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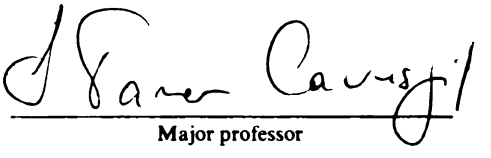

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LICENSING STRATEGIES AND PERFORMANCE: AN EMPIRICAL ANALYSIS IN THE GLOBAL PHARMACEUTICAL INDUSTRY

By

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ABSTRACT

LICENSING STRATEGIES AND PERFORMANCE: AN EMPIRICAL ANALYSIS IN THE GLOBAL PHARMACEUTICAL INDUSTRY

By

Kathleen R. Whitney

Statement of the Problem. Pharmaceutical firms have a complex problem marketing diverse products globally. They possess little theory to guide them and there is limited empirical research relating specific strategies to sales and market share performance. Further, strategies are constrained by governmental regulations. Finally, licensing seems to be used extensively without an adequate understanding of its impact upon performance. Under these conditions firms may rely upon past product and market strategies as decision criteria, possibly excluding more effective strategies. An important opportunity exists to empirically test global marketing strategy as it relates to diverse products, worldwide markets, use of strategic alliances, and regulations.

Theoretical Framework. These concerns are addressed by incorporating these issues into a theoretical framework: (1) since global product and market diversity is a problem, the number of products and markets a firm manages may impact performance; (2) licensing strategies may impact performance; and (3) global strategies may be affected by regulatory differences.

Methodology. Selected pharmaceutical product classes are studied. The pharmaceutical industry is chosen because of its extensive global experience, costly technology, and stringent governmental regulation. Secondary data are used to compile 504 observations by firm, therapeutic class, and country, for a period of dramatic industry change, 1982-1987. Approximately 76% of world pharmaceutical sales is represented by the markets studied: the United States, Japan, West Germany, Italy, France, and the United Kingdom.

Multiple regression analysis with time-lagged variables are used to test relationships between strategy and performance, past and current strategies, and regulation and product introductions. Analysis is conducted at the firm, therapuetic class, and country levels.

Major Findings. There are four major findings: (1) Sales and market share performance is enhanced by the number of product introductions and by constraining product acquisitions to a few product classes; (2) there is a critical difference between the market leader and other firms with regard to the relationship between product introductions and performance; (3) market representation does not vary with performance; and (4) product introduction behavior does not always relate to regulatory conditions as expected.

DEDICATION

For David

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I would like to gratefully acknowledge the individuals who have played a significant role in accomplishing this research. Each committee member made a unique and vital contribution. S. Tamer Cavusgil directed me to pursue my research in an industry in which I have personal strengths. Robert W. Nason persisted in drawing the best he could from me. David J. Closs provided guidance in methodology and organization. Mary Jane Sheffet gave generously of her time, reading every word of each and every draft.

As with any project of this size, considerable resources were needed. John Hornick provided access to the Upjohn Business Library and assisted in obtaining the Paul de Haen data base. The Michigan State University CIBER grant also contributed to data acquisition costs.

Finally, my family provided me with moral support and endured persistent benign neglect. I extend my special thanks and appreciation to each of them: David, my husband; Kendra, my daughter; and Ellen; my mother.

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CHAPTER I

INTRODUCTION

Statement of the Problem

Global strategic marketing requires a complex set of decisions concerning products, place, promotion, and pricing. It is more complex than domestic strategy because there is greater variation on all four elements. However, recent literature Ohmae 1986a and b; Porter 1990) reflects an emphasis on the product and place variables. Specifically, the method of acquiring new products (by internal product development or strategic alliances such as cross-licensing) has been of interest to researchers. The place element has also been addressed in global strategy because firms face a similar strategic decision (use of internal or external resources) to gain access to various geographic markets. Therefore, the primary concern of this research involves product acquisition and market access strategies.

The dramatic increase in international availability of transportation and communication technologies and the rapid rate of technological change has invalidated classic theory which supported gradual dissemination of new products into international markets (Ohmae 1986a and b). Although it is

clear that gradual dissemination of product innovations no longer works (Ayal 1981; Porter 1990), alternative global strategy concepts have not yet been empirically tested.

In light of the decreasing life-span of products, new marketable products have become more important to fill established channels. Foxall (1983), Meyer and Roberts (1988), Ohmae (1989), and Porter (1990) have emphasized continuous innovation in the form of internal product development, as an avenue to success. Porter stressed that development efforts should be aimed at updating current products, which implies focus on product categories rather than focus on a particular technology. Meyer and Roberts' (1988) findings empirically supported the importance of what they termed an innovation focus which stresses relatedness of technology rather than product categories in formulating strategy. On the other hand, Foxall (1983) also encouraged a constrained search for <u>new</u> products. New products do not necessarily supersede older products and they can be designed for existing or new functional markets.

Two notable theorists have addressed innovation or internal product development (Porter 1990) and global distribution or market access (Ohmae 1986a and b). Ohmae's "Triad World View" (1986a and b) states that to be successful, firms must simultaneously begin marketing new products in the three major developed countries: Japan, the United States, and Western Europe. Their market importance stems

from their large size with a combined population of approximately 630 million people.

Because consumers of many countries demand similar product characteristics for many products, there has been a tendency not to establish separate operations in each country. Even though in-country presence may not be necessary for purposes of adapting a product to special needs, it is recommended by Thorelli (1990) for developing and maintaining access to that geographic market. Ohmae noted that it is vital for firms to "become an insider in each of the triad regions (Ohmae 1986a, p. 18)." At the same time Thorelli (1990) and Yip (1990) emphasized the need for depth of commitment to country markets. Thorelli used the notion of networking which he defines as the process of establishing and maintaining contacts within countries. He emphasized the need to become a good corporate citizen to firmly establish an in-country network. He stressed the need to establish buyer linkages which include information, technology, and social and financial aspects. The network concept is aimed at what Yip (1989) described as committed involvement which also involves establishing in-country linkages with a long term perspective. Committed involvement requires management to take a long-term view of in-country investments.

If operations and a long-term view of investment are important, then firms face the problem of simultaneously managing continuous product acquisition and developing and

maintaining access to many country markets. The central managerial problem is how to direct both efforts most effectively for marketing success. These two tasks should not be separated from one another. Product acquisition must be directed towards identified needs and wants of consumers within or across country markets. Without an identified market segment and targeted geographic markets, products are less likely to be commercializable. Conversely, distribution channels for targeted markets cannot be efficiently developed and maintained without regard to product characteristics. For example, pre- and post-sales support for main-frame computer systems is quite different from support for tailored clothing. In effect, the planning of product acquisition and market access is inseparable because each is dependent upon the other. The current environment strengthens the bond between product acquisition and market access strategies. This will be addressed more fully in Chapter II.

The complexity of the problem does not end with the need to simultaneously manage product acquisition and market access. Managers must plan to fill the strategic gaps between current capabilities and those which are still needed for success. Ohmae describes the problem in the following statement (1989, p. 143), "With enough time, money, and luck, you can do everything yourself. But who has enough?" In a global environment in which the cost of distribution and research and development (R&D) costs are

very high, the appropriate strategy requires entente--the striking of an alliance between firms (Ohmae 1989). Management decisions need to include consideration of firm strengths and weaknesses and those of available external resources. Robinson (1978) called this the make or buy decision. An appropriate combination of internal and external product acquisition and market access strategies must be selected to fill existing gaps. But first, these strategic gaps must be identified.

Capon and Glaser (1987) succinctly state the following problems concerning acquiring and marketing new products:

- evaluation of a wide range of options for developing and acquiring technology, as well as for marketing technologies in the firm's inventory, [and]
- utilization of the technology portfolio as an organizing tool that can help the firm both to evaluate the current technological portfolio and to plan the optimal decisions for future technology scenarios (p. 12).

Limited time and money in a rapidly evolving global market lead strategists to consider obtaining specific functions externally through alliances with other firms. This decision requires evaluating potential partner strengths against strategic gaps. The above statement of Capon and Glaser (1987) specifies acquisition of technology rather than products. However, technology must be packaged as a product at some level for a specific target market. Therefore, development of marketable products rather than technology is the appropriate subject of analysis for marketers.

The second portion of the statement calls for use of a technology portfolio to identify strategic technology gaps. A useful portfolio would include both product and market elements to assist a firm in identifying specific strategic gaps, because attention to the marketability of technology is appropriate for marketers.

In summary, product acquisition and market access strategies appear to be elements which are critical to success in the global environment. Firms face parallel decisions for managing these elements more frequently in today's global environment. Not only must each element be addressed individually and in tandem, but each possesses two dimensions, depth and breadth. That is, depth of commitment to a single product or single market and breadth of commitment across several products or several markets. Once strategic elements and their dimensions have been identified, appropriate internal commitments and external alliances must be planned. Though not fully understood, product acquisition and market access, their dimensions of breadth and depth, and use of strategic alliances have all been conceptually related to success.

In Chapter II, the product acquisition and market access elements are more fully addressed and a portfolio is defined which is capable of considering them in tandem. The empirical portion of this dissertation, Chapters IV, V, and VI, relates these elements to desired performance outcomes.

The following section formalizes the empirical objectives of the study.

Research Scope and Objectives

In this section, the scope of the study is first defined, then three study objectives are presented. The scope of this research can be described as global because it addresses the strategy of firms which must operate across many national boundaries. One way of determining whether or not a firm is global is to examine the forces which shape its strategy. These forces have been called globalization drivers (Yip working paper) and are addressed in Chapter II. Because the same or similar environmental forces generally affect all the firms in an industry, one method to control for differences in globalization drivers is to study a single industry.

In this dissertation, innovative ethical pharmaceutical manufacturers are studied. The industry is experiencing a high cost of R&D, a lengthening R&D process, and a rapid rate of technological change. All three of these environmental forces add to the pressure to rapidly commercialize products which contribute to the drive for globalization. In fact the industry has decades of global marketing experience and is well suited to a study of global strategy.

Constraining the scope of the study to a single industry sample also provides relative homogeneity with respect to regulatory structure. Study of product acquisition and

market access is especially interesting in pharmaceuticals because promotion and pricing are effectively constrained by regulation.

The pharmaceutical industry is also attractive for a global study because a major portion of its global market is represented by six countries which have similar product needs. The study countries which represent approximately 75% of the world pharmaceutical market include the United States, Japan, West Germany, Italy, France, and the United Kingdom.

Many firms engage in other non-pharmaceutical businesses. This study addresses only their pharmaceutical lines-of-business which may be comprised of the entire firm, a single strategic business unit, or more than one strategic business unit.

There are three research objectives. The first two research objectives examine strategic behavior in a technology-based, highly regulated, and global industry. Product acquisition and market access strategies are specifically addressed because they should be considered together and must be addressed before the rest of the marketing mix can be determined. The third objective relates regulatory structure to market entry decisions. Each of these three objectives will be briefly described.

The first objective is to relate both past product acquisition and market access strategies to strategic decisions. This relationship is examined because Porter

(1990) implies that product acquisition should be achieved by internal innovation to achieve success. Likewise the relationship between established distribution channels and new product introductions is explored because current literature conceptually supports this linkage (Ohmae 1986a and b; Thorelli 1990).

The second objective is to relate these strategies (internal product development versus licensed product acquisition, and direct market access versus market access by out-licensing products) to performance. The external strategy chosen for this study is confined to licensing because it is more quickly accomplished than most other alternatives (i.e., joint ventures) and it is the most widely used external mechanism in the pharmaceutical industry. All of these strategies are appropriately related to industry success criteria and general performance measures.

The third objective is to examine the relationships among various industry regulatory structures and market entry decisions. This is important to policy makers who are interested in comparing actual relationships versus the relationship intended with each policy. Regulatory issues which affect product development, product introduction, and reimbursement for pharmaceuticals are examined. Regulations which affect the industry during the manufacturing and post-marketing stages are excluded because they are not expected

to heavily influence product acquisition and market access decisions.

To summarize, the research objectives of this study are to examine the following within the pharmaceutical industry:

1. the relationship between historic and current product development and market access strategies;
2. the relationship of internal and external product acquisition and market access to performance; and
3. the relationship between regulatory structure and market entry decisions.

Limitations of the Study

Limitations of the study include its relatively macro or aggregate nature, the use of secondary historical data, and the use of a single industry sample. The study emphasizes strategic behavior and performance at the line-of-business level and cannot address the idiosyncrasies of individual product attributes. Therefore issues such as importance of product, quality of product, pricing, and promotion are not accounted for in the analysis.

Use of secondary data sources brings several potential limitations which include differences in accounting policies, lack of control over inclusion of potentially meaningful businesses or products, inability to calibrate measures, and errors in reproduction. The longitudinal nature of the data also has a potential of introducing differences in accounting practices. Nevertheless,

longitudinal data provide the power to examine relationships which cannot be seen in purely cross-sectional studies.

Generalizability of findings may be problematic because the sample is confined to the pharmaceutical industry; however using a single industry removes many confounding issues such as market comparability, differences in regulatory structure and consumer behavior. Study of a single industry also provides an opportunity to more fully understand industry issues such as market segmentation, structure, and measurement techniques.

These limitations represent necessary trade-offs in this research design. The following section presents the potential contributions of this study.

Potential Contributions

Potential contributions of this research are to the global strategy literature, the pharmaceutical industry, and policy makers. Study implications are of specific interest to managers in the pharmaceutical industry and of more general interest to managers in other global, technical and/or regulated industries. The implications of firm strategic behavior as it relates to regulation and the resulting social benefits are of interest to policy makers and industry executives alike.

This study contributes to the literature by specifically addressing global product acquisition and market access licensing strategies in relationship to performance. It is

also the first global strategy/performance study to utilize a sample within an industry structure, thereby establishing sample homogeneity with regard to consumer behavior and regulatory structure. The longitudinal empirical design is also new to global strategy literature. Additionally, the measures used reflect actual pharmaceutical line-of-business behavior rather than executive perceptions as is the case in much of the literature. This study also utilizes a larger sample size, 504 observations, than is currently represented in global strategy literature.

Pharmaceutical managers also gain use of a strategic tool, an industry-specific product portfolio. The relationship between product acquisition, market access, and licensing strategies is of interest to this group.

The relationship between market entry decisions and industry-specific regulations is of interest to policy makers. They are concerned with these relationships as indicators of the effectiveness of regulation.

Organization of the Study

This dissertation is organized into five additional chapters. Chapters II and III provide a review of relevant literature and industry background. Chapter IV describes the methodology used in the research. Chapter V provides a discussion of the analysis and study results. Chapter VI addresses study conclusions and implications.

The theoretical foundations of the study are built from a review of literature in Chapter II. First, global strategy literature is used to position this research. Next, international segmentation and standardization-versus-adaptation literatures are reviewed to argue the inseparability of product acquisition and market access in strategic planning. Then specific innovation and global strategy concepts provide a foundation for measurement of these strategic elements. Strategic alliances are briefly presented as a means of accessing external resources to fill strategic gaps. Finally, product portfolio analysis literature is critiqued for the purpose of designing an industry-specific product portfolio as a research and managerial tool.

Two families of hypotheses are presented in Chapter II. The first relates historic product acquisition and market access strategies to current strategic decisions. The second relates these strategies to performance.

Chapter III provides a brief history which traces the development of regulatory environment because governmental regulation plays a role in limiting strategic options in the pharmaceutical industry. A hypothesis is presented to test the relationship between regulatory structures and market entry decisions.

A strategy framework is presented in Chapter IV to describe how product acquisition, market access, and licensing are hypothesized to relate to performance in the

pharmaceutical industry. Research design and methodology are then discussed. A profile of sample pharmaceutical lines-of-business, countries, and products is provided with a description of data sources. The chapter concludes with operationalization of the variables used to test hypotheses.

The final two chapters present the study analysis, implications of findings, and recommendations. Chapter V provides a discussion of findings relative to each hypothesis. The last chapter addresses the managerial, public policy, and methodology implications of this research. In conclusion, recommendations for future research are discussed.

CHAPTER II

SURVEY OF THE LITERATURE

Introduction

Global marketing strategy presents a more complex set of managerial decisions than domestic strategy. One reason is because of greater possible variation in the classic four controllable variables: product, place, promotion, and price. Aspects of two, product and place, are defined in this chapter as product acquisition and market access because they are important in the development of global marketing strategy.

This chapter builds a theoretical foundation for the study of product acquisition and market access strategies in the global environment. First, the study is positioned within the context of a general review of global strategy literature. Then, a justification for focus on product acquisition and market access strategies will be presented. Following that, the inseparable nature of product acquisition and market access is argued using international segmentation and standardization/adaptation literatures. Next, both product acquisition and market access are defined in the global context as having dimensions of breadth and

depth, as well as internal and external components. Robinson (1978) noted that in pursuing various strategies, firms are faced with a "make or buy" decision to accomplish strategies with internal versus external resources. Therefore a brief review of strategic alliances is provided and licensing strategy is examined because it is the dominant form of alliance in the pharmaceutical industry.

Finally, product portfolio literature is presented and critiqued for the purpose of developing an industry-specific portfolio. Industry success criteria, or rules of thumb, are used to measure and compare current and desired product acquisition and market access strategies. The portfolio is proposed as a method of identifying gaps or differences between current and desired product acquisition and market access strategies for planning utilization of internal and licensed resources.

Global Strategy Literature

Levitt (1983, p. 92) asserted that "the globalization of markets is at hand" which will drive product standardization across markets. His statement was only one of many concerning the increasing pressure for globalization. Subsequent literature casts considerable doubt upon the durability and inevitability of global products and strategies. Douglas and Wind (1987) and Kashani (1986) wrote about the problems inherent in pursuing global strategies. Kashani studied seventeen cases of global product

standardization and identified the following pitfalls: (1) insufficient use of formal research, (2) a tendency to over-standardize, (3) poor follow-up, (4) narrow vision in program coordination, and (5) inflexibility in implementation.

