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AN EMPIRICAL ANALYSIS OF SUSTAINED ADVANTAGE IN THE U.S. PHARMACEUTICAL INDUSTRY: IMPACT OF FIRM RESOURCES AND CAPABILITIES

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The authors test a model of the relationships among firm resources, firm capabilities, and sustained competitive advantage between 1971 and 1989. Sustained comparative advantage was captured by two variables: therapeutic differentiation and global NCEs. The results show that R&D and salesforce expenditures have indirect and direct effects, respectively, on sustained competitive advantage. Firm capabilities were differentiated into component and integrative capabilities. Component capabilities were captured by the firm's internal R&D efforts and therapeutic market focus, while integrative capabilities were concerned with the firm's ability to obtain FDA approvals and to develop radical new drugs. Findings on each of these four capabilities on therapeutic differentiation and global NCEs are mixed. The direct and indirect effects of these resources and capabilities on therapeutic differentiation and global NCEs suggest important managerial implications in the way firms coordinate and combine their assets so as to achieve sustained competitive advantage.

INTRODUCTION

The resource-based view has been insightful in explaining the basis by which the resources and capabilities of a firm serve as sources of sustained competitive advantage (e.g., Barney, 1991; Mahoney and Pandian, 1992; Peteraf 1993). This view does not consider the firm simply as a contractual entity. Rather, as argued by Foss (1996: 470), the firm is a repository of knowledge stocks that are accumulated in a firm-specific or path-dependent manner. Thus, the resource-based view (RBV) provides a firm-specific perspective wherein the importance of tangible and intangible resources that are unique to a firm are emphasized as the source of competitiveness.

Although the RBV has received considerable attention in the literature, few empirical studies based on this perspective exist. This may be attributable, in part, to difficulties in the identification and measurement of valuable resources and capabilities because of the industry specificity of these assets. To address the industry specificity issue, we focused this study on a single industry: U.S. ethical pharmaceuticals.[1] The pharmaceutical industry is a particularly appropriate context because competitive advantage is tied to knowledge or technology development. The industry is noted for its technological intensity and studies suggest that research and development (R&D) is an important source of advantage (Henderson and Cockburn, 1994; Dierickx and Cool, 1989). Furthermore, the technological development process in the pharmaceutical industry has relatively well-defined components that allow the RBV to be

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[1] Ethical drugs are those that have to be approved by the Food and Drug Administration (FDA) before commercialization.

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operationalized in a manner that can be applied to most major competitors within the industry.

Previous studies suggest that R&D expenditures, even if they lead to innovation, do not necessarily provide firm-specific advantages that lead to higher performance (e.g., Teece, 1987; Mansfield, Schwartz, and Wagner, 1981). Strategic group analyses of the pharmaceutical industry (e.g., Cool and Schendel, 1987; Fiegenbaum, Sudharsan, and Thomas, 1990) suggest that factors other than R&D expenditures may be responsible for performance differences. We argue that it is the firm's unique capability to deploy or transform its resources that results in sustained competitive advantage (Dierickx and Cool, 1989; Lado, Boyd, and Wright, 1992; Leonard-Barton, 1992). This argument is consistent with Penrose's observation that 'a firm may achieve rents not because it has better resources, but rather the firm's distinctive competence involves making better use of its resources' (Penrose, 1959: 54). Thus, in summary, the pharmaceutical industry represents a rich context in which to explore an RBV because both resource stocks and the capability to transform these stocks into valuable attributes appear to be important for firm success. For this industry, we propose and test the following model: firm resources → firm capabilities → sustained competitive advantage.

THEORY AND HYPOTHESES

Sustained advantage in the pharmaceutical industry

As stated previously, this study examines sustained competitive advantage from a resource-based perspective. Maijoor and van Witteloostuijn (1996) developed a framework of sustained advantage building upon the resource-based literature. Extending the work of Barney (1986), they argue that the potential for deriving sustained advantage at the firm level of analysis depends on the extent that the resources are *valuable* and *rare*. In essence, valuable and rare conditions can exploit product market imperfections that create rent-producing potential (Maijoor and van Witteloostuijn, 1996: 550–551). For this rent appropriation to be sustained, the resources must be both imperfectly imitable and imperfectly substitutable by other firms in the industry.

Based on this framework, two components of sustained advantage may be identified within the pharmaceutical industry: therapeutic differentiation and global new compound entities (NCEs). A pharmaceutical firm has a rather limited time period and number of products by which to capture rents associated with its innovation. Essentially the time period spans the date of regulatory approval to the date of patent expiration. Patent protection, particularly for the more differentiated products, creates a temporary state of factor market imperfection, as the innovation has limited imitability and substitutability. To extract the 'maximum' level of rents within this type of factor market, new drugs or NCEs must be of superior quality in terms of efficacy, application, and market potential. Furthermore, the market demand must be stimulated in an expansive and aggressive manner. Thus, high-quality products (therapeutic differentiation) that have a world market application (global NCEs) would result in the highest source of rent generation.

Therapeutic differentiation may also create intertemporal dependence that results in rents continuing past the patent expiration date. Intertemporal dependence is a situation in which a firm is able to translate a technology gap into an advantage that persists even after the gap is closed (Porter, 1983). The potential for intertemporal dependence exists in the pharmaceutical industry, as the industry is characterized by high switching costs, infrequent repeat buying (Robinson and Fornell, 1985), and expensive information-gathering processes to support purchase decisions (Schmalensee, 1982). Thus, a product with superior attributes can create first-mover advantages that may lead to a level of sustained rent generation even as the factor market imperfections diminish.

The next section describes the specific resources and capabilities within the pharmaceutical industry that are expected to impact therapeutic differentiation and global NCEs.

