.00772)	(0.0176)
FirmPMAFamilyCount_X_RivalPMAFamilyCount (H2)		-5.24e-05**			-6.46e-06
		(2.06e-05)			(2.05e-05)
FirmPMAFamilyCount_X_Startup_ID (H3)			4.524***		3.957***
			(1.637)		(1.514)
FirmPMAFamilyCount_X_FirmRecallCount (H4)				-0.00470***	0.00471**
				(0.000734)	(0.000760)
RivalPMAFamilyCount		0.000717**			-0.000116
		(0.000354)			(0.000374)
Startup_ID			-0.431		0.446
			(0.655)		(0.655)
Firm Recall Count				0.0909***	0.0913***
				(0.0161)	(0.0167)
Firm focal exploitation (510ks)	-0.0558***	-0.0573***	-0.0559***	-0.0657***	-0.0667***
	(0.00402)	(0.00418)	(0.00402)	(0.00472)	(0.00487)
Firm focal related exploration (PMAs)	-0.00398***	-0.00416***	-0.00397***	-0.00448***	0.00454**
	(0.000336)	(0.000344)	(0.000336)	(0.000332)	(0.000342)
Firm nonfocal domain exploration (PMAs)	0.00218***	0.00225***	0.00220***	0.00270***	0.00280***
	(0.000371)	(0.000376)	(0.000371)	(0.000399)	(0.000409)
Firm nonfocal domain exploitation (510ks)	-0.00105	0.000842	-0.00111	0.00261	0.00267
	(0.00240)	(0.00254)	(0.00240)	(0.00249)	(0.00252)
Firm Size (Logged)	0.190***	0.164**	0.176***	0.262***	0.244***
	(0.0622)	(0.0639)	(0.0622)	(0.0642)	(0.0658)
Observations [c]	22,012	22,012	22,012	22,012	22,012

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

c. firm, domain, and time fixed effects

Table 3.7 Probit estimations effects of PMA families on Exploitation Choice

TABLE 3.7
Robustness Check Regression Analysis (Shift to Exploitation)

	(Probit) [a]				
	DV= ExploitationChoice				
	(12)	(13)	(14)	(15)	(16)
FirmPMAFamilyCount (H1)	0.0640***	0.0873***	0.0640***	0.0785***	0.0852***
	(0.00383)	(0.0102)	(0.00383)	(0.00418)	(0.0101)
FirmPMAFamilyCount_X_RivalPMAFamilyCount (H2)		-3.18e-05***			-9.49e-06
		(1.12e-05)			(1.13e-05)
FirmPMAFamilyCount_X_Startup_ID (H3)			2.075***		1.778***
			(0.603)		(0.573)
FirmPMAFamilyCount_X_FirmRecallCount (H4)				-0.00215***	-0.00209***
				(0.000308)	(0.000314)
RivalPMAFamilyCount		0.000542***			0.000152
		(0.000187)			(0.000194)
Startup_ID			-0.00447		0.399
			(0.370)		(0.367)
Firm Recall Count				0.0397***	0.0387***
				(0.00656)	(0.00672)
Firm focal exploitation (510ks)	-0.0325***	-0.0329***	-0.0326***	-0.0366***	-0.0367***
	(0.00231)	(0.00239)	(0.00230)	(0.00249)	(0.00256)
Firm focal related exploration (PMAs)	-0.00245***	-0.00254***	-0.00244***	-0.00269***	-0.00271***
	(0.000199)	(0.000203)	(0.000199)	(0.000197)	(0.000202)
Firm nonfocal domain exploration (PMAs)	0.00142***	0.00139***	0.00143***	0.00155***	0.00156***
	(0.000184)	(0.000186)	(0.000184)	(0.000193)	(0.000197)
Firm nonfocal domain exploitation (510ks)	-0.00199	-0.000901	-0.00202	-0.000551	-0.000300
	(0.00127)	(0.00132)	(0.00127)	(0.00129)	(0.00131)
Firm Size (Logged)	0.139***	0.121***	0.129***	0.174***	0.160***
	(0.0339)	(0.0347)	(0.0340)	(0.0344)	(0.0353)
Observations [c]	22,012	22,012	22,012	22,012	22,012

