Do the Costs of Cooperation Drive the Gale of Creative Destruction? : Commercialization Strategies in the Medical Device Industry

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ABSTRACT

Theory suggests that an inventor's choice of commercialization strategy between entrepreneurship and cooperation with an incumbent firm is determined by the intellectual property environment, access to complementary assets, and transaction costs of collaborating with incumbents. However, this literature frames the choice only from the inventor's perspective, implicitly assuming that incumbents are willing to cooperate in every case where the inventor prefers this strategy. We explore this question from the perspective of the incumbent, and consider how the willingness to cooperate depends on the costs of doing so. We argue that conditions exist under which inventors would prefer cooperation to commercialize their invention, but that incumbents find cooperation too costly, leading to entrepreneurship. Using data from the medical device industry, we empirically demonstrate that when the incumbents' costs of cooperation are exogenously increased, a subset of inventors are more likely to pursue entrepreneurship and less likely to collaboratively develop new technologies.

Keywords: Entrepreneurship, Commercialization Strategies, Corporate Strategy

Introduction

An invention is only the first step in the path to technology commercialization. As the process unfolds, the inventor often must decide whether to develop, manufacture, and sell the new technology himself by launching a new entrepreneurial venture or to cooperate with an incumbent firm to commercialize the technology (Winter 1984; Audretsch 1995). These choices by inventors have the potential to shape the competitive landscape of entire industries, powering the "gale of creative destruction" posited by Schumpeter(1950) or alternatively further concentrating the market power of incumbent firms. The drivers of this critical choice of commercialization mode have been studied both theoretically and empirically (Teece 1986; Gans et al. 2002; Gans and Stern 2003). However, this literature consistently considers the selection of commercialization mode from the inventors' perspective only, implicitly assuming that the incumbent firms will always cooperate when the inventor elects to do so. This limited view leaves a gap in our understanding of the conditions under which entrepreneurship will occur, since there may be varying costs of cooperation for the incumbent firm. In this study, we extend existing theory to consider how the costs of cooperating for the incumbent firm in the "market for ideas" will influence the selected mode of commercialization. We argue that there are cases where the incumbent firm finds it prohibitively costly to cooperate, leading the inventor to pursue entrepreneurship as a second choice. Further, we provide supporting evidence using a quasi-natural experiment in the medical device industry, where a U.S. Department of Justice (DOJ) investigation increased the costs of cooperation for some incumbent firms and a subset of inventors.

The existing theory posits three key factors influencing commercialization mode: the strength of intellectual property protection, the availability and importance of complementary assets, and the costs borne by the inventor in cooperating with incumbent firms (Gans et al. 2002).

Cooperation with an incumbent firm is favored when (1) intellectual property protection is strong enough to prevent expropriation; (2) there are significant complementary assets held by the incumbent firms that are not widely available and would be costly to replicate; and (3) there are intermediaries that reduce inventor's search and transaction costs associated with cooperating with an incumbent firm (Gans et al. 2002). However, even when these conditions hold, we argue that the likelihood of cooperation depends on the availability of incumbent firms willing to engage in transactions in the market for ideas. In this paper, we extend existing theory to consider the impact of changes in the cost of cooperation for incumbent firms on inventors' commercialization strategies. When the incumbents' costs of cooperation in this market increase, incumbent firms will be less willing to work with inventors to commercialize new technologies. Even when inventors might prefer cooperation to entrepreneurial entry, these costs of cooperation for the incumbent firm may preclude such a strategy, forcing inventors to pursue entrepreneurship. Our central prediction is that an increase in the cost of cooperation borne by incumbent firms leads to less collaboration between physician inventors and incumbent firms, and more physician-founded entry.

We test this prediction using a robust empirical methodology that exploits an exogenous shock to costs of cooperation for particular incumbent medical device companies in the orthopedics sector who were investigated by the U.S. Department of Justice (DOJ) in 2005. The purpose of the legal action was to address potential conflict of interests posed by physicians that receive consulting payments from the orthopedic device firms while also being in a position to recommend their products to patients. However, the investigation had the practical impact of raising the costs of cooperation for medical device companies working with orthopedic surgeons. To test our theoretical prediction, we compare the temporal patterns in entrepreneurial entry and

cooperative patenting (including physicians and companies) in the orthopedics segment with the rest of the medical device industry, which provides a natural and well-suited control group.

Our empirical results are consistent with the prediction that exogenously increasing the incumbent firms' costs of cooperation increases entrepreneurial entry of inventors. Following the DOJ investigation, there was an increase in new venture formation in the orthopedics area, and much of this rise was attributable to an uptick in physician entrepreneurship. Further, evidence from patent assignment data suggests that physicians who invented new orthopedics technologies were significantly less likely to collaborate with US medical device companies in the years following the DOJ investigation, relative to physicians in other areas and compared to the pre-DOJ investigation level of collaboration in the orthopedics segment. These findings provide support for our theoretical prediction that increases in the costs of cooperation for incumbent firms will influence inventor commercialization strategy, leading to more entrepreneurship and less cooperation between inventors and incumbent firms.

This paper makes both theoretical and empirical contributions to the academic literature on strategy and entrepreneurship. First, we augment existing theory on commercialization strategy by considering the incumbent's strategic choice, based in part on the costs of cooperation that it bears, and demonstrate that this extension explains some cases of entrepreneurial entry. It is important to reiterate that in these cases, entrepreneurship may not be the preferred outcome for the inventor but the rather the only strategy available to him. Second, we provide an empirical test of our theoretical predictions using an exogenous shock to the costs of cooperation for a "treatment" set of incumbent firms, an approach that has seldom been used to test theories in strategy and entrepreneurship. In sum, these contributions build a more

complete theory of commercialization strategy and entrepreneurship and provide robust empirical evidence in support of these arguments.

The next section briefly reviews the established theory regarding the inventor's decision to either cooperate with established firms or pursue entrepreneurial entry to commercialize an invention. We build on this theory to further develop the choice facing the incumbent firm, whether or not to cooperate with the inventor, and demonstrate that the gap between the inventor's preferred strategy and the willing participation of the incumbent increases with the incumbents' cost of cooperating. We also explain the conceptual and methodological challenges associated with testing the effect of the availability of cooperative partners on choice of commercialization mode, and describe how we overcome these difficulties. The third section provides the details on our empirical context. The fourth section describes the empirical methodology used to test our prediction, including the data and variables. The fifth section reports the results of the empirical analysis, and the final section reviews implications for the academic literature and offers concluding remarks.

Theory on Commercialization Strategies

Existing literature explores the decision by an inventor to either commercialize a technology in their own entrepreneurial venture or with an incumbent firm. Important work by Teece (1986), Gans and Stern (2003) and Gans et al. (2002) concludes that when incumbent firms hold specialized complementary assets that an entrant would find difficult or costly to replicate, and when the intellectual property environment provides strong protection against expropriation of new inventions, technological inventors are expected to cooperate with incumbent firms rather than form new ventures to commercialize their inventions. Gans et al.