Firm resources

A conceptual framework linking firm resources and capabilities to sustained competitive advantage within the pharmaceutical industry is depicted in Figure 1. Amit and Schoemaker (1993: 35) distinguish resources and capabilities by conceptualizing resources as factor stocks that are deployed through a firm's capabilities. They

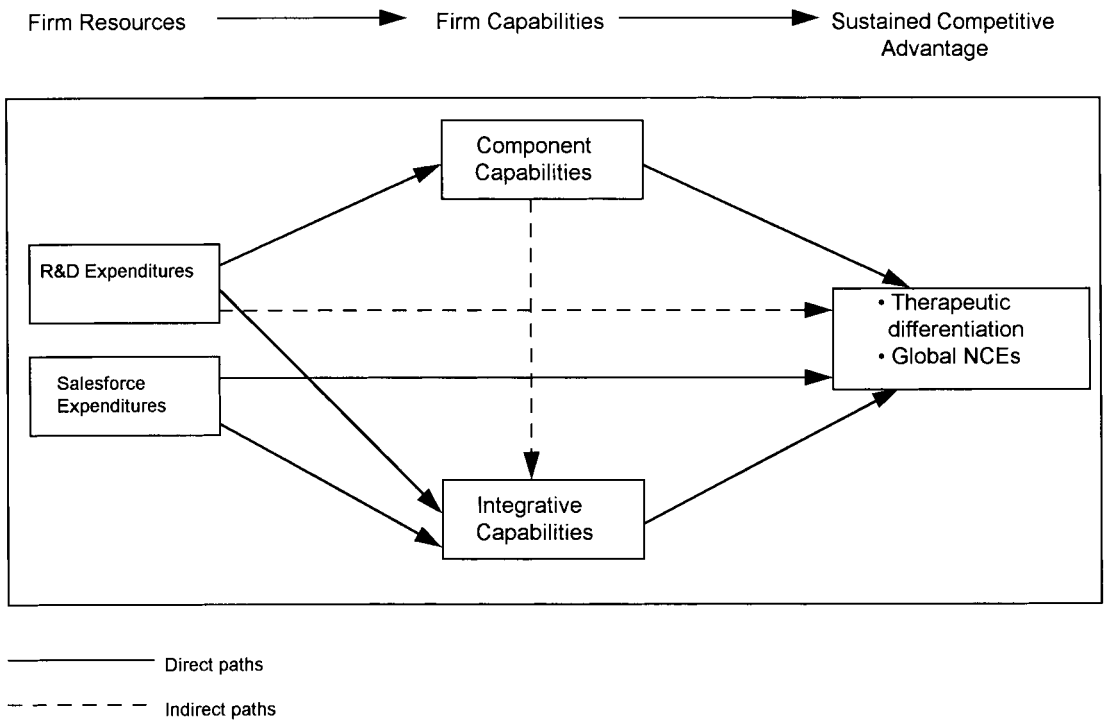

Figure 1. A resource-based model in the pharmaceutical industry

assert that capabilities are the firm-specific basis by which the productivity of resources is enhanced. Capabilities are the means by which the resources are deployed, 'to effect a desired end' (Amit and Schoemaker, 1993: 35). Know-how is embedded in resources and is transformed through capabilities.

Based on this perspective, resources are expected to be the basic input to the transforming capabilities of the firm. However, as will be argued in this section, we also allow for firm resources to impact competitive advantage directly, rather than only through organizational capabilities. While Hofer and Schendel (1978) propose various categories of resources, we focus on technological (R&D expenditures) and marketing resources (salesforce expenditures). Both academics (e.g., Cool and Schendel, 1987; Taggart, 1993) and practitioners (Arthur D. Little, 1989; *Financial World*, 1989) emphasize the importance of these two resources in the pharmaceutical industry.

Commitment to R&D spending is necessary for product innovation (Maidique and Hayes, 1984; Hambrick and MacMillan, 1985; Capon, Farley, and Lehmann, 1992). While a substantial level of R&D investment is needed to support new product development, diminishing returns to R&D have also been observed in the industry (ITC, 1991; Graves and Langowitz, 1993; Omta, Bouter, and van Engelen, 1994). Similarly, while therapeutic differentiation requires high R&D expenditures, the strength of this relationship is expected to be influenced by firm capabilities such as the ability to execute predevelopment, market-related and technological activities (Zirger and Maidique, 1990). These arguments suggest that R&D expenditures will have predominantly impact competitive advantage through the capabilities of the firm.

As stated previously, a commitment to marketing efforts also has been observed to be important in the industry. Promotional resources are concentrated largely on a 'push' marketing strategy in the form of detailing efforts to physicians, retailers, and hospitals.[2] The theory of spatial

[2] Detailing is another term for salesforce. In 1989 detailing accounted for 74 percent of total promotional outlays, advertisements in medical journals accounted for 24 percent, and direct-mail efforts the remaining 3 percent (Caves, Whinston, and Hurwitz, 1991).

preemption (Prescott and Visscher, 1977; Schmalensee, 1978) suggests that economies of scale in salesforce efforts facilitate information flows and maximize global sales by establishing positions in geographic space as quickly as possible. The importance attached to the role of scale economies is evidenced by the recent consolidation of companies and the steady growth of pharmaceutical salesforce resources (Taggart, 1993).[3] In addition, through a competent salesforce, information about emerging customer needs may be integrated into the drug discovery and development process to ensure successful differentiation in drug therapy. Studies from the new product development literature have generally found a strong relationship between marketing orientation and ultimate new product success (e.g., Cooper and Kleinschmidt, 1990).

The sustainability of a competitive advantage depends, in part, on the speed with which other firms can imitate the source of advantage. While R&D and salesforce expenditures are both important, we expect that salesforce expenditures will be a more durable source of competitive advantage. As stated previously, sustained advantage is based on a resource being valuable and rare, conditions reflected in part by the market imperfections associated with the resource. R&D resources may be traded to some extent through market transactions such as acquisitions and licensing arrangements. Although the impactedness and uncertainty that accompany intangible assets create considerable difficulty in these market transactions (Caves, 1982); i.e., the market is not perfect, R&D market-based transactions do exist. In contrast, expertise within the salesforce involves the accumulation of customer knowledge, competitor knowledge, and brand expertise. As a consequence, the ability to capture salesforce advantage through market transactions is rather constrained. As argued by Peteraf (1993: 180) imperfect resource mobility helps ensure that rents are, indeed, tied to and captured by the firm. In summary, as depicted in Figure 1, we expect resources to influence competitive advantage directly and indirectly. Specifically, R&D expenditures will indirectly influence therapeutic differentiation and global NCEs, while salesforce expenditures will have a direct influence.