A number of approaches to global strategy have been identified: organizational frameworks (Ghoshal 1987), corporate integration (Prahalad and Doz 1987), and the flexible approach (Kogut 1985). However, recent literature reviews (Walters 1985; Yip working paper) critique existing global strategy literature by pointing out that little empirical work has been published; and what is published is generally conceptual in nature and relies upon anecdotal evidence or a small sample of case studies. Furthermore, specific marketing elements have received little attention in the global context. Most of what has been done is concerned with promotion and product policy. Walters also noted limited geographic scope in sample selection in the literature.

Because this dissertation is primarily concerned with the relationship between strategy and performance, the four empirical studies which link global strategy to performance are examined. The most recent study (Yip 1991) criticizes current literature for lack of attention to globalization drivers and performance. Globalization drivers are forces which reward firms who address global markets. These drivers are of three types: market, cost, and government.

For example, market drivers include homogeneous customer needs, global customers, transferable marketing, and the effects of travel. Cost drivers include economies of scale, favorable logistics, differences in country costs, and product development costs. Government drivers include tariffs, non-tariff restrictions, compatible technical standards, common marketing regulations, competitive drivers, and global competitors. The Yip study is exploratory in nature, uses a small sample, and relies upon executive perceptions to measure strategy and performance.

Another of the more recent studies (Kotabe and Omura 1989) used a substantially larger sample size, 75 European and Japanese multinational firms, than earlier studies. They found a negative relationship between profit performance and product adaptation strategy. That is, the less products were adapted to the U.S. market, the higher firm profitability. This is a product standardization strategy which is supportive of a global approach. Their sample did not include U.S. firms and their study design did not control for globalization drivers.

Bartlett and Ghoshal (1989) studied only nine firms in three industries. The Bartlett and Ghoshal study did not empirically test the relationship of strategy to specific performance measures. Rather, they conducted case studies of firms in three industries during a period of increasing internationalization. They found that flexible manufacturing, exploitation of the learning curve, and responsiveness

to markets were consistently practiced by successful international firms. Their study used imprecise performance measures, used a small sample, and made no systematic evaluation of globalization drivers.

Roth, Schweiger, and Morrison (1989) tested the relationship between performance and three of Porter's international strategy cells. These cells are composed of a two-by-two configuration/coordination matrix: dispersed and concentrated configuration of activities by high and low coordination of activities. Configuration refers to the degree of centralization in the organization's operations. Coordination of activities refers to the degree to which operations are coordinated within the business unit. Their study surveyed 147 U.S.-based global units and found that the high coordination/concentrated configuration (pure global strategy) group did not perform better than high foreign investment strategy (high coordination/dispersed configuration) and pure domestic strategy (low coordination/dispersed configuration) groups. The study omitted the low coordination/dispersed configuration (export-based) strategy groups. This research also did not account for industry factors which may lead to globalization and the sample included only U.S. firms. Their study did use an objective measure of performance, profit. However, because there are differences in accounting practices, profit is susceptible to large between-firm and year-to-year variations which cannot be detected in a cross-sectional study.

In summary, none of the studies reviewed examined actual strategic behaviors but relied upon executive reports or perceptions for measures of strategy and performance. The Bartlett and Ghoshal and Yip studies used very small samples. The Kotabe and Omura study did not include U.S. firms while the Roth, Schweiger, and Morrison study included only U.S. firms. Globalization drivers were examined only in the Yip study.

Because the goal of strategy is to improve performance it is important to study the relationship between strategy and performance. Empirical studies are necessary to support or redirect current strategy literature. This review has positioned this dissertation as empirical and contributing to the global strategy literature by relating specific strategies to performance. Review of literature concerning these specific strategies is presented in the remainder of this chapter. The following section provides a brief overview of strategic alliances to examine possible external strategies such as joint ventures, partnerships and licensing.

Strategic Alliances

Strategic alliances in global strategy have received considerable attention in the literature. This section briefly reviews the role of strategic alliances in managing product acquisition and market access. Use of alliances in the pharmaceutical industry is also discussed.

Meyer and Roberts (1988), Porter (1990), and Ohmae (1989) all emphasized continuous innovation. Porter stressed that innovation should be aimed at updating current products and thereby implied concentration on functionally segmented markets rather than focus on a particular technology. Meyer and Roberts offered strategic advice concerning management of core technologies themselves. Their concern was support of a distinctive core technology within the firm. However, firms can obtain technologies from external resources as well. Ohmae suggested that a firm cannot expect to accomplish all strategic goals internally. Product acquisition can arise from internal innovation or external alliances.

Likewise, market access can be accomplished with resources internal to the firm or through strategic alliances (Harrigan 1987). Commitment to international markets does not require actual in-country presence on the part of all participants. Distribution can be done effectively by the originating firm, a strategic partner, distributor, or licensee. Robinson (1978, p. 12) employed the value-added chain to determine the firm's ability to balance cost and control issues in deciding between internal and external distribution strategies. The importance of deciding these issues was supported by Ohmae (1989). Because firms can rarely afford the high costs and time involved to accomplish each strategy internally, the cost of external alternatives should be evaluated. Ohmae also emphasizes evaluation and

allocation of control between the firm and its outside partners to maximize the benefit of external expertise and reduce conflict of interests.

Joint ventures, licensing agreements, research consortia, franchises, turnkey contracts, and distributor agreements are a few of the commonly used strategic alliances. Each option has advantages and disadvantages relative to commitment of resources, managerial control, profit sharing, and ownership. Joint ventures create a new entity in which participants share ownership. Research consortia do not necessarily create new entities but join firms together to accomplish specific research objectives. Franchises, which involve sale or lease of a product or service concept, require ongoing involvement of a seller/licensor to maintain quality and image standards. Turnkey contracts are relationships formed to accomplish a specific goal and once the goal is achieved full control is turned over from the seller to the buyer. Distributor agreements are strictly channel relationships which must be carefully managed. Licensing agreements, the most frequently utilized kind of alliance in the pharmaceutical industry, require no ownership, relatively little ongoing management, and are quickly established. One strategic advantage of licensing agreements is the relative speed with which they can be implemented.

One advantage to using networks is profit maximization. Other rationales for seeking network arrangements include

diversification and assortment of goods, synergy, innovation, decision support systems, economies of scale, market share and technology transfer.

The structure of the pharmaceutical industry suggests several specific advantages to strategic alliances, for example, access to sales forces or "detail forces" in developing appropriate markets. A detail force is trained to be knowledgeable about drugs within a specific therapeutic class. Some countries even require competency testing and licensing of detail personnel. Firms with established detail forces and goodwill at various levels of the system are better prepared to satisfy regulatory requirements for new product introduction. Also, entrenched firms gain insight into regulatory and market trends earlier than those without an in-country presence. Because it takes time and money to establish in-country market presence, choice of country access strategies should be evaluated relative to their importance in the global market.

Another reason for industry strategic alliances is to build relationships with foreign governments. The quality of these relationships is critical to gaining market access and favorable pricing or reimbursement. For example, in many countries, such as West Germany or England, the government is a major pharmaceutical products customer via national health plans. Other governments, such as some in the Middle East, actually purchase and warehouse all ethical drugs sold in-country. Successfully doing business with

these governments requires special consultative capabilities and a good working relationship which comes from in-country experience (Ghauri 1990).

Regardless of differences in opinion concerning the performance effectiveness of alliances, firms frequently exercise them as strategic options. The predominant form of alliances in the pharmaceutical industry is licensing products between firms. Of the 8,895 drug introduction entries listed in the combined 1989 Paul de Haen Drug Product Indices, 6,212 (69.8%) are marketed using licensing agreements and only 415 (4.6%) are marketed from joint venture firms. For this reason and because it is the most quickly achieved alliance, licensing strategy is used in this study. Increased market access can be achieved externally by licensing a product to another firm to market, or out-licensing. New products can be acquired externally by licensing a product from another firm to market, or in-licensing.

Thorelli (1990) used the term networking to describe any arrangement which promotes strategic cooperation. Networking can be exercised in many forms and at various levels of the value-added chain. The rising costs of R&D and distribution channels are contributing to an increased frequency of such arrangements. According to Harrigan (1987), "even the most bitter competitors will be sharing laboratory results to commercialize cutting-edge technology" (p. 67).

Ohmae (1989) also encouraged use of strategic alliances to enhance profitability and chances for long run survival. Success of strategic alliances depends upon three key elements: the decision process, choice of strategic partner, and planning alliance management (Devlin and Bleakley 1988, p. 20). The decision to use strategic alliances should reflect corporate global goals and formulate criteria for partner selection. Once partners are selected, Ohmae (1989, p. 147) warns of the dangers of planning for a high degree of control in managing the alliance. An important contribution of the in-country partner is its experience.

In contrast to Harrigan, Ohmae, and Thorelli, Porter (1990) did not advise the use of strategic alliances. He has hypothesized that alliances will lead to mediocrity in the long run because they erode the firms' competitive advantage. However, many firms do utilize strategic alliances to attain both short- and long-term goals. Even if Porter's long run hypothesis is correct, it would seem advisable to utilize alliances for the short term while simultaneously pursuing strategies to strengthen long-term performance.

To summarize, product acquisition and market access strategies can be achieved by internal or external means. However, use of strategic alliances is controversial and their relationship to performance is unknown. The following section uses conceptual literature to develop the product

and place (or market) variables for study in the global environment.

Product Acquisition and Market Access

Practice of global strategy requires attention to a wider range of the same details managed domestically. All four marketing variables can be influenced by each market. Product and place, however, must be established before pricing and promotion can be considered. Products must be acquired to fit the needs of target markets and markets must be accessed to commercialize innovations. Here it is argued that product acquisition and market access are not only the first marketing concerns, but they are inseparable in the planning process. Parallel definitions of product acquisition and market access are developed from global strategy literature. These definitions include two dimensions, depth and breadth. In a later section, both internal and external methods of achieving product acquisition and market access are also discussed.

Inseparability of Product Acquisition and Market Access

Two streams of research illustrate the inseparable nature of products and markets. The first is international segmentation literature and the second is the standardization versus adaptation debate.

Early literature on selection of international markets (Cavusgil and Nevin 1981, p. 201) is centered around the concept of market segmentation by nations (Goodnow and Hansz

1972; Jain 1984; Liander et al 1967; Sethi 1971; Sethi and Holton 1969). The problem with segmentation by country is that it fails to recognize heterogeneity of consumers within a country and similarities across countries. Thus, the unit of analysis for segmenting international markets has evolved into clusters (Cavusgil 1990) or strategically equivalent segments (SES) which cross national boundaries but respond similarly to products and marketing (Kale and Sudharshan 1987, p. 61). Clusters are used to define segments appropriate for a particular product class. International segmentation literature repeatedly defines markets by their response to products.

The standardization versus adaptation literature conversely defines products in terms of their markets. Levitt (1983) asserted that the same product characteristics are demanded globally by virtue of increasingly similar product needs. Opposing views (Jain 1989 and Kashani 1986) based arguments upon differences in desirable product characteristics between markets. From either perspective, standardization or adaptation, product characteristics are viewed in relationship to market characteristics.

Whether strategic planning is initiated using the market or the product variable, each is considered in relationship to the other. Therefore, for purposes of marketing planning, products and markets are inextricably combined and should be considered simultaneously.

The managerial problem is how to most effectively direct strategic efforts towards both product acquisition and market access goals. Although product acquisition and market access strategies are mutually dependant, firms also need to face decisions along each dimension separately as well as together. The dilemma arises when limited internal resources must be allocated between the costly strategies of internal product development and developing multiple markets. Decisions for managing both of these variables must be made before the remaining marketing elements, promotion and price, can be addressed. This is because heterogeneous product and place characteristics generally influence pricing and promotion by market segment.

The next two subsections will discuss product acquisition and market access to facilitate their study in tandem. Parallel dimensions of these variables include depth of commitment (the extent of continued development within product categories or markets) and breadth of commitment (the extent of development across product categories or markets).

Product Acquisition

Product acquisition can be viewed on two dimensions: depth of commitment to a product class and breadth of product line across classes. The notion of depth of strategic orientation is not new. Meyer and Roberts (1988) used the term focus to describe depth of commitment to

technology strategy. They define focus as the extent of development effort concentrated within a technology. Their study findings empirically supported the importance of a technology focus relative to performance. Their sample included 26 firms in four industry clusters. Their measure of depth of commitment to technology was based upon the core technology used to develop products. However, study of commitment to a technology rather than commitment to a product category may be problematic. It can be argued that technological content is a function of the product itself. In other words, by tracking technology, only successfully applied technologies can be observed in the form of marketable products. Formulation of the initial product development strategy may or may not have been driven by core technology. Product development strategy may have been focused upon satisfying existing market segments. Emphasis on marketability of technology directs researchers to investigate the strategic decision process based upon product category. Therefore depth of product orientation can be measured using incidence of product acquisition within a product class or category.

Recently Porter (1990) hypothesized about the important nature of innovation in firm strategy:

> Companies achieve competitive advantage through acts of innovation. They approach innovation in its broadest sense, including both new technologies and new ways of doing things. . . . Ultimately the only way to sustain a competitive advantage is to upgrade it--to move to more sophisticated types (p. 75).

Porter's thinking advocates that a firm continuously develop products which update its current products. Porter stresses that successful firms innovate replacement products for their markets before competitors do. This is also consistent with Levitt's (1963) advice for firms to seek products and services which will update their current line.

Simultaneous attention to product and market are also evident in Porter's hypothesis. In suggesting that firms upgrade their competitive advantage, Porter implies two strategies: (1) the firm's new products or processes replace their own older ones with similar but improved or changed products; and (2) the firm's innovations be directed toward current functional markets. His hypotheses are specific to the sustained direction of innovation rather than the process. This is consistent with the notion of depth of commitment to products rather than technology. To summarize, depth of commitment to products is the extent to which a firm continues to develop products within a product class. To appropriately test this concept of depth of product development efforts, the relationship between past and current product development becomes important. Depth of commitment to products can also be achieved by licensing strategies. That is, products within a therapeutic class may be licensed <u>from</u> another firm. The firm may subsequently commit internal resources to the development of products in a class in which in-licensing had

been the predominant strategy. The following hypothesis formalizes these relationships:

H-1a In-house product developments in a therapeutic class is a function of the number of products a business previously developed and the number of products previously in-licensed.

Porter's innovation strategies also suggest that future product success is positively related to past product development within a product category or class. A commonly used measure of innovation success in the pharmaceutical industry is development of a drug which achieves top-performer status (Caglarcan, et al 1978). Product development and in-licensing strategies are related to this industry performance criterion in the following hypothesis:

H-1b The number of top sales producing drugs the business markets in a therapeutic class is a function of the number of products a business previously developed and in-licensed.

Foxall (1983) hypothesized that by limiting efforts relative to established patterns of new product development, the search for new products is facilitated. In other words, because efforts are constrained across product classes they are more successful. This suggests that breadth across classes as well as depth within classes is important in product acquisition strategies. This may be true whether they are internally developed or obtained externally through licensing agreements. Breadth can be measured by the number

of product classes in which product acquisition occurs. Foxall's hypothesis indicated a negative relationship between the number of product classes and successful innovation. The following hypothesis relates breadth of past product development to current product development success:

H-1c The number of current products developed by a business is a function of the number of therapeutic classes in which a business previously developed products.

Many levels of innovation or product development have been defined. The Meyer and Roberts (1988) study identified minor improvements, major enhancements, new related technology, and new unrelated technology. Again technology and products can be made parallel and applied to the pharmaceutical industry. Minor improvements are uninteresting and may be unmarketable. On the other hand, major enhancements have a competitive advantage over existing products.

To capture the essence of the major enhancement concept in the pharmaceutical industry, the unit of analysis for measurement of new product development adopted for this study is introduction of a single chemical entity (SCE). The SCE is a unique chemical compound which may be marketed in several dosages, product forms, and under numerous trade names. Therefore, measurement of innovation incidence uses a count of single chemical entities at the time of beginning marketing.

In terms of marketable products, the relatedness of new to old technology is less important in an environment of consumable products which do not rely upon predominant industry technology or standards. This is the situation with pharmaceutical products. Although relatedness of new technology to existing technology is of importance to managers, it is of less importance to marketers. Because various types of pre- and post-sales support is required for different products, marketers are more concerned with the relatedness of products. Products which have similar uses, thereby sharing target markets, are more likely to require similar support channels. Therefore, functional similarity of products is more likely to ease the marketing management task than technological similarity. It follows from this discussion that study of product acquisition should incorporate measures of product similarity not measures of technology similarity.

Since technology can also be obtained external to the firm through strategic alliances, marketers are also interested in external strategies for obtaining marketable technology. Therefore, studying external sources of innovative products is as important to marketers as the study of internal product development. External product acquisition is discussed independent of internal product development in the strategic alliances section of this chapter. The next section explores the market elements in the context of global strategy. Then, both internal and external product

acquisition and market access strategies are examined in relationship to performance in hypotheses 2a and 2b.

Market Access

The depth and breadth dimensions can also be used to measure market access. This section uses multinational organization and strategy literature to develop these measures of market access. A hypothesis relating past and current market access strategies is then presented.

Firms generally use a geographic orientation to structure their organizations, segment their markets, and make product decisions. Ethnocentric organizations offer standard products which were initially designed for their domestic markets. Polycentric firms operate much like several independent ethnocentric organizations offering products specific to each of many markets. Firms with a centralized global orientation tend to offer standardized products to all markets. Geocentric firms are organized into multi-country regions. These firms adapt major product characteristics to the needs of each region. Minor adaptations are made for market segments within regions.

The typical structure has evolved from an ethnocentric (domestic) to a global (worldwide) and currently to a geocentric (regional) structure. The concept of the geocentric ideal (Simmonds 1985, p. 8) is reflected in multinational organizations at the regional level. It is typified in the slogan, "Think Globally, Act Locally." These changes

in typical structure have accompanied the classic standardization vs. adaptation debate (Buzzell 1965; Levitt 1983; Jain 1989).

