

Pioneer (Dis-)advantages in Markets for Technology

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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 entirety of the innovation and commercialization 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. Pioneers enjoy an early-mover advantage in the form of a higher likelihood of acquisition, with the disadvantage that 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

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1 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 and commercialization process and that all firms aim to monetize their innovations in (emerging) 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 (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).

In an MFT setting, the question of first-mover (dis)advantages appears in a new light. While being a product market pioneer may result, among other things, in higher sales and customer lock-in, a technology or entire firm that is sold to an exclusive buyer can only be sold once. For such a binary event, the questions of both “if” and “when” become central. Does being an early-mover increase the probability of being

acquired? If so, and if being acquired is desirable, then being an early-mover implies an important advantage in this setting. In fact, in industries where new ventures typically lack the complementary assets needed for successful commercialization of their innovations (Teece, 1986), being acquired may even be essential. This raises the second question: conditional on being acquired, are early-movers acquired at a younger or older age than later movers? If entry timing and acquisition age are related, and if being acquired earlier is advantageous—for example, because VCs seek a timely exit or the venture runs out of funds—that would imply a second type of early-mover advantage (or, as a corollary, being acquired later would imply an early mover disadvantage).

The advantages and disadvantages of early entrants in MFTs are not addressed in the existing literature on first- and early-mover (dis)advantages. Research on technology acquisitions does address potential advantages of being early; it focuses however on early buyers in acquisition waves (Carow et al., 2004; McNamara et al., 2008), while the majority of existing research on technology acquisitions addresses various other aspects of timing (Graebner and Eisenhardt, 2004; Alvarez and Stenbacka, 2006; Puranam et al., 2006; Ransbotham and Mitra, 2010; Luo, 2014; Allain et al., 2016; Arora et al., 2018; Stein and Henkel, 2018).

This study outlines a novel way of evaluating questions of early-mover advantage versus 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 often enjoy advantageous market positioning, higher switching costs of customers, lock-in effects, and cooperation with desirable partners, while having to deal with 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. However, new aspects also become relevant: early entrants in MFTs must consider information asymmetries between potential transaction partners, firm risk preferences, and the potential linkage of complementary resources. Importantly, MFTs result in an observable binary outcome: there is either a transfer of innovation from an originator to an exclusive buyer through an acquisition—or not.¹

¹ 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 to acquisitions, while only 11% correspond to technology licensing, and 16% to distribution agreements (analyses from Evaluate MedTech).

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 these beliefs. 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 suited to a study of first-mover advantages because the emergence of new, independently defined product categories allows for a clear observation of entry order by product market, 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, 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.

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, a desirable 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 (as in Gans

et al., 2009). Inherently, this milestone—establishment of a novel product type—has to be achieved by a pioneer. 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 regulatory approval of a first-of-a-kind product and by the formal 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, outcomes of interest are traditionally continuous, time-varying measures like sales and revenues. Third, later prospective buyers necessarily 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 buyers are final product market customers who, absent binding capacity constraints, can all buy from the pioneer.

2 Background: Markets for technology and pioneer advantages

2.1 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 context of medical technology, where pioneers

need 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 brand 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 strong 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, 2018, 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 asymmetric information

between the seller and buyer, there is additional technological and market uncertainty in MFTs. This phenomenon is even more apparent for pioneer technologies because a benchmark for valuing the new product type does not yet exist.

2.2 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 advantages specific to the MFT context. *Ceteris paribus*, being a pioneer in a new product category should result in more media coverage, more attention from investors, and financing from more reputable investors. Therefore, the company is likely to be better positioned to find an attractive buyer for its technology down the road.

Finally, Schoenecker and Cooper (1998) empirically show that market pioneering and early market entry are positively associated with greater technological resources in a 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, independent of its actual technology quality.

All these factors 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 adaptation of Ransbotham and Mitra, 2010). Thus, such 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.

3 Hypotheses development

We build upon the theoretical implications of pioneer (dis-)advantages outlined above in order to develop several hypotheses. The first focuses on acquisition likelihood and the following ones on the timing of such acquisitions.

3.1 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 in settings where established firms have a significant comparative advantage in later stages of the innovation and commercialization process. In our empirical context, the medical device industry, this preference is confirmed by our study and was articulated in supplementary interviews with veteran investors. This is also broadly consistent with the theory of technology markets: where there is specialization among firms in different parts of 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, suggesting that they can serve as the basis for durable competitive advantages. These include high switching costs among customers, favorable market position (due to high visibility combined with 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.

3.2 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 dearth of information/knowledge about a product type at the time when a pioneer enters a market. As a result, at a comparable age, a pioneer will carry greater uncertainty and therefore more technological and market risk than later followers. In our hypotheses, we consider these challenges and how they play into risk aversion, information asymmetry, and expectations.