(2002) provide a simple model of the inventors' commercialization strategy selection that incorporates a cost to cooperating with incumbent firms borne by the inventor. The comparative statics from the model suggest that as the inventor's costs of transacting with established firms fall, the inventor is more likely to choose cooperation (and vice versa).[1] This existing theoretical literature, and the empirical studies related to it, consistently consider the commercialization mode decision only from the inventor's perspective and implicitly assume that the incumbent firms will be willing to cooperate with inventors when inventors so choose. However, we argue that when incumbent firms incur costs of cooperating in the market for ideas, there may be conditions under which the inventor would prefer to cooperate, but incumbent firms are not willing to do so.

We build our argument using the theoretical framework advanced by Gans et al. (2002). We consider the decision of the incumbent firm (I) of whether or not to cooperate with the potential entrant (E) by comparing the expected payoffs from cooperation and competing with the entrant if the incumbent elects not to cooperate. The model provided in the appendix demonstrates the condition under which the incumbent is willing to cooperate, incorporating of cost of cooperation borne by the incumbent, T. In Figure 1 we represent the decision space of the incumbent and the entrant, as a function of T.

[Figure 1 Here]

It is evident from Figure 1 that there is a range of values where the inventor would prefer cooperation with the incumbent, but the incumbent would prefer entry and competition to cooperation with the inventor. Each party would prefer cooperation when the payout from cooperation exceeds their respective gains from entry and competition (see appendix for

[1] The authors do not test this prediction directly, although they do examine whether venture capital (VC) funded companies are more likely to cooperate with established firms than ventures funded by the Small Business Innovation Research (SBIR) program. They argue that VC funding reduces uncertainty, and therefore the costs of cooperating. However, it is likely that the allocation of inventions and inventors to venture capital funding and

derivation of the preferences). The shaded area between these lines is the range over which inventors would like to cooperate, but incumbents are unwilling to do so. As the incumbents' costs of cooperating, T, increase, this wedge increases: there is an increasing range over which the inventor would prefer cooperation and the incumbent is not willing to cooperate. This shaded area represents the instances where the inventor will pursue entrepreneurial entry when he would otherwise prefer to cooperate with the incumbent firm. Thus, our central prediction is that as the incumbents' costs of cooperating increase, we will see less cooperation between inventors and incumbents and more entrepreneurial entry by inventors.

Related Literature and Conceptual Challenges

Existing research has considered commercialization strategies in other industries, including Orsengio, (1989), Shan (1990), Lerner and Merges (1998), Arora and Gambardella (1990) in the biotechnology industry and Christensen (1997) in electronics. For example, Shan (1990) finds evidence that the size of the firm, its internal capabilities, its competitive position in the industry, and whether it is competing in a foreign market all influence the likelihood of cooperation. Gans et al. (2002) use a survey of venture-backed and SBIR-backed start-ups across multiple industries to develop a cross sectional test of the predictions that stronger intellectual property rights protection, greater importance of complementary assets, and lower transaction costs are associated with cooperation, rather than independent development of an innovation. Based on their sample of 118 start-ups, they find evidence consistent with these predictions.

As mentioned above, our work is distinct from the prior work because we examine the effect of a change in the cost of cooperation borne by the incumbent firm from the perspective of the incumbent's willingness to cooperate. A related line of inquiry considers the impact of the availability of venture capital on commercialization strategies (Hellmann and Puri 2002) and

finds that greater availability and lower cost of venture capital funding are associated with more entrepreneurial entry. Our work is complementary to these papers, as we consider the impact of variation in the availability of the inventor's alternative to entry: cooperating with an incumbent firm.

An important challenge faced by empirical studies of entrepreneurial commercialization mode choice is that there are many unobserved characteristics of the focal innovation that influence the mode of commercialization and are likely to be correlated with the drivers of commercialization mode that we care about. For example, Shane (2001) finds that the nature of technological opportunity has an impact on firm formation. However, the potential market value of a particular invention is usually unobserved. The market value is likely to be correlated with the strength of intellectual property protection for the focal invention (less potential for imitation by rivals means a greater opportunity to capture rents). When market value is unobserved, it is impossible to know whether a positive correlation between intellectual property rights and cooperation with incumbents reflects the effect of strong intellectual property rights or whether cooperation is the results of greater willingness of incumbent partners when the expected market value is greater.

As a second example, technologies in more established technological areas (i.e. further along the technology life cycle trajectory) are likely to have two characteristics both favoring cooperation with incumbents: a proven market and the need for more significant complementary assets. If we observe only the need for complementary assets, and not the expected market size for the innovation, we cannot infer that the need for complementary capabilities favors cooperation with incumbents. Existing empirical work examining the drivers of commercialization mode typically tries to control for at least some of the other relevant

characteristics of the technology, or selects subsets of innovations that are argued to be similar across the critical dimensions.[2] But, in the absence of an exogenous shock to the dimension under study, the problem of potential unobserved drivers of commercialization mode remains an issue.

In our study, we exploit an exogenous shock to the costs of cooperation in one segment of a market for technology. This approach allows us to overcome this common empirical challenge. The increase in the cost of collaborating was imposed exogenously, not correlated with any particular characteristics of the inventions. In addition, it was imposed on one segment of the medical device industry, provided a natural control group with the remainder of the industry. This control group allows us to account for other (unobserved) changes that might be affecting the medical device industry.

Empirical Setting: Medical Devices and the Department of Justice Investigation

The medical device industry is an ideal context to test theories about the market for technology and commercialization strategies. First, the two conditions that favor cooperation with incumbent firms to commercialize a new invention hold consistently across this industry. Patents on inventions provide very strong intellectual property protection in the medical device industry (Cohen et al. 2002), and complementary assets including manufacturing expertise, knowledge of regulatory approval process and reimbursement procedures, marketing, sales and distribution capabilities, and a network of relationships with doctors are all held by the established medical device firms and are costly to replicate. If previous theory is applicable,

[2] Gans, Hsu, and Stern (2002) examination of transaction costs of cooperating does both, comparing venture backed and SBIR-backed ventures matched to be similar and also controlling for project-level characteristics. They propose that the presence of venture capital backing reduced costs of transacting by provided information that facilitates cooperation. They find that venture backed inventors are more likely to cooperate, rather than start new ventures, to commercialize technology. This may reflect that venture capital backing is associated with higher quality inventions, and that incumbent firms are more willing to cooperate on higher quality inventions.

these conditions suggest that medical device inventors would elect to cooperate with established firms rather than form new companies to commercialize new inventions.

Previous studies have documented the important role of practicing physicians as inventors and entrepreneurs in the medical device industry (Chatterji and Fabrizio 2009a; Chatterji and Fabrizio 2009b; Smith 2010). Physicians contribute about 20% of the patented inventions in medical devices, and their inventions are on average more cited and more likely at the leading edge of new technologies (Chatterji and Fabrizio 2011). In many cases, physicians and medical device companies work together to identify unmet clinical needs and develop successful products. Physician often act as paid consultants for firms, an arrangement that has raised significant scrutiny in recent years (Chatterji et al. 2008). Company executives argue that these relationships are essential to successful product development since physicians are uniquely positioned to offer insights into product attributes. Critics suggest that the lucrative consulting arrangement can provide improper incentives for physicians to recommend a particular brand to hospital administrators and patients, irrespective of clinical evidence. A significant number of conflict of interest cases have involved orthopedic companies and surgeons, where the market is heavily concentrated among 5 leading incumbents and brand loyalty is a significant barrier to competition and entry.