More recently Ohmae (1986a, 1986b) centered the notion of geocentric thinking around the world's largest developed markets: Japan, the United States, and Western Europe. "The Triad World View" clusters these developed population centers into a single global market with similar, but not the same tastes. Market segments within each of these key country markets are remarkably like segments in other Triad nations (Ohmae 1986a, 1986b). This thinking is a formalized geocentric ideal, in which each country market becomes a launching pad for smaller geographically-close markets. A similar change in product adaptation strategies has followed the evolution of organizational structures.

Centrism (albeit ethno-, poly-, or geo-) implies both strategic depth and breadth. Hence these measures of strategic commitment within and across markets can be viewed in a similar fashion as product acquisition within and across product categories. Continuing the parallelism, market access strategies can also be internal or external to the firm. Internal market access strategies can be measured by the number of products a firm markets directly in a particular geographic market. Market access can be gained externally through strategic alliances. Diversity or breadth of global market access can be measured across countries and by market presence in key markets.

Global distribution commitment requires a high level of channel utilization to support the cost of maintaining those channels (Hamel and Prahalad 1985, p. 142). Thus single product firms will have difficulty fully utilizing their channels. Thus, the cost of channel maintenance becomes an effective barrier to entry for these firms.

Continued marketing presence in a country is reinforced by the addition of products to a firm's existing line. Instead of a considered choice of channels in which existing channel support is evaluated, Anderson and Coughlan (1987, p. 72) found that the degree of product complementarity seemed to be secondary in a firm's choice of markets. That is, firms generally use existing channels regardless of their appropriateness for the new product in an attempt to cement current arrangements. Portfolio analysis should assist a firm to identify markets and channels which can provide new products with appropriate pre- and post-sales support. Portfolio analysis is proposed for this purpose and reviewed in a later section of this chapter.

The process of gaining access to international markets has been described as a gradual process over a long period of time (Cavusgil 1980; Johanson and Wiedersheim-Paul 1975). Researchers report a need for committed involvement to fully develop market potential and establish insider presence (Cavusgil 1980; Ohmae 1989; Thorelli 1990; Yip 1989). Committed involvement requires that resource allocation be based upon international opportunities and strategies be

geared for the long term. Globalization drivers of the pharmaceutical industry (large economies of scale, rapid technological change, and regulation) demand that innovating firms operate using a criterion of international committed involvement (Yip 1989, p. 29).

Accessing international markets requires not only appropriate use of expensive channels but also a long term commitment to each market. Because commitment to a particular market can be made by direct product introduction or out-licensing to another firm, both may be related to further product introductions. Therefore a fourth hypothesis is formalized as follows:

H-1d The number of current product introductions into that country is a function of the number of products previously introduced to a country market.

Both market access and product acquisition can be achieved by external as well as internal means. The following section relates licensing strategies and product acquisition and market access strategies, which were discussed in earlier sections, to performance.

Strategy and Performance

A major contribution of this study is to relate product acquisition, market access, and licensing strategies to performance. This section will define the performance measures used and provide hypotheses to test these

relationships. Industry criteria are also considered with general performance measures.

Both product acquisition and market access must be managed for firm success in a global, highly technology-based industry. Literature suggests some relationship between the elements of strategic orientation and performance. In applying Thorelli's networking and Yip's committed involvement concepts to strategic focus, the degree of market depth is predicted to be positively related to firm success. This is consistent with Porter's (1990) innovation and Meyer and Roberts' (1988) technology focus hypotheses.

Foxall (1983) implied that some degree of breadth is desirable but warned that a reasonably narrow search is positively related to performance indicators. Together with Levitt's (1960) admonition to avoid a myopic or too narrow approach, it is reasonable to hypothesize that the relationship may be a U-shaped curve. Because product acquisition and market access can be achieved externally through licensing these strategies are also expected to be related to performance.

The relationship between licensing strategy and performance has been predicted to be both positive (Ohmae 1989) and negative (Porter 1990). Therefore, here it is assumed only that there is a relationship; no directionality is predicted.

Accounting systems cannot technically measure financial performance with precision (Curtis 1985, p. 59). However it

is measured, financial performance can vary considerably from year to year due to economic fluctuations, management practices, or changes in accounting procedures. Actual results must be compared to some type of standard, which means that some sort of objective or goal must be determined in advance.

The long-term pay back scenario of the pharmaceutical industry and the low hit rate of R&D makes it difficult to place trust in profitability measures (such as ROI and ROS) which incorporate extensive amortization techniques. International firms and participation of both public and private firms in the industry render stock prices unacceptable as measures. Stock prices in recent years have tended to be reflective more of public trust than of value of a firm (Curtis 1985).

Sales are a better measure of a firm's marketing efforts because they are subject to fewer accounting adjustments and are more readily compared across firms. Since market share can be calculated using sales, it is also subject to fewer adjustments. In addition, market share is measured relative to market size which also provides information about competitive strength. Therefore the general performance measures adopted for this study are sales revenue and market share. The following hypotheses relate breadth and depth measures of product acquisition and market access, licensing behavior, and successful product development to performance:

H-2a Pharmaceutical business sales revenue is a function of the number of products developed, the number of product introductions into country markets, the number of in-licensed products, the number of out-licensed products, breadth of product development, product line breadth, the number and breadth of top drugs, and market representation.

H-2b Pharmaceutical business market share is a function of the number of products developed, the number of product introductions into country markets, the number of in-licensed products, the number of out-licensed products, breadth of product development, product line breadth, the number and breadth of top drugs, and market representation.

To summarize, product acquisition and market access dimensions and licensing strategies are thought to have some relationship to performance. The expected nature of these relationships is discussed in Chapter IV. All of these strategic elements must be managed individually and together to accomplish global strategic goals. Product portfolio analysis has been suggested as a method for managing these elements. The next two sections address portfolio analysis and define an industry-specific portfolio.

Product Portfolio Analysis

This section critiques product portfolio literature for the purpose of developing a tool to simultaneously identify strategic gaps in current product acquisition and market access strategies. The following section will develop and define a dual goal portfolio for the pharmaceutical industry.

During the early 1970s the Boston Consulting Group (BCG) introduced a product portfolio tool comprised of a two-by-two matrix depicting market attractiveness (or growth) and competitive position (see Figure 1). This four-box matrix was designed as a management decision tool. The matrix was developed based upon the product life cycle and included four categories of products: stars, cash cows, problem children, and dogs. Star products have a high growth rate and a dominant market share. Cash-cow products have a low growth rate and dominant market share. Problem children, or question marks, are products which have a high growth rate and low market share. Dogs are products which have a low growth rate and low market share (McCarthy and Perrault 1989). The matrix was developed from financial portfolio analysis (Devinney and Stewart 1988) and applied to marketing strategy. The BCG matrix has been used to analyze products as diverse as financial products (Guiltinan and Donnelly 1983), insurance (Sherden 1983), and grain and feed products (Carlson 1983).

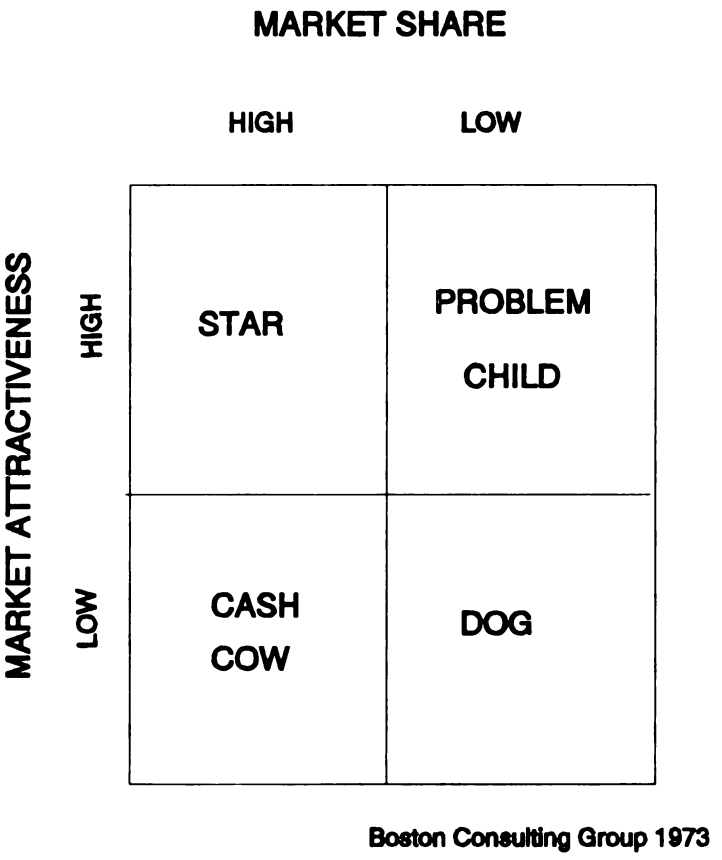


FIGURE 1 THE BOSTON CONSULTING GROUP

Various criteria have been used to tailor the original BCG matrices for specific needs. Bennett and Cunningham (1985) added profitability to their general framework model. Technology was used to focus product innovation and plan R&D strategy (Bitondo and Frohman 1981; Capon and Glazer 1987; Meyer and Roberts 1988). Product attributes such as cost position (Sherden 1983, p. 113) have also been used.

The dimensions generally pertain to the strategic business unit level of analysis. Market segments (Bennett and Cunningham 1985; Cunningham and Daley 1981) and line-of-business (Wind and Mahajan 1981) have also been used. The product portfolio has been internationalized using country attractiveness to define market segments (Harrell and Kiefer 1981). A more complex international model combined stochastic dominance and analytical hierarchy approaches (Wind and Douglas 1981). The hierarchial approach carries a wealth of information in its contingencies and decision rules but appears unwieldy to use because of its complexity. The product portfolio analysis technique can be useful in multiple levels of analysis but requires attention to design to ensure that it is easy for managers to use.

Most matrices serve simply as frameworks for categorizing product potential. The BCG model offers a generalized risk return analysis for each matrix cell stemming from accompanying decision rules (Cardoza and Smith 1982). For instance: (1) "star" products have the highest probability of success and therefore should receive resources necessary

to realize this success, and (2) "dog" products have little chance of success and should be dropped. In contrast, Devinney and Stewart (1988) used a more complex and quantitative approach in their hypothetical multi-product investment model. Their model offered an estimate of actual product performance rather than simple strategy advice.

Generalized rules originally offered by the Boston Consulting Group (BCG) matrix have been tested by numerous researchers. For example Hambrick and MacMillan (1982) tested the general cash flow rule concerning "dogs." The BCG rule expected negative cash flow from these products whereas this study showed they have a tendency to generate cash (p. 89). Hambrick and MacMillan suggested a new strategy: that dogs be given first rate managers to maintain corporate morale rather than divesting them.

Other researchers (Hambrick, MacMillan, and Day 1982, p. 58) concluded that clear tradeoffs between market share and cash flow or profitability were not necessary in most cases. Only "star" products were found to have a consistently inverse relationship. The Hambrick et al. study showed that multiple objectives can be pursued and called for more research into "well rounded" strategic effectiveness. Though Hambrick and MacMillan (1983) offered no simple solutions using portfolio analysis, they note that its power and simplicity are evident in the conceptual gains brought about from its widespread use.

As early as 1981 literature reviews included comparisons of the many variations of the BCG matrix approach. Wind and Mahajan (1981) identified three elements to differentiate portfolios: (1) use of a general prescriptive framework versus a company-specific framework; (2) the dimensions identified in the model; and (3) the extent to which resource allocation rules are provided (p. 155). They concluded that company-specific designs are superior because they embody idiosyncrasies of the firm, cover particular risk-return dimensions, provide a creatively involved exercise for management, and offer clear guidelines for resource allocation within the portfolio. The problem with company-specific portfolios is that they require portfolio design expertise be available directly to the firm. From a research perspective firm-specific portfolios make comparisons across firms difficult.

This review has revealed a lack of product portfolio literature which incorporates a sufficient level of detail to manage both product acquisition and market access variables in the global environment and which is sufficiently simple to use. The next section defines a product portfolio for the pharmaceutical industry to incorporate product- and industry-specific market variables.

Pharmaceutical Global Product Portfolio

The objective of a portfolio design is to incorporate as much relevant experience as possible into the tool

without making it difficult for managers to use. Specifying an industry portfolio has the potential of providing this important balance between detail and simplicity. Knowledge common to the industry can be freely incorporated without danger of overloading users with new detail. This section develops a portfolio for the pharmaceutical industry incorporating product acquisition and market access as called for by Capon and Glaser (1987) and industry experience in the global environment.

Global marketing requires decisions concerning allocation of resources to achieve product acquisition and market access. Firms must invest in updating their current products (Porter 1990, p. 74). At the same time, distribution channels must be maintained and prepared for expansion and introduction of new products. Despite Porter's admonition against using alliances (1990, p. 93), high tech industries face a dilemma trying to manage both product development and market presence. Both product development and global market access are expensive strategies to support. In the face of a potentially shortened commercial product life-span, trade-offs are necessary in strategy formulation.

Portfolio management can be used to decide upon product development and marketing access strategies which will maximize performance goals. In adapting a portfolio specifically for firms in the global pharmaceutical industry, these strategies are analyzed individually and together. Desired product and market goals are defined using industry

experience and market potential and expressed as decision criteria, or rules of thumb. Desirable products are most usefully defined and grouped by function using therapeutic class (Cocks and Virts unpublished). Market attractiveness is captured by the size of country markets accessed relative to the size of the world market. A comparison of the current and desired portfolio of products and markets identifies gaps which should be addressed in future strategies.

The unit of analysis used is the firm's pharmaceutical line-of-business. A line-of-business may be comprised of a single business unit, multiple business units, or an entire firm. Defining portfolio parameters at the industry line-of-business level decreases the variance in market segments, product classes, and market size which occur when the entire firm is examined (Wind and Mahajan 1981). The portfolio measures individual pharmaceutical lines-of-business against industry parameters and thereby provides a basis for comparison.

The pharmaceutical industry has developed two current rules of thumb against which future success of the pharmaceutical line-of-business is gauged (Hornick 1990). These criteria are a product of over two decades of industry experience and executive assessment of current strategies necessary to attain or maintain future performance goals. These rules of thumb are incorporated into the Pharmaceutical Global Product Portfolio presented in Figures 2 and 3:

