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RESEARCH NOTES AND COMMENTARIES

LEARNING AND PRODUCT ENTRY: HOW DIVERSIFICATION PATTERNS DIFFER OVER FIRM AGE AND KNOWLEDGE DOMAINS IN U.S. GENERIC DRUG INDUSTRY

XUANLI XIE1* and HUGH M. O'NEILL2

¹ National School of Development, Peking University, Beijing, China

This study uses learning theory to show how knowledge domains affect product extension decisions and how these product decisions change as firms age. Faced with the choice of new product-markets, a firm might decide to introduce a similar product, by leveraging existing firm knowledge, or to experiment with a less familiar product, which requires new knowledge. Using data on new drug introductions in the US generic pharmaceutical industry, the analyses showed clear support for heterogeneous product-market entry patterns across knowledge domains as the firm ages. Across time, the form of learning shifts from exploration to exploitation. Copyright © 2013 John Wiley & Sons, Ltd.

INTRODUCTION

One product is rarely sufficient for success, and the introduction of new products is critical for firm survival and growth (Argarwal and Gort, 2002; Cottrell and Nault, 2004; Kim and Kogut, 1996). Though many studies explain firm product diversification choices (Penrose, 1959; Teece, Pisano, and Shuen, 1994), a feature of these works is that they rarely observe choices directly (Bingham and Eisenhardt, 2011). As Furr, Cavarretta, and Garg (2012) state, 'because we often identify established firms by their stable product line,

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we tend to forget that, early in life, these same ventures change course frequently as they search for attractive opportunities (2012 p. 236).'In this paper, we observe the choices of firms at an early stage in their development, and compare those choices to older firms in the same industry. We use learning theory to note that decision makers with different knowledge backgrounds within the firm will make different choices. Knowledge gained after enacting the different choices leads to the frequent course changes that Furr *et al.* (2012) describe. In making the varied choices, firms move from novice to expert decisions and develop capabilities by a process that extends over time (Bingham and Eisenhardt, 2011).

In our use of knowledge as a construct, we follow the logic of Kogut and Zander (1992) in that we accept knowledge as a form of 'know-how' (p. 384). The forms of know-how we assess are based

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² Kenan-Flagler Business School, University of North Carolina, Chapel Hill, North Carolina, U.S.A.

^{*}Correspondence to: Xuanli Xie, National School of Development, Peking University, Beijing, 100871, PRC 86-10-62757267, China. E-mail: xxl@gsm.pku.edu.cn

on routines for making/designing a product (which we define as technology knowledge) and routines for selling/marketing the product (which we call marketing knowledge). The different routines used over time by individuals in technology and marketing lead to different espoused theories of action (Argyris and Schon, 1978), different ways of framing information (Dutton and Jackson, 1987; Ireland et al., 1987), and reliance on different information searches (Rosman, Lubatkin, and O'Neill, 1994). Our work is based on the premise that technology knowledge and market knowledge will each exert a different influence on a firm's new productmarket choices. In turn, we expect that the pattern of choices would vary across firms, as the relative influence of each knowledge base evolves in the firm.

THEORY AND HYPOTHESES

Organizational age and product-market entries

Although diversification as a general phenomenon has been found to be local and path-dependent (Chang, 1996; Teece et al., 1997), the patterns and effects may not be homogenous across firm age or firm knowledge domains (Kazanjian and Drazin, 1990; Miller and Friesen, 1984). New firms have a lower level of structural complexity than established firms (Haveman, 1993b), which means less bureaucratization and formalization and more direct connection between employees' effort and firm results. New firms have fewer resources and more newly emergent competencies (Stinchcombe, 1965) with less reproducibility, reliability and accountability (Hannan and Freeman, 1984). A young firm's heuristics for making choices provide a template for learning across time, as the firm adds and tests new choices. The firm's choices both converge and diverge across time (Bingham and Haleblian, 2012).

In contrast, older and more established firms are more likely to be constrained by their existing knowledge, so they are more likely to enter product-markets related to their past knowledge areas. Older firms usually have practiced their routines for a longer period of time, so they have greater competence in performing their existing routines (Levitt and March, 1988). The increase in competence leads to successful outcomes (Levinthal and March, 1993; Levitt and

March, 1988). This motivates the organization to further repeat these routines.