We assume that technology buyers and their shareholders are risk averse and will worry about increased 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. Radical innovations by small new firms are relatively high risk, which is reflected by their frequent venture capital financing. This implies that *ceteris paribus*, a reduction in risk favors a transfer of the innovation to a (typically publicly traded) 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, or a particular firm offering it should increase the probability of the firm being acquired. As such, we hypothesize:

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.

We note that part of the uncertainty surrounding a small new entrant will be 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, all else equal. A potential counteracting mechanism is related to H1. If pioneers have structural advantages, then potential buyers may compete for acquiring a pioneer not only by

raising their bids, but also by accepting higher levels of uncertainty and therefore acquiring a target at a younger age. However, the advantages of having acquired an early mover are moot if the novel product category fails as a whole. Hence, when there is a significant risk of failure, technology- or market-related, the acquisition-delaying effect of uncertainty should dominate. Thus:

H2d: Among acquired firms, pioneers will wait longer for acquisition after market entry if novel product categories face a significant risk of failure (where we note that H2d builds on H2a and H2b).

4 Empirical setting

4.1 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 can grant 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 period of commercialization.

4.2 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 product 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 Makadok,

1998; Schoenecker and Cooper, 1998; Gómez and Maicas, 2011; 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 is tantamount to market entry.²

The date of entry into an MFT is harder to pin down. The firm's foundation date is typically too early, since few firms will have acquirable technology at that point. Also the date of filing of the firm's first patent, if any, is not a good candidate since it indicates an invention, but not necessarily a saleable technology. We circumvent the issue of defining the date of entry into the MFT by focusing on *relative* entry timing: we define the first-mover in a new product class as the first small new entrant receiving FDA approval for its product. This choice is vindicated by the fact that most acquisitions in our sample (74 of 86, or over 86%) take place after FDA approval.

4.3 CMS coverage: discrete reduction in market risk

In the regulated medical device setting, innovator firms often have to convince payers (health insurance firms) 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 often 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.

4.4 Comparability of products and substitutes

Equipped with a method for market entry date identification, we establish which products belong to the same product market in order to understand each market's timing and chronology of entrants. In this respect, FDA regulatory data are 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. Alternatively, when an innovation represents a truly novel kind of product, an independent FDA committee establishes a new product code.³ Regulators then track subsequent approvals (by

² FDA approval requires that regulators visit and inspect up-and-running manufacturing plants and supply chain facilities as part of the approval process, so products are typically ready-to-ship shortly after regulatory approval. 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.

³ For more information, see: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm> (checked 03/10/2020).

calendar date) in this product code over time. As of Q4 2017, the FDA had established 324 unique product codes for high-risk medical devices.

4.5 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 arrival of all subsequent entrants. This allows us to use a continuous definition of “pioneers” based on timing of market entry, rather than simply considering entry order, which is discrete and does not account for elapsed time. While both measurements are potentially useful (Lieberman and Montgomery, 1988), the former is more appropriate in this study’s context, as factors potentially determining early-mover (dis-)advantages change as time elapses, rather than with entry order. Among high-risk medical devices, full observation of FDA product approvals over multiple decades facilitates this approach.

4.6 Acquisition of small new entrants

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.

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. Indeed, over 70% of firms in our sample that were classified as small new entrants experienced acquisition during our period of observation. Publicly listed incumbent firms were responsible for nearly two thirds of all acquisitions (65%). In our data, 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 product-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.

5 Data and methodology

5.1 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 allows us to observe complete and standardized outcome information for all products and firms that received regulatory approval in this time period for a full seven years afterward. We consider a total of 203 unique product codes for high-risk devices that were established by the FDA over our period of study. In these 203 product codes, the FDA approved 627 novel devices during the observation period, and these approvals constitute our baseline sample. 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 medical device market (see e.g., Chatterji, 2009), but also represents a window of time that is short enough to allow us to focus on capturing 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 (December 31, 2017).

We focus on the firms in our sample that will allow us to operationalize our research questions. These 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 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.⁴ Finally, we exclude devices in product codes with fewer than two successful FDA applications during our observation period in order to avoid niche products with limited therapeutic relevance. These criteria identify 80 small new entrants.

These 80 small new entrants are unambiguously relevant to this study, however we may fail to capture small new entrant firms that were acquired *prior* to their products' FDA approvals. 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 of a smaller innovator firm (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]

5.2 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

⁴ We identify 12 firms with one previous product approval each prior to the “focal” product approval, but have strong reason to believe that their acquisition, if any, is associated with the second, focal device. First, in only four of these cases was the previous device also a novel, high-risk device (PMA). In all other cases, the firm's first device was a moderate-risk product representing only incremental innovation (FDA, 2014). Second, press releases at the time of the acquisition indicate a clear link between the focal device and the acquisition, if any. We can also exclude all these firms and devices from our regression analyses (done in robustness checks) without meaningful changes to our results.

of each acquisition (announcement date) as well as transaction 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 appear that pioneers are more/less often purchased by top acquirers in the industry,⁵ nor does it seem to be the case that pioneers are more/less often purchased by publicly listed firms.