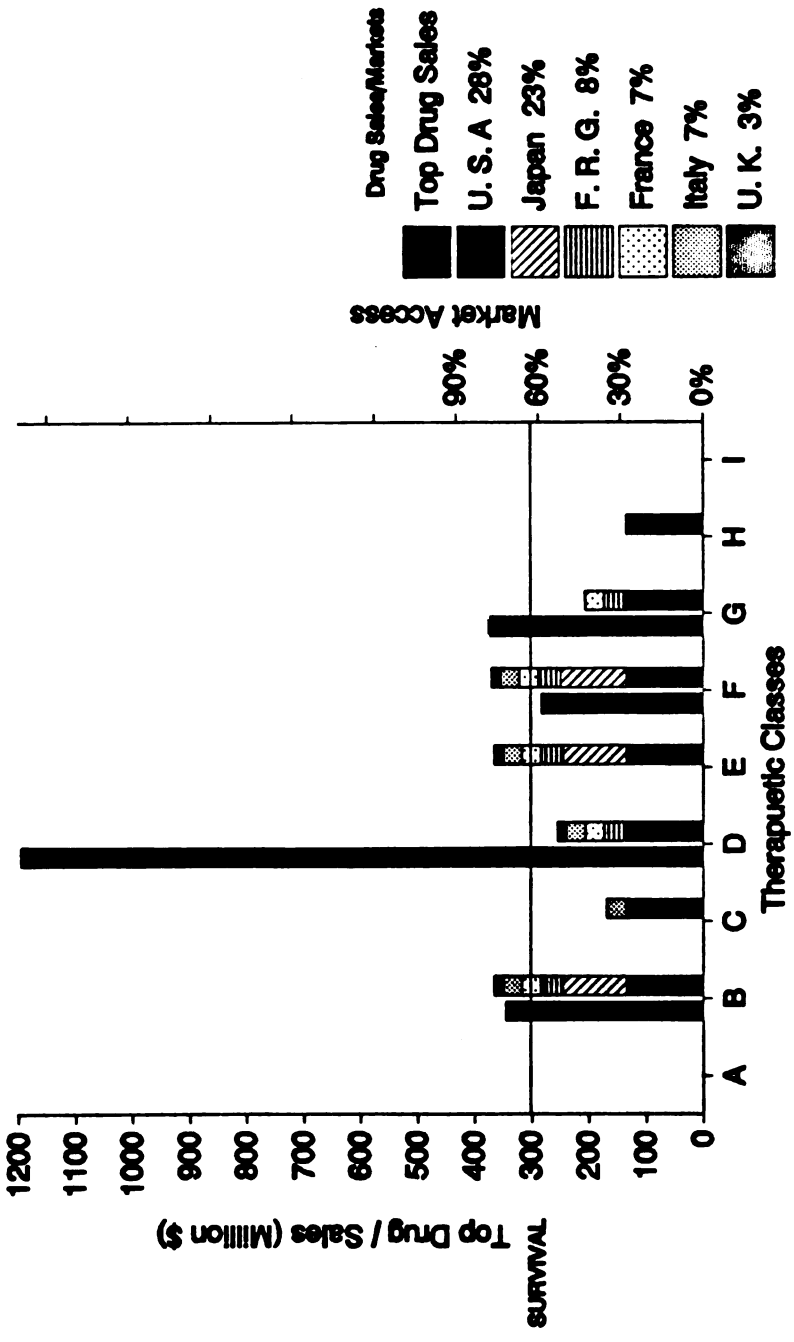


FIGURE 2 LINE-OF BUSINESS RANKED FIRST -- 1987

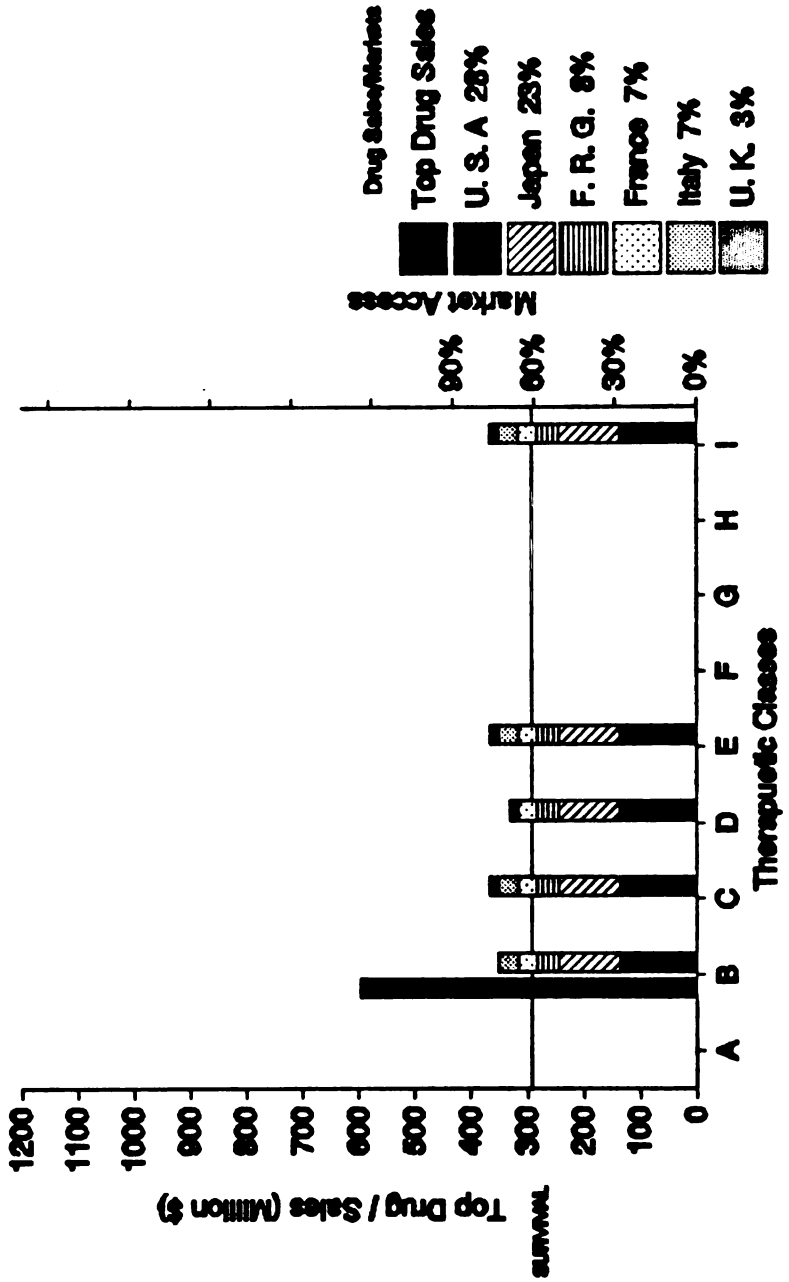


FIGURE 3 LINE-OF-BUSINESS RANKED FIFTEENTH–1987

1. A pharmaceutical line-of-business will need to have three top-performing products (in three different therapeutic classes) with revenues in excess of $300 million each for future success.

2. A successful product must be introduced simultaneously into each of the three major markets: Japan, the United States, and West Germany.

It is not coincidental that these country markets represent 60% of the world market and are consistent with the triad concept. Two pharmaceutical lines-of-business can be compared using the portfolios illustrated in Figures 2 and 3. The two entities can be compared by the relative position of the bars to the "survival line" which is a graphic representation of the threshold for satisfying each industry criteria.

A portfolio for the early 1970s would have incorporated a lower survival line at the floor performance level of the top thirty drugs because at that time the first criterion stipulated only one top drug as a product success measure. This illustrates the need to update portfolio criteria for the tool to remain useful. In the 1970s the market access bar would not have been used since there was then no criterion concerning market entry strategies. The current market access rule is a reflection of the increased drive for globalization of the pharmaceutical industry.

Criterion one (see above) defines the relevant product breadth of the Pharmaceutical Global Product Portfolio using nine major therapeutic classes (see Table 2). These classes correspond to the major causes of mortality in the

key country markets (see Table 3). Sales volume of the top-performing drugs within each therapeutic class is recorded using the solid bar (top drug bar) and measured in millions of dollars against the left scale.

Using criterion one, survival of the pharmaceutical line-of-business is not assured unless top drugs in three therapeutic classes reach the survival line. Criterion two defines the right scale as the percentage of the global market accessed in that therapeutic class. The percentage of world market size represented by each country market accessed is summed within a therapeutic class and recorded in the variegated bar.

The second criterion defines market access relative to the size of the total global pharmaceutical market. That is, in what percentage of the world market is the business represented in a therapeutic class. Market representation is weighted for each class using the percentage of the total global market represented by the country: Japan (23%), Western Germany (8%), France (7%), Italy (7%), the United Kingdom (3%), and the United States (28%). See Table 1 for a listing of countries in the study.

The vertical scales are normalized such that both criteria are satisfied when both bars in a therapeutic class (top drug and market access) reach the survival line. This design captures both depth and breadth of market access and acquired products.

TABLE 1

ESTIMATED VALUE OF LEADING PHARMACEUTICAL MARKETS--1987-1988

Country/Area	Estimated 1988 Market £Million	Percent of World Market	Annual Percentage Growth 1987
United States	17,900	28	+15
Japan	15,100	23	+6
West Germany	5,300	8	+8
France	4,200	7	+16
Italy	4,300	7	+15
United Kingdom	2,300	3	+13
Balance of Free World	12,700	20	+21

Source: Glaxo Annual Report 1989

TABLE 2

MAJOR DRUG PRODUCT CLASSIFICATIONS

Antihistamine Drugs
Anti-Infective Agents
Antineoplastic Agents
Cardiovascular Drugs
Central Nervous System Agents
Eye, Ear, Nose, & Throat Preparations
Gastrointestinal Drugs
Hormones and Synthetic Substitutes
Skin and Mucous Membrane Agents

Compiled from American Hospital Formulary Service 1990

TABLE 3

MAJOR CAUSES OF HEALTH-RELATED MORTALITY IN COUNTRIES OF INTEREST

Country	Cancer	Circulatory Diseases	Respiratory Diseases
France, 1986	35.9%	24.5%	7.0%
West Germany 1986	50.1	21.8	6.7
Great Britain 1986	44.7	23.9	10.6
Japan 1985	45.2	29.4	8.0
Switzerland 1987	44.9	27.5	5.5
Sweden 1986	54.7	21.2	7.9
USA 1986	46.2	22.3	3.2

Source: Demographic Yearbook Series

In 1989 the left and right scales represent $300 million in top drug sales and 60% market access, respectively. This is because during 1989 a drug with $300 million in sales ranked among the top thirty performers. The 60% market access is derived by summing the percent of world market represented by the United States, Japan, and West Germany. As already noted these criteria require annual calibration of the survival line to set it equal to both sales of the drug ranked thirtieth and the percentage of world market represented by the three triad countries.

This approach maximizes generalizability while controlling for structural idiosyncrasies within the industry. However, variance in complementarity and substitutability between products within therapeutic classes is not captured using this classification scheme. By using top drug performance within therapeutic classes, the portfolio does capture the notion of a highly successful major product enhancement. Global market attractiveness is also designed into the portfolio by including and weighting approximately 75% of the world market.

This industry-driven portfolio analysis can be made more sophisticated by employing expected growth rates of various country and therapeutic markets when calibrating the survival line. By so doing, management intuition and industry projections can be incorporated into analysis of strategic gaps. In its present form it graphically represents the current situation against the desired position,

thereby identifying strategic gaps. These gaps become management decision points for selecting internal and external product acquisition and market access strategies. Management must then decide how to obtain new product technology or market access in a particular therapeutic class. This next step necessarily includes transaction cost analysis to select internal versus external strategies. Strategic planning incorporates decisions to invest in product development or to obtain new products by in-licensing arrangements. Market access strategy involves decisions to invest in training a qualified detail force in a therapeutic class for a particular market. The alternative is to out-license the product to firms who already have trained sales networks in desired markets. A combined product acquisition and market access strategy is required to push both portfolio bars within a class over the survival line. According to current industry criteria, to be successful a firm must push three pairs of bars over the survival line to assure future success.

The portfolio introduced in this section incorporates industry variables, global market variables, and product categories. The portfolio measures success against industry defined criteria. The tool is also useful in strategic planning to identify strategic gaps as they relate to product acquisition and market access. This portfolio approach is also useful in comparing strategic positions

between firms and serving as a model for development of other industry portfolios.

Conclusion

This chapter has identified gaps in the existing global and portfolio literatures and introduced an industry product portfolio. A conceptual basis for the study has been developed and positioned relative to the literature.

First, the review of global strategy literature reveals a lack of empirical work specifically relating product acquisition, market access, and licensing strategies to performance. Second, product acquisition and market access are argued to be inseparable for the purpose of strategic planning. Third, these strategic elements are developed in parallel with respect to breadth and depth dimensions and licensing. Fourth, product portfolio literature does not currently provide an example of a well-specified and easy-to-use dual goal portfolio model. Fifth, there is no empirical work which tests the relationship between licensing strategy and performance.

This dissertation provides an incremental research step by addressing identified weaknesses in current global strategy/performance studies (see Table 4). First, specific marketing variables are related to performance in the global context. Second, it is the first such study to utilize a large sample within a single industry structure, thereby establishing relative sample homogeneity with regard to

TABLE 4

SYNTHESIS OF GLOBAL LITERATURE
THE STRATEGY-PERFORMANCE RELATIONSHIP

Study	Identified Design Flaws	Incremental Contribution
Kotabe and Omura (1989)	-excludes U.S. firms	links specific product strategies to performance
Bartlett and Ghoshal (1987)	-small sample size -excludes globalization drivers -imprecise performance measures -exploratory -broad study	links organizational frameworks to global success
Roth, Schweiger, and Morrison (1989)	-excludes globalization drivers -uses only U.S. firms -broad study	empirical test of Porter's international strategy cells
Yip (working paper)	-uses executive perceptions -exploratory	includes globalization drivers

consumer behavior, and regulatory structure. This contributes a degree of control regarding globalization drivers andprovides an opportunity to systematically evaluate those which are industry-specific. Third, the longitudinal design is new to global strategy literature. Next, the design includes firms from Japan, the United States, and Western Europe. Strategies are also examined across six country markets. Finally, the measures used reflect actual strategic behavior and performance rather than executive perceptions and utilizes a larger sample size (503 observations) than is currently represented in global strategy literature.

The objectives identified in Chapter I have been rewritten as testable hypotheses. These hypotheses are centered around a synthesis of product acquisition, market access, and licensing strategy literature. Product acquisition and market access were grounded in literature as containing depth and breadth components. Additionally, each can be achieved using internal or external means of achieving strategic goals.

The product portfolio, designed specifically for the pharmaceutical industry, incorporates product acquisition, market access, industry expertise, and the global environment into a decision tool. The portfolio also provides a basis for strategic planning comparing businesses within the industry and for analyzing the performance related hypotheses presented in this chapter.

Chapter III provides an historical background on the pharmaceutical industry. Then, Chapter IV returns to the third objective of the study and formalizes a theoretical framework for the concepts presented in this chapter.

CHAPTER III

PHARMACEUTICAL INDUSTRY BACKGROUND

Introduction

This chapter presents the environmental background and a historical perspective for this research. First, a framework for strategic global marketing is explained and applied to the pharmaceutical industry. Using that framework, the chapter discusses industry regulatory structure and strategic marketing options (see Figure 4). Firm performance measures specific to the pharmaceutical industry have been addressed in Chapter II.

The study specifically examines the global strategy of ethical pharmaceutical manufacturers who invest in research and development (R&D) for the purpose of developing new commercial drugs. Excluded are manufacturers who engage only in the production and marketing of over-the-counter drugs and manufacturers who do not engage in the research and development process. This delineation also eliminates manufacturers who specialize only in generic drugs or the production of drugs no longer protected by patent. However, many innovative ethical drug manufacturers do compete in other industries as well. This study is concerned only with

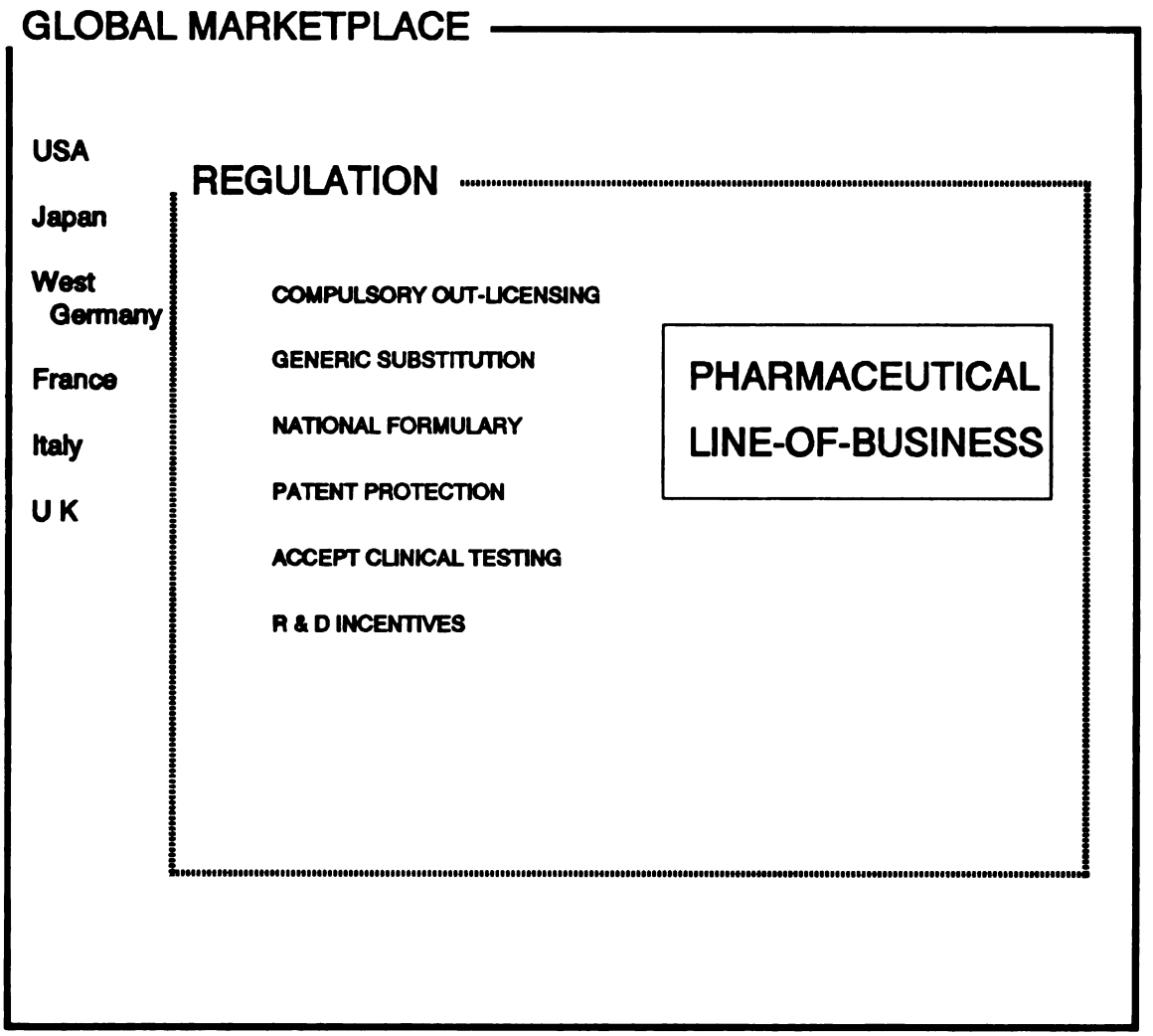


FIGURE 4 GLOBAL REGULATORY ENVIRONMENTAL FRAMEWORK FOR PHARMACEUTICALS

the strategic decisions as they relate to the pharmaceutical line-of-business. Pharmaceutical manufacturers and marketers operate in an environment which is highly technology based, heavily regulated, R&D intensive, and highly competitive. The combination of a rapid rate of technological change and a lengthy product approval process shortens the commercial period in which R&D investment must be recovered. As a consequence, the industry must operate in a worldwide market to maximize sales potential during this period (Burstall 1985, p. 119). This portion of the literature review addresses differences and similarities in the country markets selected for this study. Environmental variation among these markets largely relates differences in country regulatory systems. Marketing variables specific to the pharmaceutical industry are also addressed.

Study Position within the Pharmaceutical Industry

The pharmaceutical industry, the subject of much academic literature, is interesting to researchers, economists and regulators. The Center for the Study of Drug Development sponsors industry research concerning the innovation process and associated costs and the effects of regulation upon drug introductions. The Pharmaceutical Manufacturer's Association studies industry innovation performance and new drug introductions.

The economic literature generally relates to performance of the industry subject to regulatory constraints and

competition. The effects of patent protection on the industry have been addressed by Cieslik (1984), Kirim (1985), and Scherer (1985). Competitive structure, a popular topic in pharmaceuticals, has been studied by Backhaus (1983), Commonar (1979), Lall (1978), Scott and Reekie (1985), and Vernon (1971).