Also, inertia increases with firm age. Members in older firms are more willing to invest in firm-specific skills as the performance of legacy routines is reliable and less costly than other routines (Hannan and Freeman, 1984). Through time, mature firms institutionalize structures and routines. Interests and power vested in a certain course of action create pressures for persistence. As a result, older firms are less likely to choose novel routines (Aldrich and Auster, 1986; Haveman, 1993a). For example, Evans (1987) found that firm growth and variability of firm growth decrease with firm age. Younger ventures, less constrained by existing knowledge, search more broadly than established firms.

Given the shifts across time, aging will have a U-shaped effect on firm new product-market entries that build on existing knowledge. In the earliest stage of firm development, if the firm survives the initial hazards of founding, initial success will increase firm resources and viability and increase the likelihood of exploration. However, as firms mature, 'liability of aging' becomes a dominant effect and firms tend to stick to their established routines. Argarwal and Gort (2002) found that firm failure rates decline between year 3 and 7 (that is, after the earliest hazards of founding) and remain plateaued through year 16. Our arguments are based on the belief that the progressive learning after initial survival is based on search across alternatives that represent exploration. Success in exploration then later leads to a narrowing of the scope of search as the firm ages. Thus

Hypothesis 1 (H1): Firm age will have a U-shaped effect on product-market entries that build on existing knowledge.

Market and technology knowledge

Entry into new product-markets builds on knowledge of technology and of markets (Danneels, 2002; Mitchell, 1992). As the firm ages, knowledge about technology and markets becomes increasingly differentiated and individuals become identified and specialized with routines within the different knowledge bases. The managers with different knowledge sets differ in the form of information they use to make decisions and in their

perceptions of how skills might transfer to other product applications (Rosman *et al.*, 1994; Stimpert and Duhaime, 1997).

Technology knowledge gives the firm the ability to design and manufacture a physical product with certain features. Market knowledge gives the firm the ability to serve certain customers. Both technology and market knowledge are necessary for a firm to provide a final product. Technology knowledge, which is about R&D and production, accumulates as firms design and manufacture their products. Market knowledge is positioned in the complementary assets (Teece, 1986) that improve the firm's ability to market and distribute the new products.

A decision maker's background experience in a specific domain influences the decision maker's approach to scanning information and integrating new and novel information (Argyris and Schon, 1978; Fern, Cardinal, and O'Neill, 2012; Walsh and Ungson, 1991). Knowledge fields differ in their degree of tacitness, and individuals with experience in codified knowledge fields will find it easier to detect and implement novel options for action (Galunic and Rodan, 1998). Technology knowledge in the pharmaceutical industry involves routines covering production facilities, process, and patents. In contrast, market knowledge involves less tangible and codifiable components. There may not be a handbook or standard to follow, and specific elements of the knowledge are embedded in individuals, contacts, and relationships. When knowledge is more tacit, the ease of using that knowledge to find novel uses for the knowledge declines (Galunic and Rodan, 1998). Individual decision makers in marketing, where knowledge is less codified, face greater costs and risks in uncovering new market areas.

A second reason for difficulty in extending market knowledge to a new market is that market knowledge is socially complex and embedded in an external network. Building new market competence involves developing knowledge about new customers, gaining access to them through sales and distribution channels, researching new competitors and new customers, and developing new advertising and pricing strategies. As a firm builds exchange relationships with these external network stakeholders, its external ties and reputation become institutionalized. These ties constrain the firm within specific market areas (Christensen,

1997). In a case study of technological competence leveraging, Danneels (2007) illustrated the difficulty of applying an existing technology to a new market, as compared to levering an existing customer base to a new technology.

A final reason that market experience may recombine less readily than technology experience to novel uses in other contexts can be traced to the inherent differences in learning styles and incentives in the two fields. Fleming and Sorenson (2004) find that technology is based on the scientific method, which provides a norm for experimentation and a public forum for focusing search in particular areas. Given the uncertain nature of work outcomes, scientists are generally paid for behavior, rather than outcomes. In contrast, there are fewer standards prescribing learning methods in marketing, and professionals in marketing are frequently compensated based on sales outcomes (Christensen, 1997). Thus we hypothesize:

Hypothesis (H2): The effect of firm age on patterns of firm product-market entries will be stronger for technology knowledge than for market knowledge.