In response to these growing concerns, the U.S. Department of Justice (DOJ) launched an investigation in March 2005 against the five largest US orthopedic device makers, Biomet, the DePuy Orthopedics unit of Johnson and Johnson, Smith and Nephew, Stryker Orthopedics, and Zimmer. These companies comprised 93-95% of sales in the hip and knee implant market in the US (Healy and Peterson 2009). The investigation alleged that the companies violated the anti-kickback statue, in essence paying physicians to favor their own products in orthopedic

procedures. According to media accounts, the deferred settlement agreements had a dramatic impact on the operations of the companies involved, and smaller firms in the orthopedic market (Healy and Peterson 2009).

In November 2007, a settlement was reached where 4 of the companies signed deferred prosecution agreements (Healy and Peterson, 2009). Under these agreements, the companies agreed to increased transparency with substantial new disclosures, including prominently posting any payments to physicians on their websites. The companies also agreed to substantial oversight, including a monitor appointed by the Department of Justice, and a compliance officer who would report to the Department of Health and Human Services Office of Inspector General. If the companies succeeded in satisfying the conditions of the agreement, the Department of Justice stipulated that the conditions of the deferred prosecution agreements would expire in 18 months (March 2008), although the corporate integrity programs established with the Office of the Inspector General were to stay in place for five years, until September 2012 (Healy and Peterson, 2009).

While the companies reorganized their practices to satisfy the conditions of the settlement agreements, including posting payments to physicians, obtaining monitors, and fulfilling the other conditions of the agreements, "business as usual was suspended" (Healy and Peterson, 2009: 1974). Payments to physicians, as well as funding for scholarships, grants, and research, were canceled or put on hold. Once practices had been aligned with requirements, any companies desiring collaborations with physicians had to first pursue needs assessments, precertification of the work, and an evaluation of fair market value for the work performed by the physicians (frequently much lower than the rates the physicians were accustomed to, causing complaints).

A byproduct of the DOJ investigation was that cooperation between orthopedic physicians and medical device firms became much more costly and difficult for the firms. This turn of events impacted physician inventors whose inventions had applications in the orthopedics. The investigation and settlement agreements did not prohibit licensing inventions from physicians. But they did reduce the willingness of companies to cooperate with physicians and increase the costs of working with the physicians on an on-going basis. Because ongoing interaction, consultation, and transfer of "tacit" inventor knowledge (Elfenbein 2007) are often necessary to effectively develop and commercialize new technological inventions, the increased difficulty and costs involved in working closely with companies reduced the potential for physician inventors to license new technologies to orthopedic firms. As a direct result, we expect a decrease in collaborative physician-firm patenting and an increase in new venture activity in the orthopedics area following the initiation of the DOJ investigation as more physicians develop and commercialize their inventions independently from incumbent firms.

Empirical Methodology

There are two aspects of this context that are critical for empirically identifying the impact of the cost of cooperation on entrepreneurial entry and collaborative patenting. First, the DOJ investigation provides an exogenous shock to the costs borne by incumbent orthopedics firms participating in the market for ideas from physicians. The increase in costs of cooperation, and the resulting decrease in willing cooperative partners, is not endogenous to technology or market characteristics. Second, we have a natural control group to which to compare the temporal pattern of entrepreneurship and collaborative patenting. The DOJ investigation involved only orthopedics companies. Physicians are active inventors in many other medical

device segment (Chatterji and Fabrizio 2011). We can therefore compare the pattern of entrepreneurship and collaborative patenting in orthopedics to that in other medical device segments. Other market characteristics, such as economy-wide fluctuations, the availability of venture capital, and the strength of intellectual property rights are constant across the segments of the medical device market, and so this comparison controls for all of these other common factors. To the extent that other medical device companies, outside of the orthopedics segment, were impacted by the actions of the DOJ, this will bias our results toward non-significance.

We test our prediction in two ways. First, we look directly at new venture formation and explore whether there was an increase in new physician founded ventures in the orthopedics segment after the DOJ investigation. Based on the set of new ventures founded between 2000 and 2009, we examine whether the likelihood of physician founding is greater for orthopedics ventures founded during the settlement period, relative to outside of this period and relative to new medical device ventures in other segments. One limitation of the data on new ventures is that the number of annual new ventures, especially within a limited segment like orthopedics, is quite small.

We therefore also pursue a second analysis, using patent data to explore the extent to which physicians working in the orthopedics area reduce collaborative innovation with US companies following the DOJ investigation. We estimate a difference-in-differences model exploring the likelihood that a given physician-invented patent is assigned to a company (indicating collaborative invention) to explore whether the change in likelihood of collaboration from pre-investigation and settlement to during the investigation and settlement was significantly different for patents in the orthopedics segment, relative to other medical device patents. The benefit of this analysis is that we are able to control for both persistent differences between the

orthopedics segment and other medical devices and changes over time that are common across orthopedics and other segments.

Data and measures

The measures used on our analyses are summarized in Table 1. To develop data on new ventures founded in the medical device industry, we use information from the Capital IQ database. Capital IQ is an online searchable database of information on private and public companies provided by Standard and Poor's. We select all companies classified with a primary designation in Healthcare Equipment, Medical Equipment, Medical Testing, Analyzing, and Diagnostic Equipment, or Healthcare Supplies that are located in the US and were founded since the year 2000. This yielded 1234 companies. We reviewed the company descriptions for each of these companies to identify medical device companies and identified 377 such companies.[3] We also relied on the company descriptions to identify the 29 of these companies that are orthopedics companies. The descriptions are quite detailed, and usually listed the types of devices and markets that the company targets. Based on the founding year provided in the Capital IQ data, we identified the number of medical device ventures founded annually from 2000-2009 and how many of these firms were in the orthopedic segment.

[Table 1 Here]

We also utilized the biographical information provided in the Capital IQ database to research the founders and key executives. The biographical information typically includes the relevant work history of the individual, his or her educational background, and his or her position (and history) within the focal firm. For each medical device venture, we coded whether or not the

[3] We first identified any company for which the description included the term "medical device" and then reviewed each of these descriptions manually to eliminate companies that, for example, were suppliers to medical device companies or were purely incubators for medical device companies.

founding team included a physician and created an indicator variable *DocFounded*.[4] For the cases where executive team data were not available from Capital IQ (approximately 20% of the ventures), we supplement these data with web searches to identify the company founders and establish whether or not they are physicians.[5] Based on this information, we identify 98 of the 377 (26%) medical device ventures as physician-founded. Within the orthopedic firms, 9 of the 93 (10%) ventures were physician founded.