Component and integrative capabilities

In the previous section, we discussed the relationship between firm resources and sustained advantage. Our focus now turns to capabilities within the firm. We argue that firm capabilities account for differences in sustained advantage beyond those accounted for by resource levels. Based predominantly on the work of Henderson and Cockburn (1994), two dimensions of a firm's capability to transform its resources are distinguished: *component capabilities* and *integrative capabilities*. Component capabilities are local abilities that are fundamental for day-to-day problem solving (Henderson and Cockburn, 1994: 65). They are economies of experience, the knowledge and skills embedded within the firm, or organizational routines which are regular patterns of activity achieved through coordination by individuals in a company over time (Nelson and Winter, 1982). Often, these routines require highly complex interactions. Integrative capabilities refer to the ability of a firm to use resources and component capabilities to support organizational renewal. Integrative capabilities reflect the ability to deploy or use both resources and component capabilities in new or flexible ways to support organizational renewal. The relationship between each capability and advantage is discussed in the following sections.

Component capabilities

There are two important component capabilities within the pharmaceutical industry that build upon economies of experience: internal R&D efforts and therapeutic market focus. As discussed previously, R&D expenditures can be directed toward internal development activities or toward acquiring technology in the factor market. We posit that the deployment of R&D resources within the firm is more efficient, and qualitatively more productive in the long term, because of the opportunity for acquiring economies of experience (Porter, 1980). This experience and internal learning will allow the firm to apply the acquired know-how continuously and intimately to the

[3] In the United States, salesforce personnel made 30 million calls on office-based doctors in 1989. This figure represented an increase of nearly 50 percent over 1982 and this occurred without any rise in the number of American doctors. Globally, the increase in the size of salesforce has also allowed companies to accomplish a worldwide launch in only 4 years, where they once required 8–10 years.

manufacture of existing and new drugs, or the undertaking of follow-on research.[4] The amount of resources available to the firm imposes constraints upon the range of organizational routines that can be performed. Thus, we expect firms with a strong focus on internal R&D efforts to support this strategic initiative with higher R&D expenditures.

Due to the high adjustment and transaction costs of shifting R&D and sales efforts from one therapeutic market to another, as well as the rising costs of large-scale R&D programs, firms are compelled to develop unique competencies in particular disease states. For example, through cumulative expertise in the anti-inflammatory segment, Feldene, Pfizer's anti-inflammatory agent for the treatment of arthritis, contributed substantially to the company's growth throughout the early 1980s. Similarly, Eli Lilly is often regarded as a leader in the area of diabetic therapy. As shown by Henderson and Cockburn (1994), the development of local knowledge and ability in particular disease areas is a function of the prior resource investments of the firm. In this particular context, we expect a firm's component capabilities to be driven primarily by R&D expenditures. Specifically, R&D expenditures are expected to have a direct influence on internal R&D efforts and therapeutic market focus.

Integrative capabilities

The integrative capability dimension is similar to the notions of 'combinative capabilities' (Kogut and Zander, 1992) and 'architectural competence' (Henderson and Cockburn, 1994). To capture the deployment or use of resources to support organizational renewal in the pharmaceutical industry, we focus on integrative capabilities that can be linked directly with the innovative efforts of the firm. Two important integrative capabilities are suggested: drug approval success and an emphasis on radical innovation. Competitive advantage in these dimensions is often based on processes or assets that are not easily replicated and require sophisticated knowledge or complex operations systems that may be tacit in nature. As described by Peteraf,

> Such [nontradeable] assets tend to defy imitation because they have a strong tacit dimension and are socially complex. They are born of organizational skill and corporate learning. Their development is 'path dependent' in the sense that it is contingent upon preceding levels of learning, investment, asset stocks, and development activity (Peteraf, 1993: 183).

Drug approval success is a proxy for accumulated R&D competence in developing a potential drug from its initial discovery stage to a stage closer to approval for marketing (Cool and Schendel, 1987).[5] 'Radical innovations' refers to the development of NCEs vs. the reliance on modified or combination products and, as such, relates to competitive advantage sought through innovation rather than through imitation. While R&D expenditures are expected to affect innovative productivity, previous studies suggest that the development of knowledge-based learning from cumulative investments in R&D is a more enduring success factor than is R&D spending alone (Ghemawat, 1986; Dierickx and Cool, 1989). Similarly, Hamel and Prahalad (1993) note that successful resource leverage requires concentrating resources on key strategic goals and the effective accumulation of resources. Thus, higher R&D expenditures will not necessarily lead to higher drug approvals if the firm is unable to leverage them strategically in a way that they are more difficult for competitors to imitate. In this study, whether R&D resources will have an important bearing on a firm's integrative capabilities depends on whether the resources are leveraged in core therapeutic areas and whether the firm maximizes learning from the accumulated resources. Thus, we expect R&D expenditures to have a direct influence on both approval success and radical innovations, as well as an indirect influence through component capabilities.

Considering marketing activities, the salesforce serves a potentially critical role in gathering market-based information and providing direction throughout the value creation process, from discovery and development to the total life cycle of the product in the market. Thus, even before the

[4] Doing work in-house also helps to develop 'absorptive capacity' to integrate information spillovers from other firms (Cohen and Levinthal, 1989).

[5] The three major phases of new drug development are the Investigational New Drug (IND), New Drug Application (NDA) and NCE stages. From the 10,000 compounds synthesized, only about 10 will advance to the NDA stage, of which on average only one will be approved for commercial introduction as an NCE (Sheck *et al.*, 1984).

prelaunch stage, salesforce efforts are necessary to create awareness about and interest in promising drugs in the approval pipeline (SRI International, 1989). By conditioning the target audience about potential new drugs, pharmaceutical firms can attempt to influence preferences rather than merely respond to them. Therefore, salesforce expenditures are expected to influence approval success and radical innovations directly.

Impact of capabilities on sustained competitive advantage

The component and integrative capabilities of a firm can lead to sustained competitive advantage only if firms that do not possess these capabilities cannot acquire them and/or replicate them successfully (Barney, 1991; Peteraf, 1993; Collis, 1994). Given that integrative capabilities are born of organizational skill and cumulative corporate learning, they tend to be imperfectly imitable and, thus, become enduring sources of competitive advantage for pharmaceutical firms. Global NCEs represent the most innovative of all new products and such a product orientation strategy tends to be successfully supported from the history-dependent nature of a firm's human capital (Burgelman and Maidique, 1988). Similarly, to the extent that the ability to offer unique and differentiated drugs is also dependent on prior learning, this capability is not easily replicated. New drugs that are perceived to offer real therapeutic advantages are expected to have higher FDA approvals. At the same time, successful approvals by the FDA may facilitate the acceptance of drugs in other countries. Thus, integrative capabilities will impact sustained competitive advantage directly. In particular, radical innovations and high approval success are expected to influence both therapeutic differentiation and global NCEs.

