

Pioneer (Dis-)advantages in Markets for Technology

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Working Paper 19-043



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Funding for this research was provided in part by Harvard Business School.

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Abstract

This study sheds new light on first- and early-mover advantages in the context of product innovation. Research on this classic topic often assumes that each firm participates in the entire innovation process. However, a division of labor between innovative new entrants and incumbents with complementary assets is common in many industries. In such settings, small new entrants have the additional option to be acquired in a “market for technology.” Using data from the U.S. medical device industry, we find that pioneers “pave the way” for a new product type to reduce the technological and market risks, where the former is of paramount importance. Although pioneers ultimately realize a higher likelihood of acquisition, they wait longer to be acquired. Therefore, to some extent, later movers can free ride on early-movers’ efforts.

Keywords: First-Mover Advantages, Markets for Technology, M&A, Technology Acquisition, Medical Devices

Acknowledgements: We are grateful to Richard G. Hamermesh, Ashish Arora, George Ball, Josh Krieger, David Ku, Hong Luo, and Thomas Rønde for helpful discussions and to Jacqueline Chen and Lila Kelso for wonderful research assistance. We thank seminar participants at Harvard University, the Technical University of Munich, the Ludwig Maximilian University of Munich, the Max Planck Institute for Innovation and Competition, the TUM Heilbronn Workshop on Technology Acquisitions, and the Academy of Management for helpful comments. EvaluateMedTech (EMT) generously provided regulatory and product data. Moritz Fischer gratefully acknowledges financial support from the Schöller-Stiftungen, TUM Graduate School, and Harvard Business School. Ariel D. Stern gratefully acknowledges support from the Kauffman Junior Faculty Fellowship.

INTRODUCTION

The question of when and how to enter a new market is central to a firm's innovation strategy. Scholars have identified a number of advantages and disadvantages to being a first-mover (Lieberman and Montgomery 1988 and 1998, Kerin et al. 1992, VanderWerf and Mahon 1997, Suarez and Lanzolla 2007). While this body of research has greatly improved our understanding of the (dis)advantages of early entry into new markets, existing scholarship often implicitly assumes that each firm participates in the entire innovation process and that all firms aim to monetize their innovations in (emergent) product markets. However, in many cases, pioneering small entrants have an additional path for realizing returns on an innovation: they can also sell their innovation to a larger and established firm (Granstrand and Sjölander 1990, Gans and Stern 2003).

There may be gains from such a division of labor in the innovation process, with smaller firms playing a greater role in early-stage innovation and larger firms specializing in later-stage activities (Arora et al. 2001). Many scholars have recognized this: Schumpeter (1912) noted that pioneers (i.e. first- or early-movers to enter a new product market) are often new and/or small entrants—i.e. firms not previously established in that industry (Scherer 1980, Teece 1986, Christensen 1997), while others have shown that large firms are likely to already possess expertise in core activities such as sales, marketing, manufacturing scale-up, and distribution in final product markets (see e.g., Teece, 1986, Christensen, 1997). As a result, intermediate “markets for technology” (MFTs) are common and found in industries ranging from pharmaceuticals and chemicals to semiconductors, software, and telecommunications (e.g., Arora et al. 2001, Angell 2004, Higgins and Rodriguez 2006, Warner et al. 2006, Ransbotham and Mitra 2010, Brueller et al. 2015, Henkel et al. 2015, Allain et al. 2016) and scholars have acknowledged the important role they play in helping firms to stay competitive in industries characterized by technological complexity, and reliance on highly specialized skills and expertise (Ranft and Lord, 2002).

This study outlines a novel way of evaluating questions of early-mover advantage vs. disadvantage in settings when the primary path to monetizing an innovation is selling that innovation in an MFT rather than in a final product market. In doing so, we bridge the gap between the literature on first- and early-mover advantages and the literature on MFTs. In traditional product markets, early entrants are influenced by advantageous market positioning, higher switching costs of customers, lock-in effects, cooperation with desirable partners, and

higher technological and market uncertainty. All of these factors remain relevant in our context as long as an early-mover position in an MFT coincides with early entry in the corresponding product market. In addition, early entrants in MFTs must consider information asymmetries between potential transaction partners, firm risk preferences, and the linkage of complementary resources. Furthermore, MFTs often result in a binary outcome: there is either a transfer of innovation from an originator to an exclusive buyer through an acquisition—or not.

We evaluate pioneer (dis-)advantages in a context where innovator firms typically seek acquisition and where potential buyers are equipped with superior resources for product market sales and other later-stage commercial activities. We ask two questions: first, is it advantageous for small new entrants to be pioneers in an MFT setting if they wish to be acquired? Second, how does being a pioneer relate to the timing of acquisition? Since a small new entrant will typically lack the complementary assets required to successfully commercialize an innovation, it is widely believed that being acquired and being acquired earlier are desirable outcomes, and we provide empirical evidence that supports this reasoning. Thus, analyzing outcomes for small new entrants can inform both a theoretical and empirical study of early market entry as it relates to strategic advantages and disadvantages in MFTs.

Our empirical setting is the U.S. medical device industry. We assemble a comprehensive dataset covering all high-risk medical devices that came to market over a roughly 25-year period. This context is particularly appropriate for a study of first-mover advantages because the emergence of new, independently defined product categories allows for a clear observation of entry order, and detailed administrative data facilitate precise identification of market entry dates. Combined with a newly assembled dataset of medical device firm acquisitions, we reconstruct detailed product histories and timelines for each device and innovator firm in the sample. Consistent with theoretical considerations regarding research- and development (R&D)-intensive settings, robust MFTs characterize the medical device industry, and the division of labor between innovative entrants and established companies manifests itself in frequent acquisitions of small firms by larger industry incumbents.

We find that for small new entrants, being a first- or early-mover (a “pioneer”) in a new product category is associated with a higher likelihood of acquisition, which is the desired outcome for such firms. Furthermore,

we find that the hazard of acquisition increases significantly at the time when the U.S. Food and Drug Administration (FDA) establishes a new product category for the focal type of device. This event signals a discrete and publicly observable reduction in the general technology risk of a new product type, and assures potential buyers of the product’s technical viability, facilitating technology transfer via a concrete reduction of uncertainty (compare Gans et al. 2009). Inherently, this milestone—establishment of a novel product type—has to be achieved by one of the pioneers. Among acquired firms, we find that pioneers are acquired at a later stage, which can be explained by higher levels of commercialization uncertainty relative to followers. Considering alternative explanations of this acquisition timing, we compare pioneers’ acquisition prices to those of later entrants, but fail to find any evidence that small new entrants in this setting can expect higher exit prices in the case of later acquisitions. We supplement our empirical analysis with qualitative evidence from expert interviews, supporting the view that small new entrants have a strong preference for early acquisition.

We conclude that pioneers’ (dis-)advantages in an MFT setting differ from more traditional product market settings in three ways. First, there is (depending on the timing of the technology transfer) potentially more technological uncertainty in MFTs as compared to traditional product markets that have already resolved technological uncertainty prior to market launch through product testing. This is highlighted in our empirical models by the strong increase in the acquisition hazard observed when technological uncertainty declines as a result of FDA approval of a first-of-a-kind product and the establishment of a new product category (a so-called “product code”). Second, in MFTs, there is a binary outcome—i.e., whether a small new entrant is acquired, while in a traditional product market, the outcomes of interest are sales and revenues (which are continuous and spread over time). Third, later prospective buyers need to select their acquisition targets from among the firms not yet acquired (often later movers). This could potentially lead to the acquisition of a firm whose product is of comparable or even lower quality than that of the already acquired firms if the buyer perceives the presence in the new product category as strategically important. This outcome stands in stark contrast to the situation seen in traditional product markets, where, absent binding capacity constraints, buyers are final product market customers, who can buy from the pioneer.