5.3 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 was ever acquired.

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 over 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 focal product approval, rather than the establishment of the firm itself.

Conditional on acquisition, *Time to acquisition* reflects the elapsed time between a device's FDA approval and its innovator firm's acquisition. This variable 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

⁵ Top 30 acquirers determined by historic deal-data in the medical device space covering more than 7,300 transactions between 1970-2016. Source: Capital IQ.

of Chaudhuri et al., 2005; Ransbotham and Mitra, 2010; 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.

5.4 Independent variables

Consistent with our hypotheses, all independent variables are time- or timing-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 every 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 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 tvc 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, CMS starts 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).

5.5 Control variables

A number of control variables capture characteristics of the target firm 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, the variable *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. For simplicity, 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.⁶ 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* is a *tvc* 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 Bucorius, 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-

⁶ The FDA-defined class of *Cardiovascular* devices is not further aggregated beyond this, as it is unique and represents the largest category of high-risk devices (25% of sample). We also consider *Radiology* devices separately (7% of sample) due to their technological uniqueness, combined with the large (typically millions of dollars) investments that are required for commercialization of a single device. All other devices are bundled into *Other devices*.

approved in the same regulatory medical specialty as the small new entrant's product (e.g., cardiovascular devices). Second, a potential buyer must be a firm with at least five years of acquisition experience and a minimum of three acquisitions. We use cutoffs of five years and three acquisitions based on empirical evidence that shows decreasing 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 inclusion principles were separately validated during expert interviews.

6 Results and discussion

6.1 Descriptive results

Table 2 and Table 3 provide summary statistics and correlations, respectively, for the variables in our empirical analysis. Our sample of 119 small new entrants is comprised of 56 first-movers (47%) and 63 followers (53%). Across all small new entrants, 86 firms (72%) were acquired. Alone, these summary statistics confirm that a robust MFT exists in the high-risk medical device space.

[Table 2 and Table 3 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, firms that were acquired experienced an acquisition 6.57 years after their products' FDA approvals.

We further note that, for firms that are acquired, the timing of FDA approval and of acquisition are correlated. FDA approval precedes 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 ($r = 0.30$, $p = 0.004$).

6.2 Validation of assumptions

One of our central assumptions is that it is desirable for small new entrants to be acquired, 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, for those firms for which data are available, deal values of acquired small new entrants to the revenues 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.⁷ In contrast, among the 75 acquired firms with deal value information, median and mean acquisition prices were ~\$157 million and ~\$590 million, respectively. Comparing the more conservative median value 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 ten strategic M&A acquirers in healthcare and medical devices has historically been around four to six.⁸ Even beyond the potential selection issues in the above comparison, high exit multiples in the medical device 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 more deficient than incumbent firms in a broad set of 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 likelihood will be positively correlated with firm quality. Thus, at least part of 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).

6.3 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

⁷ For the remaining 15 of the 33 non-acquired firms, revenue data are not available on a year-by-year basis, which indicates they have remained small—or perhaps never became profitable and/or went bankrupt.

⁸ 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.

applying a multinomial logit specification, in which the variable, *Firm status*, reflects whether a small new entrant fails, remains independent, or experiences acquisition.

The leftmost columns in Table 4 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 decrease in the likelihood of acquisition—a substantial difference.

As an alternative independent variable instead of *Product code age at approval*, we consider *Cumulated approvals before FDA*. The variable reflects the cumulated number of FDA-approved devices (startups plus incumbents) in a given 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) is associated with a significantly lower likelihood of acquisition of the focal firm.

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 5). Post-estimation tests (Wald and Likelihood ratio tests) justify collapsing the two potential firm statuses “failed” and “independent,” which is done in our Logit model with “acquired” as a binary outcome. 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 a goal, being early to market seems to be associated with an advantage for small new entrants.

[Table 4 and Table 5 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 in the discussion below, the timing of FDA approval is highly correlated with that of FDA submission (which happens on average 1.55 years earlier) and thus reasonably well known in advance.

6.4 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 that was 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, comprising the 86 acquired and 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 $Z_i(t)$ can then be modeled as follows:

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

where $t_{\text{FDA,FM}}$ 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 with daily observations, 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).

The left column of Table 6 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.⁹

[Table 6 and Figure 1 about here]

⁹ 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.

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.