Industry performance has been studied relative to introduction of critical regulations in the United States and using cross-country comparisons. Examples of these studies include Cocks (1973); Goedde (1982); Grabowski and Vernon (1979); Hartley, Lavers, and Maynard (1986); Maynard and Hartley (1984); Reekie and Allen (1985); Schifrin (1982); and Temin (1979). Brand (1974) studied industry performance measured by the number of new product introductions, differences in product introduction time between countries, and product safety.

Another significant research stream deals with prescription drug advertising. Buc (1982) and Fishrow (1987) review promotional techniques and regulatory issues. Until recently in the United States, drug promotion has traditionally been directed to the physician. Direct-to-consumer advertising is now a topic of interest (Deutsch 1989, Masson and Rubin 1986, Novitch 1984, Perri and Nelson 1987). Researchers are concerned about the role of prescription advertising: does it serve to persuade or inform consumers (Leffler 1981); does it promote over-utilization of ethical drugs (Deutsch 1989); and, does it provide value to the

consumer (Sheffet and Kopp 1990). Morris and Millstein also studied the presentation of ethical drug advertising.

The economics literature also addresses technology transfer (Brada 1978; Moran 1986), pricing behavior (Cocks and Virts 1974; Reekie 1979), and innovation (Backhas 1983; Grabowski, Vernon, and Thomas 1978).

These studies address industry performance in the aggregate as well as strategic variables such as advertising and product innovation. To date only one published study in the pharmaceutical industry relates strategic behavior to firm performance. Cool and Schendel (1988) examine differences in performance between members of strategic groups. However, their study does not link specific strategic behavior of these firms, such as product innovation or advertising, to performance. The economic literature cited above also included the relationship between regulation and aggregate industry performance, but did not attempt to link strategic choices to regulatory environments.

This research will contribute to industry academic literature in two ways. First, this study clearly examines the relationship between pharmaceutical line-of-business strategy and performance. Second, it also looks at these strategic choices in direct relationship to market regulatory environments.

High R&D costs and the rapid pace of technological change force innovating pharmaceutical manufacturers to plan access to global markets. The study model (see Figure 4)

assumes a global marketplace and addresses the various regulatory issues that impact the industry. The model uses the controllable strategic marketing variables: product, place, promotion, and price. These variables are presented as they relate to the pharmaceutical industry later in this chapter.

An Historical Perspective

The global pharmaceutical industry was estimated to be worth $130-160 billion U.S. dollars in 1988 (Scrip Yearbook 1990, p. 10). Hundreds of pharmaceutical firms operate in many countries, but only a handful have an outstanding record of innovation and marketing performance. These major companies usually operate on a worldwide basis. Only the Japanese have traditionally focused exclusively upon their domestic market (Burstall 1985, p. 19). However, they too are becoming more globally focused (Yashikawa 1989). Of the top fifteen sales-producing firms in the 1988 period, eight are of U.S. origin, three are Swiss, two are German, one is Japanese, and one is British (see Table 3). The competitive strength or world rank of these firms did not change appreciably during the 1970s (Burstall 1985, p. 6).

Nature of the Industry

The industry is characterized by its large volume in major markets, a small number of top-performing drugs, and consistently top-performing firms (Scherer 1985). Though the number of players is large in the overall sense, the

number of firms that conduct the largest volume of business is quite small (Table 5), with a small number of drugs which account for the bulk of a firm's profit. Teff (1985) illustrated firm dependence upon on a few products by compiling statistics for 31 top sales-producing firms. Table 7 reports the number of drugs which represent 50% or greater of the revenue of these firms.

Generally speaking, a top-performing product such as Glaxo's Zantac ($2,373 million in 1989) and SmithKline's Tagamet ($1,030 million in 1989) can literally carry a firm. Tagamet accounted for nearly half of SmithKline-Beecham's operating profits in 1988 (Koenig and Lublin 1989). The top thirty performing drugs in 1989 are presented in Table 6. Note how sharply revenue volumes drop with rank: many drugs ranking in the top thirty show worldwide sales below $300 million. These top thirty performers represent 11% of worldwide sales volume. This appears quite uneven considering the number of registered drug products marketed in European countries ranges between 2,058 and 12,800 among the countries. A few of these drugs fill very large markets while many low-volume drugs fill smaller niches at the bottom (Slatter 1977). Table 6 lists new drug introductions by product category.

Fifty percent of the U.S. market, valued at $38,572 million in 1988, was held by the largest eight U.S. firms. Japan's market has been less top-heavy with only about 35% held by the top ten producers. At the same time 72% of the

TABLE 5

MAJOR ETHICAL DRUG MANUFACTURERS--1988

Firm (rank ordered)	Country	Annual Ethical Drug Sales ($millions)	Ethical Drugs As % of Co.Sales
Merck & Company	United States	$4,983.7	83.9
Glaxo	Great Britain	4,577.8	100.0
Hoechst	West Germany	3,958.0	17.0
Bayer	West Germany	3,712.6	16.1
Ciba-Geigy	Switzerland	3,531.7	29.3
Takeda	Japan	3,471.4	64.8
American Home Products	United States	3,218.0	58.5
Sandoz	Switzerland	3,147.0	45.4
Eli Lilly	United States	2,679.8	65.8
Abbot	United States	2,599.0	52.6
Pfizer	United States	2,539.0	47.1
Warner-Lambert	United States	2,509.0	64.2
Bristol-Meyers	United States	2,508.8	42.0
Eastman Kodak	United States	2,500.0	14.7
Roche	Switzerland	2,410.2	40.6

Source: Scrip's Pharmaceutical Company League Tables 1989

TABLE 6

TOP THIRTY SELLING DRUGS WORLDWIDE --1988 and 1989

Drug Brand Name	Manufacturer	Revenue in $Millions	
		1989	1988
Zantac	Glaxo	2,373	2,076
Capoten	Bristol-Myers Squibb	1,267	1,065
Vasotec	Merck & Co.	1,195	1,000
Tagamet	SmithKline Beecham	1,030	1,021
Tenormin	ICI	1,020	997
Voltaren	Ciba-Geigy	975	743
Adalat	Bayer/Takeda	850	971
Ceclor	Eli Lilly	696	605
Cardizem	Marion	658	506
Naprosyn	Syntex	645	618
Omnipaque	Sterling/Daiichi	620	450
Rocephin	Hoffman-LaRoche	597	475
Feldene	Pfizer	585	616
Mevacor	Merck & Co.	556	250
Ventolin	Glaxo	555	507
Zovirax	Wellcome	537	429
Augmentin	SmithKline Beecham	497	409
Zaditen	Sandoz/Sankyo	484	428
Ortho-Novum	Johnson & Johnson	450	400
Procardia	Pfizer	440	364
Xanax	Upjohn	425	395
Seldane	Marion Merrell Dow	410	326
Ciprobay	Bayer	400	125
Sandimmun	Sandoz	400	340
Primaxin	Merck & Co.	345	300
Pepcid	Merck & Co.	372	280
Calan	G D Searle	355	242
Claforan	Hoechst	353	376
Prozac	Eli Lily	350	120
Amoxil	SmithKline Beecham	348	402

Source: Scrip Annual Report 1990, p. 22

TABLE 7

NUMBER OF DRUGS REPRESENTING 50% OR GREATER OF COMPANY SALES--1985

Number of Drugs	Number of Firms
1	8
2	8
3	6
4	2
>4	7

Source: Teff 1985, p. 428

antibiotic market was controlled by the same firms, 40% was accounted for by only three firms. Thus, niche markets can be considerably more concentrated and lucrative (Yashikawa 1989).

The total number of pharmaceutical manufacturers is difficult to assess because of the relatively small market share held by all but the top 100-200 firms. However, innovative firms are highly visible because of their high sales volume and top-performing drugs. In 1974 in the United States the Pharmaceutical Manufacturers Association (PMA) had 135 members and an estimated 650 firms were not members. At that time PMA members accounted for 95% of industry volume (Silverman and Lee 1974). Current lists name 119 member firms (PMA 1990, p. 28). Japan currently has over 1,300 pharmaceutical firms, most of them are newer and smaller than in the United States and the European Community (EC) firms. The total number of EC firms is in excess of 2,700 (Burstall 1985). Of this large group of firms, only

about 190 meet the definition of an innovative ethical drug manufacturer used in this study.

Environmental Constraints

The channel through which pharmaceutical products reach the marketplace is anything but straightforward. The end-consumer generally does not select the product and, more often than not, does not fully pay for it. The industry has directed the majority of its marketing efforts toward the physician who fills the role of learned intermediary or surrogate buyer in writing prescriptions.

The regulatory environment surrounding the industry has focused upon health and safety, antitrust, and patent protection issues. The Federal Drug Administration (FDA) in the United States and its counterparts throughout the world require extensive drug testing for efficacy and safety. This process involves a minimum of two to five years pre-marketing commitment for each developed drug in each clinical market. The industry has become accustomed to simultaneously managing parallel testing and administrative processes to meet a multitude of regulations. Industry-wide positive economies of scale are primarily driven by two forces: the high cost and uncertainty of research and development and the regulatory environment. The highly regulated nature of the industry has created the need for a large amount of administrative support to manage the

plethora of documentation required to bring even a single product to market.

Civil law in the United States and many European countries also plays a large role in strategic decisions for these firms. Product liability is a major industry concern. Many countries have rapidly put significant legislative reforms into place in both Europe and the United States in the wake of the thalidomide tragedies. The sensitive nature of pharmaceuticals carries heavy legal and moral responsibilities. Perhaps due in part to this sensitivity, the industry has been described as highly conservative in lobbying efforts that address safety issues.

Research and Development

The productivity of research and development is uncertain. In Japan approximately 7,000 compounds are investigated to develop one which is pharmaceutically promising (Yoshikawa 1989). Estimates in the European Community (EC) range as high as 10,000 to one. This hit ratio requires a large investment in R&D which is difficult for small scale firms to finance. The cost of developing a single new medicine is estimated to be $231 million U. S. dollars in 1990 (PMA 1990, p. 5). R&D expenditures are reported to be 16.8% of sales in 1990, up from 11.7% in 1980. In absolute terms, current growth of R&D expenditures is at a rate of 12.3% annually.

New Chemical Entities (NCEs) and New Drug Applications (NDAs) are indicators of industry research and development productivity. Between 1961 and 1980, 710 NCEs were registered by the EC firms, 353 by U.S. firms, and 155 by Japanese firms. The origin of major drugs in the EC market in 1982 included 175 from EC firms, 55 from U.S. firms, and 17 from Japanese firms. Sources for this data (Burstall 1985, p. 119) comment that Japanese firms have been conspicuous by their absence from the EC market. Between 1961 and 1980, 353 new drugs were introduced in the United States and only 153 in Japan. One explanation for these differences is the relative immaturity of Japanese manufacturers compared to United States and EC firms. Japanese firms began marketing a total of 61 NCEs in 1987 and 53 in 1988.

Regulatory Issues

The world's largest pharmaceutical markets are the United States, Japan, and Western Europe (Scrip Annual Review 1990), accounting for approximately three-fourths of global volume (see Table 1). The domestic legal environment in these markets has a profound effect upon pharmaceutical manufacturers.

The U.S. market has an interesting legal history which has shaped the structure of consumer drug procurement and the pharmaceutical industry. A brief presentation of this historical perspective is presented later in this chapter. In Japan, a close second in size, legislation has been

highly protective of domestic pharmaceutical firms, though Market-Oriented-Sector-Selective (MOSS) negotiations have increased access to this market. Reimbursement in Japan is strongly affected by its National Health Insurance plan. The Western European market is still somewhat diverse in its regulation but continues to converge under the influence of the EC. Most EC countries also have national health insurance plans which affect purchasing patterns and pricing. A country-specific listing of relevant regulation is summarized in Table 8.

National Health Insurance Plans

With the exception of the United States, all countries represented in Table 8 provide nation-wide health care coverage for their citizens. National health plans create two countervailing forces which act upon the pharmaceutical industry. First, the positive impact is removal of the ability-to-pay consideration at the individual level. The negative force stems from the vested interest of governments to constrain drug pricing.

National Formulary Systems

National formularies appear in the form of positive and negative lists of marketed drugs. Positive lists specify drugs that can be marketed; negative lists specify only those which cannot be marketed. Some countries require a positive listing for any drug to be marketed. Others require positive listing only for those drugs which are

TABLE 8

NUMBER OF NEW CHEMICAL ENTITIES INTRODUCED, BY DRUG CATEGORY--1987 and 1988

	1987	1988
Cardiovasculars	12	20
Anti-Infectives	14	11
Psychotropics	7	5
Gastro-intestinal	5	3
Antihistamines	3	2
Anticancers	5	2
Other	15	10
TOTAL	61	53

Source: Scrip's New Chemical Entity Review, Scrip 1441, p. 20.

reimbursed by national health plans. In the United States some private payors use insurance coverage plan-specific formulary systems. Negative lists specify drugs for which there is no national health plan reimbursement. Sometimes this occurs in the form of categories of drugs such as contraceptives and diet aids.

R&D Pricing Incentives

Pricing incentives are built into some national health plan drug reimbursement schemes. Differential pricing is intended to encourage research and development activity of pharmaceutical firms. Incentives are based upon relative availability of similar drug therapies and/or marketing firm's investment in R&D. For instance, in Japan a drug entering the market will obtain higher reimbursement if it is not viewed as an alternative therapy to a drug already marketed in Japan.

Acceptance of Nondomestic Clinical Testing

All countries represented in Table 9 require pre-marketing clinical testing. Some accept clinical tests performed in other countries to satisfy product registration requirements. Non-acceptance of testing performed in other countries acts as a protectionist barrier against non-domestic pharmaceutical firms.

Patent Protection

With the exception of Italy, the countries of interest have consistently provided some form of patent protection for pharmaceutical firms. Firms have reportedly avoided entry into Italy to avoid the risk of losing control over their intellectual property. Without patent protection drugs can be reverse-engineered, manufactured, and marketed by competing firms. Sole marketing rights, however, are not guaranteed by patents alone.

Compulsory Out-Licensing

In some countries, such as Great Britain, firms holding legal patent rights in a country may be forced to out-license production and marketing rights to competitors. The rationale for compulsory out-licensing is to maximize availability of drugs to consumers. The practice also has

TABLE 9

SUMMARY OF COUNTRY REGULATIONS

Regulation	France	West Germany	Great Britain	Italy	Japan	USA
National Health Plan	yes	yes	yes	since 1979	yes	NO
National Formulary	NO	NO	yes	yes	yes	NO
R&D Pricing Incentives	yes	NO	NO	NO	yes	NO
Acceptance of Nondomestic Clinical Testing	since 1986	NO	yes	yes	NO	NO
Patent Protection	yes	yes	yes	since 1978	yes	yes
Compulsory Out-licensing	yes but seldom	NO	yes often	yes but seldom	yes but seldom	NO
Generic Substitution	since 1981	since 1989	yes by MD	NO	NO	since 1984

Compiled from various sources.

the effect of price competition early in the commercial life of a product.

Generic Substitution

Generic substitution is the practice of dispensing a non-branded drug in the place of a branded drug. In most countries generic substitution is possible only if specifically endorsed by the prescribing physician. The United States, Great Britain, and West Germany are exceptions. In the United States, generic substitution for certain drugs is required for reimbursement by the Federal Medicare system. Many state Medicaid policies have emulated this practice. Great Britain is tracking physician utilization of branded products versus unbranded products to encourage generic substitution. The program is likely doomed to failure because physicians have consistently resisted loss of autonomy in prescribing treatments and reporting diagnoses. The new policy instituted by Germany in late 1989 has a stronger substitution language. Pharmacists must dispense generics unless specifically requested by the physician to provide branded drugs.

Regulatory Issues and Strategy

Industry participants operate within this highly regulated environment and necessarily manage market access relative to regulatory issues. The following hypothesis relates regulatory status to strategy:

H-3 The number of products a business introduces into a country market is a function of regulations concerning compulsory out-licensing, generic substitution, national formularies, national health plans, acceptance of nondomestic clinical testing, and pricing incentives.

Note that patent protection is excluded from the hypothesis because there is no variation between study countries during the 1982-1987 time period.

In the United States

The character of the drug delivery system has evolved almost accidentally as a result of interactions among a number of legislative changes (Temin 1980). The first federal law was the Pure Food Act of 1906 which was amended by the Federal Food, Drug and Cosmetic Act in 1938. The 1906 legislation was the result of public concern over food safety. The major provisions of the legislation were safety oriented and specifically addressed the issue of product adulteration and misbranding (Gibson 1976). In fact, drug consumption at this time was largely of patent medicines. Any drug could be obtained directly from the pharmacist.

Physicians' prescriptions were largely used to provide a remedy recipe for the compounding of drugs. Major structural revisions and a new focus on drugs came with the 1938 Act which addressed concerns about the overall safety of chemical substances. This legislation accomplished four

objectives: (1) instituted a requirement for New Drug Applications (NDAs), (2) stipulated that drug instructions be provided for consumers, (3) required that drugs be labelled with appropriate warnings (with some exceptions), and (4) outlawed unsafe drug products. This bill did establish procedures for monitoring new drugs marketed; however, the FDA had no process for enforcement of new drug approval. Manufacturers were free to act unless the FDA interfered. The volume of prescribed drugs was still less than a quarter of the current total and the FDA's original intent was safer self-medication not its elimination.

The FDA evidently had a change of heart between passage of the Kefauver-Harris amendments and instituting regulations. Temin (1980) hypothesized that the dramatic surge in the physiologic power of pharmaceuticals was the reason. Both therapeutic effectiveness and seriousness of adverse side effects from new drug therapies increased dramatically. Knowledge of clinical usefulness of penicillin increased, spurred its use, and the search for additional powerful drugs increased. Wide-spread use of prescriptions was an effect of regulations put into effect in the two years following the 1938 Act rather than a result of the act itself. These regulations required prescriptions for dispensing a new class of drugs which, according to the FDA, could be dangerous in the hands of the consumer. These newer more potent drugs are repackaged before dispensing to the consumer and therefore exempt from labeling

requirements. Consequently the U.S. ethical or prescription drug distribution channel requires a learned intermediary to choose individual drug therapy. Since NDAs were not subject to a critical review process until the 1962 Drug Amendments, this new class of drugs was in effect defined by the drug companies under exceptions to the labelling regulation. The only controls for specific drugs remained those listed for FDA supervision under the Pure Food and Drug Act of 1906, and the Harrison Anti-Narcotics Act of 1914 which is enforced by the Justice Department. It is also notable that little or no evidence of either American Medical Association or drug manufacturer lobbying accompanied either the 1906 or 1938 Acts (Temin 1980). Based on this, Temin hypothesized that the emergence of prescription medicines was an artifact of regulation, a function of the exceptions to labelling clause of the 1938 legislation.