For firms that lack research abilities or have a weak drug portfolio, a licensing-in strategy is an alternative source for new products (Capon and Glazer, 1987; Sapienza, 1993). However, it is often argued that technological purchases are not a substitute for technical competence (Gold, 1987). A study by the International Trade Commission (ITC, 1991) found a significant relationship between internal R&D and global market share, which is consistent with Dierickx and Cool's (1989) contention that the firm's unique history enhances resource inimitability. The RBV suggests that a firm's ability to acquire and exploit resources depends upon its historical accumulation of assets. Thus, incumbent firms that have emphasized the development of internal R&D capabilities are able to sustain their competitive advantage from this time-dependent trajectory, as other firms cannot easily replicate it.

While organizational routines may improve efficiency, these same capabilities may render the firm inflexible in dealing with novel situations. Internal R&D efforts could have a negative impact on competitive advantage if these institutionalized capabilities do not evolve concurrently with environmental changes. For example, technological discontinuities can destroy existing competencies within an industry (Tushman and Anderson, 1986). Similarly, while the economies of experience from a strong therapeutic focus facilitate drug development, this capability can turn into a disadvantage if the firm is unable to transfer its experience into new emerging areas of research. Skills and knowledge embedded in individuals can either turn into core rigidities because they are less amenable to change or turn into core capabilities by enabling the firm to pursue a strategy of related diversification (Grant, 1991; Leonard-Barton, 1992). Thus, the direction of the relationship between component capabilities on a firm's sustained competitive advantage is equivocal. As depicted in Figure 1, internal R&D efforts and therapeutic market focus will influence therapeutic differentiation and global NCEs directly but also indirectly through the firm's integrative capabilities.

RESEARCH METHOD

Sample

The sample for this study was defined narrowly to include a rather homogeneous set of firms. This approach was considered important in that the resource accumulation process should be sufficiently similar across the firms studied that it is appropriate to pool them together. While a restricted sampling approach may limit the generalizability of the research, it enhances confidence that the findings are a result of the proposed relationships. This consideration led to the use of three criteria to identify the sample.

First, for a firm to be included in this study it

had to be active in the ethical drug business. Firms that derive more than 50 percent of their sales from either proprietary drugs or branded generics were excluded due to the heterogeneity in competitive orientation of firms in these sectors. Second, biotechnology companies were excluded from the study. It is unclear at this stage whether the processes critical to advantage within the biotechnology-based segment are comparable to the resources and capabilities that support pharmaceutical firms. Furthermore, the large differences in size and markets between biotechnology and pharmaceutical companies make cross-comparison difficult. Third, mergers and acquisitions can affect a firm's scale and scope of business. Therefore, we limited our study to firms that operated as separate entities between 1971 and 1989. The mergers and acquisitions that occurred in the industry after 1989 (e.g., SmithKline-Beecham; Bristol Myers-Squibb; Hoechst-Marion Laboratories) potentially introduce sampling error from a changed sample. In total, 20 firms were included in the study (see the Appendix).

Variables and data

The variables and their measurements were determined through a two-stage process. First, the secondary literature was reviewed to determine the resources and capabilities that are important for competition in the industry. These secondary sources included company annual reports, books on the industry, articles in the marketing, management, and innovation journals, and medical journal articles. The second stage involved interviews with product and marketing managers at several pharmaceutical companies as well as with industry experts at the Pharmaceutical Manufacturers' Association. In our interviews, informants were requested to identify the types of capabilities that they felt were critical for future success in the industry. These interviews were conducted in person as well as over the phone, using a structured questionnaire. In total, 20 individuals were interviewed. The list of resources and capabilities identified in the first stage had a high level of consistency with those obtained in the field interviews. The variables, measurements, and data sources are summarized in Table 1. For each firm the information detailed in Table 1 was collected from 1971 through 1989.

Several issues related to variable operationalization should be noted. In their discussion of strategic assets, Dierickx and Cool distinguish between stocks and flows, where 'strategic asset *stocks* are *accumulated* by choosing appropriate time paths of *flows* over a period of time' (Dierickx and Cool, 1989: 1506). In this study, we focus on stocks as defined by aggregated flows over the specified time period. This approach was thought to reflect firm resource accumulations while recognizing the path dependency of such accumulations.

Companies seldom report ethical sales figures. Thus, firm R&D and salesforce expenditures were expressed as a proportion of worldwide health care sales. All new drugs must first successfully pass the Investigational New Development (IND) stage and, second, the New Drug Application (NDA) stage. Approval success rates are defined as the proportion of NCEs with NDA submission that have obtained marketing approval from the time of the NDA submission. Although the IND phase is sometimes used to capture success rates, we decided to focus, instead, on the NDA phase. Inasmuch as the clinical development time from the IND to the NDA stage takes much longer and is subjected to higher attrition rates, concentrating on success rates for NDA submissions is more relevant as the review period is shorter and their impact on a firm's output competencies can be better assessed.

Radical innovations are measured by the ratio of NCEs to all other new products. For the purpose of this study, NCE is defined as a new molecular compound not previously tested in humans. Incremental new products refer to duplicate single products, compound products and alternate dosage forms. Duplicate single products are follow-up marketing of an NCE that was previously introduced by another manufacturer, compound products are those having more than one active ingredient, and alternate dosage forms were products previously marketed in tablets and are now offered in ampules, capsules, etc. In terms of the origin of the NCE, all self-originated NCEs that are synthesized and developed by the firm are considered under the variable, internal R&D efforts. Thus, we excluded NCEs that were licensed, purchased, or otherwise acquired from outside agents (e.g., another firm, a university, a government agency).