Our second analysis relies on the evidence of collaboration between physicians and medical device firms available from the patent data. Because the DOJ investigation was fairly recent (beginning in 2005), and granted patents only emerge 2-3 years after a patent application, we use data on both granted and not-yet-granted applications. Using the Delphion patent database, we select all granted patents and patent applications for application years 2001-2008 in the technology classes that the US Patent and Trademark Office identified as medical device technologies (US PTO 2005). Our time period for analysis is necessarily truncated because the requirement to disclose applications only took effect in 2001, and applications are disclosed with an 18 month lag, so that many from 2009 were not yet public when the data were downloaded. For each patent (or application), we collect information including the technology class and subclass, the application year, the assignee, and the name (first, middle, and last) and address (city, state, and country) of each inventor. Using the technology classifications provided by the USPTO office, we identified which of these patents were for orthopedic inventions, and created an indicator variable, *OrthoPat*.

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[4] The database usually indicates which individual was the founder. When no founder is indicated, we coded the firm as having a physician founder is one of the top key executives is an MD and was with the firm at the time of founding. When the only MD on the executive team is the Medical Advisor, for example, and this person joined the firm after the founding year, this was not counted as a physician-founded firm.

[5] After the web searches, we were still unable to identify whether the founders of 12 of the companies included a physician. We assumed that these were not physician-founded, based on our experience that companies with physician founders appear to advertise that fact. We report a sensitivity analysis below excluding these companies.

In order to identify physician-generated inventions, we rely on the American Medical Association (AMA) Masterfile data. The AMA Physician Masterfile contains the name, demographic information, address, history of prior locations, type of practice, and medical school information for all licensed US physicians. With this information, we were able to match the inventor data to the AMA list of physicians and identify which inventors listed on our sample of medical device patents were physicians.

We perform this match in several steps. First, we identified any physicians with the same last name, first name, and state location as an inventor listed on a medical device patent. We used the physicians' historic and current locations listed in the AMA data and the inventors' addresses provided in the patent data for this match. After identifying possible matches, we evaluated them more closely to assure a true match. For each record, if there was a middle name or initial available from both sources (the patent data and the AMA data), we verified that these records matched and eliminated any for which they did not match. When one or both of the middle initial observations was missing, we verified that the observations matched by city. Observations lacking sufficient middle name data that did not match exactly based on city were flagged for closer manual evaluation. Based on this match, we created an indicator variable equal to one for patents that included at least one physician inventor, *DoctorPat*.

In order to obtain more information about the patent assignees, we also merged this patent level data with the patent and assignee data available from the Patent Data Product, sponsored by the National Bureau of Economic Research. Through this merge, we are able to identify which of the assignees are US companies (as opposed to foreign companies or other organizations, such as government or academic institutions). We are also able to merge our patent data to the Patent Data Project mapping to public companies in order to identify which of

the assignees in our data are public companies. We use this information to create an indicator equal to one for US Company-assigned patents (*CompanyPat*), and an indicator equal to one for patents assigned to publicly traded US Companies (*PublicCompanyPat)*.

[Table 2 Here]

Summary statistics

The summary statistics for the dataset of new medical device ventures is presented in Table 2. More than a quarter (26%) of the ventures were founded by physicians, and 7% of the ventures were orthopedic device companies. Figure 2 provides the temporal patter of new venture founding in medical devices, in orthopedics specifically, and even more specifically founding by physicians in the orthopedics sector. Note that there were no new orthopedic ventures founded while the DOJ investigation was in process, during 2005 and 2006, possibly as a result of the uncertainty in this segment during that time. There is a marked rebound in new venture formation in the orthopedics sector in 2007, after the settlement agreement was in place and some uncertainty was resolved. Most interesting (for our purposes) is that we also see that a large proportion of the new orthopedics ventures in the settlement period included a physician founders.

[Figure 2 Here]

Summary statistics for the dataset of medical device patents are reported in Table 3. Eighteen percent of the medical device patents in these years included a physician inventor. Five percent of medical device patents were in orthopedics technology classes. Figure 3 compares the percentage of physician inventions that were company-assigned in orthopedics to other medical device technologies over time. During much of this period the percentage of orthopedics physician patents that were company assigned was higher than the percentage of physician

patents that were company-assigned in other segments of medical devices. However, there is a substantial decrease in company-assignment of orthopedic physician patents in 2007 and 2008, during the settlement period of the DOJ investigation.

[Table 3 Here]

[Figure 3 Here]

Regression Results

Evidence from New Venture Formation

Our first empirical analysis takes a more robust approach to examine these patterns. Using the data on all identifiable new medical device ventures founded between 2000 and 2009, we test whether there is a statistically significant increase in physician founded new ventures in in 2007 and 2008 (during the settlement agreement) in the orthopedics segment, relative to the rest of the medical device market. The dependent variable is an indicator equal to one for physician founded companies (*DocFounded*) and zero otherwise. Using a probit model, we predict the likelihood that a given venture is physician-founded as a function of the market segment (orthopedics or other) and the year of founding (in the settlement period or not). In order to control for common patterns of physician entrepreeurship over time, we include year indicators for each year 2001-2006 and 2009. The year 2000 is the excluded year, and years 2007 and 2008 are grouped in the "Settlement" indicator. Note that because there were no new orthopedics ventures founded during the investigation period (2005 and 2006), it is not possible to estimate an analogous regression for the investigation period.

[Table 4 Here]

The first column in Table 4 reports the results of this analysis. The insignificance of the estimated coefficient on the Orthopedics indicator suggests that ventures in orthopedics are on average equally likely to be founded by physicians as ventures in other segments. The insignificance of the estimated coefficient on the Settlement indicator suggests that the likelihood that a new medical device venture included a physician on the founding team was not significantly different during the Settlement period. However, the positive and significant coefficient on the interaction of the Settlement and Orthopedics indicators suggests that orthopedics ventures were more likely to be founded by a physician during the settlement period. This result is robust to excluding the 12 observations for which we are not able to satisfactorily confirm the lack of a physician founder (see results in column 2).

As with all non-linear models, the marginal effect of the coefficients cannot be read directly off of the table, and depend on the values of the other variables at which the model is evaluated. We use the Clarify software (King et al. 2000; Tomz et al. 2003) to calculate the expected change in the likelihood the a new venture includes a physician founder. Based on the results reported in column 1, new orthopedics ventures were 43% mode likely to include a physician founder during the settlement period than orthopedics ventures founded in other years. Another way to think about the results is the comparison of orthopedics firms to other medical device firms. Using the Clarify software, we calculated that during the settlement period, new orthopedics ventures were 34% more likely to be founded by doctors, relative to new ventures in other segments. Recall that in other periods, there was no difference in the likelihood of a physician founder between orthopedics and other ventures. These results are consistent with the prediction that the settlement would be associated with an increased likelihood that physician

inventors of orthopedic devices would elect to commercialize their inventions through entrepreneurship rather than collaboration with an incumbent firm.