DATA AND METHODS

Sample and data sources

Data on the U.S. generic pharmaceutical industry serve to test the hypotheses. In the pharmaceutical industry, generic pharmaceutical firms produce copies of branded pharmaceuticals once the original patent expires. The milestone that started the modern generic pharmaceutical industry was the Waxman-Hatch Act of 1984, which allowed generic firms to submit Abbreviated New Drug Applications (ADNAs) for drugs approved since 1962. The number of generic drug applications increased after 1984.

The U.S. generic pharmaceutical industry provides an ideal setting to test our hypotheses for several reasons. This is an industry in which the external market plays a significant role on firm new product market choices. This context provides strong support for our argument on knowledge-based diversification if the effect of domain knowledge on new product-market entry choices is found.

Moreover, generic pharmaceutical companies face lower costs of entry into new product-markets compared to innovative pharmaceutical companies. This provides two advantages to test our hypotheses. First, generic pharmaceutical companies introduce a greater number of products in a relative shorter time span. Secondly, the generic pharmaceutical industry witnessed a high rate of new entrants over the study period due to low entry barriers. Throughout the period, entry activities have been common in this industry.

We collected the data on the generic pharmaceutical industry from multiple sources. Our primary data source was the drug applications database documented by the U.S. Federal Drug Administration (FDA). A second source was e-fact database, used to match each drug to an appropriate therapeutic area. A third source was Verispan SPA, which provided sales figures of therapeutic areas. Finally, firm founding dates and mergers and acquisitions were gathered from the Thomson Company, Lexis-Nexis, and SDC database.

The data contain the population of ANDA applications during 1984–2004. A firm demonstrated a new product-market entry when it received a new FDA approval to produce a generic drug. An approval is qualified as 'new approval' only when the following criteria were met: (1) the approval had a different application number from the previous approvals and (2) the approval was not for a relatively minor enhancement (i.e., different strength or dosage). There are 284 unique firm applicants in this dataset. As firms had a different number of approvals across different years, our data search yielded an unbalanced panel of 4,540 new product-market entries.

Variables and measures

We used targeted diseases as a measure of markets and forms of drug delivery as the measure of technology. The choice of target market for the drug is a critical step in the entry process. The choice of an appropriate therapeutic market segment is important because different areas have different market attractiveness; and they require different marketing knowledge concerning customers, distribution channels and area-specific reputations. The choice of drug format (for example, pill vs. liquid vs. cream) and delivery platform (for example, oral vs. injection vs. topical application) is a critical technology decision. Because drugs in

different forms require very different production equipment and processes (Scott Morton, 1999) and the choice of the drug's delivery platform affects how the drug is absorbed into the body, a new drug form also requires new knowledge and learning.

For the target market, a sample firm could choose from 19 major therapeutic (disease) areas. The classification on therapeutic areas is provided by FDA. On the technology dimension, a firm can choose among six major forms.

The dependent variable, the level of match with existing markets, is measured by the weighted number of prior products in the same therapeutic area as the new entry. Similarly, the level of match with technology is measured as the weighted number of prior products with the same technology. A greater number of products using the same market/technology as the newly chosen product indicate a higher fit between new entries and prior firm knowledge in market/technology. We use drug market size (in million dollars) as the weight to count for the variance of different drugs' impact on knowledge accumulation.

The independent variable, age, is measured by calculating the number of years between the firms' founding year and the year of its entry into the generic market.

The study includes controls for both market and firm factors that might influence the product choices. Market size is measured by drug sales (in million dollars) in the chosen therapeutic area. Market density is constructed by counting the cumulative number of drugs within the same therapeutic area. Similarly, technology density captures the number of drugs that use the same technology. To control for multimarket competition, we created a measure of multimarket contact following Fuentelsaz and Gomez (2006):

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¹ The 19 therapeutic classes are Anesthetics; Antidotes; Antimicrobials; Hematology; Cardiovascular-renal; Central nerve system; Contrast media/Radiopharmaceuticals; Gastrointestinals; taboics/Nutrients; Hormones/Hormonal Mechanisms; Immunologics; Skin/Mucous Membranes; Neurologics; Oncolytics; Ophthalmics; Relief of pain; Antiparasitics; Respiratory tract; and Unclassified/Miscellaneous.