Therapeutic market focus attempts to capture

Table 1. Variable operationalization and data sources

Variables	Operationalization	Data sources
Firm resources		
R&D expenditures	Total firm R&D expenditures/Worldwide health care sales	Annual Reports, 10-K reports
Salesforce expenditures	Total firm salesforce expenditures/Worldwide health care sales	Annual Reports, 10-K reports, SCRIP
Firm capabilities		
1. Component capabilities		
Internal R&D efforts	Total number of self-originated drugs/Total number of all NCEs introduced	SCRIP World, Pharmaceutical News
Therapeutic market focus	Ethical sales in three largest therapeutic areas/Total health care sales	Annual Reports, Paul de Haen Drug Survey and New Product Analysis
2. Integrative capabilities		
Approval success	Total number of NCEs approved/Total number of NDAs submitted	FDA, Paul de Haen New Drug Index and New Product Survey
Radical innovations	Total number of NCEs introduced/Total number of new products introduced	Paul de Haen New Product Analysis and New Product Survey
Sustained competitive advantage		
Therapeutic differentiation	Total number of NCEs given an A or B rating/Total number of NCEs introduced	FDA
Global NCEs	Total number of NCEs that are marketed in the major seven countries/Total number of NCEs introduced	The Compendium of New Drug Approvals in Eleven Industrialized Countries, SCRIP World, Paul de Haen New Product Survey
Size	Ln (Number of employees)	Annual Reports, 10-K

the degree of firm therapeutic concentration. In this study 12 major therapeutic areas were considered: anti-infectives, antineoplastics, antihistamines, autonomics, cardiovascular, skin and mucous membrane, central nervous system, gastrointestinal, hormones, musculoskeletal, biologicals, and spasmolytics. In any one year, therapeutic market focus was determined as the ratio of sales in any three categories to total health care sales. A similar measure was used by Cool and Schendel (1987) as an indicator of the breadth of a firm's product–market scope.

Therapeutic differentiation was captured using the FDA rating system. NCEs that are found to represent a significant gain, a modest gain, or little or no gain over existing therapy are given a 1A, 1B, or 1C rating, respectively. In this study, the total of 1A and 1B rated NCEs in the firm's product portfolio is emphasized. While NDAs are categorized by their therapeutic potential upon receipt by the FDA, the final classification is assigned upon approval as NCEs.

Global NCEs are defined as those drugs that are introduced in six of the major seven countries within 4 years. The seven countries of interest include the United States, France, Germany, Japan, Italy, Switzerland, and the United Kingdom. These markets generally are recognized as having the world's most sophisticated and demanding consumers and are also the home

countries of the major pharmaceutical competitors.

Control variable

Firm size was included as a control variable in the overall model because it has been found to impact product innovation and marketing efforts (Ettlie and Rubenstein, 1987; Capon *et al*., 1992). First, firm size affects the scope of resource allocation such as money, people, and facilities (Ettlie, 1983). Radical innovations are found to require more slack resources relative to incremental products. Increases in firms' internationalization efforts also require corresponding increases in marketing efforts.

Second, in terms of pharmaceutical R&D personnel, large-scale research is necessary to pursue enough leads to yield a significant probability of success. Given that drugs must be screened through a number of different therapeutic areas to detect unwanted side effects, firms with in-house research staff in many therapeutic markets are likely to have a greater competitive advantage. Omta *et al*. (1994) found that firms that spend a larger part of their R&D expenditures on the discovery phase tend to appoint a larger number of scientists. Finally, investments to recruit highly specialized scientists and to support their efforts with advanced equipment and superior working conditions are more feasible among larger firms. Consequently, size is included to complement the measures of R&D and salesforce expenditures and should be positively related to firm component and integrative capabilities, and also influence firms' sustained competitive advantage.

In this industry firm size is typically captured by annual dollar sales (Scherer, 1980; Cool and Schendel, 1987), or number of employees (Vernon and Gusen, 1974; ITC, 1991; Graves and Langowitz, 1993). Sales are an outcome of firm resources and capabilities and, therefore, would be correlated with the competitive advantage measures used in this study. Thus, to reduce potential multicollinearity effects, the number of employees was used given that its influence on R&D productivity can be determined more directly. For example, increases in R&D employees were found to lead to a greater concentration of internalized R&D compounds in the pipeline (ITC, 1991) but to have a diminishing effect on innovative effectiveness as measured by the number of NCEs (Graves and Langowitz, 1993). Since data on R&D employees were not available for all firms, the total employee count was used to reflect firm size. A logarithmic transformation of the number of employees was used to correct for the diminishing effect of size (Blau, 1970).

Analysis

The EQS software, using the covariance matrix as input, was used to estimate the model in Figure 1. EQS was selected as, consistent with our posited model, it does not require both measured and latent constructs to be specified (Bentler, 1989). Furthermore, given that the variables in the study are measured directly with single indicators, EQS is an appropriate approach to our modeling situation. Furthermore, EQS decomposes total effects for the endogenous variables into their direct and indirect effects. The indirect effects are expressed in terms of their total indirect effects; that is, they summarize how one variable influences another regardless of the number of particular paths chosen to trace from one variable to another. Similar to direct effects, indirect effects are sample statistics and, since they have sampling variability, their significance can be tested using the *t*-test.

RESULTS

The correlation matrix and the mean and standard deviation for each variable are reported in Table 2. Using Maximum Likelihood as the estimation procedure, the observed variables have reasonable skewness and kurtosis (i.e., less than 1.00) suggesting the adequacy of the data and the normal distribution underlying the dataset. The overall goodness-of-fit of the model is determined with the χ^2-test in which well-fitting models tend to produce a small χ^2-value or a *p*-value that is greater than 0.05. With a *p*-value of 0.502 (χ^2 = 5.336; d.f. = 6), the overall model fits well.

In Table 3, we present standardized parameter estimates with respective *t*-values and significance levels. For the individual structural equations, the squared multiple correlations, which are the proportion of variance explained, are as follows: (1) internal R&D efforts, 20 percent; (2) therapeutic market focus, 25 percent; (3) approval

Table 2. Correlation matrix and summary statistics

Variable	Mean	S.D.	1	2	3	4	5	6	7	8
1. R&D expenditures	0.26	0.11								
2. Salesforce expenditures	0.16	0.08	0.317***							
3. Internal R&D efforts	0.62	0.22	0.131**	0.226***						
4. Therapeutic market focus	0.71	0.22	0.279***	–0.160**	0.380***					
5. Radical innovations	0.43	0.16	0.104*	0.196**	0.255***	0.332***				
6. Approval success	0.30	0.11	0.377***	0.147**	0.218***	0.232***	0.418***			
7. Therapeutic differentiation	0.22	0.16	0.066^{ns}	0.075^{ns}	0.275***	0.116*	0.105*	0.225***		
8. Global NCEs	0.16	0.13	0.244**	0.226**	0.355***	0.367***	0.107*	0.151*	0.404***	
9. Size	6.47	1.04	0.052^{ns}	0.109*	0.419***	0.311***	0.482***	0.179***	0.403***	0.323***

***$p < 0.001$; **$p < 0.01$; *$p < 0.05$

success, 29 percent; (4) radical innovations, 21 percent; (5) therapeutic differentiation, 22 percent; and (6) global NCEs, 40 percent.