Evidence from Collaboration on Inventions

Our second analysis examines the propensity for physician inventors to collaborate with an existing medical device firm by evaluating the likelihood that a physician-inventor's patent is assigned to a firm. Conceptually, this is a difference-in-differences estimation, wherein we are comparing the change in probability of company assignment from pre-settlement to post-settlement for two group of patents: physician-invented orthopedics patents and physician-invented medical device patents in other segments. Our prediction is that company assignment will decrease more during the settlement period for physician-invented patents in the orthopedics segment than for other physician-invented patents.

Using patent level data, we estimate a probit model predicting the likelihood that a patent is assigned to a US company (*CompanyPat*), including indicators for whether the patent is an orthopedic technology (*OrthoPat*) and this indicator interacted with the indicators for the years of the DOJ investigation (*Investigation*) and settlement (*Settlement*). We include year indicators for the years 2002-2004 (year 2001 is the excluded year) to account for any common time trends that affect the overall the percentage of medical device patents that were assigned to US companies, such as the rise (or fall) of foreign companies in this market. We also include a full set of technology class indicators, controlling for differences in the share of patents assigned to US companies across technologies. We report robust standard errors in all regressions.

[Table 5 Here]

In the initial models, we use the sub-sample composed of only the physician-invented patents. This estimation answers the question: what is change in the likelihood that a physician-invented patent is assigned to a US company in the settlement (or investigation) period? As results reported in column (1) of Table 5 demonstrate, the likelihood that a physician-invented patent was assigned to a US company decreased significantly during both the investigation and settlement periods. As predicted, the decrease in company-assignment during the settlement period is greater for physician-invented orthopedic patents than for other physician-invented patents (the interaction of the Orthopedics indicator and the Settlement indicator is negative and significant). For physician-invented patents in the orthopedics segment, there was a 21% decrease in the probability of company-assignment during the settlement period, relative to other periods. This can be compared to the estimated 14% decrease in the probability of company-assignment during the settlement period for physician-invented patents outside of the orthopedics segment. These two estimated decreases are statistically and economically significantly different. These results are consistent with the expectation that the increase in costs of collaborating associated with the settlement agreements reduced collaboration between physicians inventing orthopedic devices and the medical firms that could commercialize them.

The indicator, *CompanyPat*, used as the dependent variable in this estimation includes all US companies, and therefore one might be concerned that it also reflects physician-invented patents assigned to their own start-up companies. In the second column, we use the same sample of physician-invented patents, but estimate instead the likelihood that a patent is assigned to a public US company (*PublicCompanyPat*). Based on the results in column (2), the estimated decrease in likelihood of public company assignment for physician-invented orthopedic technologies during the settlement is 8%.

One concern with this analysis is that it is possible that US companies might have appeared as assignees on orthopedic patents less often (relative to other medical device patents) during the settlement period for reasons unrelated to the DOJ investigation, such as the entry of a major foreign competitor in the orthopedics segment. This could generate the observed negative coefficient on the interaction of the Orthopedics and Settlement indicators. In other words, the pattern presented here for physician inventions could be true of *all* inventions, which would undermine the interpretation that it was caused by an increase in the costs of firms collaborating with physicians. To address this, we estimate models using the full sample of all medical device patents (not only physician invented patents), and examine the likelihood of a patent being assigned to a US company. We include in the model a physician inventor indicator (*DoctorPat*), and test whether the negative coefficients on the interactions for *OrthoPat* and the settlement years indicator (*Settlement*) remain. Models (3) and (4) in Table 5 present this full estimation on the complete set of medical device patents.

The results demonstrate that the decrease in the likelihood of US company (and US public company) assignee-ship on orthopedic patents in the settlement years was due entirely to patents that included a physician inventor. The estimated coefficients on the interaction of *OrthoPat* and *Settlement* are not significant, indicating that the assignment pattern for non-physician-invented orthopedics patents was not different during the settlement period than in other years. The estimated coefficient on the interactions of the physician-inventor indicator (*DoctorPat*) and the investigation and settlement indicators confirm that physician-invented patents were less likely to be company-assigned during these periods (though this does not hold for assignment to public companies). Further, the interaction of the physician-inventor indicator and settlement period indicator with the indicator for orthopedic technologies confirm that the

reduction in company-assignment was greater for physician inventions in orthopedics. Based on the results in column (3), patented physician-invented orthopedic technologies were 21% less likely to be assigned to US companies during the settlement years, relative to physician invented orthopedic technologies in other years. Results in column (4) suggest that the decrease in assignment to public companies was of approximately 8%. These results are consistent with those based on the sample of physician invented patents, and confirms that the change in assignment likelihood during the settlement concentrated on physician inventors, and did not impact medical device patents more broadly.

Some of the estimated coefficients on the control variables are also of interest. For example, doctor patents are less likely to be assigned to companies, especially public companies, relative to other patents. Also, doctors inventing orthopedic devices appear more likely to assign their patents to companies, especially public companies, relative to other doctors. This is consistent with the expectation that complementary assets are even more substantial in this segment than in other segments of the market.

Discussion

The theoretical and empirical literature on commercialization strategy and entrepreneurship has focused on market characteristics such as the strength of intellectual property rights and the availability of complementary assets to explain the choice of inventors to work with incumbent firms or pursue entrepreneurial entry. However, this prior work has not considered how costs may differ across incumbent firms, in some instances precluding collaboration and fostering entrepreneurship as a default, rather than the preferred choice for the inventor. We extend existing theory to consider the perspective of the incumbent firm, creating a

theoretical framework that can more fully explain entrepreneurial entry as a chosen commercialization strategy.

We find empirical support for our prediction in the medical device industry using a novel empirical context that exploits a DOJ investigation and settlement that raised the costs of cooperation for a subset of incumbent firms and inventors. Unlike previous studies, our empirical approach provides a superior solution to the methodological challenges related to omitted variable bias, whereby the same forces driving commercialization choice are also driving the willingness of incumbent firms to cooperate with innovators. By comparing trends in orthopedics over time and comparing orthopedics to sub-sectors of the medical device industry that were not affected by the investigation and settlement, we are able to identify the impact of an increase in the costs of collaboration more precisely than in previous work. We find a 43% increase in physician-founded new ventures in the orthopedic segment during the years covered by the DOJ settlement relative to other years, and physician founding was 34% more likely in this period for orthopedics ventures than for other medical device ventures. Also during these years, inventions of physicians were 21% less likely to be developed collaboratively with orthopedic medical device firms, and were instead developed by the physicians independently. By promoting new entry instead of collaboration, the DOJ investigation shifted competitive dynamic in the market, perhaps inadvertently powering the gale of creative destruction in the orthopedic industry.