² The six technology forms are oral solid; oral liquid; topical; injection; OTIC/ocular; and others.

Here n presents the technology market area of firm i's new entry at time t, m is the technology market area where firm has entered at time t. Firm j is the incumbent in market n. I_{imt} (I_{jmt} , I_{jnt}) is an indicator taking value 1 if firm i(j) is established in market m(n) at time t. This measure ranges between 0 (when firm i does not have any contact with incumbents in market n), and the total number of m (when firm i has contact with every incumbent j in every market m).

Firm size is measured as the number of drugs a firm produces. As experience before 1984 may influence choice (Nickerson and Silverman, 2003), we controlled for prior experience with a dummy variable, which we call *Pre84adna*. This is coded 1 if firms produced generic drugs before 1984, 0 elsewise. Because firm experience with patent drugs may affect their decisions (King and Tucci, 2002), we control for firms that produce both patent and generic drugs by using a dummy variable named innovative. We also use dummy variables labeled independent to control whether a firm is an independent business firm and foreign to control whether the firm is from countries other than the United States. Because a firm's knowledge may be affected by mergers and acquisitions, we use the dummy variable MAbuy to indicate whether the focal firm acquired another firm one year before the new entry. We also include the dummy variable MAsell to indicate whether the focal firm was a M&A target one year before the new entry. Finally, we controlled for firm breadth of knowledge, which is measured by the number of distinct market and technology classes a firm currently covers.

Analysis

In the dataset, some firms may not enter into more than one product-market. As our focus is on multiple entries, single entries might bias our results. In order to correct for this bias, we first estimated the probability of introducing a second generic drug, then used the estimator obtained from this analysis to predict subsequent entry patterns (Heckman, 1979).

The hypotheses presented in this paper are tested using panel data. A Hausman test for the orthogonality of the random effects suggests the random-effect and fixed-effect estimates are consistent, and individual effects are uncorrelated with the other variables in the model, suggesting

that the use of the random-effects model is preferred (Greene, 2000).

Results

The descriptive statistics and correlations are presented in Table 1 and regression is presented in Table 2.

Age and technology knowledge

Three models are used to test the hypotheses. Model 1, the test of the control variables, is significant (p < 0.001). In particular, technology density is positively related to the choice of a technology in the firms' knowledge base (p < 0.001). Market size is positively related to technology similarity (p < 0.001). Firms tend to enter less similar technology areas when multimarket contact is higher (p < 0.001). Firm size is positively associated with technology similarity (p < 0.001). The coefficient of Pre84adna is positive and significant (p < 0.01), suggesting de alio entrants are more likely to enter technology areas that match previous knowledge. Independent firms (p < 0.001) tend to enter less similar product-markets. Firms who acquired other firms are more likely to enter similar productmarkets (p < 0.001).

Model 2 adds the effect of age, and Model 3 further includes the quadratic term for age. The insignificant improvement from Model 1 to Model 2 and the significant improvement of model fit from Model 2 to Model 3 (p < 0.001) suggest a U-shaped relationship between age and the direction of new product-market entry. Firm age is negative and significant (p < 0.001), and the quadratic term is positive and significant (p < 0.001). The sign indicates aging will first decrease the constraints of knowledge on new technology field entries and then strengthen the bounds of knowledge. This supports Hypothesis 1.

Age and market knowledge

We use three models to test the effect of age on market knowledge. Model 4 to Model 6 present the regression results. The first model tests the control variables and is significant (p < 0.001). In terms of specific control variables, market density is positively related (p < 0.001) to the choice of markets that match the firm's knowledge base. Firms

0.28 91 -0.0115 4 0.08 0.19 0.19 0.17 -0.10 $0.01 \\ 0.15$ 12 0.07 -0.020.03 0 -0.030.40 6 0.02 -0.07 9 0.17 0.30 0.61 0.01 0.10 -0.04Descriptive statistics and correlations^a 58,508.50 S.D. ,468.02 878.88 similarit **Fech breadth** Mkt breadth density ndependent Mkt density Variable Mkt. MMC nnovative re84adna irm size oreign MAbuy MAsell Table 1.

also tend to enter less similar markets when multimarket contact is higher (p < 0.001). Similar to technology, firms are more likely to enter markets requiring similar knowledge when there is a larger market size (p < 0.001) and when firm is at a larger size (p < 0.001). De alio entrants and independent firms are more likely to enter similar markets (p < 0.001). Firms who previously acquired other firms enter markets similar to past choices (p < 0.001). Market breadth is positively associated with the number of similar markets (p < 0.01).