Firm resources and sustained competitive advantage

R&D expenditures positively and indirectly influence therapeutic differentiation (0.094; $p < 0.001$) and global NCEs (0.119; $p < 0.001$) through the firm's component and integrative capabilities. Salesforce expenditures did not have a significant impact on therapeutic differentiation. However, salesforce expenditures have direct (0.300; $p < 0.001$) and indirect effects on global NCEs (–0.046; $p < 0.05$). The negative indirect effect occurs through the following paths: (–0.038) salesforce → radical innovations and (–0.008) salesforce → approval success → differentiation.

Firm resources and capabilities

R&D expenditures are expected to directly influence firm component capabilities. The paths between this variable and internal R&D efforts (0.153; $p < 0.001$) and therapeutic market focus (0.257; $p < 0.001$) are significant. R&D expenditures were found to directly influence approval success (0.327; $p < 0.001$). While R&D expenditures indirectly and positively influence radical innovations (0.097; $p < 0.001$), they also have a direct and negative impact (–0.069; $p < 0.010$). The indirect effects occur through the interactions between R&D and each of the component capability dimensions. As expected, salesforce expenditures directly and positively influence radical innovations (0.281; $p < 0.001$). However, they also positively and indirectly affect approval success (0.101; $p < 0.001$) through the radical innovations → approval success link.

Firm capabilities and sustained competitive advantage

Findings about the effects of integrative capabilities on sustainable competitive advantage partially support our expected relationships. Approval success directly influences therapeutic differentiation (0.182; $p < 0.001$) but influences global NCEs (0.060; $p < 0.001$) indirectly through therapeutic differentiation. Unexpectedly, radical innovations negatively and directly influence global NCEs (–0.136; $p < 0.001$). Radical innovations affect therapeutic differentiation directly (–0.083; $p < 0.010$) and indirectly (0.065; $p < 0.05$) through the radical innovations → approval success link.

Component capabilities were expected to influence sustained competitive advantage both directly and indirectly through the firm's integrative capabilities. Internal R&D efforts were found to influence global NCEs (0.353; $p < 0.001$). In addition, internal R&D efforts have a negative and direct (–0.131; $p < 0.001$) as well as an indirect and positive impact (0.051; $p < 0.005$) on therapeutic differentiation. The majority of the indirect effects (0.03421) occur through the firm's integrative capability dimensions. A strong therapeutic market focus has a positive direct influence on therapeutic differentiation (0.182; $p < 0.001$). Therapeutic market focus also influences global NCEs both directly (0.201; $p < 0.001$) and indirectly (0.030; $p < 0.010$). The indirect effects are captured by the following links: focus → differentiation (0.059) and (–0.029) focus → approval success and focus → radical innovations.

Table 3. EQS model results: Structural model

	Standardized estimate	*t*-value
Firm resource → Sustained competitive advantage		
R&D expenditures →		
Therapeutic differentiation	0.094 (indirect)	3.824***
Global NCEs	0.119 (indirect)	4.170***
Salesforce expenditure →		
Therapeutic differentiation	–0.005 (indirect)	–0.352[ns]
Global NCEs	0.300	6.527***
	–0.046 (indirect)	–2.114**
Firm resource (R&D expenditures) → Component capability		
Internal R&D efforts	0.153	3.342***
Therapeutic market focus	0.257	5.698***
Firm resource (R&D expenditures) → Integrative capability		
R&D expenditures →		
Approval success	0.327	7.239***
	0.023 (indirect)	0.878[ns]
Radical innovations	–0.069	–1.289*
	0.097 (indirect)	3.993***
Salesforce expenditures →		
Approval success	0.101 (indirect)	4.270***
Radical innovations	0.281	5.314***
Integrative capability → Sustained competitive advantage		
Approval success →		
Therapeutic differentiation	0.182	3.590***
Global NCEs	0.060 (indirect)	3.261***
Radical innovations →		
Therapeutic differentiation	–0.083	–1.571*
	0.065 (indirect)	2.321*
Global NCEs	–0.136	–2.844***
Component capability → Sustained competitive advantage		
Internal R&D efforts →		
Therapeutic differentiation	–0.131	–2.446***
	0.051 (indirect)	2.216**
Global NCEs	0.353	7.687***
Therapeutic market focus →		
Therapeutic differentiation	0.182	3.531***
Global NCEs	0.201	4.206***
	0.030 (indirect)	1.371*
Size → Capabilities		
Size → Component capabilities		
Internal R&D efforts	0.425	9.285***
Therapeutic market focus	0.235	4.778***
Size → Integrative capabilities		
Approval success	0.122 (indirect)	3.841***
Radical innovations	0.185 (indirect)	5.650[a]
Size → Sustained competitive advantage		
Therapeutic differentiation	0.392	7.553***
Global NCEs	0.308 (indirect)	8.680***

***$p < 0.01$; **$p < 0.05$; *p 0.10 (one-tailed tests) Standardized estimates are direct paths unless otherwise indicated.

Effects of size

Finally, size directly influences firms' component capabilities but indirectly influences integrative capabilities at $p < 0.01$ or better. Additionally, size directly and indirectly influences therapeutic differentiation and global NCEs, respectively. These significant effects demonstrate the 'size imperative' commonly found in studies of structure and support the inclusion of size as a control variable.

Total effects

In Table 4, we present the direct, indirect, and total effects of firm resource expenditures and component and integrative capabilities on sustained competitive advantage. For unstandardized estimates, the total effect is the sum of the direct and indirect effects. The following conclusions can be made about the direct and indirect effects. First, therapeutic differentiation is directly influenced by therapeutic market focus and approval success but inversely related to internal R&D efforts and radical innovation. Second, therapeutic differentiation is positively and indirectly influenced by R&D expenditures, internal R&D efforts, and radical innovation. Third, global NCEs are positively and directly influenced by salesforce expenditures, internal R&D efforts, therapeutic market focus, and therapeutic differentiation, but inversely and directly related to radical innovation. Fourth, global NCEs are positively and indirectly influenced by R&D expenditures, therapeutic market focus, and approval success, but inversely influenced by salesforce expenditures.