BACKGROUND: MARKETS FOR TECHNOLOGY AND PIONEER ADVANTAGES

Pioneer disadvantages

As seen in Jones et al. (2001), pioneering a new product type is often associated with disadvantages such as “discontinuous technological change and characterized by a high[er] degree of technical uncertainty [...]” (p. 261). We note that this argument is particularly relevant in the healthcare context because it takes pioneers longer to demonstrate technical feasibility, product quality, safety, and effectiveness (Stern 2017). Furthermore, pioneer entrants face higher market uncertainty than followers regarding the rate and extent of (potential) user adoption, preferences, and readiness. In an experimental study, Zhou and Nakamoto (2007) show that when buyers are less familiar with a product category, they will “prefer a product with enhanced features [i.e. improvements of existing products] to one with unique features [i.e. pioneering products]” (p. 53). Such preferences may further raise the bar for adoption of products developed by first- and early-movers in a new product market. These product market arguments also carry over to MFTs, to the extent that earlier entry in an MFT is associated with earlier product launch—which, as we show, is the case in the setting we study.

Even with perfect predictability, a pioneer will typically face higher costs when developing a technical solution and educating the market (Lieberman and Montgomery 1988). Unless barriers (such as broad patents, brands, or preemption of scarce resources) prevent imitation, followers will benefit from spillovers through reduced costs of new product development (Stern 2017). Relatedly, Rasmusen and Yoon (2012) discuss the phenomenon of missing information superiority, or the lack of precedent for pioneer entrants. As a result, pioneers bear the cost and risk of gathering resources, which may turn out to be “wrong” as the market evolves (Lieberman and Montgomery 1998).

In the context of MFTs, additional considerations are likely relevant. While the technology-seller/technology-buyer dyad faces the same pioneer disadvantages as an integrated innovator, the transaction occurring between the two adds new aspects to the relationship. First, there is greater asymmetric information and transactional uncertainty for buyers due to the technological uncertainty of pioneers’ products (see, e.g., Stein and Henkel, 2017, who argue that information asymmetry between technology sellers and buyers is particularly high if a product with a new functionality is subject to acquisition. This is close to our definition of a pioneering product). Second, publicly listed firms are likely to have more risk aversion when deciding to acquire smaller

firms (e.g., Frijns et al., 2013), which is relevant for our setting because publicly listed firms dominate the buyer landscape. This then makes early acquisitions of pioneer technologies less attractive, as the buyer's absolute uncertainty tolerance may increase the transaction costs. Thus, on top of the potential information asymmetric information between the seller and buyer, there is additional technological and market uncertainty compound in MFTs. This phenomenon is even more apparent for pioneer technologies because the benchmark for valuing the new product type does not yet exist.

Pioneer advantages

Previous literature on product markets has outlined a number of characteristic advantages associated with being a pioneer, and two of these characteristics are particularly prominent. First, market position is beneficial for early-movers (Lieberman and Montgomery 1988): pioneers that avoid “me-too” positioning are among the first to capture a significant share of a finite market and can team up with the most desirable partners. Consequently, first- and early-movers often enjoy sustainable pricing and market share advantages (Makadok 1998). In addition, uncertain buyers tend to stick with the first brand that offers a certain product or service when only imperfect information on product quality is available (Schmalensee 1982). Second, the presence of post-adoption switching costs among customers and users is typically seen as an advantage for pioneers (Lieberman and Montgomery 1988, Gómez and Maicas 2011). Before competitors arrive, pioneers can not only capture a bigger share of market volume, but also lock-in customers, allowing them to maintain their market position. This is particularly true if a product requires supplier-specific learning for successful use. Consequently, high switching costs often “enhance value of market share obtained early in the evolution of a new market” (Lieberman and Montgomery 1988, p. 46, referring to Klemperer 1987 and Wernerfelt 1986, 1988). Mojir and Sudhir (2017) underscore this argument with empirical evidence from the medical device space itself, finding that buyers often face “pushback from the user (i.e., surgeon) when deciding to switch to a new (i.e., different) technology” (p. 38).

In addition, pioneer entrants accrue several context-specific advantages. *Ceteris paribus*, being a pioneer in a new product category should result in more media coverage, more attention from investors, and additional

financing from more reputable investors. Therefore, the company is better positioned at later stages to find an attractive buyer for its technology.

Finally, Schoenecker and Cooper (1998) empirically show that a firm's market pioneering and early market entry are positively associated with greater technological resources in that firm. If potential acquirers use this association as a heuristic for their acquisition strategy, then being early becomes an advantage for small new entrants because it sends a signal: established firms will expect to gain (better) access to desirable technology, skills, and capabilities by acquiring a pioneer, even if its technology is not of superior quality.

All these advantages will translate into advantages for the pioneering technology-seller in an MFT to the extent that being early in an MFT accompanies early entry into the product market (an adaption of Ransbotham and Mitra 2010). These pioneer advantages should translate into higher acquisition likelihood for early-movers as long as the acquirer can capture (some of) the value of pioneer entry.

HYPOTHESES DEVELOPMENT

We build upon the theoretical implications of pioneer (dis-)advantages outlined in the previous sections in order to develop two hypotheses. The first focuses on acquisition likelihood and the second on the timing of such acquisitions. In the Online Appendix, we summarize additional considerations and related literature behind our hypotheses.

Acquisition likelihood of pioneering small new entrants

Entrepreneurs often value independence and control over their firm (e.g., Wasserman 2008). However, in general, founders will prefer to sell their firm (or technology) to an incumbent if established firms have a significant comparative advantage in later stages of the innovation and commercialization process. This dynamic is confirmed by our study and was separately articulated in interviews with veteran investors in the medical device industry, our empirical context. This is also broadly consistent with the theory of technology markets: where there is specialization among firms in the new product development process (e.g. R&D, commercialization, sales, manufacturing, scale-up, etc.), "gains from trade" will exist.

The central question we consider is whether and how the buyer of a technology cares if a small new entrant is a pioneer entrant in a product market. As noted above, many pioneer advantages are structural advantages,

giving reason to believe that they can serve as the basis for durable competitive advantages. These include high switching costs among customers, favorable market position (high visibility plus a large number of desirable partners), as well as high-quality technological resources, skills, and capabilities (due to self-selection). Thus, we hypothesize that, conditional on successful market entry, pioneers are more likely to experience acquisition:

H1: Earlier market entry by a small new entrant is positively associated with acquisition likelihood.

Acquisition timing of pioneering small new entrants

Many challenges associated with pioneer entry are dynamic and diminish (or even disappear) over time. Perhaps the most obvious challenge is the absence of (accumulated) knowledge of a certain product type at the time when a pioneer enters a market that, by definition, was previously non-existent. As a result, at comparable points in their product life cycle, pioneers are likely to carry greater technological and market risk than later followers. In our hypotheses, we consider these challenges as well as risk aversion, information asymmetry, and expectations.

We assume that technology buyers and their shareholders are risk averse and will worry about high(er) levels of uncertainty around an acquisition (Asquith 1983; Frijns et al. 2013). This should be particularly true for publicly traded firms because they are under constant scrutiny from analysts and accountable to shareholders. In contrast, radical innovations by small new firms are relatively high risk, which is reflected by the frequent need for venture capital financing. This implies that *ceteris paribus*, a reduction in risk favors a transfer of the innovation to an incumbent.

Information asymmetries may lead to similar dynamics. Assuming that the managers of a small new entrant firm know more about the prospects of its technology than a potential acquirer, the latter may want to delay an acquisition until uncertainty is sufficiently reduced, lest it encounter a “lemons problem.”