Models 5 and 6 include variables assessing the age effect. The changes in chi-square statistics of Model 6 over the base model (Model 4) as well as the linear age model (Model 5) are highly significant (p < 0.001). Again, a U-shaped interaction is found. The coefficient of the linear effect of age is negative and significant (p < 0.001), and the coefficient of the quadratic effect is positive and significant (p < 0.01). This also lends strong support for Hypothesis 1.

Comparing technology and market choices

In comparing the analyses on technology and market choices (Model 3 and Model 6), we found the impact of age on entries is stronger for technology knowledge than for market knowledge. This is because the coefficient of the quadratic term of age is 1.96 (s.e. = 0.431) for technology similarity and 0.57(s.e. = 0.205) for market similarity. The former is almost four times the latter. The larger the absolute value of this coefficient, the smaller the opening of the U-shaped curve will be. So the curve for technology knowledge is steeper with a smaller opening, while the curve for market knowledge is flatter with a larger opening. We illustrate this difference in Figure 1. To test the significance of this difference, we follow Mayer and Nickerson (2005) and Blum, Fields, and Goodman (1994) and use the unbiased test of equality of regression coefficients (Clogg, Petkova, and Haritou, 1998). The z score is 2.914, which is significant at the 0.01 level. This lends support for Hypothesis 2.

All coefficients greater than 0.02 are significant at the 0.05 level. n = 4.540 expect for technology and market density n = 4.315.

Overall, the regression on the impacts of market and technology knowledge provides strong support for our hypotheses. Age was found to have a U-shaped effect on the new product entries that build on existing technology or market knowledge. This finding lends support to the argument that firm diversification patterns

Table 2. Regression results^a

		L	Technology similarity	ý		Market similarity	
Variables	Labels	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Age	Firm age		-25.13	-342.47*** 1 06***		-33.64*	-125.69*** 0.57**
Controls	rii iii age square			0.1			0.0
Tech. density	Technology density	49.22***	49.17	49.52***	-0.21	-0.31	-0.020
Mkt density	Market density	-16.69^{*}	-16.54^{*}	-15.85	60.56	60.62	60.63
Mkt size	Market size	3.65***	3.66***	3.70^{***}	2.23	2.25^{***}	2.27
Tech/Mkt MMC	Multimarket contact	$-72,946.27^{***}$	$-72,476.60^{***}$	$-70,728.64^{***}$	$-5,879.95^{***}$	$-5,963.23^{***}$	$-6,063.96^{***}$
Firm size	Firm size	$2,207.27^{***}$	$2,210.03^{***}$	$2,220.44^{***}$	454.24***	457.60^{***}	460.24^{***}
Pre84adna	Pre1984 generic drug	10,313.52**	$10,413.92^{**}$	10,460.65**	$9,492.90^{***}$	9,593.78***	$9,573.99^{***}$
Innovative	Innovative drug	-2,241.88	-1,867.50	-530.70	1,863.50	$2,343.06^\dagger$	$2,711.92^*$
Independent	Independent firm	$-17,036.93^{***}$	$-16,935.59^{***}$	$-16,109.37^{***}$	$2,753.94^*$	$2,921.53^*$	$3,190.55^*$
Foreign	Firm origin	-240.39	392.56	-3,982.81	$2,408.45^*$	4,266.24**	$5,321.25^{***}$
MAbuy	Acquisition acquirer	$20,026.97^{***}$	20,304.73***	$20,911.83^{***}$	5,865.54***	$6,232.61^{***}$	$6,404.94^{***}$
MAsell	Acquisition target	$8,804.00^\dagger$	$8,821.82^{\dagger}$	8,186.18	673.11	704.29	529.41
Tech breadth	Total technology forms	2,379.19	2,568.02	3,295.27	-842.32	-458.42	-141.94
Market breadth	Total therapeutic areas	-110.42	-188.66	-245.71	993.20^{**}	923.79^{**}	949.22^{**}
V	Corrector for selection bias	-70.05	-1,280.13	$-9,584.68^{\dagger}$	-3,113.29	$-4,749.73^{*}$	$-7,183.32^{**}$
Intercept		$-34,494.68^{***}$	$-33,706.85^{***}$	$-29,429.42^*$	$-22,196.55^{***}$	$-21,084.05^{***}$	$-19,784.44^{**}$
\mathbb{R}^2		0.832	0.832	0.833	0.573	0.574	0.574
Wald χ^2		$20,710.57^{***}$	$20,709.65^{***}$	$20,828.31^{***}$	$5,597.83^{***}$	$5,609.11^{***}$	5,625.79***
χ^2 Change			-0.92	119.18***	1	11.28***	16.68^{***}