Penicillin was not patentable because it was a known substance prior to establishing its enormous clinical value and it was initially produced by many firms. Streptomycin, on the other hand, was purposefully extracted for clinical use. Merck succeeded in patenting the process of extracting Streptomycin. Though a landmark for the industry, Streptomycin did not change the way drugs were marketed. Merck licensed its production process to other manufacturers on an unrestricted basis.

Senator Kefauver introduced legislation designed to foster competition among drug companies and increase FDA

safety surveillance over drug manufacturing and new drugs. The proposed legislation would have made out-licensing of drug patents compulsory. However, the Kefauver-Harris bill, which was passed in late 1962, did not include this provision. This legislation did make three significant contributions to law. It (1) changed the standards for approving a new drug, (2) required FDA approval of NDA, and (3) gave the FDA jurisdiction over new drug testing. The change in new drug approval standards went from "efficacious" to "effective." The FDA then commissioned the Drug Efficacy Study from the National Research Council of the Academy of Sciences. The three-year study began in 1966 and its findings were based on the expert opinion of panels of clinicians. The process used to establish product efficacy was the forerunner of FDA product approval for NDAs and over-the-counter drugs.

Thus, the worldwide pharmaceutical industry became subject to lengthy testing procedures in its largest market. The 1962 Drug Amendments gave a decided short-term advantage to firms with existing, patented, approved drugs and to firms who had established testing facilities. The overall effect of the new legislation was to reduce the availability of new drugs by lengthening the approval process thereby reducing the effective life of patents due to time spent in clinical testing.

In April of 1979 the Carter Administration asked Congress to overhaul the nation's pharmaceutical regulations.

The overall aim was to speed marketing approval of new drugs and encourage the sale of relatively inexpensive drugs. In May the Pharmaceutical Manufacturing Association (PMA) was denied the right to block federal promotion of generics. Medicare Title XVII was ultimately passed and forced the industry toward a stronger focus on product innovation. New products were needed from a strategic standpoint to bolster shrinking profits. For Medicare recipients to receive reimbursement they must accept generic substitution for all but a specific few branded pharmaceuticals. Medicaid Title XIX adopted similar policies which applied to outpatient drug coverage. Patented drugs receive favorable pricing since no generic substitutes are available.

General business legislation also impacted the industry during the 1970s. The IRS tightened loopholes in foreign corporate tax shelters. This specifically hurt those firms with highly profitable subsidiaries in Puerto Rico.

Tort law made a mark on the industry during this decade. The Supreme Court remanded the Sindell vs. Abbott Laboratories et al. (1980) case back to California courts for trial. Due to the time lag between use of the drug and its deleterious side effects, it was impossible to trace the manufacturer of the actual product. When the manufacturer is unknown this ruling effectively allocated blame to all product manufacturers according to market share (Sheffet 1983). The case established a new doctrine of causation in

product liability, which is called market share liability. However, this has been accepted in a only few states.

Japan

Japan has been characterized as highly protective of its domestic pharmaceutical industry. The most striking restriction has been the Foreign Exchange Control Law. This law imposed strong controls over market access which stimulated the MOSS negotiations. Foreign companies were required to obtain the sponsorship of a Japanese firm in order to apply for government approval (shonin) and a license (kyoka). This requirement was eliminated in the mid-70s opening doors to foreign competition (Yoshikawa 1989).

A current constraint to pharmaceutical trade in Japan is its strong national formulary system. Drugs cannot be marketed unless they are listed under the formulary. Additionally, Japan's National Health Insurance (NHI) covers virtually the entire population when it sets prices. The NHI cut 1980 pricing 44% by 1986. Industry analysts have noted that new products receive more favorable reimbursement. Currently as the world's second largest pharmaceutical market, Japan's favorable treatment of new drugs adds urgency to the global search for new drugs and places special emphasis on early market entry because the opportunity for favorable pricing can be lost to competing products which enter the market first.

European Community

The twelve members of the European Community are striving to eliminate trade barriers that restrict the flow of products, services, capital, and people. These nations retain their independent sovereignty but have agreed to harmonize numerous trade laws to make them competitive in the global market. The pharmaceutical industry is watching the development of an EC with mixed feelings. Easier movement of capital and goods, and streamlined policies, will lessen the administrative burden associated with the product approval process. The EC White Paper Agreement calls for unity in product technical and safety standards. The savings to the pharmaceutical industry worldwide is expected to be considerable.

On the other hand, the industry fears the spread of policies which reduce allowable reimbursement costs for drug products. An example of one such policy has already been mentioned, the newly enforced West Germany generic substitution requirement. The EC must also focus on making social benefits similar among the member nations to prevent workers from crossing borders to obtain better benefits. Countries of the community have long participated in socialized medicine. Free movement of workers among the nations could greatly amplify costs to some firms and governments if benefits are not equal among the member nations.

The EC acknowledges that in the United States and Canada new drug testing and safety regulations are more

stringent than the community's (Burstall 1985). Even with standardized regulation within the EC, firms in member states must continue to meet U.S. standards to access the 29% of the world market controlled by those standards.

Competitive Environment

In the current regulatory environment, product introduction is possible only for the largest firms with pockets deep enough to finance not only research and development but also product introduction. The NDA process is such that considerable investment is required beyond the discovery period for clinical testing and, once approved, large scale promotion. Promotion is required to foster rapid product adoption, maximize product life-span, increase overall profitability, and sustain a first mover advantage in market share. R&D and promotion are very expensive in the pharmaceutical industry and, because of the large necessary investment, affordable by only the large firms. Competitive market entry and growth of smaller firms are thus preempted in the highly profitable therapeutic classes. However, thousands of smaller firms continue to address geographically smaller and less lucrative market niches.

Reimbursement regulations strongly influence the ability of successful firms to compete with an innovative strategy. These regulations may reduce the role of pricing when the market might support higher pricing. Assuming substantial investment is required for R&D and advertising, an

innovative strategy cannot be sustained by smaller firms. Again, the cycle is reinforced in favor of larger firms. As a result, few newcomers have risen to the top 20 global industry players in the last twenty years.

Patent Protection

The length of time required to clinically test a new drug is justification enough for the industry to be highly protective of its products. However, the R&D process is also expensive and lengthy, adding considerably to the time required to begin marketing a new drug. Additionally, product protection and differences in health and safety regulations among countries require a large amount of administrative effort and expense long before a compound's market potential can be tapped. Even with the most aggressively managed patent policies, companies are not able to effect complete protection. The problem is exacerbated in countries which either lack patent laws or refuse to enforce them. Examples include India and some Latin American countries. Differences have also been significant in the more developed nations. For instance, Italy offered no patent protection whatever between 1939 and 1978.

Historically, only Belgium and Panama offer protection as comprehensive as in the United States (Silverman and Lee 1974). The EC Patent Convention offers 20 years protection from date of filing. Many but not all European countries have adhered to the rule. The effective patent life, post-

product approval, ranges from eight to twelve years (Key Note Euroview 1988, p. 74) in Europe.

The Regulatory Life-Cycle

Faro (1990) used a life-cycle model to study regulation governing the introduction and diffusion of hip joint replacement prostheses. Medical products such as equipment, prosthetics, and pharmaceuticals have similar regulatory environments associated with product introduction, marketing, and post-marketing stages. The model is adapted here as a framework for discussion of the pharmaceutical industry (see Table 10).

During the product development stage regulation addresses protection of intellectual property and development of "orphaned drugs." Orphaned drugs are those which have a socially beneficial use but are abandoned due to excessive cost of further development or product launching. These regulations provide subsidization for the development of drugs which are not commercially viable. Because of their low commercial value these drugs are not of interest in this study.

The length of the market approval process is determined by the regulation of clinical trial testing for safety and efficacy and the product registration mandated by law. The approval process varies in length among countries as a function of clinical standards and whether foreign clinical trials are accepted. As already noted, the United States

TABLE 10

REGULATORY LIFE-CYCLE OF PHARMACEUTICAL PRODUCTS

Life-Cycle Stage	Type of Regulation
Development	Intellectual Property Orphan Drug Laws
Market Approval	Clinical Trials for Safety and Efficacy Product Registration
Manufacture	Good Manufacturing Practices Good Laboratory Practices Packaging and Labelling
Purchase	Prescribing and Dispensing Promotion
Reimbursement	Government Health Plans Generic Substitution Formulary Price Listing
Post-Marketing Surveillance	Adverse Drug Reactions Drug Recall Procedures

Adapted from Faro (1990).

has the most stringent standards for product acceptance.

Manufacturing regulations are generally uniform among the developed countries. Much variation exists among developing and third world countries; however, the developed country-markets and regulations are not of interest to this study.

Regulations which govern access to ethical pharmaceuticals also tend to be practiced uniformly in these markets. Some differences in how particular drugs are classified occur with some drugs such as older antibiotics available over-the-counter (rather than by prescription) in some Western European countries. However, most of these drugs are accessed under the recommendation of a physician,

if not by prescription. These differences are at the product level rather than the firm or country level and are therefore not of interest in this study.

Restrictions governing promotional practices also influence purchasing behavior. Again, the largest markets tend to be similar in their promotional regulation and practices. Currently promotional efforts are directed almost exclusively at the physician. Some changes are in process, however. In the United States, some ethical drug advertising now targets the end consumer.

To protect the consumer, post-marketing surveillance is centered around monitoring adverse drug reactions and drug recall procedures. These generally do not affect marketers except through the promotion variable. However, the United Kingdom is attempting to institute a computerized drug utilization system to monitor appropriate utilization of drugs. Physicians will be required to report each prescription and the condition for which it is prescribed.

It is important to note that the discretionary power exercised by the physician can circumvent attempts to regulate the use of pharmaceutical products. Off-label prescribing is the practice of prescribing drugs for uses which have no official clinical testing documentation. Physicians very frequently prescribe off-label and communicate efficacy and adverse side effects through medical journals. It is common practice for physicians to enter secondary or inaccurate diagnoses to obtain reimbursement for procedures. The

practice can easily be extended to drug therapies to protect the physician's latitude in drug utilization. The intent of the U.K. system is to justify prescription utilization and reduce off-label prescribing. While the number of prescriptions can be monitored if tied to reimbursement procedures, it is unlikely that off-label prescribing can be avoided as long as physicians can exercise latitude in assigning diagnoses.

Analysis of Industry Strategic Elements

Marketing strategy can be defined as a set of principles used to adjust the firm's marketing mix to environmental changes. The strategy employed by current industry leaders can be described as emergent which Hofer and Schendel (1978) describe as reactive rather than proactive. Industry channel structure has been hypothesized to be an unintended result of legislative interactions (Temin 1979). Industry leaders were not active in lobbying for industry interests until the 1962 Drug Amendments (Temin 1979). Marketing elements which are controllable by the firm, the classic four Ps, (place, price, promotion and product) are highly constrained in the pharmaceutical industry.

Place

Place can be evaluated in terms of where the consumer obtains pharmaceuticals, and the territory of the firm. The distribution systems for the pharmaceutical industry are well developed. The vast majority of ethical products are

distributed to retailers or physicians via wholesalers in each of the three major markets. Legislative or regulatory changes would be required in the largest world markets to change the point of sale for drugs.

Industry rules of thumb dictate simultaneous product introduction in the three largest country markets: Japan, the United States, and West Germany (Hornick 1990). Firms deem it especially favorable to gain rapid access to the Japanese market to ensure favorable pricing prior to introduction of a competing product. Market selection and entry strategy are appropriate to the industry and this study.

Price

Price has been largely mitigated by national health plans in Japan and Western Europe and health maintenance organizations and maximum allowable costs in the United States. Price competition is not viable because it is highly controlled by outside agencies. The one possible exception is a new drug which has no substitute.

Pharmaceutical pricing is frequently controlled by country-specific legislation. In this study pricing is viewed as a structural element of country markets and examined in its relationship to market selection and market entry decisions.

Promotion

Promotion is the most highly controllable variable available to the pharmaceutical manufacturer. Promotion

takes many forms including selling, advertising, direct mail, and detail men (sales personnel). A 1970 study by the FDA revealed that physicians rely heavily upon detail men, advertising in medical journals, and direct mail to provide them with up-to-date drug information.

Detail men are considered essential to the success of a product. A typical U.K. pharmaceutical company will call on about 17,000 of the 24,500 general practitioners at least once a year. Of these about 6,000 high frequency prescribers are visited three to four times annually (Slatter 1977). The Pharmaceutical Manufacturers Association (PMA) estimates 25,000 U.S. detail representatives were employed at a cost of over $25,000 per employee (Silverman and Lee 1974). Current salary costs can be conservatively estimated at $40,000 per employee. Cooperative agreements between firms with noncompeting products have been made to access domestic detail sales force. For example, Glaxo rented F. Hoffman-LaRoche & Co.'s team of 800.

Study of the effectiveness of promotion is difficult because current figures on the promotional aspects of pharmaceutical marketing are very difficult to obtain. Given the high level of sensitivity toward profits obtained in the industry, these costs are generally obscured at the product and line-of-business level in most public documents. Industry promotional practices also tend to be obscured when analyzed at the firm level. The study of promotion is more meaningful at the product level since these strategies are

product-specific. For instance, in the year a product is launched promotional costs may easily exceed sales. Blitzing efforts later in the product life-cycle may be in response to the entry of competing products such as with non-steroidal anti-inflammatory agents and beta blockers. On the other hand, some products such as the anti-ulcer drug Prozac have few competitors, enjoy a large degree of press attention, and require little promotional spending.

Product

Product has been the area of highest differentiation between firms. Marketing a single successful product has been considered a worldwide prerequisite to the success of a pharmaceutical firm (Slatter 1977). The gestation period for developing a new drug is upwards of ten years. In-house costs prior to the 1962 Drug Amendments were estimated at $500,000 per NDA, costs immediately post-1962 were estimated to be over $7.5 million per NDA (Scherer 1975). Current costs for development of a single commercializable product are calculated to be $231 million (DiMasi et al 1990, p. 3). Joint ventures have also been in evidence at least as early the 1970s. Unfriendly takeovers, however, have not been considered a risk until recently as illustrated in this quote from The Wall Street Journal:

> ... Hoffmann-LaRoche & Co.'s $4.2 billion tender offer for Sterling Drug Inc. marks the end of an era in which an unspoken gentleman's agreement' among major drug firms has all but prevented hostile takeover in the industry. (January 4, 1988, p. 4)

The number of licensing agreements, mergers, and joint ventures in the news jumped from six in 1979 to twenty in 1988 (Wall Street Journal Indices 1979 and 1988).

Product extensions are also highly useful in differentiating pharmaceutical products. As many as 200 dosages, forms, and packagings may be used for a single product in the international market.

Threats to competitive product advantage include superseding technology in the form of newer, better drugs; cures for conditions and diseases; change in public attitudes (e.g., towards usage of tranquilizers); changes in medical practice; and expiration of patent rights. The market life of a patent is considerably shortened by the testing and approval processes, however for many drugs their effective patent life is determined by these other threats. Therefore, the competitive advantage of a highly differentiated product must be maximized quickly. Promotion and market access provide this key. Management of the product variable relates largely to the R&D process.

Conclusion

The current state of the pharmaceutical industry requires a high degree of focus on product acquisition and market access strategies. The rapid pace and high cost of R&D are industry drivers towards globalization (Yip 1991). The legislative environment brings multiple forces to bear upon the industry. These forces simultaneously increase the

cost of commercializing drug products while decreasing product pricing. Clearly the challenge of the future is to effectively manage resources to maintain firm performance in both the short and long runs.

The methodology for testing the hypothesis formulated in this chapter is presented in Chapter IV. A discussion of the results follows in Chapter V. Then implications for further research are presented in the final chapter.

CHAPTER IV

RESEARCH DESIGN AND METHODOLOGY

Introduction and Design Objectives

The empirical phase of the study draws upon relevant literature and industry experience to address the research objectives stated in Chapter I. These objectives have been developed and restated as testable hypotheses in Chapters II and III. This chapter addresses study design and methodology used to empirically test these hypotheses. First a theoretical framework is presented and explained to illustrate hypothesized relationships. For reference purposes hypotheses are restated in families according to study objectives. Variables are then related to the hypotheses with statistical tests. This is followed by data collection methodology and a profile of the study sample. Next, variables are operationalized using secondary data. Finally, the statistical techniques for testing study hypotheses are discussed.