Despite these contributions, there are some limitations to our study. We cannot evaluate the impact of raising the costs of collaborating on the number, quality, or timeliness of innovative progress in the medical device industry. We can conclude that raising such costs shift inventions that would have been developed via collaboration to be commercialized instead via entrepreneurial entry. Given that with lower costs of collaboration, inventors would have chosen

to commercialize their inventions via collaboration, it is clear that entrepreneurship is sometimes a second best alternative from the perspective of the inventor. New entrants may have to replicate the significant complementary assets already held by incumbent firms in these instances, an investment that may not be optimal from a social welfare perspective. However, entry and subsequent increased competition in the market may be social-welfare improving in the longer term. It is also possible that some inventions that would have been commercialized in cooperation with incumbent firms are not commercialized at all when the cost of cooperation increases. We do not have any empirical evidence on this point, but further research might identify technologies for which the necessary investments in complementary assets are too large to merit entrepreneurial entry.

We also do not examine the impact of the DOJ investigation on products approved by the FDA and eventual sales. If the DOJ investigation led to more entrepreneurship in orthopedics, the product development cycle may have looked different in this sub-sector than others such as cardiovascular and neurology. It is possible that these physician founded ventures have been or will be acquired by larger firms who will further develop these innovations, gain FDA approval and bring these products to markets. On the other hand, it is also possible that smaller, venture capital backed companies in orthopedics are more likely to develop products on their own, building their own complementary assets and eventually changing the competitive environment in the industry, a result that would take many more years to observe.

Conclusion

The choice of an inventor to become an entrepreneur or collaborate with an incumbent firm is a key topic of interest in the study of strategy and entrepreneurship and also of interest to

policy makers seeking to foster economic growth and development. The short term and long term implications of these decisions influence the trajectory of markets and firms, powering the gale of creative destruction as entrepreneurs enter and compete with incumbents, or consolidating the power of existing firms who own the crucial complementary assets. As we gain more insight into commercialization strategies, we begin to understand more about the evolution of firms and markets themselves, building promising linkages between the study of strategy and entrepreneurship.

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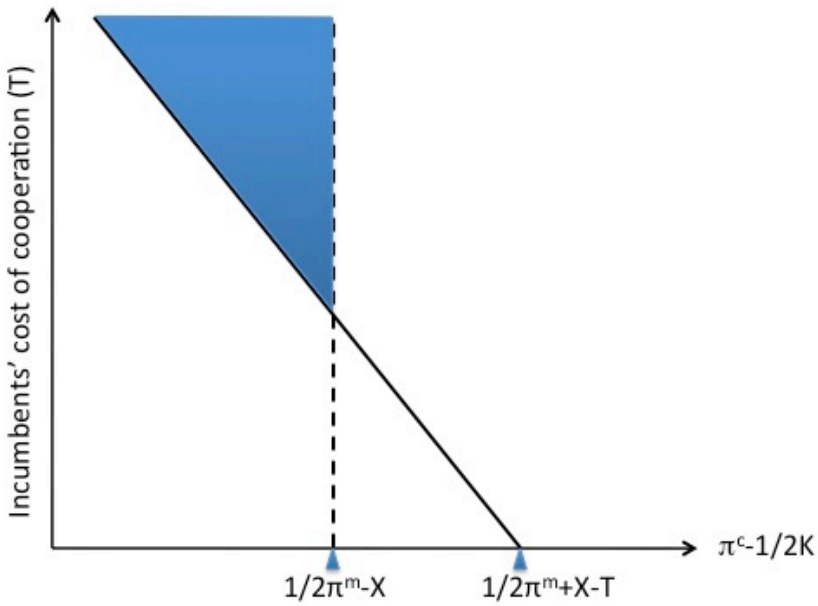
Figure 1: The gap between inventor and incumbent preferences increases with incumbents' costs of cooperating



where $X = \Delta p_r(1-\theta)(1-p_d)$

The incumbent wants to cooperate to commercialize the inventor's technology for values to the left of the solid line. The entrant want to cooperate with the incumbent for values to the left of the dashed line. When T, the costs of cooperation, increase, the incumbent is less willing to cooperate – he will cooperate only at lower and lower levels of profits available from competition.

The shaded area between the lines indicates the range of values where the inventor would prefer to cooperate with the incumbent, but the incumbent is not willing to do so. Note that this range increases with an increases T, the cost of cooperation.

Table 1: Description of Variables

Variable	Level of observation	Description	Source
New Ventures	Annual	Number of new medical device ventures founded in a given year	Capital IQ
New Orthopedics Ventures	Annual	Number of new orthopedics medical device ventures founded in a given year	Capital IQ
Investigation Year	Annual	Equal to 1 in years of the DOJ investigation (2005 & 2006), zero otherwise	Press releases
Settlement Year	Annual	Equal to 1 in years of the DOJ settlement (2007 & 2008), zero otherwise	Press releases
Doc Founded	Company	Equal to 1 if a given new venture was founded by a doctor, zero otherwise	Capital IQ and supplemental web searches
Ortho Company	Company	Equal to 1 if a given new venture is an orthopedic company, zero otherwise	Capital IQ and supplemental web searches
Ortho Pat	Patent	Equal to 1 for patents w/ orthopedics technology classifications	Delphion patent database and US PTO Technology Profile report.
DoctorPat	Patent	Equal to 1 for patents with at lease one doctor inventor	Delphion patent database combined with AMA Physician masterfile
CompanyPat	Patent	Equal to 1 for patents assigned to companies (rather than individuals, governments, or unassigned).	Delphion patent database and Patent Data Product
PublicCompanyPat	Patent	Equal to 1 for patents assigned to public companies (rather than private companies, individuals, governments, or unassigned).	Delphion patent database and Patent Data Product

Table 2: Summary Statistics for New Ventures in Medical Devices, 2000-2009

(N=370)

		Mean	Correlations:		
			1	2	3
1	Doc Founded (0/1)	0.26			
2	Ortho Company (0/1)	0.07	0.04		
3	Investigation Year (2005-6) (0/1)	0.20	-0.04	-0.14	
4	Settlement Year (2007-8) (0/1)	0.18	0.06	0.09	-0.23

Table 3: Summary Statistics for Patented Inventions in Medical Devices, 2000-2008 (N=111,117)

		Mean	Correlations:			
			1	2	3	4
1	CompanyPat (0/1)	0.36				
2	PublicCompanyPat (0/1)	0.18	0.61			
3	DoctorPat (0/1)	0.18	-0.07	-0.09		
4	OrthoPat (0/1)	0.05	-0.01	-0.04	0.04	
5	DoctorPat X OrthoPat (0/1)	0.01	-0.02	-0.02	0.24	0.48

Figure 2: New Venture Formation by Founding Year (comparing orthopedics to all medical device sectors)