Finally, differences in expectations may also affect acquisition timing. If the prospective seller is more optimistic about the target’s future value, then it will prefer to delay a transaction until uncertainty is resolved rather than accepting a price discount (Allain et al., 2016). All three arguments presented here are consistent with Alvarez and Stenbacka’s (2006) finding that uncertainty can delay takeovers and acquisitions until the associated risk has reached a certain acceptable threshold.

As a result, reducing uncertainty around a new technology, its market, and a particular firm offering it should increase the probability of the firm being acquired. We argue that part of the uncertainty surrounding a

small new entrant is related to a novel product category, not the firm itself. Thus, it will take longer for pioneers' products to fall below an acceptable risk threshold before acquisition. As such, we hypothesize that:

Acquisition hazard increases following events that reduce

H2a: ... the general technology risk of a new product type.

H2b: ... the general market risk of a new product type.

H2c: ... the firm-specific technology risk.

Thus:

H2d: Among acquired firms, pioneers wait longer for acquisition after market entry (where we note that H2d is interrelated with H2a and H2b.)

EMPIRICAL SETTING

Study setting and defining pioneer entrants

Our empirical setting is the U.S. medical device industry. We assemble a comprehensive dataset covering all high-risk medical devices that came to market over a roughly 25-year period. The U.S. medical device industry is an ideal setting to study first- and early-mover advantages for two primary reasons. First, the innovation process is highly standardized; any incumbent and new entrant must pass the same set of milestones throughout the innovation process. Second, the regulatory environment allows for complete and precise observation of market entry, which is a valuable feature for investigating both of our timing-related hypotheses on market entry. Combined with a newly assembled dataset of medical device firm acquisitions, we reconstruct detailed product histories and timelines for each device and innovator firm in the sample.

Consistent with theoretical considerations regarding research and development (R&D)-intensive settings, the medical device industry is characterized by robust MFTs, and the division of labor between innovative entrants and established companies manifests itself in frequent acquisitions of small firms by larger industry incumbents. In this context, over 70% of firms in our sample classified as small new entrants experienced acquisition during our period of observation. Publicly listed incumbents were responsible for nearly two thirds of all acquisitions (65%). 19% of all U.S. Food and Drug Administration (FDA) approvals in the product categories established between 1985 and 2010 are tied to small new entrants, and the share of new product

categories established by these entrants is even larger (28%). The market that we consider is not a market for standalone technologies, but rather one for young technology firms. However, because this study focuses on small new entrants that are technologically focused, each firm essentially corresponds to one technology. The business strategy in this setting is precisely that of quintessential MFTs: the technology changes hands because the acquirer is better positioned than the original owner to execute on the remaining steps of the innovation and commercialization process.

We define small new entrants based on two characteristics: (1) they have fewer than five years of high-risk device experience in total, and (2) they have a small or non-existent portfolio of previous products (for our purposes, no more than one other device). Both criteria are assessed based on a firm-specific FDA product history. We measure the “earliness” of entry based on elapsed time since the establishment of a product category (rather than as a discrete function of entry order). While both measurements are potentially useful (Lieberman and Montgomery 1988), the former is more appropriate in this study’s context, as factors potentially determining first-mover (dis-)advantages change over time, rather than with entry order.

The U.S. medical device industry and FDA approval

The United States is the world’s largest medical device market and is worth more than \$140 billion USD annually (Statista, 2018). In the United States, the FDA regulates all medical devices: it is the sole authority that grants market access to a medical device manufacturer wanting to sell a product in the United States. FDA approval of a high-risk device marks the endpoint of a lengthy, costly, and uncertain new product development process. The presence of entry regulation largely determines several steps and actions that firms must take along the way. For example, after idea generation and early technological development, innovators typically work with the FDA to design clinical trials that are likely to meet the regulatory standards required for device approval (Kaplan and Stern, 2018). Such an approval results in the resolution of a great deal of technological uncertainty around a specific product’s safety and effectiveness. However, market uncertainty may take longer to resolve and may last well into the device’s commercialization.

CMS coverage: discrete reduction in market risk

In the regulated medical device setting, innovator firms often have to convince national payers to reimburse health care providers for use of a new product type. For example, in the United States, this includes both the Centers for Medicare and Medicaid Services (CMS), as well as private payers, who typically follow CMS's decisions. Thus, there is an implicit reduction in market risk when national payers decide to reimburse providers for the use of new products.

Clear point of market entry

The U.S. medical device regulatory approval process is an asset for empirical research, as it ensures full observability of market entry. Lieberman and Montgomery (1988) agree with other scholars that the standard criterion for defining a first-mover is a firm that is first to bring a new product type to market (see also Schoenecker and Cooper, 1998, Makadok, 1998, Gómez and Maicas, 2011, and Rasmusen and Yoon, 2012). In the U.S. medical device setting, we can obtain precise (to the day) information on the timing of FDA approval of a new device, which signifies product market entry. Consistent with this, we note that the manufacturers of all high-risk devices that were granted FDA approval between December 1, 2016 and January 31, 2017 began marketing each product within a few days or weeks of their approval date.

Comparability of products and substitutes

After outlining a method for market entry date identification, we establish which products belong to the same product market to understand each market's timing and chronology of entry. In this respect, FDA regulatory data is valuable; FDA teams independently classify all devices and organize them into distinct and specific product codes and classes of therapeutic use. Products within the same code are comparable and substitutable with one another. In the Online Appendix, we provide an example of FDA medical device classification. As of Q4 2017, the FDA had established 324 unique product codes for high-risk devices.

Delineation of pioneers and later followers

Both of our hypotheses are related to the timing of market entry and the total time a product market has been in existence. Therefore, it is crucial to accurately measure elapsed time since the first-mover entered the market and the entrance of all follow-ons. This allows us to use a nuanced definition of "pioneers" based on timing of market entry rather than simply considering entry order, which is discontinuous and does not account for

elapsed time. Among high-risk medical devices, full observation of FDA product approvals over multiple decades facilitates this approach. For example, when an innovation represents a novel product category, an independent committee classifies and establishes a new product code. The FDA then tracks approvals (by calendar date) in this product code over time.

DATA AND METHODOLOGY

Analysis Population

We begin with a comprehensive survey of all high-risk medical devices brought to market in newly established product codes from 1985 to 2010. This provides complete and comparable outcome information for all products and firms for a full seven years after regulatory approval. We consider a total of 203 unique product codes for high-risk devices established by the FDA over our period of study. (As noted above, an independent classification panel assigns product codes, which identify a specific, categorical product type. For more information, see: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm>). In the 203 relevant product codes, the FDA approved 627 novel devices during the observation period, and these approvals constitute our baseline sample, allowing us to see all products that came to market over our period of study. FDA product approval data come from the Evaluate MedTech database (EMT), which provides full coverage of all high-risk device approvals over recent decades.

Because our theoretical context concerns new product categories, we include all firms that either established a new FDA product code or had a product approved in a newly created product code in the first seven years after that product code's establishment. Choosing a cut-off of seven years is likely to be long enough to capture the vast majority of followers in the long-cycled medical device market (see e.g., Chatterji 2009), but also represents a window of time that is short enough to allow us to capture followers rather than later generations of a device type. We also follow all small new entrants beyond the seven-year period from the time of product code creation. For example, if the FDA created a product code on January 2, 2000, we would track and include all entrants in that product code through January 1, 2007. However, for all *products* approved during that window, we continue to track acquisitions through the end of our period of observation (2017).

We next focus on the firms in our sample that will allow us to operationalize our research question, which are small new entrants in therapeutically relevant fields. We consider a firm *new* to the medical device industry if it has no more than five years of previous high-risk device experience before FDA approval of a given product. This criterion excludes any established firm with significant device industry experience. In addition, a firm is considered narrowly focused (*i.e. small*) if the number of previous high-risk medical devices it has commercialized is less than or equal to one. This ensures that the firm (and, if applicable, its acquisition) can clearly be associated with a specific technology, rather than a broad portfolio of products. Finally, we exclude devices in product codes with fewer than two successful FDA applications during our observation period in order to exclude niche products with limited therapeutic relevance. These criteria identify 80 small new entrants.