This study is designed to explore the relationships between (1) past and current product acquisition and market access strategies, (2) product acquisition, market access, licensing strategies and line-of-business performance, and

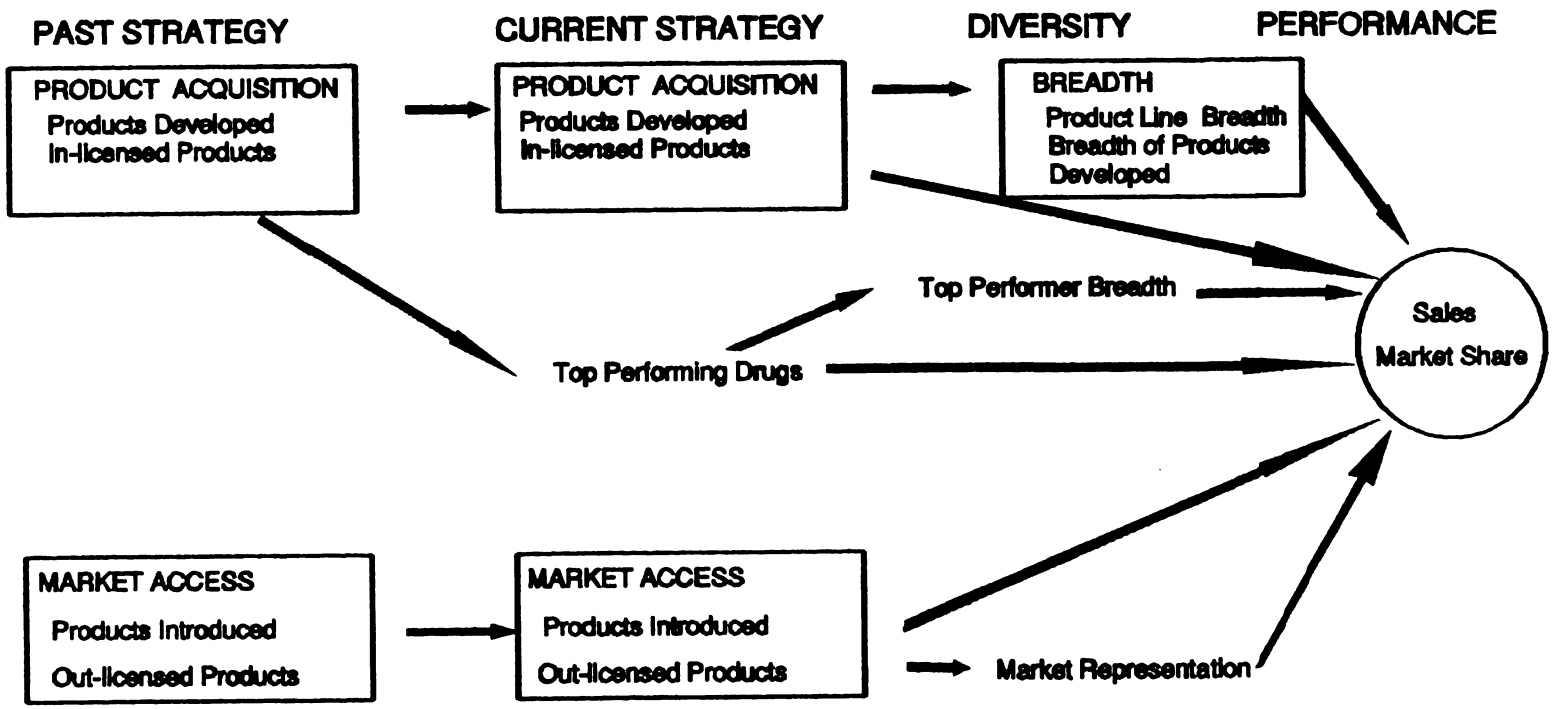
(3) specific regulations and product introduction into country markets. The study also considers the element of time and is designed for a global context.

Theoretical Framework

The theoretical framework for this study is drawn from the previous discussion of relevant literature and the industry overview. The study specifically addresses global product acquisition and market access in the form of licensing versus use of internal resources.

Figure 5 illustrates the relationships predicted in the first two families of hypotheses which relate past to current strategies, and strategy to performance. The last hypothesis relates specific government regulations to pharmaceutical product introduction into country markets. This third set of relationships is illustrated in Figure 5. Since these regulations are fully discussed in Chapter II, only a brief review is provided in the hypothesis section of this chapter. This section will present a full discussion of the framework for the first two families of hypotheses.

The number of products previously developed, in-licensed, introduced, and out-licensed are shown as contributing to a business's current product line and access to markets. These measures of past strategy are hypothesized to be related to current internal product development and market introduction strategies. Product acquisition variables are measured within a therapeutic



KEY: CONCEPTS Variables

FIGURE 5 GLOBAL STRATEGY FRAMEWORK FOR PHARMACEUTICALS

class and market access variables are measured within a country market. Theoretically, the greater the number of past product developments and in-licensed products, the greater the efforts towards current product developments and introductions within a therapeutic class. Likewise, the greater the number of past in-house product introduction and out-licensed products, the greater the efforts toward current product introductions within a country market. Following this reasoning a step further, the greater the number of total products developed, the greater the number of top-performing drug products.

Under current strategy, the framework combines product acquisition and market access variables across therapeutic classes and country markets respectively, to relate them to performance at the level of the pharmaceutical business. This variation is preserved across therapeutic classes and country markets in the framework under diversity because the variation of global products and markets is hypothesized to affect business performance. Product line diversity is functionally defined according to therapeutic class and represented by the number of classes which the business markets. Likewise, diversity of internal product development is defined as the number of classes in which the business has developed products. The notion of breadth of top-performing drugs is similarly captured. Variation in market access is a more complex measure because the size of the potential markets is also predicted to impact

performance. Therefore firm market representation is more useful as a percentage of world volume rather than the number of country markets accessed. Product line breadth, development breadth, and market representation are considered as they relate to performance. Licensing strategies are also hypothesized to have some relationship to general performance. Finally, industry criteria, top-performing drugs and the number of classes of top drugs, are related to sales performance and market share. All current strategy and diversity variables are related to performance at the business level.

The next section provides a discussion of the nature of these relationships and sets forth three families of hypotheses which are designed to test them.

Hypotheses

Hypotheses developed in Chapters II and III are restated in this section and grouped as they relate to research objectives. A full key to the variables used in this study is provided in Appendix B. An explanation of how the variables are operationalized is provided in a sub-sequent section of this chapter. The reader is also provided a summary of strategy and performance variables in Table 11 and a summary of hypotheses tested in Table 12.

TABLE 11

SUMMARY OF STRATEGY AND PERFORMANCE VARIABLES

VARIABLES	DESCRIPTION
Internal Strategies	
Products developed	The number of new products a firm develops
Products introduced	The number of new products a firm introduces
External Strategies	
In-licensed products	The number of products a firm licenses from another firm
Out-licensed products	The number of products a firm licenses to another firm
Strategy Diversity	
Breadth	The number of therapeutic classes in which a firm markets products
Market representation	The percentage of the world market in which a firm has an in-country marketing presence
Development breadth	The number of therapeutic classes in which a firm develops products
Industry Performance Criteria	
Top-performing drugs	The number of drugs a firm markets which rank in the top thirty sales performing drugs
Top-performer breadth	The number of therapeutic classes in which a firm markets top-performing drugs
General Performance Criteria	
Sales	The sales volume of a pharmaceutical line-of-business in U.S. dollars
Market share	A surrogate measure[1]--the percentage of total sales of a constant pool of pharmaceutical firms

[1]Note: A surrogate market share measure is used because global pharmaceutical volume is calculated only with proprietary data which has not been made available for this study.

TABLE 12

TESTS OF HYPOTHESES

H_o	Independent Variable(s)	Dependent Variable	Test
	Past and Current Strategy		
1a	$A_1x_1 + A_2x_2^2$	P_1	MR
1b	$A_1x_1 + A_2x_2^2$	P_2	MR
1c	$A_1x_3^2$	P_1	cor across product class
1d	A_1x_4	P_3	cor within countries
	Global Strategy and Performance		
2a	$B_1y_1^2 + B_2y_2^2 + B_3y_3^2 + B_4y_4^2 + B_5y_5^2 + B_6y_{62} + B_7y_7 + B_8y_8 + B_9y_9$	S_1	MR across years and countries
2b	$B_1y_1^2 + B_2y_2^2 + B_3y_3^2 + B_4y_4^2 + B_5y_5^2 + B_6y_6^2 + B_7y_7 + B_8y_8 + B_9y_9$	S_2	MR across years and countries
	Regulatory Structure and Market Selection		
3	$C_1z_1 + C_2z_2 + C_3z_3 + C_4z_4 + C_5z_5 + C_6z_6$	I	MR across countries

TABLE 12 (cont'd)

Key to Variables

Past

x_1 = products developed in-house within a class
x_2 = products in-licensed within a class
x_3 = breadth of products developed
x_4 = total products marketed to a country

y_1 = products developed in-house
y_2 = products introduced
y_3 = in-licensed products
y_4 = out-licensed products
y_5 = breadth of in-house product development
y_6 = product line breadth
y_7 = top-performing drugs
y_8 = top-performer breadth
y_9 = market representation

z_1 = compulsory out-licensing
z_2 = generic substitution
z_3 = national formulary
z_4 = national health plan
z_5 = acceptance of non-domestic clinical testing
z_6 = R&D pricing incentives

Current

Within a Class

P_1 = products developed

P_2 = top-performing drugs

Within a Country

P_3 = products introduced

By Firm

S_1 = Sales
S_2 = Market Share

By Country

I = Products introduced within a country

Past Position and Strategy

The first study objective and family of hypotheses predicts a positive relationship between historic product and market position and subsequent product innovations and introductions. The past variables are measured by year using the number of products which a firm developed within a product class or introduced within a country market during the previous nine years. Current year variables are similarly measured for the observed year only.

H-1a Product developments in a therapeutic class is a function of the number of products a business previously developed and the number of products previously in-licensed.

H-1b The number of top sales producing drugs the business markets in a therapeutic class is a function of the number of products a business previously developed and in-licensed.

The expected relationship of products developed to current product development and top sales is expected to be positive. The relationship of in-licensed products to subsequent product development is expected to be an inverted U-shaped curve. This is because in-licensing is a form of commitment to a product class but does not build internal resources. Firms which do in-license are building channel resources to effectively market the drugs. Because this variable is calculated upon a fixed nine-year period the downturn of the inverted U may not be present in the data

even if it does exist when not constrained to nine years. Therefore, both linear and curvilinear relationships are tested.

H-1c The number of current products developed by a business is a function of the number of therapeutic classes in which a business previously developed products.

Based upon Foxall's notion of constrained search for new products, the relationship between breadth of product development and current products developed is expected to be negative.

H-1d The number of current product introductions into that country is a function of the number of products previously introduced to a country market.

The relationships expressed in this hypothesis are based upon Yip's notion of committed involvement (1989), Thorelli's networking concept (1990), and Cavusgil's (1980) progressive internationalization of firms. Previous product introduction and out-licensed products are expected to be positively related to subsequent product introductions in a country.

Strategy and Performance Goals

The second family of hypotheses is designed to test the relationships between product acquisition and market access strategies and performance. These strategies include

licensing, the variety, and diversity of products and country markets, and top sales performing products.

Since a firm can acquire products by internally developing or licensing them to market, the number obtained in each manner is used. Likewise, a firm can market its own products or license them to other firms to gain access to markets.

The variety of products, product line breadth, is measured by the number of therapeutic classes in which a firm markets products. The variety of products developed is the number of therapeutic classes in which a firm develops products. To capture market representation, the percent of world market represented by each country in which a firm does business is summed. All of these strategy variables capture nine years of historic data plus observed year data.

The number of top sales performing drugs and breadth of product development, i.e., the number of therapeutic classes, are measured across the case year. This is to avoid multiple counts of the same drug product and to provide an accurate representation of the current competitive environment.

H-2a Pharmaceutical business sales revenue is a function of the number of products developed, the numb er of product introductions into country markets, the number of in-licensed products, the number of out-licensed products, breadth of product

development, product line breadth, the number and breadth of top drugs, and market representation.

H-2b Pharmaceutical business market share is a function of the number of products developed, the number of product introductions into country markets, the number of in-licensed products, the number of out-licensed products, breadth of product development, product line breadth, the number and breadth of top drugs, and market representation.

The relationship of the number of products developed and the number of products introduced to sales and market share is expected to form an inverted U-shaped curve. This is because experience with products and markets should lead to better performance up to a point. Beyond that hypothetical point, efforts may be spread too thinly to be effective. This is consistent with Foxall's (1983) notion of constrained search for new products and markets. For the same reasons breadth of product development is expected to have an inverted U-shaped relationship to performance measures. However, the nature of strategy studies tends toward a bias of successful firms, consequently the downswing in the inverted U may not be visible in the data. Therefore, these three variables are tested for both a linear and a curvilinear relationship to sales and market share.

However, market representation, as the percent of world market in which a firm does business, should have a linear and positive relationship to performance measures. This

assumes that the industry must operate in a global environment to survive. This is consistent with industry expert opinion as expressed in Chapter II. It is also consistent with the review of the industry and its globalization drivers which was presented in Chapter III.

The relationship of in-licensed and out-licensed products to sales and market share is also expected to be an inverted U-shaped curve. This relationship is a proposed synthesis of two opposing viewpoints. The upswing in the curve is based upon Ohmae's (1989) hypothesis which expresses a positive relationship between use of strategic alliances and performance. The downswing in the curve is based upon Levitt's (1990) hypothesis that long-term performance will suffer with use of strategic alliances. Both of these variables may not demonstrate the downswing in the inverted U because they are constrained to a nine year period. Therefore these two variables are tested for both a linear and curvilinear relationship to market share and sales.

The relationship between top-performing drugs and breadth of top performers is expected to be linearly positive. There are two reasons for expecting this relationship. First, top-performing drugs and top-performer breadth are in themselves a subset of current performance and would be expected to remain positively related to sales and market share at any level. Second, industry experts predict this relationship.

Regulation and Market Decisions

The relationship between government regulation and pharmaceutical line-of-business strategy is examined with this hypothesis. Choice of markets and timing of entry into country markets is thought to be affected by the regulatory environment. The specific regulations analyzed are (1) compulsory out-licensing which requires firms to license products to competitors to gain market access, (2) generic substitution which permits nonbranded drugs to be replaced by branded drugs, (3) national formularies which require every drug be approved and listed by the regulatory agency to be marketed, (4) national health plans which often restrict reimbursement for pharmaceuticals, acceptance of nondomestic clinical testing which can reduce drug approval time, and (5) pricing incentives which reward innovating firms with higher drug reimbursement. Patent protection is excluded from the hypothesis because there is no variation in the study sample. The following hypothesis addresses the relationship between country regulatory structure and a business introducing a pharmaceutical product into a country:

H-3 The number of pharmaceutical products a business introduces into a country market is a function of regulations concerning compulsory out-licensing, generic substitution, national formularies,

national health plans, acceptance of nondomestic clinical testing, and pricing incentives.

The relationship between each regulation and product introduction into a country market can be predicted based upon constraints to competition and barriers to entry. Compulsory out-licensing, generic substitution, national health plans and national formularies are anti-competitive forces. These are expected to be somewhat negatively related to timing of market entry. Acceptance of non-domestic clinical testing and R&D pricing incentives are pro-competitive forces which should positively affect product introductions.

Data Collection

This section describes the data collection technique and profiles the study sample. Secondary data sources are presented for all data elements. Then selection and relevant characteristics of the study sample are discussed.

The basic unit of analysis is the pharmaceutical line-of-business accompanied by measures of product acquisition and market access strategies and performance. Data has been gathered for the time period 1982-1987 because it was a period of dramatic industry change. This change was characterized by impending patent expiration of many top-performing drugs, an increase in licensing activity, and the beginning of industry consolidation. To calculate some

variables information from nine additional years (1973-1981) is required.

Multiple sources were used to obtain the data required to test hypotheses. However, for all variables, the same source was used to measure all observations. Product acquisition and market access data are measured from two proprietary data bases. The Drug Product Indices are maintained by Paul De Haen International, Inc. (De Haen 1989 a and b). This data is a collection of worldwide product information and is updated annually. Data is maintained on marketed drugs in eight countries. On-line data searches and professional medical and pharmaceutical journals are routinely accessed by Paul de Haen International, Inc. for current information. The data bases are widely accepted by the pharmaceutical industry (Schifrin 1983).

The Paul de Haen International data spans the years 1970-1988 and the U.S. data spans 1950-1988. Each data base consists of nine elements: non-proprietary drug name, trade name, therapeutic class, manufacturer, country manufacturer, originating firm, originating country, date of beginning marketing in-country, and country market. The international database focuses upon the Western European and Japan markets with over 3,000 entries and the United States database with over 5,000 entries.

Each observation in the data base represents the initial marketing of a product in a country. One entry is made for each drug, or single chemical entity (SCE), in each

country. Only one entry is made at the time marketing begins regardless of the number of product forms, dosages, or trade names eventually marketed. Information is recorded by SCE, which is the unique name associated with all product forms, dosages, and trade names.

The International and United States Paul de Haen data bases have been merged for the purposes of this study. The product and market sample from which variables were calculated includes all single chemical entities represented which are marketed in the six major markets and belong to one of the nine major therapeutic classes presented in Table 13. These therapeutic classes were selected to correspond to the major causes of mortality in the study countries (see Table 3). These causes were very similar among countries and provide a degree of sample homogeneity with regard to country markets.

A longitudinal data base has been constructed by pharmaceutical line-of-business and year. Variables which measure product development and introductions are calculated from these merged de Haen data bases using a series of crosstabs. 3,395 single chemical entities were used to calculate these variables for each pharmaceutical line-of-business.

Selection of pharmaceutical lines-of-business was based upon sales performance data which was obtained from Scrip League Tables (1983-1988). By virtue of inclusion in the Scrip League Tables, these firms rank in the top 100-150

TABLE 13

SAMPLE SINGLE CHEMICAL ENTITIES BY THERAPEUTIC CLASS

Therapeutic Class	Number of Single Chemical Entities
Antihistamines and Antiallergy	71
Anti-infectives	949
Antineoplastics	192
Cardiovascular Agents	471
Central Nervous System	674
Eye, Ear, Nose, and Throat	70
Gastrointestinal	184
Hormones and substitutes	411
Skin and mucous membrane	373
Total Sample	3,395

sales producers. However, the number of businesses which compete globally is small. Therefore, with reasonable assurance, small firm bias is avoided within the set of global competitors. Table 14 provides a breakdown of sample businesses by country.