In considering the 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 in a statistically significant way with 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” (20 firms whose product was approved less than one year after product code creation and that were acquired more than ten 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: $\beta = 0.003$; $p = 0.929$). Thus, 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 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 firm-specific technological risk in an MFT setting well 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 6 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 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. Table 7 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 indicates that *Time to acquisition* decreases by 0.8 to 0.9 years for every year that has elapsed between product code establishment and a subsequent 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 when a) excluding first-movers ($\beta = -1.335$, $p = 0.001$), b) excluding firms which

are acquired prior to FDA product approval ($\beta = -0.732$; $p = 0.025$), and c) excluding firms with a previous FDA product approval ($\beta = -0.937$; $p = 0.004$).¹⁰

[Table 7 about here]

6.5 *Controlling for acquisition price*

Given the above findings, one might wonder: 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 key explanatory variable in a predictive model of *Deal value*—all other variables remain unchanged. 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. Building on these results, Table 8 presents estimates of an OLS model (M5), as described above, and suggests that a longer *Time to acquisition* is not associated with higher deal values. This result speaks against the story that “it pays to wait.”

[Table 8 about here]

7 Conclusion

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

¹⁰ In this regression we use the number of patents held by the firm at the time of acquisition—which could not be used in the earlier regressions since not all firms experienced acquisition. Using the number of patents at the time of FDA approval in M4 renders the patent count variable insignificant, but leaves all other coefficients qualitatively unchanged.

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 types and classes of the U.S. medical device industry make it straightforward to identify comparable small new entrants and to differentiate between pioneering firms and later followers.

7.1 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 should consider additional contextual 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, they are not well positioned to scale-up their businesses: small new entrants do not have the same depth and breadth of already-established complementary resources, such as manufacturing capacity, sales, and marketing. 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 also support the idea that gains from technology markets might be higher than gains from product markets: for those firms for which such data are available, 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 of being acquired creates different opportunities and threats for small new entrants in MFTs as compared to innovators entering emergent product markets, and thus has important 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. Indeed, 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. 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 if they want to compete in the respective device market. This is notably different from traditional product markets, where customers are the end users and can buy directly from the pioneer.

7.2 Limitations

The empirical setting for this study is the U.S. high-risk medical device industry. This context is advantageous for undertaking such research because regulatory approval ensures the full observability of crucial information on firms, 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.

As to timing, 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 controlled by 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.¹¹

Again related to timing, 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. However, this effect may be mitigated by a mechanism suggesting the opposite association between quality and the timing of regulatory approval: a firm might sacrifice possible quality improvements to accelerate market entry. Our findings on deal values—although they cannot be interpreted causally—mitigate some 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.

¹¹ 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.

Finally, there is a potential selection issue insofar as unobserved firm quality should be associated with the likelihood of being acquired. However, such a correlation will affect our hypotheses only if—and to the extent that—firm quality is associated with entry order, as discussed above.

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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
Dependent	Firm status						
	Failed	119	0.050	0	0.220	0	1
	Independent	119	0.227	0	0.421	0	1
	Acquired (Acquisition status)	119	0.723	1	0.450	0	1
	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	7.01
Control	Patents at approval	119	24.7	4	139.3	0	1510
	Patents at acquisition	86	54.5	14.5	277.0	0	2564
	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
Overview of (sub-) samples	Full sample	119					
	First movers	56	47%				
	Non-first movers	63	53%				
	Acquired	86	72%				
	Acquired before approval	12	14%				
	Acquired after approval	74	86%				

Table 3: Correlations

Variable	1	2	3	4	5	6	7	8	9	10	11	12
1 Failed	1.0000											
2 Independent	-0.1248	1.0000										
3 Acquired	-0.3720*	-0.8745*	1.0000									
4 Time to acquisition	.	.	.	1.0000								
5 Deal value	.	.	.	0.1245	1.0000							
6 Product code age at approval	0.1458	0.1552	-0.2165	-0.3619*	0.0235	1.0000						
7 Patents at approval	-0.0380	-0.0504	0.0657	0.0890	0.0250	0.0647	1.0000					
8 Patents at acquisition	.	.	.	0.1582	0.0837	0.0466	0.9849*	1.0000				
9 Potential buyers at acquisition	.	.	.	0.4992*	-0.1426	-0.1012	-0.0369	-0.0078	1.0000			
10 Cardiovascular	-0.1338	-0.1297	0.1867	-0.1641	-0.0026	0.1473	-0.0086	-0.0626	0.0450	1.0000		
11 Others	0.0755	-0.0163	-0.0217	0.2112	0.0268	-0.1816	0.0251	0.0698	-0.0185	-0.8476*	1.0000	
12 Radiology	0.0915	0.2552*	-0.2835*	-0.1564	-0.0712	0.0826	-0.0318	-0.0263	-0.0796	-0.1559	-0.3920*	1.0000

Note: * < 0.01

Table 4: M1: Logit 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 5: M2: Multinomial Logit 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 6: 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 7: 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 8: 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