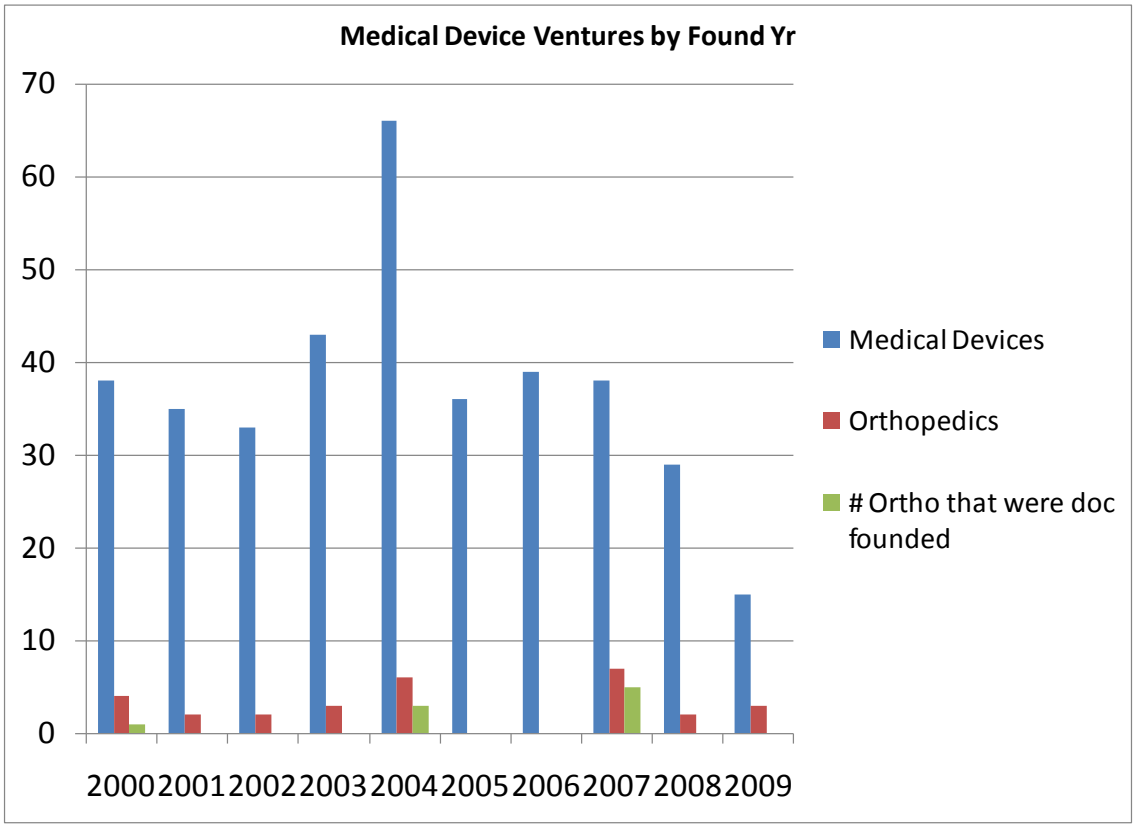


Figure 3: Company-assigned Physician Patents by Application Year (comparing physician-invented orthopedics inventions to other physician-invented medical device inventions)

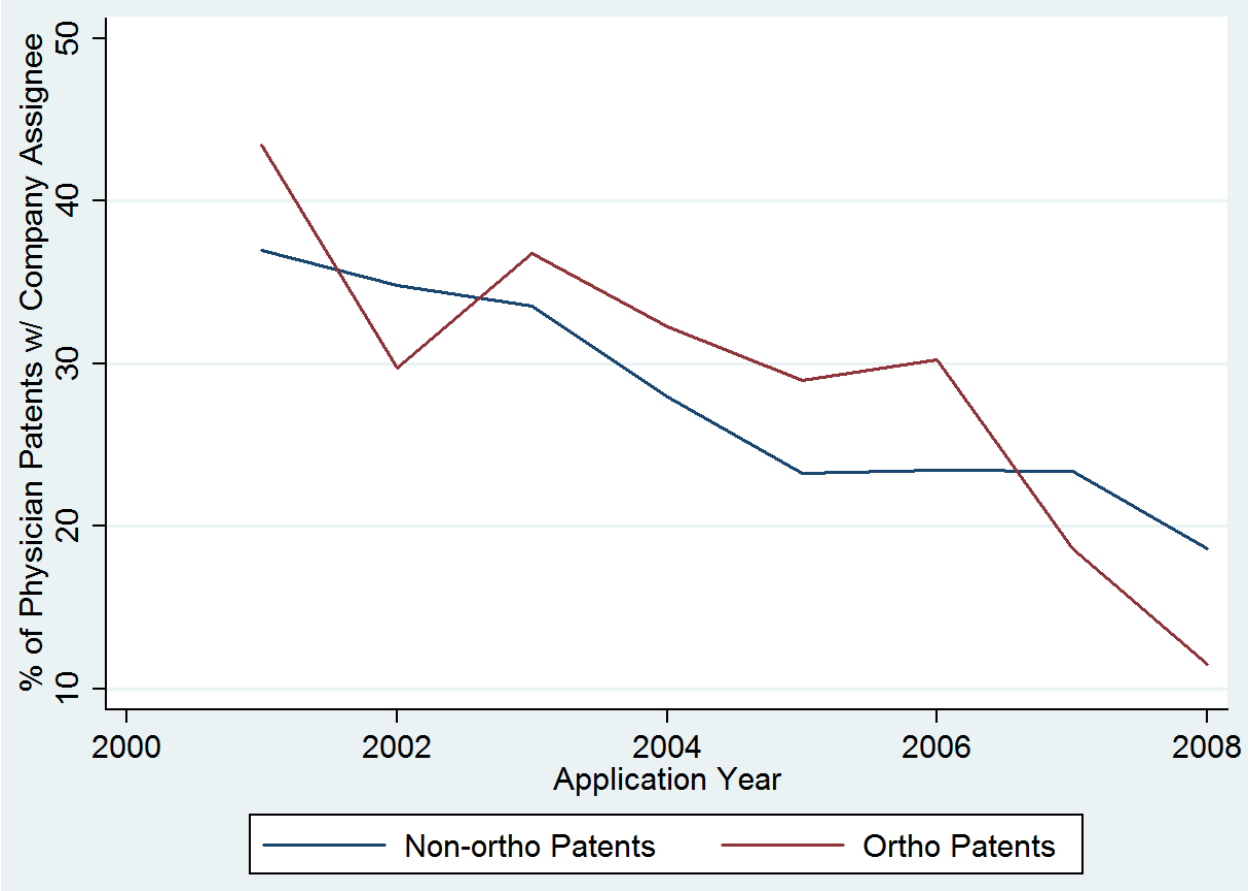


Table 4: Physician Founded Orthopedic Ventures Were More Likely When Collaboration was More Costly

	(1)	(2)
	Prob of Doc Founded Venture	Prob of Doc Founded Venture
Ortho Company X Settlement	1.160	1.134
	(0.594)*	(0.595)*
Settlement	0.096	0.118
	(0.286)	(0.290)
Ortho Company	-0.246	-0.265
	(0.343)	(0.344)
Constant	-0.691	-0.668
	(0.226)**	(0.228)**
Log Likelihood	-210.50	-198.14
Observations	370	358

Robust standard errors in parentheses; * significant at 5%; ** significant at 1%
Probit regressions, all specifications include year 2002-2006 and 2009 indicator variables, Years 2007 and 2008 are grouped in "Settlement" indicator.
DV equal to 1 for physician founded ventures, zero for all others.