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

c. firm, domain, and time fixed effects

Table 3.8 Cloglog estimations effects of PMA families on Exploitation Choice

TABLE 3.8
Robustness Check Regression Analysis (Shift to Exploitation)

	(Cloglog) [a]				
	DV= ExploitationChoice				
	(17)	(18)	(19)	(20)	(21)
FirmPMAFamilyCount (H1)	0.0605***	0.0803***	0.0604***	0.0721***	0.0781***
	(0.00351)	(0.00875)	(0.00352)	(0.00379)	(0.00875)
FirmPMAFamilyCount_X_RivalPMAFamilyCount (H2)		-2.88e-05***			-1.13e-05
		(9.40e-06)			(9.55e-06)
FirmPMAFamilyCount_X_Startup_ID (H3)			1.535***		1.241***
			(0.407)		(0.374)
FirmPMAFamilyCount_X_FirmRecallCount (H4)				-0.00148***	0.00140**
				(0.000224)	(0.000228)
RivalPMAFamilyCount		0.000586***			0.000285*
		(0.000154)			(0.000158)
Startup_ID			0.218		0.515
			(0.334)		(0.323)
Firm Recall Count				0.0258***	0.0241***
				(0.00453)	(0.00463)
Firm focal exploitation (510ks)	-0.0308***	-0.0307***	-0.0310***	-0.0343***	-0.0338***
	(0.00225)	(0.00233)	(0.00226)	(0.00227)	(0.00236)
Firm focal related exploration (PMAs)	-0.00240***	-0.00249***	-0.00239***	-0.00255***	0.00256**
	(0.000196)	(0.000199)	(0.000196)	(0.000195)	(0.000197)
Firm nonfocal domain exploration (PMAs)	0.00141***	0.00133***	0.00142***	0.00143***	).00138***
	(0.000146)	(0.000148)	(0.000146)	(0.000152)	(0.000155)
Firm nonfocal domain exploitation (510ks)	-0.00390***	-0.00297***	-0.00391***	-0.00282***	-0.00247**
	(0.00105)	(0.00107)	(0.00105)	(0.00104)	(0.00105)
Firm Size (Logged)	0.160***	0.140***	0.149***	0.186***	0.167***
	(0.0275)	(0.0283)	(0.0277)	(0.0278)	(0.0288)
Observations [c]	22,012	22,012	22,012	22,012	22,012

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

c. firm, domain, and time fixed effects

Table 3.9 OLS estimations effects of PMA families on Exploration Choice

TABLE 3.9

Robustness Check Regression Analysis (Shift to Exploitation)

	(OLS) [a]				
	DV= ExplorationChoice				
	(22)	(23)	(24)	(25)	(26)
FirmPMAFamilyCount (H1)	-0.0113***	-0.0224***	-0.0114***	-0.0128***	-0.0224***
	(0.00118)	(0.00264)	(0.00118)	(0.00118)	(0.00266)
FirmPMAFamilyCount_X_RivalPMAFamilyCount (H2)		1.35e-05***			1.19e-05***
		(2.58e-06)			(2.58e-06)
FirmPMAFamilyCount_X_Startup_ID (H3)			-0.159**		-0.168**
			(0.0644)		(0.0657)
FirmPMAFamilyCount_X_FirmRecallCount (H4)				0.000245***	0.000224***
				(3.77e-05)	(3.73e-05)
RivalPMAFamilyCount		-0.000315***			-0.000304***
		(4.30e-05)			(4.33e-05)
Startup_ID			-0.219***		-0.243***
			(0.0526)		(0.0527)
Firm Recall Count				-0.00338***	-0.00296***
				(0.000696)	(0.000689)
Firm focal exploitation (510ks)	0.00618***	0.00641***	0.00620***	0.00624***	0.00639***
	(0.000513)	(0.000520)	(0.000513)	(0.000531)	(0.000539)
Firm focal related exploration (PMAs)	0.000440***	0.000466***	0.000439***	0.000442***	0.000463***
	(6.61e-05)	(6.70e-05)	(6.61e-05)	(6.57e-05)	(6.67e-05)
Firm nonfocal domain exploration (PMAs)	-0.000380***	-0.000412***	-0.000385***	-0.000396***	-0.000432***
	(3.19e-05)	(3.25e-05)	(3.19e-05)	(3.20e-05)	(3.27e-05)
Firm nonfocal domain exploitation (510ks)	-0.00171***	-0.00182***	-0.00169***	-0.00192***	-0.00196***
	(0.000246)	(0.000246)	(0.000246)	(0.000249)	(0.000249)
Firm Size (Logged)	0.0211***	0.0263***	0.0226***	0.0196***	0.0250***
	(0.00668)	(0.00701)	(0.00670)	(0.00669)	(0.00704)
Observations [c]	22,376	22,376	22,376	22,376	22,376