While these 80 small new entrants are unambiguously relevant to this study, we may otherwise fail to capture firms that were acquired *prior* to FDA approval. These firms represent a challenge because the “commercializing firm” listed in approval documents will not be the firm that created the device. To correct for potential mis-assignment of innovator firm status, we perform an exhaustive search of press releases for all remaining 546 FDA approvals (*i.e.* those by established firms), and identify and re-classify 39 small new entrants beyond the existing sample of 80 firms, where press releases at the time of the acquisition indicate a clear link between the focal device and the acquisition (for 12 out of these, the acquisition had taken place before FDA approval of the target’s device). This leads to a total of 119 small new entrants in the final sample. Table 1 presents examples of products included in this study, as well as details on their acquisition activities.

[Table 1 about here]

Product and financial data

For each new product, it is essential to have a clear understanding of innovation milestones, such as the establishment of intellectual property and a pathway for compensation, before and after FDA approval. Therefore, we collect data on patents from the U.S. Patent and Trade Office (USPTO) database and data on the timing of reimbursement decisions from the Centers for Medicare and Medicaid Services (CMS), including local and national coverage reports.

To properly classify entrepreneurial outcomes for small new firms in our sample, we collect data on each firm's status (failed, standalone, or acquired) and data on annual revenues from Mergermarket, Google Finance, and company press releases. For firms that were acquired, we also collect additional information on the timing of each acquisition (announcement date) as well as transactional values, where known. Following other scholars, we consider the announcement date as the date of acquisition (e.g., Puranam et al. 2009, Ransbotham and Mitra 2010, Brueller et al. 2015). Press releases reliably report the announcement date (but not the closing date), especially for small transactions. For 29 of the 86 acquisitions in our sample, we know both dates; press releases suggest only a small lag of 1.77 months between acquisition announcement and closing (standard deviation 1.98 months). Acquisition data come from the sources noted above, as well as from S&P Capital IQ and Bloomberg. In order to look for evidence of patterns in acquisition behavior, we investigate acquirer firms further but do not find evidence of selection in acquisition behavior. In our sample, it does not seem that pioneers are more/less often purchased by top acquirers in the industry (top 30 acquirers were determined by historic deal-data in the medical device space covering more than 7,300 transactions between 1970-2016, Source: Capital IQ), nor that pioneers are more/less often purchased by publicly listed firms.

Dependent variables

To evaluate Hypothesis 1, we consider two indicator variables. *Firm status* is measured by a multinomial variable that takes on the value of 0 if a small new entrant failed, the value 1 if the entrant remained standalone, and the value 2 if it was acquired over the seven years after coming to market. *Acquired status* is a binary version of firm status that takes on the value of 1 if the small new entrant is acquired. As alternatives to being acquired, an innovator firm can sell unit licenses or distribution agreements of its technology. We focus on acquisitions, which represent the majority of medical device transactions in MFTs. Indeed, when cataloging different forms of collaboration between large and small medical device firms in the period from 1971 to 2017, we trace 73% of all insourced technologies to a company were via acquisition, while only 11% correspond to technology licensing, and 16% to distribution agreements (analyses from Evaluate MedTech).

To evaluate Hypotheses 2a through 2d, we look at variables around acquisition timing. *Time since incorporation* reflects a focal firm's age. While this measure varies with time, Table 2 reports summary statistics for the

points in time when a firm is acquired, fails, or to the end of the observation period (December 31, 2017). We calculate *Time since FDA approval* similarly; the only difference is that this period begins with the date of a given firm's approval.

Conditional on acquisition, *Time to acquisition* reflects the elapsed time between a device's FDA approval and its acquisition and is negative in the rare cases in which a firm was acquired prior to FDA approval. This measure is a good proxy for a firm's maturity at the time of acquisition (an adaptation of Chaudhuri et al. 2005, Ransbotham and Mitra 2010, and Brueller et al., 2015). *Deal value* is the natural logarithm of the acquisition price (in millions of U.S. dollars). Data on transaction values are available for 87% of all acquired firms.

Independent variables

In accordance with our hypotheses, all of our independent variables are time related.

Product code age at approval represents the elapsed time between the establishment of a product code (FDA approval of the first-mover) and the market entry of a given device (FDA approval of the focal firm). By definition, first-movers have a *product code age at approval* of 0, while other entrants can have any value up to 7 years. Translated into a time-varying covariate (tvc) for the survival analysis, *Product code age* reflects the age of a product code at any point in time until the firm fails, is acquired, or the observation period ends.

Product code established is also a tvc, defined by the date of FDA approval of the first-mover in a product code. The variable takes the value of one starting on the date of FDA approval, and is only considered in the survival analysis. This binary variable's change from zero to one marks a discrete and significant drop in technological risk for *any* firm that enters this product code beyond this date.

Similarly, *FDA approval* is a tvc that changes from zero to one on the specific date of the focal firm's FDA approval. This also marks a discrete drop in technological risk associated with the focal firm's device.

Product code reimbursed is also a time-varying covariate that takes the value of one following the date on which CMS makes a positive coverage decision for a product type. Beginning on this date, payers start to reimburse for procedures performed with this device type, implying a significant drop of market risk for any firm that enters this product market. In our sample, a positive reimbursement decision occurs on average 2.75 years after the first-mover's FDA approval for a product type (standard deviation 3.72 years).

Control variables

A number of control variables capture characteristics of the target and the M&A environment. *Patents at approval* gives the natural logarithm of the number of U.S. patents (+1) associated with a small new entrant at the time of FDA approval. Accounting for changes in the number of patents over time, *Patents* reflects the time-varying natural logarithm of the count of patents (+1) a focal firm holds at all points in time during the observation period. We construct a linear interpolation between three distinct points in time: the date on which a given firm receives an initial patent, the date of the device's FDA approval, and the end of the observation period (date of shutdown, acquisition, or December 31, 2017).

Medical specialties are a set of categorical variables indicating the different therapeutic areas of the devices in our sample. These represent 20 regulatory medical specialties defined by the FDA, which we aggregate into three broad categories with the support of a physician coder: (1) cardiovascular devices, (2) radiology devices, and (3) other devices. These categories allow us to account for differences across medical practice areas, which may have different sales models, customer bases, and applicants, as well as different innovation models (such as investments requirements, typical length of new product development cycles, product-life cycles, R&D process, etc.).

We also account for regulation and likely buyer competition in MFTs: *Number of potential buyers at acquisition* gives the natural logarithm of the number of potential acquirers (+1). This measure controls for the degree of buyer competition in the cases where a small new entrant is acquired. Consistent with our patent control, *Number of potential buyers* translates this logic into a time-varying covariate reflecting the natural logarithm of the number of potential buyers at any point in time until the end of the observation period. We construct a linear interpolation between the same distinct points in time as those used for the patent control. For both buyer-related variables, we follow Allain et al. (2016), who argue that the number of firms with a track record in related markets represents a reasonable proxy for the number of potential acquirers, since they have the capabilities needed to evaluate a potential acquisition target and to market that firm's device. Acquiring a small new entrant likely requires specific organizational capabilities on the part of the buyer to ensure a sufficient degree and speed of integration (e.g., Ranft and Lord 2002, Angwin 2004, Homburg and Bucerius 2006, Puranam et al. 2009,

Bauer and Matzler 2014). Therefore, we follow three principles in identifying the relevant set of potential buyers. First, a potential buyer must be active in a proximate product space. In our context, this means firms have an existing product that is FDA-approved in the same regulatory medical specialty as the small new entrant's product (e.g., radiology devices). Second, a potential buyer must be a firm with at least five years of acquisition experience and a minimum of three acquisitions. We choose cutoffs of five years and three acquisitions based on empirical evidence that shows deteriorating incremental value of M&A experience both from acquisitions dating further back in time and from a higher number of such deals (Sampson, 2005). Finally, a potential buyer's acquisition experience must be relatively recent: the last acquisition must be within three years of the focal date. These principles were separately validated in our expert interviews.