Alternate models

Two other competing models were explored. These included: (1) approval success as a separate firm outcome and as an antecedent to sustained competitive advantage; and (2) sustained competitive advantage as the major antecedent of firm resources and capabilities. For the first model, we tested the following relationships: firm resources → firm capabilities → approval success → sustained competitive advantage. The model achieved a poor fit of $\chi^2 = 228.953$ (d.f. = 16; $p < 0.001$). The Bentler–Bonnett (1980) normed and non-normed fit indices also did not meet the cut-off value of 0.90; respectively they were 0.72 and 0.38. The average off-diagonal standardized residuals (AOSR) were equal to 0.06. Given that the AOSR exceeds 0.05, the possibility of the model being ill fitting is fairly high. While firm capabilities significantly influenced approval suc-

Table 4. Direct, indirect, and total influences on therapeutic differentiation and global NCEs

	Unstandardized estimates (standard errors)					
	Direct	Indirect	Total	Direct	Indirect	Total
Resources and capabilities			Therapeutic differentiation			Global NCEs
R&D expenditures		0.137*** (0.036)	0.137***	0.071[ns] (0.057)	0.141*** (0.034)	0.212***
Salesforce expenditure		–0.010[ns] (0.028)	–0.010[ns]	0.487*** (0.075)	–0.074** (0.035)	0.413***
Internal R&D efforts	–0.095*** (0.039)	0.037** (0.017)	–0.058**	0.208*** (0.028)	–0.020[ns] (0.017)	0.188***
Therapeutic market focus	0.130[a] (0.037)	–0.001[ns] (0.009)	0.129***	0.118*** (0.028)	0.018* (0.013)	0.136***
Radical innovation	–0.083* (0.053)	0.065** (0.028)	–0.18[ns]	–0.110*** (0.039)	–0.022[ns] (0.019)	–0.133***
Approval success	0.263*** (0.073)		0.263***	–0.071[ns] (0.057)	0.071*** (0.022)	0.000[ns]
Therapeutic differentiation				0.268*** (0.034)		0.268***

***$p < 0.01$; **$p < 0.05$; *$p < 0.10$ (one-tailed test)

cess, having high approval rates did not translate into higher sustained competitive advantages for the firm (i.e., the impact of approval success on global NCEs and therapeutic differentiation were nonsignificant).

Given that firms' outcomes could lead to additional investments in resources and capabilities, we also examined the following model: sustained competitive advantage$_{(t-1)}$ → resources$_{(t)}$ → capabilities$_{(t)}$. This structural model achieved an overall poor fit: $\chi^2 = 167.76$ (d.f. = 5; $p < 0.001$). The Bentler–Bonnett normed and nonnormed fit indices were 0.79 and 0.51, respectively. However, the AOSR were less than 0.05 (i.e., AOSR = 0.04). While success from global NCEs had a significant and positive impact on both R&D and salesforce expenditures ($t = 5.36$, $p < 0.01$; $t = 4.12$, $p < 0.01$, respectively), the impact of therapeutic differentiation on resource expenditures was nonsignificant. Similarly, advantages from global NCEs had a significant and positive influence on firms' internal R&D efforts and therapeutic market focus ($t = 7.02$, $p < 0.01$; $t = 4.625$, $p < 0.01$, respectively). Although the impact of therapeutic differentiation on internal R&D efforts was nonsignificant, the need to maintain advantage from therapeutic differentiation had a significant impact on the external acquisition of technology as suggested by the negative relationship ($t = -4.15$, $p < 0.01$).

In summary, the chi-square statistics for the two models suggest that the two models can be further improved.[6] The other lack-of-fit indices for the first model also reject approval success as a separate outcome influencing firm sustained competitive advantage. While having high approval success rates reflects the firm's superior technological capabilities, it is also a function of the stringency of the FDA approval process. Since the FDA approval standards are expected to affect pharmaceutical firms equally, we do not expect that having approval success is a 'distinctive competence' by itself. Rather, sustained advantage results through defining and integrating this capability within the firm's other strategic resources and capabilities.

The second model attempts to investigate how changes in firm strategies affect firms' resource allocations and capability patterns. Capturing and modeling strategic changes in response to external (e.g., environment) and internal (e.g., performance) variables has generated interest in the organizational adaptation literature (e.g., Ginsberg, 1988). Our findings suggest that a firm's competitive advantages in the previous period had an impact on its subsequent resources and capability patterns. Despite the differences in findings among the fit indices for the second model, the relationships uncovered hold promise for future understanding of 'fit' within the context of the RBV of the firm.

DISCUSSION

We have taken an initial step toward empirically testing the relationships among firm resources, component and integrative capabilities, and sustained competitive advantage. Although this study was limited to pharmaceutical firms, our findings confirm the usefulness of the RBV. In this study, therapeutic differentiation and global NCEs represent important areas of sustainable advantage since: (1) in any one year, less than 50 percent of NCEs approved are given an A or B rating, and (2) less than 20 percent of approved NCEs are eventually introduced in seven major markets within a 4-year time period (Di Masi, Seibring, and Lasagna, 1994). Given that these advantages vary among pharmaceutical companies, we attempted to understand this asymmetry within the context of firm resources and capabilities. More specifically, by exploring the indirect and direct effects, we demonstrated how resources and capabilities directly and indirectly enhance firms' sustained competitive advantages in therapeutic differentiation and global NCEs.

The analysis suggests that sustained competitive advantage in the pharmaceutical industry requires firm strategies that capitalize on resources and capabilities. In particular, we found important resources to be those that depend on scale imperatives (e.g., salesforce and R&D expenditures), are difficult to understand (e.g., development of therapeutically differentiated drugs), and in which the firm possesses clear ownership and control (e.g., knowledge and understanding of drug development in certain

[6] Several studies have discussed the sensitivity of the chi-square statistic to large sample size (Bagozzi and Yi, 1988). That is, as the sample size increases, the chance of rejecting a model increases. Thus, other indices of fit such as the Bentler–Bonnett normed fit index are recommended to aid in the interpretation of findings.

therapeutic areas). This finding has a potentially important implication for the resource-based view. Resource-based arguments recognize that different types of tangible and intangible assets are the source of firm advantage. Research often will identify the specific assets or stocks critical within a particular industry context (e.g., Maijoor and van Witteloostuijn, 1996). However, within a set of identified resources, additional understanding is needed regarding the different roles or contributions of the resources. In this study, one set of resources is valuable because it contributes to transforming another set of resources. This finding suggests that the resource-based view may need to recognize and develop the hierarchical structure or layering of resources as they relate to competitive advantage.