a. Standard errors in parentheses, *** p<0.001, ** p<0.01, * p<0.05, + p<0.1, two sided tests

b. Standard errors clustered in firm ID, two sided tests

c. firm, domain, and time fixed effects

Figures

Figure 2.1 Hypotheses and model for Chapter II

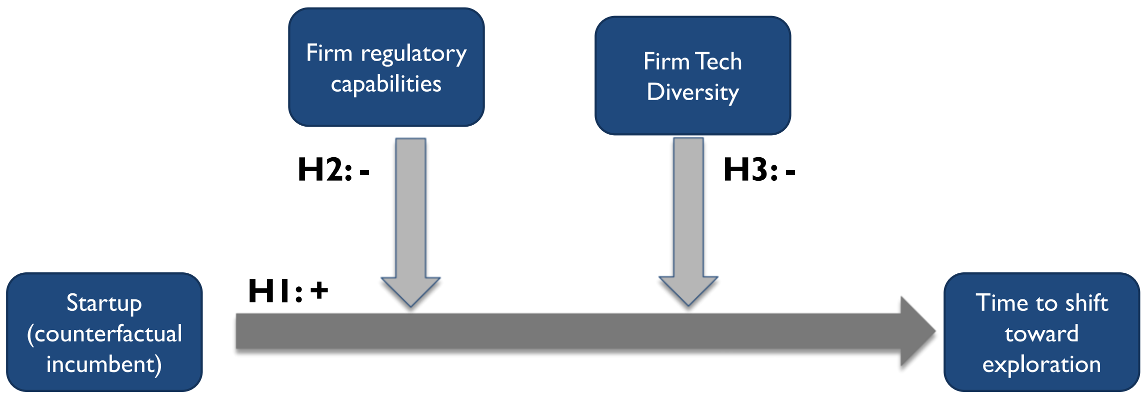


Figure 2.2 Sample of medical device FDA PMA entry

Device	Replacement Heart-valve
Regulation Description	Replacement heart valve.
Definition	Call for pmas to be filed by 12/9/87 (52 fr 23137 (6/17/87))
Regulation Medical Specialty	Cardiovascular
Review Panel	Cardiovascular
Product Code	DYE
Premarket Review	Cardiovascular Devices[6] (OHT2) Circulatory Support, Structural and Vascular Devices (DHT2B)
Submission Type	PMA
Regulation Number	870.3925[7]
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	No

Recognized Consensus Standards

- 3-145 ISO 5840-1 First edition 2015-09-15
  Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements[9]
- 3-147 ISO 5840-2:2015 First Edition
  Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes[10]

Figure 2.3 Sample of medical device FDA 510K entry

Device	Pacemaker Lead Adaptor
Regulation Description	Pacemaker lead adaptor.
Regulation Medical Specialty	Cardiovascular
Review Panel	Cardiovascular
Product Code	DTD
Premarket Review	Cardiovascular Devices[6] (OHT2) Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A
Submission Type	510(k)
Regulation Number	870.3620[7]
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	No