RESULTS AND DISCUSSION

Descriptive results

Table 2 provides summary statistics for the variables in our empirical analysis. We construct a balanced sample of 119 devices originating from small new entrants. These consist of products from 56 first-movers (47%) and 63 followers (53%). Across all small new entrants, 86 firms (72% of those observed) were acquired. Alone, these summary statistics suggest that a robust MFT exists in the high-risk medical device space.

[Table 2 about here]

Conditional on acquisition, the vast majority (86%) of small new entrants were acquired *after* their products' respective FDA approval (and thus after the first-mover's FDA approval). On average, an acquired firm experienced a sale 6.57 years after its product's FDA approval.

One may be concerned that, due to the FDA's internal processes, the timing of approval (and, thus, of market entry) is only partly under the control of the respective firm. However, the date of the FDA approval is highly correlated ($r = 0.98$) with that of the FDA submission, and the latter is—to a large extent—under the control of the focal firm. Indeed, formal regulatory review deadlines exist (e.g., 180 days for review of a novel high-risk device), which allow firms to anticipate when a new product will be approved (conditional on the firm having submitted a complete regulatory approval application and dossier). For pairwise relationships, we find that among 84 dyads of entrants within the same product code, there were only five cases in which a later-

submitting firm received an earlier approval. Thus, the entrant's position as a pioneer or a later mover in the MFT is to a large extent within the entrant's control.

In the Hypothesis Development above, we argue that in an MFT setting, considerations relating to product market entry timing are important for acquisition. This is the case in the medical device industry, where FDA approval appears to be a condition for acquisition in the vast majority of cases, with only 12 out of 86 targets acquired before approval. The correlation between the date of FDA approval and that of acquisition is positive and significant ($r = 0.30, p = 0.004$).

Validation of assumptions

One of our central assumptions is that it is desirable for small new entrants to experience acquisition, as is the case in other high-tech settings such as software (see, e.g. Henkel et al. 2015). Our dataset provides descriptive support for this argument. Comparing deal values of all acquired small new entrants to the revenues for a majority of non-acquired entrants, we find that mean firm revenues five years after market entry are \$13.5 million for the 18 non-acquired firms, with only two of these firms earning annual revenues greater than \$30 million. In contrast, among the 75 acquired firms for which deal value information is available, median and mean acquisition prices were ~\$157 million and ~\$590 million, respectively. Comparing the more conservative median deal value of acquired firms with the average of revenues of non-acquired entrants results in a price/revenue-multiple of about 11 to 12. Such a scenario is likely quite attractive to a (potential) seller because the average price/revenue-multiple of the top 10 strategic M&A acquirers in healthcare and medical devices has historically been around four to six (analyses of historic average price/revenue-multiples are based on >600 transactions of Medtronic, GE, Essilor, Boston Scientific, Stryker, Integra Lifescience, Alere, Compus Medical, Siemens, Qiagen. Source: Capital IQ). High exit multiples in the industry suggest that acquisitions are desirable for small new entrants, supporting the assumption that they would seek acquisition, even beyond the fact that small new entrants are likely to be deficient in a broad set of necessary, complementary assets required to scale their business.

At the same time, endogeneity concerns prohibit a causal interpretation of these findings. To the extent that the highest quality small new entrants are acquired, acquisition will be positively correlated with firm quality.

Thus, the hypothetical multiple of 11 to 12 calculated above would reflect selection of high-quality acquisition targets (and as a corollary, lower quality of non-acquired firms), rather than the expected outcome of acquisition for all small new entrants. However, insights from discussions with entrepreneurs suggest that it is beneficial for *any* small new entrant to experience acquisition—even at a lower acquisition price: “It’s a win-win situation...[because] it prevents us from duplicating resources necessary to reach all these customers” (Chief Commercial Officer of a small new entrant).

Analysis 1: Acquisition likelihood

In order to assess whether early market entry is positively associated with a higher likelihood of acquisition, we estimate two empirical models: the first, M1, applies logit regression and considers *Acquisition status* as the dependent variable. The second model, M2, takes a slightly richer approach to considering firm outcomes by applying a multinomial logit specification, in which the variable, *Firm status*, reflects whether a small new entrant fails, remains independent, or experiences acquisition. In the Online Appendix, we introduce an example of three small new entrants A, B, and C in the same product code to illustrate the various firm-specific measures included in these models.

The leftmost columns in Table 3 report our logit estimates from M1. The first column shows results for the full sample of 119 firms; among these, acquisition likelihood is unequally distributed in favor of pioneers ($p = 0.005$). Coefficients reflect marginal effects at the sample means and suggest that entering a product code one year later is associated with a 4.0 percentage point lower likelihood of acquisition ($\beta = -0.040$). A one standard deviation increase in the timing of entry is associated with a nearly 11 percentage point (pp) decrease in the likelihood of acquisition—a substantial difference.

As an alternative independent variable, we consider *Cumulated Approvals before FDA*. The variable reflects the cumulated number of FDA-approved devices (startups plus incumbents) in the relevant product code at the time when the focal firm receives FDA approval. Using this metric as a control yields highly similar results for M1 and M2: a high number of comparable, previous approvals (by startups or incumbents) leads to a significantly lower likelihood of acquisition of the focal firm. We avoid using *Cumulated Approvals before FDA* in the same regression models with *Product code age at approval*, since these variables are highly collinear.

Moreover, and as reflected by the marginal effects in the second panel ($\beta = -0.032$), third panel ($\beta = -0.049$), and fourth panel ($\beta = -0.045$) of M1, different sub-samples confirm the magnitude and direction of the results seen in the main specification. Excluding first-movers from the sample (second panel), reduces our sample by nearly half. As one would anticipate, this leads to reduced statistical significance, but the key coefficients are highly comparable. Similar results are observed when excluding the subset of firms acquired before FDA approval (third panel), and when excluding firms with previous FDA approval experience (fourth panel). Consistent with these findings, our multinomial logit specification, M2, shows that firms with a lower product code age at approval are more likely to be acquired and less likely to end up failing or remaining independent (Table 4). Post-estimation tests (Wald and Likelihood ratio tests) justify collapsing the two potential firm statuses “failed” and “independent,” which is done implicitly in our Logit model with the binary outcomes acquired vs. non-acquired. These robustness tests increase our confidence that the core findings are not driven by a particular sub-sample of small new entrants. Broadly, our results support H1, which predicts that earlier market entry will be positively associated with acquisition likelihood. Thus, when acquisition is the goal, being early to market seems to be a clear advantage for small new entrants.

[Table 3 and Table 4 about here]

We note that 12 out of 86 acquisitions took place before the target product entered the market. One might worry that in these cases, causality could be reversed—i.e., having been acquired affects the likelihood and timing of FDA approval. While we cannot rule out some mechanism working in this direction, the proposed effect of entry timing on acquisition likelihood should persist. Even before the FDA’s decision, potential acquirers should be able to predict (likely with some degree of uncertainty) whether a target will be an early or a late market entrant; as noted above, the timing of FDA approval is highly correlated with that of FDA submission (which happens on average 1.55 years earlier).

Analysis 2: Acquisition timing

In the next set of analyses, we test our second set of hypotheses related to whether newly introduced products need to surpass an (implicitly or explicitly) acceptable risk threshold before acquisition. We employ two different types of regression models: M3 investigates H2a, H2b, and H2c and represents a survival analysis based on

a Cox Proportional Hazard Model (CPHM). M4 is an ordinary least squares model (OLS) and tests H2d. The two models differ in terms of data structure, estimation mechanism, and underlying sample.