In the pharmaceutical industry, sustained competitive advantage is dependent on: (1) sales and technological strengths, and (2) having a unique, superior product with a differentiated advantage in the market. Although it is often perceived in the industry that new product success is primarily R&D-driven, successful NCEs benefit significantly from the firm's existing marketing and technological strengths. This is demonstrated from the salesforce expenditure → radical innovations → approval success link. The results are consistent with Hamel and Prahalad's (1990) call for greater integration across organizational boundaries to enhance firms' core competencies.

The findings between radical innovations on both therapeutic differentiation and global NCEs were unexpected. Radical innovations often face greater FDA scrutiny due to the higher medical riskiness in NCEs, and this negative impact seems to affect the commercialization of NCEs. Roberts (1989) found that the more new technology that was embedded in the product, the more risky the product was perceived to be in physicians' evaluations. Although the total effect of radical innovation on therapeutic differentiation was nonsignificant, there was a significant indirect effect through the radical innovation → approval success → therapeutic differentiation. This indirect link suggests that, despite the perceived medical riskiness in NCE development, drugs that are perceived to provide strong therapeutic potential tend to enjoy higher FDA approvals.

Technological innovativeness may well be a curse rather than a benefit. Because the costs of failures are substantially higher for NCE development, firms frequently need to maintain a balanced technology product portfolio along the discovery–development continuum. For example, incremental innovations from improvements on the original drug discovery[7] or differential improvements in drug therapy[8] also contribute to sustaining firms' competitive positions. As suggested by the negative relationship between R&D expenditures and radical innovations, rather than limiting R&D resources on NCE development, firms may need to broaden their new product development scope to include incremental innovations while maintaining an emphasis on radical innovative strategies.

Unlike certain types of capabilities that are easily imitated by replication, internal R&D capabilities and their stock–flow relationships with the firm's other resources and capabilities are based upon highly complex organizational routines which tend to defy successful replication. Our findings suggest that a strategic focus on internal R&D development may not necessarily lead to the development of therapeutically differentiated drugs. As others argue, firms with weaker research abilities can be technologically competitive by acquiring technology from elsewhere and recovering through strong developmental skills (Capon and Glazer, 1987). This argument is reinforced through the significant positive link between internal R&D efforts and integrative capabilities and therapeutic differentiation.

Firms with a strong internal R&D focus also enjoy greater international success as indicated by the positive direct relationship between internal R&D efforts and global NCEs. Global success is achieved by licensing the drugs to other companies so that simultaneous approvals can be achieved among several countries within a short time period.

Without focused attention on a few therapeutic markets in which the firm has clear competitive advantages, improvement efforts are likely to be diluted to the extent that the company may end up a perpetual laggard in every therapeutic market

[7] Continuous improvements on the original drug discovery results in a more acceptable form of therapy. For example, the beta blocker atenolol is widely regarded as an improvement of the original compound pronethalol both in terms of tolerability and efficacy.

[8] Examples of differential improvements in drug therapy are those that have a longer duration of action in the body or which make the therapy more acceptable to the patient.

in which it competes. As argued by Maidique and Hayes (1984), a focused R&D strategy also enables businesses to dominate research, particularly the more risky, leading-edge expectations.

While no specific propositions were forwarded with respect to size, the results of this study contribute to understanding the nature of size effects. Size was found to influence component capabilities directly and integrative capabilities indirectly. These findings are important for two reasons. First, size advantages are apparently important for certain types of capabilities. In this study, the benefits over time of experience effects based on size contribute to strong internal R&D capabilities and a therapeutic market focus. Size also had a strong direct effect on therapeutic differentiation, suggesting that, in addition to the experience curve effects, a 'critical mass of resources' is necessary for innovative success.

Second, the indirect effects of size on integrative capabilities and global NCEs suggest the importance of the notion of access advantages. Specifically, superior access to information from the benefits of experience (emphasis on radical innovations) and preferred access to markets from mechanisms such as reputation and relations (e.g., ability to work with the FDA) are more important for sustaining these capabilities over time than is size alone.

The purpose of this study was to explore the resources and capabilities that lead to sustained advantage within the pharmaceutical industry. It was argued that advantage is defined by the extent that a firm emphasizes or produces therapeutic differentiation and global new compound entities. While the RBV is fundamentally interested in explaining sustained advantage by understanding resource bundles and capabilities, the expectation is that this advantage leads to higher than average rents (Peteraf, 1993). Thus, even though our focus was on explaining sources of advantage, the normative assumption made was that the specific sources examined lead to superior firm performance. This assumption was necessitated in part because of data limitations. Most pharmaceutical firms compete in multiple industries or industry segments and, therefore, performance data tied to a specific segment generally are not available through secondary sources. Despite this limitation, we considered it important to offer a preliminary assessment of the performance outcomes associated with the therapeutic differentiation and global new compound entities dimensions. Two performance measures were considered: global market share and return on sales (ROS). Incorporating these two measures into our model and adding a direct path from each source of advantage indicated that therapeutic differentiation had a nonsignificant impact on ROS but a significant impact on global market share (0.18, $p < 0.01$). Global NCEs had a positive impact on both ROS (0.14, $p < 0.01$) and global market share (0.38, $p < 0.001$). While these relationships are not matched precisely to the focus of the firm resources in our model, they suggest tentative support for the normative assumptions made in the posited model.

An important limitation that should be recognized is that this study focused only on the human and technological resources. Organizational resources such as managerial skills and reputation also have been found to influence firms' competitive advantages (Castanias and Helfat, 1991). For example, strong leadership under Vagelos and Girolami propelled Merck and Glaxo, respectively, to the forefront of innovative drug research. Corporate reputation also displays similar longevity—Merck has consistently been ranked highly on its financial soundness, quality of products, innovativeness, and ability to attract, develop, and keep talented people. Indeed, while environmental turbulence may shorten the life span of many resources, it is possible that it has the effect of bolstering brand and corporate reputations. Examining the relative impact of these various categories of resources on sustained competitive advantage should provide better insights on how firms build and maintain their core competencies.

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APPENDIX: U.S. Pharmaceutical Companies Included in the Study

Abbott	A.H. Robins
American Cynamid	Rorer
American Home Products	Schering-Plough
Bristol Myers	Searle
Carter Wallace	SmithKline
Eli Lilly	Squibb
Johnson & Johnson	Sterling Drugs
Marion Laboratories	Syntex
Merck	Upjohn
Pfizer	Warner Lambert