^a Hypothesis 1 was tested in Models 1–3 (technology similarity as dependent variable) and Models 4–6 (market similarity as dependent variable). Step-wise regression was used to show the curvilinear effect of age. Hypothesis 2 was tested through the comparison of regression coefficients of agesquare variable.

† p < 0.10; * p < 0.05; ** p < 0.001; *** p < 0.001.

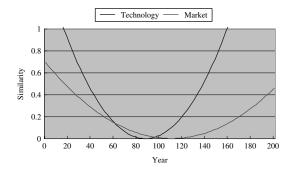


Figure 1. The effect of aging on technology and market similarity. The similarity axis is rescaled to make a clear presentation. The curve is not affected by the scale.

change as the firm ages. Moreover, the effect of age differs in relative strength for technology knowledge and market knowledge.

DISCUSSION AND CONCLUSION

This study used the population of U.S. generic pharmaceutical companies, including both young and old firms, to explain how firms explore and learn new capabilities (or their limits). The first important finding of this study is that younger ventures and established firms behave differently. The tendency of entering product-markets related to prior firm knowledge is not constant and is influenced by firm stage. Aging was found to have a U-shaped effect on entries to similar product-markets, which means firm age is first negatively, then positively, associated with related entries. This finding reveals an exploratory learning process in younger firms. This finding complements recent field research on learning in new ventures (Bingham and Eisenhardt, 2011).

Moreover, this finding has critical implications for organizational theory because it shows that younger firms learn through exploration. Then, as firms become relatively old, a conservative pattern is dominant, reducing the likelihood that firms enter product-markets unrelated to their past. The later stage of inertia and rigidity has been the focus of a number of scholars (Christensen, 1997; Leonard-Barton, 1992). By linking the age-dependent arguments to the phenomenon of product-market entry rather than to survival, this study delves deeper into the early development of capabilities, thus enriching our understanding of the genesis of capability development.

The second set of relationships explored in this study examined the impact of two dimensions of knowledge: technology knowledge and market knowledge. Interestingly, the two types of knowledge have distinct impacts on the pattern of product entry choices. Entry into a new market area requires that the firm understand new customers, hire new sales people, and build new contacts. The logic or recipe for obtaining this market knowledge is less well developed than the logics for making changes in technological regimes, when the technological regimes are based on science.

Overall, this study provides new insights on how organizations make product-market entry choices. Diversification, learning, and evolutionary literature predict knowledge exploitation and related product-market entry are more common among organizations, especially as they accumulate experience in a certain area. While our results confirm organizations tend to enter product-markets that are close to their current knowledge and capabilities over the long term, we find that the tendency varies in pattern across time and in strength across knowledge types. The learning process revealed in the paper demonstrates the evolution of routines as first an experimental process across diverse paths, leading to the eventual formulation of dominant paths.

The hazards of experimentation and the switch from experimentation to exploitation remain as underinvestigated areas. The difference in the learning styles between knowledge domains suggests the potential for conflict in the organization as different managers make different choices. How the conflict becomes evident and finds resolution is not obvious. There will be champions for different forms of strategic initiatives, and they will attempt to influence each other in a variety of ways (Lechner and Floyd, 2012). Managers may need to recognize and resolve conflict (Eisenhardt, Kahwajy, and Bourgeois, 1997), but the form of championing and conflict created by different knowledge-based preferences for product entry has not been studied directly.

Several limitations of this study should be noticed. The study is based on a single industry, and the product choices are not observed directly. A more direct and finer grained measure could be the expertise of the firm's sales force or specific knowledge of the firm's technologists. Future studies can integrate other industries and research

methods such as field study or questionnaires to address this limitation.

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