There are two main components of a CPHM: 1) the baseline hazard function, which reflects how the “risk” of being acquired changes over time when covariates are held constant, and 2) terms which reflect how the hazard changes relative to the baseline due to differences in the explanatory covariates across firms and over time. The CPHM assumes that the hazard $h_i(t, X_i(t))$ of individual observation i is a product of the (typically unspecified) baseline hazard function, $h_0(t)$, and a second term, $\exp(Z_i(t))$, which is an exponential function of all independent and control variables that are part of our model (see, e.g., Bradburn et al. 2003). The so-called “failure event” is defined here as an acquisition. As is typical of similar models, a failure event may or may not be observed before the end of the period of observation and we consider a small new entrant not acquired by the end of the observation period as right censored. This feature allows us to include data from the full sample in our models, and to compare the 86 acquired vs. 33 non-acquired small new entrants.

Another advantage of using a CPHM is that it allows us to account for date-specific influential (“milestone”) events on the path to acquisition, since the model can incorporate time-varying covariates. Here, these include an indicator for “product type has been established”, product code age, an indicator for “focal firm’s product has received FDA approval”, an indicator for “product type has received positive reimbursement decision by major public health insurers”, the number of patents held by the focal firm, and the number of potential buyers. The term $Z_i(t)$ is as follows:

$$Z_i(t) = \beta_0 + \beta_1(t_{\text{FDA},i} - t_{\text{FDA},\text{FM}}) + \beta_2\text{FDA}_{\text{FM}_i}(t) + \beta_3\text{FDA}_i(t) + \beta_4\text{CMS}_{\text{FM}_i}(t) \\ + \beta_5\text{PAT}_i(t) + \beta_6\text{BUY}_i(t) + \text{Medical Speciality Controls},$$

where $t_{\text{FDA},\text{FM}}$ and $t_{\text{FDA},i}$ denote the dates when the first-mover of the relevant product type and the focal firm i , respectively, receive FDA approval. Applying this model to our dataset requires us to transpose the data into a panel structure in which the time variable counts the days from the date of incorporation. We use the date of incorporation (rather than that of the firm’s FDA approval) as the starting date of our survival model in order to test Hypotheses H2a and H2c that FDA approval (of the first-mover and the focal firm, respectively) will

increase the hazard of acquisition. Furthermore, doing so allows us to account for those firms that were acquired before receiving FDA approval. The CPHM then estimates how the hazard of being acquired is associated with constant, firm-specific characteristics (e.g., *Cardiovascular* as medical specialty), and whether the hazard changes with milestone events occurring at observable points in time (e.g., *FDA approval* of the focal firm's product). In the Online Appendix, we illustrate this data structure using the previously introduced examples from three small new entrants.

The left column of Table 5 reports estimates of the CPH model (M3). Figure 1 illustrates the results of the survival analysis and clusters the firms into first-movers and followers. (Before running these regressions, we conduct a test on the scaled Schoenfeld residuals at failure time and find that M3 fulfills CPHM assumptions (see Grambsch & Therneau, 1994). A central, underlying assumption of the CPHM is that the log hazard-ratio function of the model is constant over time. Using a nonzero slope test, we validate this assumption in terms of all variables individually and for the model entirely and find no deviation.)

[Table 5 and Figure 1 about here]

All coefficients in this table are logarithms of the respective hazard ratio, where $\beta > 0$ indicates that an increase in the associated covariate is associated with a higher acquisition hazard. In turn, a negative coefficient signifies a factor that decreases the hazard that a firm experiences acquisition.

With respect to general technological risk of a new product type, we find evidence of a sustained increase in acquisition hazard beginning at the time of FDA approval of the first-mover's device (*Product type established*: $\beta = 0.138$, $p = 0.003$). Results of a CPHM regression including only *Product type established* and controls for medical specialty confirm these results (*Product type established*: $\beta = 0.136$, $p = 0.000$). This finding supports H2a, which hypothesizes that acquisition hazard will increase when the general technology risk of a new product type falls.

The variable capturing reduction of the general market risk of a new product type has a positive coefficient in the CPHM, but the result is not statistically significant at conventional levels—that is, acquisition hazard does not increase after the first major decision for public insurers to reimburse for the product (mean of 2.75 years between FDA approval of the first-mover and CMS decision with a standard deviation of 3.715). Thus,

we do not find evidence to support H2b, which states that the acquisition hazard will increase when the general market risk of a new product type falls. Notably, there is no firm-specific market risk that can be measured in this setting because CMS coverage applies to an entire product category rather than to a specific firm's product.

FDA approval of the focal firm's innovation (firm-specific technology risk) also does not have a significant impact on its acquisition hazard. However, acquisitions of "long-lag-pioneers" (those approved <1 year after product code creation and subsequently acquired >10 years after approval) can explain the negative coefficient of FDA approval of a focal firm's device. When this sub-sample is re-moved from regressions, the coefficient becomes positive (though it remains statistically insignificant: $\beta = 0.003$; $p = 0.929$). Therefore, we do not find evidence to support hypothesis H2c (acquisition hazard increases at the time at which the firm-specific technology risk falls). However, this finding might not be too surprising because once a first-mover's innovation is FDA-approved, potential buyers can compare any given technology in the same product code to the reference technology of the first-mover. As such, it might be relatively easy to assess the firm-specific technological risk in an MFT even before FDA approval of the focal device.

We find a negative, statistically significant association between the control variable, *product code age* (at the time of FDA approval of the focal device), with the acquisition hazard. This finding is consistent with other evidence we find to support H1, which states that later market entry (i.e., later FDA approval) is associated with a lower likelihood of acquisition.

The rightmost column of Table 5 presents a robustness test, in which the CPH model begins with the date of the FDA approval of the focal firm's device (rather than the firm's date of incorporation). The coefficients on our explanatory variables (*product type reimbursed* and *product code age*) have the same signs and similar levels of statistical significance as in the main specification; the decline in market risk (public insurance reimbursement coverage) remains statistically insignificant, while later market entry is significantly associated with a reduced acquisition hazard. Consistent with M1, M2, and M4, we perform further robustness checks (unreported here), which yield similar results to those seen in the main sample. These include removing a) first-movers, and b) firms with a previous FDA approval in the survival analysis; overall results remain unchanged when excluding these sub-samples.

Model M4 represents an OLS analysis conditional on acquisition and specifically considers the *Time to acquisition* of firms that are acquired. Based on our selection criteria, we narrow our analysis to the 86 ultimately-acquired small new entrants. Again, we illustrate the data structure in the Online Appendix using three example firms.

Table 6 reports the estimates of the M4 Ordinary Least Square (OLS) model. Considering all 86 firms (leftmost column), we find that a higher *Product code age at approval* is negatively associated with *Time to acquisition* ($\beta = -0.858$; $p = 0.003$). The coefficient $\beta = -0.858$, therefore, means that *Time to acquisition* decreases by 0.8 to 0.9 years for every year that has elapsed between product code establishment and a product's FDA approval in that product code. This result supports H2d, which states that, conditional on acquisition, early market entry is positively associated with a longer time to acquisition. The middle and right columns check for robustness by performing the same analysis but exclude first-movers or firms acquired prior to their product's FDA approval. Robustness tests indicate that all effects remain statistically significant and the coefficients of interest remain comparable both when a) excluding first-movers ($\beta = -1.335$, $p = 0.001$), b) excluding firms which are acquired prior to FDA product approval ($\beta = -0.732$; $p = 0.025$), or c) excluding firms with a previous FDA product approval ($\beta = -0.937$; $p = 0.004$).