Table 5: Company-Physician collaborative patents were less likely when collaboration became more costly

	(1)	(2)	(3)	(4)
	CompanyPat	PubCompanyPat	CompanyPat	PubCompanyPat
OrthoPat	-0.029	0.102	-0.170	-0.414
	(0.057)	(0.069)	(0.030)**	(0.038)**
OrthoPat X Investigation	0.123	0.157	0.183	0.116
	(0.096)	(0.113)	(0.048)**	(0.063)
OrthoPat X Settlement	-0.284	-0.336	0.072	0.054
	(0.094)**	(0.117)**	(0.051)	(0.066)
DoctorPat X OrthoPat X Investigation			-0.050	0.042
			(0.108)	(0.130)
DoctorPat X OrthoPat X Settlement			-0.346	-0.398
			(0.107)**	(0.134)**
DoctorPat X OrthoPat			0.148	0.604
			(0.060)*	(0.074)**
DoctorPat			-0.220	-0.475
			(0.014)**	(0.018)**
DoctorPat X Investigation			-0.095	0.072
			(0.027)**	(0.035)*
DoctorPat X Settlement			-0.156	0.046
			(0.029)**	(0.036)
Investigation	-0.387	-0.194	-0.179	-0.253
	(0.033)**	(0.042)**	(0.012)**	(0.016)**
Settlement	-0.450	-0.160	-0.181	-0.184
	(0.034)**	(0.042)**	(0.013)**	(0.017)**
Constant	-0.407	-1.556	-0.413	-0.992
	(0.047)**	(0.072)**	(0.019)**	(0.024)**
Log Likelihood				
Observations	19311	19311	111117	111117

Robust standard errors in parentheses; * significant at 5%; ** significant at 1%

Probit regressions, all estimations include technology class indicator variables and indicators for years 2002-2004. Year 2001 is excluded year. Years 2005-6 grouped into "Investigation" indicator, years 2007-8 grouped into "Settlement" indicator.

Sample in (1) and (2) is physician-invented medical device patents; Sample in (3) and (4) is all medical device patents.

DV in (1) and (3) equal to 1 for patents assigned to US Companies; DV in (2) and (4) equal to 1 for patents assigned to public US companies.

APPENDIX

A model of commercialization strategy from the incumbent's perspective

We draw on the simple model presented by Gans, Hsu, and Stern (2002) (henceforth GHS) to consider the incumbent's willingness to cooperate with a potential entrant. We retain all of the key features of that model, but consider the incumbent's payoffs from cooperating or competing with the potential entrant, instead of the entrant's payoffs. This allows us first to demonstrate that there is a non-zero range of values where the potential entrant (E) would prefer to cooperate, but the incumbent (I) prefers to compete. We add to the model a cost of cooperating with the entrant, borne by the incumbent firm (T), and show that the range where entrant prefers cooperation but incumbent is unwilling to cooperate grows with this cost.

Figure A1 illustrates the choices and payoffs faced by the incumbent firm (I) in the model. We follow the notation used in GHS to ease the integration of the results. Monopoly profits are denoted π^m. The entrant (E) and incumbent (I) both earn competitive profits π^c under the competitive strategy. Sunk costs of entry K are incurred by the entrant in order to enter and compete. In either strategy, E faces the possibility that I will imitate his innovation.

If E competes with I, I may imitate E's innovation with probability $(1 - p_r)$. With probability θ E successfully enforces it's IPR. Therefore, I commercializes an imitative technology with probability $(1 - \theta)(1 - p_r)$. Assume that introduction of an imitative technology by I raises I's profits by Δ and reduces E's by the same amount.

Under the cooperative outcome, we follow GHS and allow the profit sharing between I and E to be determined by a Nash bargaining solution, where the bargaining involves the potential risk of "expropriation" of E's technology by I. I imitates E's technology with probability $1 - p_d$ and E can enforce its intellectual property rights successfully with probability θ. As in the competitive strategy, the impact of imitation is to raises I's profits by Δ and reduces E's by the same amount. Thus, by negotiating to cooperate, E faces the risk that I will commercialize an imitative innovation with probability $(1 - \theta)(1 - p_d)$ if bargaining breaks down. As in GSH, the outcome of the bargaining game is that the two parties split the net gains from trade (Aghion and Tirole 1994). The transfer from I to E in the absence of expropriation is equal to $\tau = \frac{1}{2}(\pi^m - K) - \Delta(1 - p_r)(1 - \theta)$. The transfer from I to E under expropriation depend on whether E enforces his IPR, as follows:

With successful IPR enforcement $(\theta = 1)$: $\tau_0 = \frac{1}{2}(\pi^m - K)$

Without successful IPR enforcement $(\theta = 0)$: $\tau_1 = \frac{1}{2}(\pi^m - K) - \Delta$

Based on these payouts, the incumbent will cooperate if the benefit from doing so exceeds the payoff from competing. This occurs when the following condition is met:

$$\underbrace{\tfrac{1}{2}(\pi^m + K) + \Delta(1-\theta)(1-p_r p_d)}_{\text{I's payoff from cooperating}} > \underbrace{\pi^c + (1-\theta)(1-p_r)\Delta}_{\text{I's payoff from competing}}$$

This reduces to the following condition that must be met <u>for I to prefer cooperation</u> to competition:

$$\frac{1}{2}\pi^m + \Delta p_r(1-\theta)(1-p_d) > \pi^c - \frac{1}{2}K$$

We can compare this to the following condition <u>under which E prefers to cooperate</u>, taken from GHS:

$$\frac{1}{2}\pi^m - \Delta p_r(1-p_d)(1-\theta) > \pi^c - \frac{1}{2}K$$

Comparing these two conditions, it is easy to see that there exists a range of potential values where I prefers to cooperate but E prefers to compete. The left hand side of the I's condition to cooperate exceeds the left hand side of E's condition to cooperate whenever θ (the probability of successful IPR enforcement by the entrant) is less than one and $p_r$and p_d (the probability of incumbent imitation and expropriation) are non-zero. Intuitively, this suggests that when there is some likelihood that I will imitation / expropriate E's technology and E can not be certain of successfully enforcing his intellectual property rights, this risk favors E entering the market rather than cooperating with I.

More importantly for our study, it is intuitive that when I bears a cost to cooperation, T, this reduces I's payoff to cooperation. I's condition for cooperating when it must incur a cost to do so is:

$$\frac{1}{2}\pi^m + \Delta p_r(1-\theta)(1-p_d) - T > \pi^c - \frac{1}{2}K$$

As T increases, the range over which I prefers cooperation decreases while the relative payoffs to the entrant are unchanged. When T reaches the point at which

$$T > 2\Delta p_r(1-\theta)(1-p_d)$$

then it is possible that the entrant will prefer cooperation to competition, while the incumbent prefers competition to cooperation. Increases in incumbent's costs of cooperating with inventors force inventors, who would otherwise have elected cooperation, to enter and compete. This results in the costly duplication of complementary assets and changes the nature of competition in the industry.

Figure A1: Model of Incumbent's Choices and Payoffs