Recognized Consensus Standard

- 3-132 ISO 27185 First edition 2012-02-15
  Cardiac Rhythm Management Devices - Symbols to be Used With Cardiac Rhythm Management Device Labels, and Information to be Supplied - General Requirements[9]

Figure 2.4 Research Design for Chapter II

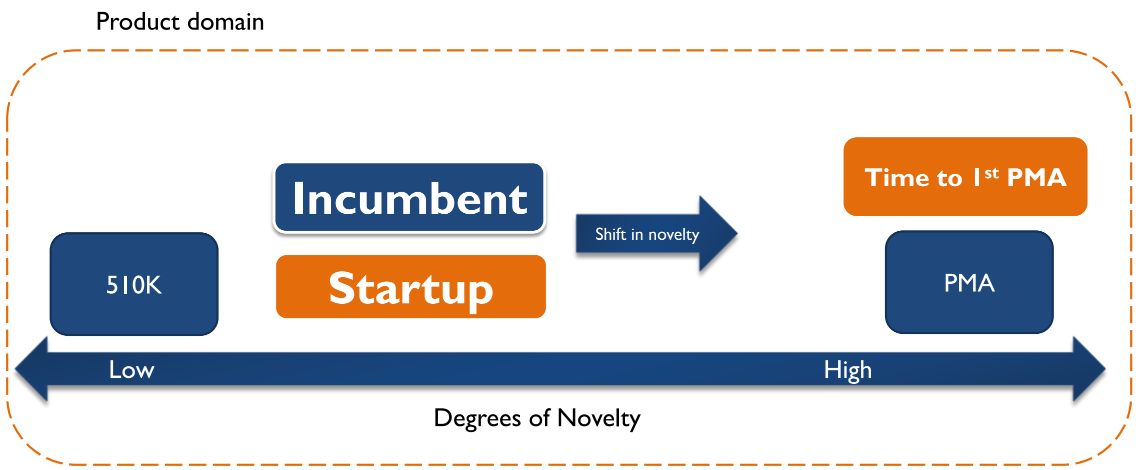


Figure 2.5 Kaplan Meier Plot of main effect Chapter II

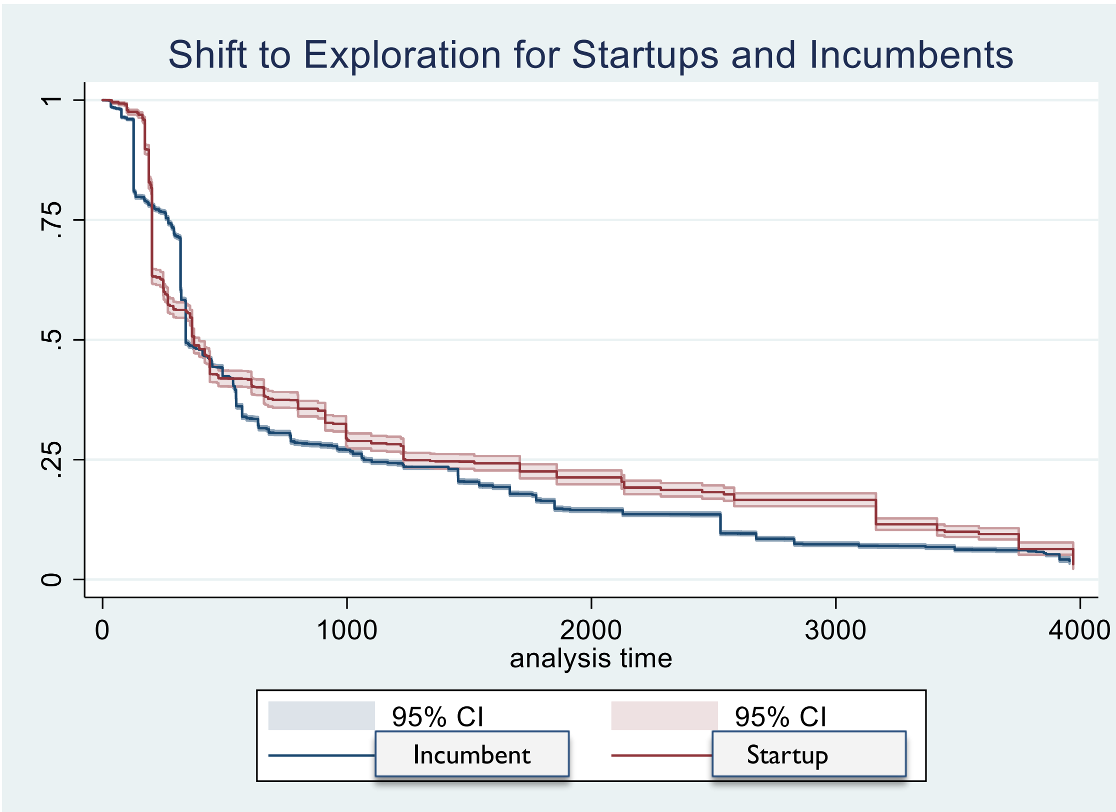


Figure 2.6 Kaplan Meier Plot of FDA review time difference for incumbents and startups Chapter II