[Table 6 about here]

Controlling for acquisition price

Is acquisition at a later maturity (i.e., following a longer elapsed time between market entry and acquisition) an advantage for pioneers? In other words, do pioneers have an incentive to postpone an acquisition in order to realize greater financial returns? In order to assess this potential story, we use the dependent variable from the previous model, *Time to acquisition*, as the explanatory variable in a predictive model of *Deal value*—all other variables remain unchanged. Data on the dependent variable, *Deal Value*, is available for 75 of the 86 acquired firms in our sample. Because there might be systematic selection in the availability of this information, we perform a Heckman two-stage test. The selection stage includes the independent variables and all control variables, as well as the binary selection variable *Buyer Public*, indicating whether the acquiring company is a publicly listed firm. We use *Buyer Public* as a selection variable since privately held firms have less strict reporting

requirements and, thus, will be less likely to release information on deal values. Table 7 presents estimates of an OLS model (M5) and suggests that a longer *Time to acquisition* (later maturity) is not associated with higher deal values.

[Table 7 about here]

CONCLUSION

Our study underscores the need to consider pioneer advantages in settings where MFTs are prevalent. Our empirical findings show that over our period of observation, a high share (72%) of small new firms that generated medical device innovations experienced acquisition. This finding highlights a need to revisit the theoretical underpinnings of pioneer (dis-)advantages in the specific context of MFT-dominated settings.

Methodologically, the empirical context of this study allows us to address many key conceptual issues of the early-mover advantage research. Auspiciously, the clearly delineated product categories and hierarchies of the U.S. medical technology industry make it straightforward to identify comparable small new entrants and to differentiate between pioneering firms and later followers.

Summary and contribution

Previous research often assumes that *one* firm completes the entire innovation and commercialization process of a new technology and that pioneers aim to monetize their innovations on product markets. However, MFTs play an important role in a number of industries, and we argue that scholars must consider additional factors when assessing first- and early-mover (dis-)advantages of small new entrants in such settings.

A key assumption underlying our study is that acquisition is desirable for small new entrants. This is because these firms are well positioned to innovate, but relative to incumbents, are not well positioned to scale-up their businesses, as small new entrants do not have the same depth and breadth of already-established complementary resources. This perspective was confirmed through expert interviews with managers of large firms, which frequently acquire small new entrants as well as with venture capital investors, who focus on supporting small new entrants with the goal of realizing an acquisition. Descriptive findings from our dataset support the idea that gains from technology markets might be higher than gains from product markets; the median deal value of

roughly \$150-160 million among acquired entrants is high relative to the approximately \$13.5 million in annual revenues of non-acquired firms five years after their product's FDA approval.

We argue that the binary outcome (i.e., being acquired, yes/no) creates different opportunities and threats for small new entrants in MFTs as compared to innovators entering emergent product markets, and thus has important new implications for whether it is advantageous to be early to market.

We find support for our first hypothesis, which predicts that acquisitions will be more likely among first- and early-movers; entering the market one year closer to the establishment of a new product type is associated with a four percent higher likelihood of acquisition. Thus, to the extent that acquisition is a goal, early market entry seems to be advantageous. However, our results indicate that pioneers need to reduce uncertainty (technological uncertainty in particular) before they have a serious chance of experiencing acquisition. In survival models, we find evidence that a discrete change in the hazard of acquisition occurs after the general technological risk of a new product type is resolved (Hypothesis 2a), which happens when the first-mover's product receives regulatory approval. Moreover, there are weak indications from some of our robustness tests that the acquisition hazard may also increase when the general market risk of the same product type is reduced (Hypothesis 2b). We do not find support for Hypothesis 2c, which states that the acquisition hazard increases at the time a given firm's innovation receives regulatory approval and the firm-specific technology risk falls.

In summary, we find that due to the binary nature of acquisition outcomes, pioneer (dis-)advantages in MFT settings are more nuanced than those (dis-)advantages documented in simple product markets. Because pioneers have to overcome higher uncertainty, they face the disadvantage of waiting longer than later entrants to be acquired, which supports our hypotheses. Conditional on acquisition, we find evidence that early market entry is positively associated with a longer time to acquisition (Hypothesis 2d); entering the market one year closer to the establishment of a new product type is associated with a 10.3-month longer wait for acquisition following product regulatory approval.

This dynamic may be advantageous for founders: given that benefits of control tend to be important to entrepreneurs (Shane et al., 2003), they may prefer a delayed, but higher likelihood of acquisition. However, investors in pioneering firms, such as venture capitalists, will likely take a different view, weighing the financial

pros and cons quantitatively. In contrast, later entrants are less likely to be acquired overall, but can piggyback on early entrants' investments in mitigating technological and market uncertainty. Moreover, later entrants may not need to convince prospective buyers that their offerings are superior to those of the firms acquired earlier, because later buyers necessarily need to identify acquisition targets among the small firms remaining in the MFT. This is notably different from traditional product markets, where customers are the end users and can buy directly from the pioneer.

Limitations

The empirical setting for this study is the U.S. high-risk medical device industry. This context is a uniquely advantageous setting for undertaking such research because regulatory approval ensures the observability of crucial information on market entry and timing. However, different industries may have unique features that could lead to differences in how and when technologies are de-risked, and thus, how and when incumbents approach technology acquisitions.

Further, we are constrained to small new entrants that were successfully commercialized—i.e. we do not observe the full set of products for which small new entrants embarked on very early stage R&D activities. However, the same is also often the case for early-mover studies in traditional product markets, since new product development projects that were abandoned before market launch are difficult or impossible to observe. Because our hypotheses focus on activities that occur in the commercialization stage of new product development, we are less concerned with earlier R&D failures, although additional study of their determinants among new entrants versus incumbents merits attention.

Finally, we note an inherent concern around the endogenous nature of first-movers and pioneers. It might be the case that higher quality firms are able to both obtain FDA product approval earlier *and* are more likely to have acquisition success. Alternatively, an explanation suggesting the opposite association between product quality and the timing of regulatory approval is that a firm might sacrifice possible improvements in product quality to accelerate its market entry. Our findings on deal values—although they cannot be interpreted causally—mitigate many endogeneity concerns; despite the fact that early-movers experience acquisition at a later

maturity, there is no indication that they experience acquisition at higher deal values, which in other settings are associated with higher quality and value.

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TABLES

Table 1: Extract of the data sample

FDA code	Code description	Created	Total	Acq.	% Acq.	First-mover	Non-first-mover	Medical specialty
Total			119	86	72%	56	63	
MTV	Device, Needle Destruction	1997	7	3	43%	1	6	Non-Cardiovascular
MUA	Bone Sonometer	1998	5	1	20%	0	5	Radiology
LPB	Cardiac Ablation P. Catheter	1994	4	4	100%	1	3	Cardiovascular
MAF	Stent, Coronary	1991	4	4	100%	0	4	Cardiovascular

Table 2: Summary statistics

Variables	Obs	Mean	Median	Std. Dev.	Min	Max	
Firm status							
	Failed	119	0.050	0	0.220	1	
	Independent	119	0.227	0	0.421	1	
	Acquired (Acquisition status)	119	0.723	1	0.450	1	
Dependent	Time since Incorporation (y)	119	21.92	19.70	14.30	2.93	84.68
	Time since FDA (y)	119	9.64	9.81	8.17	-6.87	30.09
	Time to acquisition (y)	86	6.57	6.05	6.65	-6.88	28.35
	Time until FDA (from incorp.) (y)	119	12.28	9.00	11.47	1.91	77.05
	Deal value (mio. USD)	75	589.8	157.0	1113.1	0.40	6200
	Revenue Independent (5y. after FDA)	18	13.50	3.46	19.16	0.10	76.27
	Independent	Product code age at approval (y)	119	1.86	0.52	2.34	0
Patents at approval		119	24.7	4	139.3	0	1510
Patents at acquisition		86	54.5	14.5	277.0	0	2564
Control	Potential buyers at acquisition	86	53.38	44	40.72	0	152
	Cardiovascular	119	0.252	0	0.436	0	1
	Others	119	0.681	1	0.468	0	1
	Radiology	119	0.067	0	0.252	0	1
Full sample							
Overview of (sub-) samples	First movers	56	47%				
	Non-first movers	63	53%				
	Acquired	86	72%				
	Acquired before approval	12	14%				
	Acquired after approval	74	86%				