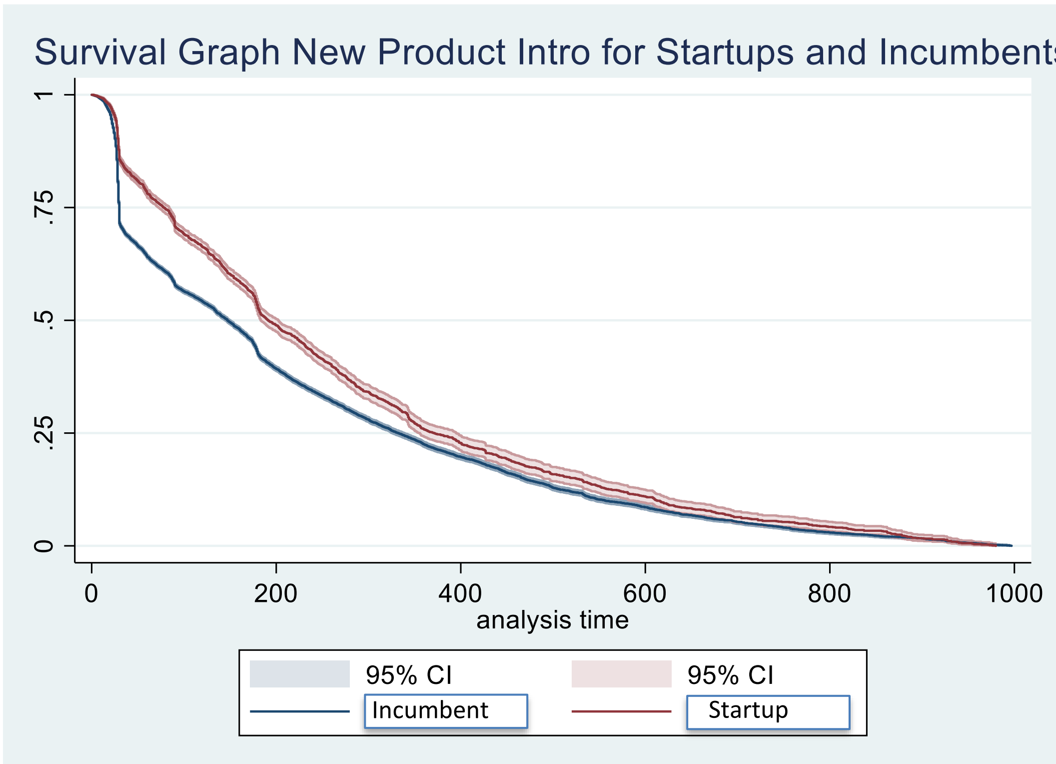
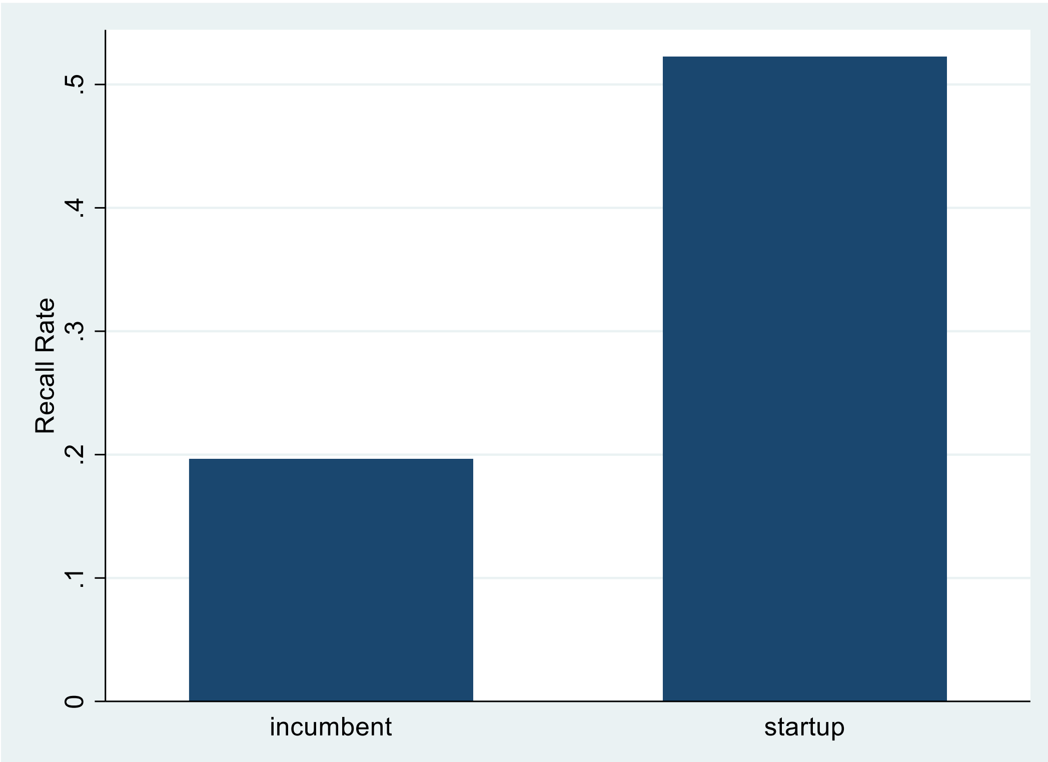
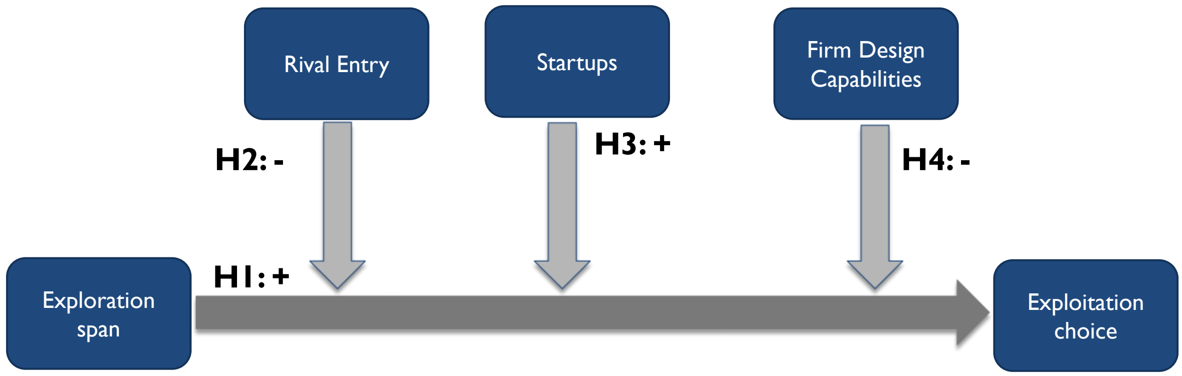


Figure 2.7 Recall rate difference for incumbents and startups Chapter II



Note*: recalls include class 1 and 2 (most serious and most common)

Figure 3.1. Hypotheses and model for Chapter III



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