Table 3: M1: Logit (M1) estimates on acquisition likelihood

	1	2	3	4
Product code age at approval (y)	-0.0402** (0.0144)	-0.0320 (0.0241)	-0.0488*** (0.0148)	-0.0453** (0.0143)
ln(Patents at approval+1)	0.0303 (0.0310)	0.0198 (0.0392)	0.0282 (0.0325)	0.0285 (0.0309)
Cardiovascular	0.5016*** (0.1481)	0.8172*** (0.1776)	0.6012** (0.1862)	0.6043*** (0.1800)
Others (except radiology)	0.3154* (0.1352)	0.3466* (0.1714)	0.4184* (0.1784)	0.3971* (0.1682)
N	119	63	107	107

1: All firms; 2: Without first-movers; 3: Without firms acquired before FDA approval; 4: Without firms with previous device

Significance levels: † < 0.10 * < 0.05 ** < 0.01 *** < 0.001

Coefficients represent marginal effects at mean; values in brackets represent

Table 4: M2: Multinomial Logit (M2) estimates on acquisition likelihood

	1			2			3			4		
	Failed	Indepdt	Acqrd	Failed	Indepdt	Acqrd	Failed	Indepdt	Acqrd	Failed	Indepdt	Acqrd
Product code age at approval (y)	0.0147† (0.0083)	0.0253† (0.0145)	-0.0400** (0.0144)	0.0158 (0.0172)	0.0163 (0.0254)	-0.0321 (0.0240)	0.0157† (0.0086)	0.0329* (0.0154)	-0.0485** (0.0148)	0.0132 (0.0083)	0.0318* (0.0147)	-0.0450** (0.0142)
ln(Patents at approval+1)	-0.0354 (0.0245)	-0.0009 (0.0295)	0.0363 (0.0317)	-0.0350 (0.0378)	0.0100 (0.0404)	0.0251 (0.0399)	-0.0366 (0.0255)	0.0032 (0.0317)	0.0335 (0.0331)	-0.0276 (0.0229)	-0.0051 (0.0299)	0.0327 (0.0315)
Cardiovascular	-0.6490 (42.3271)	-0.1754 (16.5197)	0.8245 (25.8083)	-1.0640 (133.3904)	-0.1664 (68.2533)	1.2303 (65.1375)	-0.6955 (34.9880)	-0.2106 (15.6540)	0.9061 (19.3356)	-0.6230 (40.0100)	-0.2510 (17.4539)	0.8740 (22.5573)
Others (except radiology)	-0.0403 (0.0501)	-0.2776* (0.1230)	0.3179* (0.1347)	-0.0511 (0.0805)	-0.2964† (0.1526)	0.3476* (0.1712)	-0.0551 (0.0568)	-0.3651* (0.1592)	0.4202* (0.1779)	-0.0673 (0.0518)	-0.3306* (0.1538)	0.3979* (0.1683)
N	119			63			107			107		

1: All firms; 2: Without first-movers; 3: Without firms acquired before FDA approval; 4: Without firms with previous device

Significance levels: † < 0.10 * < 0.05 ** < 0.01 *** < 0.001

Coefficients represent marginal effects at mean; values in brackets represent standard errors

Table 5: M3: Cox Proportional Hazards Model (CPHM) on acquisition hazard rates

	Starting time: incorporation of the focal firm	Starting time: FDA approval of the focal firm
Product type established (tvc)	0.1383** (0.0457)	
Product type reimbursed (tvc)	0.0244 (0.0217)	0.0417 (0.0456)
Product code age (tvc)	-0.0035** (0.0012)	-0.0290* (0.0113)
FDA approval (tvc)	-0.0413 (0.0361)	
Patents (tvc)	0.0168** (0.0056)	0.0374*** (0.0107)
Buyers (tvc)	0.0260*** (0.0078)	0.0176 (0.0184)
Cardiovascular	2.0119** (0.7518)	1.9011† (1.0485)
Others (except radiology)	1.4973* (0.7259)	1.6671 (1.0228)
N (subjects)	119	107
N (failures)	86	74
Log likelihood	-283.86	-262.32
LR chi2	77.90	29.55

Significance levels: † < 0.10 * < 0.05 ** < 0.01 *** < 0.001

tvc: Time-varying covariate

Values in brackets represent standard errors

Table 6: M4: OLS on time to acquisition

	1	2	3	4
Product code age at approval (y)	-0.8575** (0.2818)	-1.3351*** (0.3578)	-0.7317* (0.3184)	-0.9375** (0.3194)
ln(Patents at acquisition+1)	0.9993* (0.4294)	1.6463** (0.5253)	0.4369 (0.4742)	1.1102* (0.4531)
ln(Potential buyers at acquisition+1)	1.8711*** (0.4789)	2.1140*** (0.5507)	1.7266** (0.5788)	1.9190*** (0.5130)
Cardiovascular	4.0415 (4.1282)	1.4344 (5.1882)	6.8587 (5.5340)	6.7179 (5.9180)
Others (except radiology)	5.3981 (3.9998)	0.9517 (5.0906)	8.4795 (5.4173)	8.1274 (5.7755)
constant	-6.0807 (4.2062)	-2.7904 (5.0106)	-6.4859 (5.9511)	-9.1406 (6.1666)
N	86	39	74	78
R2	0.3509	0.5545	0.2200	0.3520

1: All acquired firms; 2: Without (w/o) first-movers; 3: w/o firms acquired before FDA approval;
4: w/o firms with previous device

Significance levels: † < 0.10 * < 0.05 ** < 0.01 *** < 0.001

Values in brackets represent standard errors

Table 7: M5: Heckman OLS on deal value

Variable	1	2	3	4
Time to acquisition	-0.0263 (0.0389)	-0.0239 (0.0718)	0.0008 (0.0462)	-0.0126 (0.0375)
ln(Patents at acquisition+1)	0.4629** (0.1624)	0.2787 (0.2788)	0.5197** (0.1792)	0.3979* (0.1575)
ln(Potential buyers at acquisition+1)	-0.3522† (0.1815)	-0.5305* (0.2616)	-0.4544* (0.2170)	-0.3604* (0.1769)
Cardiovascular	0.4984 (1.4124)	2.7978 (2.0411)	-1.0568 (1.9840)	-0.5919 (1.7679)
Others (except radiology)	1.1516 (1.3828)	3.1065 (1.9970)	-0.5099 (1.9839)	-0.4063 (1.7629)
constant	4.5084** (1.4902)	3.3582† (2.0280)	6.0747** (2.1823)	5.9374** (1.9415)
selection stage				
Buyer_Public	0.7726* (0.3580)	0.6134 (0.5240)	0.8778* (0.3862)	0.6898† (0.3733)
constant	0.7019** (0.2548)	0.7916* (0.3760)	0.6456* (0.2604)	0.7363** (0.2716)
N	86	39	74	78
N (uncensored)	75	39	64	68
Wald chi2	13.89	9.59	13.41	11.67
Prob>chi2	0.0163	0.0878	0.0198	0.0396

1: All acquired firms; 2: Without (w/o) first-movers; 3: w/o firms acquired before FDA approval; 4: w/o firms with previous device

Significance levels: † < 0.10 * < 0.05 ** < 0.01 *** < 0.001

Values in brackets represent standard errors

FIGURES

Figure 1: Kaplan-Meier survival estimates