Country markets were selected to represent the majority of worldwide pharmaceutical sales volume. France, Germany, Great Britain, Italy, Japan, and the United States represent approximately 66% of the global pharmaceutical market (Scrip Yearbook 1990, p. 21). These countries also represent a homogeneous market group in terms of economic development and therapeutic needs. Other country markets represent two percent or less of the world market and are therefore less likely to affect the global strategies examined here. Country information concerning regulatory status has been gleaned from a combination of secondary sources including interviews with industry executives, legal journals, on-line databases, and reference books. Table 9 provides a summary of regulations by country.

The original sample includes 101 top-performing global pharmaceutical firms during the six year period 1982-1987. Of the potential 606 observations by firm (101 firms times six years) 504 observations were constructed using data at the line-of-business level. The range of sales performance of sample business is $750 million to $ 16,340 million in 1982, and $1,520 million to $26,800 million in 1987.

TABLE 14

PHARMACEUTICAL LINE-OF-BUSINESS SAMPLE BY DOMESTIC COUNTRY

Country	Number of Pharmaceutical Lines-of-Business
Japan	37
United States	26
West Germany	9
United Kingdom	8
France	6
Italy	5
Switzerland	4
Sweden	2
Belgium	1
Denmark	1
Finland	1
Netherlands	1
Total Sample Size	101

Operationalization of the Variables

The longitudinal nature of this study is captured in two ways. First, the data base covers a six-year time period and is constructed by year. Second, although observations are pooled across years, use of moving counts in calculating past variables (nine years) incorporates information and current year variables into a pooled cross-sectional analysis. These variables capture the number of products a firm markets by therapeutic classes and by country during their peak commercial period as defined by average effective patent life.

Variables measured include products developed, breadth of product development, products introduced, in-licensed products, out-licensed products, product line breadth, market representation, top-performing drugs, and top-performer breadth calculated for the time period 1982-1987 from the proprietary data base. Information regarding the number of top sales-producing drugs by therapeutic class and sales is also compiled from Scrip League Tables (1983-1988). Since actual world volume is proprietary information, when available, a surrogate measure of market share must be used. These are be calculated for each company by year using a sum of actual annual sales from all businesses which consistently appear in the six study years.

Longitudinal studies are subject to changes in measurement over time. An obvious but controllable measurement change in this study is the value of financial statistics.

These values are corrected for inflation using Gross National Product deflators (U.S. Bureau of the Census 1983 and 1990) prior to analysis.

All strategy and performance measures relate directly to the pharmaceutical line-of-business. Variable measures were derived by an appropriate count of single chemical entities (SCEs) from the Paul de Haen data base. The Paul de Haen variables are defined in the following section followed by operationalization of the strategy, performance, and regulatory variables.

Paul de Haen Variables Used

Single Chemical Entity (SCE)

The non-proprietary drug name uniquely associated with a chemical compound regardless of product form, dosage, or brand name.

Therapeutic Class (THERAPY)

The therapeutic class of the single chemical entity as recorded by the American Hospital Formulary System. This study uses the two digit codes associated with the therapeutic classes in Table 2.

Marketing Firm (MARKETER)

The manufacturer and marketer of a single chemical entity for a country market.

Country Market (COUNTRY)

The country in which this single chemical entity is marketed under the brand name specified.

Year Introduced in Country (YEAR)

The year in which this single chemical entity was introduced in this country market.

Originating Manufacturer (INNOVATR)

The firm which developed this single chemical entity in-house.

Pharmaceutical Line-of-Business Data

Pharmaceutical Line-of-Business (PLB)

Designates the line(s)-of-business of a firm which are engaged in ethical drug manufacturing. The same codes are used for INNOVATR and MARKETER in the merged Paul de Haen data base.

Year (YEAR)

The year for which case data is recorded.

Products Developed within a Therapeutic Class (PRDEV)

Innovative efforts are measured by a count of SCEs, within a therapeutic class, which are self-innovated and marketed by a business. The historic variable is a moving count of SCEs introduced during the nine previous years. The nine year time period corresponds to the average effective patent life of pharmaceutical products during the study time frame. The therapeutic classes examined in the study are summarized in Table 2. Count {SCEs within THERAPY for nine previous years (past)} and {SCEs within THERAPY for YEAR (current)} where INNOVATOR = PLB and PLB = MARKETER}.

Total Products Developed across Therapeutic Classes (TPRDEV)

This variable is the sum of current and past PRODDEV across therapeutic classes for each business and represents ten years of information.

Breadth of Product Development (DEVCLASS)

This variable is the number of classes in which a business has developed product during the current year or previous nine years.

In-licensed Products Within a Therapeutic Class (INLIC)

In-licensing arrangements are measured by a count of new SCEs introduced. The past variable is a moving count of SCEs introduced during the nine previous years. The nine year time period corresponds to the average effective patent life of pharmaceutical products. The current variable is a count of SCEs introduced in the case year. Count {SCEs for nine previous years within THERAPY (past)} and {SCEs for YEAR within THERAPY (current)} where MARKETER = PLB AND MARKETER not = INNOVATR}. In this study, INLIC is used only as an intermediate variable to calculate PRODNO.

Total Number of In-licensed Products (TINLIC)

The total number of drugs a firm has acquired by in-licensing is the sum of current and past INLIC.

Total Number of Drugs Marketed within a Therapeutic Class (PRODNO)

The number of drugs a business markets within a therapeutic class is the sum of TPRDEV and TINLIC.

Product Line Breadth (BREADTH)

Breadth of product line is the sum of the number of therapeutic classes marketed in the current year or previous nine years.

Product Introductions within a Country Market (PRINTRO)

This variable is a count of the number of SCEs a business introduces in a country. The past variable is a moving count of the SCEs introduced in the previous nine years. The current variable is a count of self-innovated and marketed product introductions within a country. This is a measure of a business's commitment to a country market. To calculate: Count {SCEs where YRINTRO = YEAR - 1 to YEAR - 9 (past)} and {SCEs where YRINTRO = YEAR within a country (current)} and MARKETER = case PLB.

Total Product Introductions across Country Markets (TPRINTRO)

This variable is the sum of current and past (nine previous years) product introductions across country markets for each business.

Out-licensing (OUTLIC)

Products innovated but not marketed by a business are out-licensed to access markets. The past variable is a moving count of SCEs innovated by a business and licensed to another business for marketing in a specific country during the previous nine years. The current variable is a similar count for the case year. To calculate: Count {SCE where YEAR = YRINTRO and PLB = INNOVATR and INNOVATR not =

MARKETR. In this study, OUTLIC is used only as intermediate variable to calculate MKTNO.

Total Out-licensing (TOUTLIC)

This variable is the sum of current and past (nine previous years) products out-licensed across country markets.

Number of Drugs Marketed within a Country (MKTNO)

The number of drugs marketed within a country is the sum of TOTINTRO and TOTOUTLIC for that country.

Marketing Representation across Country Markets (MKTREP)

Marketing representation is measured as the percent of world market accessed by a business. This variable is calculated by multiplying the percent weight for each country market in which the firm markets a therapeutic class times the number of products marketed in that class, and summing across countries. This product is then divided by the total number of drugs marketed in that country. The highest value for this study variable is 66, which means that the business markets in sixty-six percent of the world ethical pharmaceutical market. Values used to weight country markets are provided in Table 1. To calculate: Σ (MKTNO $\div$ TPRDEV) x country market weight.

Product Marketing Success (TOPDRUG)

Market-winning innovations for the current year are represented in this variable. Single chemical entities which ranked in the top thirty global sales performers during the year are counted.

Breadth of Market-Successful Products (TOPTHER)

This variable captures top product performer breadth. The information is recorded as the number of therapeutic classes in which the pharmaceutical line-of-business has a top-performing drug during the year. This variable provides a measure of the pharmaceutical line-of-business against industry criterion one which is discussed on page 49.

Pharmaceutical Line-of-Business Sales (SALES)

Revenue of each pharmaceutical line-of-business is recorded in current year dollars and deflated using Gross National Product deflators (U.S. Bureau of the Census 1983 and 1990) prior to analysis across time periods.

Pharmaceutical Line-of-Business Market Share (SHARE)

The size of the world pharmaceutical market is not easily determined nor readily available. Therefore a surrogate market share measure is computed relative to the sales volume of the entities which consistently appear in every study year. Summed sales of these businesses is used as the denominator for the entire study period. To compute: SALES ÷ {Σ SALES of the firms which are represented in each study year}

The Regulatory Environment

Hypothesis three examines a business's product introduction decisions relative to country regulatory structure. Information was obtained from industry literature and regulatory agencies to dummy variable regulatory issues over

the study time frame. These variables are coded as 1 if there is a formalized regulation and 0 if there is no formalized regulation.

Country (COUNTRY)

The study is conducted across six countries. This categorical variable represents one of the following: France, Great Britain, Italy, Japan, the United States, or West Germany.

Compulsory Out-Licensing (COMPLIC)

COMPLIC records the presence or absence (1,0) of mandatory out-licensing within a country during the year.

Regulation Encouraging Generic Substitution (GENERIC)

GENERIC records the presence or absence (1,0) of a regulation which encourages generic substitution within a country during the year.

Country National Formulary System (FORM)

FORM records the presence or absence (1,0) of a national formulary system within a country during the year.

National Health Plan (PLAN)

PLAN records the presence or absence (1,0) of a nationally funded health care plan within a country during the year.

Country Acceptance of Non-domestic Clinical Trials (CLINIC)

CLINIC records the presence or absence (1,0) of a country's acceptance of other non-domestic clinical trials during the year.

R&D Pricing Incentives (INCENT)

INCENT records the presence or absence (1,0) of pricing policies which provide an incentive for R&D investment.

In summary, these variables are calculated from reliable secondary sources to test research hypotheses stated earlier. All strategy and performance measures represent actual recorded behaviors and/or performance. The regulatory measures are dummy variables which correspond to the formal regulatory environment of each country by year during the study period.

Method of Analysis

Because this study is limited to specific relationships, a full path analytic technique is not employed. Rather, a combination of univariate, multivariate, and modified time series techniques are used. For each hypothesis, observations are pooled across years for empirical testing. However, though the statistical tests themselves use pooled data, multiple regression, and in some instances simple correlations, the time series nature of the study is captured in operationalization of the variables. Variables are calculated in a modified time series fashion to calculate moving sums incorporating nine prior years of information.

In the first family of hypotheses, both univariate and multivariate analysis is indicated to examine the relationship between past and current strategies. Each observation

by firm and year provides observations in nine therapeutic classes and six country markets. Therefore hypotheses 1a, 1b and 1c are tested using 4,536 observations and hypothesis 1d is tested using 3,024 observations. A bare bones meta-analysis is used to test and correct for sampling error prior to pooling (Hunter and Schmidt 1990, p.100). Hypotheses 1a and 1b are then analyzed using multiple regression analysis. A quadratic polynomial is used for in-licensed products because the relationship is hypothesized to have a curvilinear monotonic relationship to further product development and top drugs.

Hypothesis family 2 is multivariate and uses quadratic polynomials for products developed, breadth of product development, products introduced, in-licensed products, out-licensed products, and product line breadth because they are all hypothesized to have a curvilinear monotonic to both performance measures. Hypothesis 3 is analyzed using multiple regression analysis.

All multiple regression analyses are first tested using backwards step-wise multiple regression analysis. To ensure homogeneity of error distribution among independent variables, a second simultaneous regression equation is then run with only those variables found to be significant in the step-wise regression (Cohen and Cohen 1983). Standardized regression coefficients are reported and used for comparison purposes among the predictor variables.

In summary, this chapter has presented a theoretical framework for testing study hypotheses which relate global product acquisition and market access strategies to performance. The objective of the study design and methodology is to measure and test these relationships over time.

Chapter V presents an analysis and discussion of results by hypotheses. Then, study implications for global strategy literature, marketing managers, the pharmaceutical industry, and policy-makers are explored in Chapter VI. Recommendations for further research conclude the chapter.

CHAPTER V

ANALYSIS AND RESULTS

Introduction

This chapter presents the analysis and the empirical results associated with each study hypothesis as presented in Chapters II through IV. First, the analysis and results are presented in three groups by families of hypotheses. Then, these results are related to the study objectives as stated in Chapter I. The reader is referred to Table 15 for a summary of the acronyms and variables which are used during the following discussion.

Testing of Hypotheses

The first family of hypotheses is concerned with the relationships of past product acquisition and market access strategies on the one hand; and on the other hand current strategy, firm sales, and product success. The second family of hypotheses is concerned with the relationships of firm sales and product success to product acquisition, market access, and licensing. The third hypothesis family relates product introductions to regulatory issues which impact the pharmaceutical industry.

TABLE 15

SUMMARY OF ACRONYMS AND VARIABLES

ACRONYMS	VARIABLE DESCRIPTION
HPRDEV	Products previously developed in-house within a class
CPRDEV	Products currently developed in-house within a class
HINLIC	Products in-licensed within a class
DEVCLASS	Breadth of products developed in-house
HPRINTRO	Products previously introduced into a country
CPRINTRO	Products currently introduced into a country
HPRODUCT	Products introduced into or out-licensed to reach a country market
TPRDEV	Total products developed in-house across classes
TPRINTRO	Total products introduced across countries
TINLIC	Total products in-licensed from another firm
TOUTLIC	Total products out-licensed to another firm
BREADTH	Product line breadth across classes
MKTREP	Market representation
TOPDRUG	The number of top-performing drugs by firm
TOPTHER	The number of therapeutic classes in which a firm has top-performing drugs
ASALES	Firms sales were totaled across sales in all countries as reported in U.S. dollars and then adjusted by annual Gross National Product Deflators for observed years
SHARE	A surrogate measure of firm market share in observed year*
COMPUL	Compulsory out-licensing regulation
GENERIC	Generic substitution regulation
FORM	National formulary system
PLAN	National health plan
CLINIC	Acceptance of non-domestic clinical testing
INCENTIV	R&D pricing incentives regulated

* A surrogate market share measure is used because global market size is available only through proprietary sources which were not made available for this research.

Hypothesis--Family One

H-1a In-house product developments in a therapeutic class is a function of the number of products a business previously developed and the number of products previously in-licensed.

The sample is composed of 4,536 observations, with 504 observations in each of nine selected therapeutic classes (see Table 13). Using a backwards stepwise regression analysis, each of the two independent variables, past in-house product development (HPRDEV) and past in-licensing (HINLIC), was regressed on the dependent variable, current product developments (CPRDEV). The variable, products previously developed in-house (HPRDEV), is hypothesized to be positively related to current product development (CPRDEV). The number of products previously in-licensed (HINLIC) is hypothesized to positively affect the subsequent effectiveness of in-house product development up to a point and then negatively beyond that point. Therefore, HINLIC was used as a quadratic polynomial. HINLIC was also modelled as a monomial since the U-shaped relationship may not be apparent because the element of time was constrained to nine years in this model. See Table 16 for a summary of results of both models. Figure 6 also provides a graphic representation of the results for the entire first family of hypotheses.

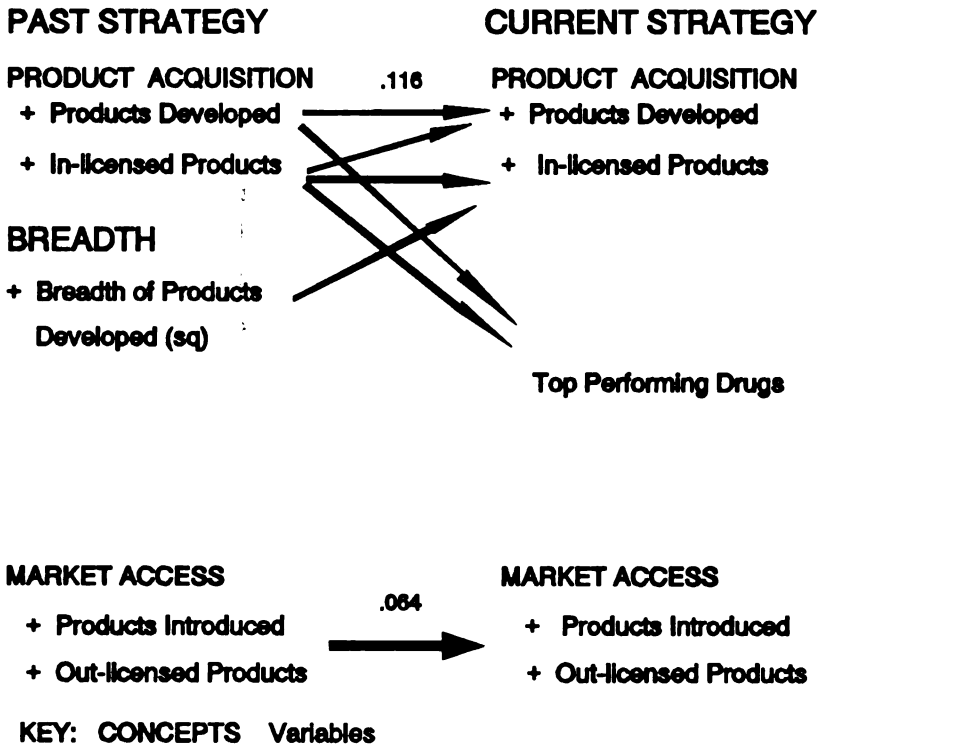
The quadratic regression equation first loaded both variables resulting in an adjusted R^2 of .1170 but was

TABLE 16

SUMMARY OF RESULTS--HYPOTHESIS 1A AND B PAST IN-HOUSE PRODUCT DEVELOPMENT AND IN-LICENSING STRATEGIES

	BETA WEIGHTS	STANDARD ERROR OF BETA	T - STATISTIC	ADJUSTED R^2
H-1a:				
Dependent Variable - Current products developed				
Linear equation				
HPRDEV	.341	.016	21.841[a]	.1301
HINLIC	.040	.016	2.567[a]	
Quadratic equation				
HPRDEV	.342	.034	10.021[a]	.1156
$HINLIC^2$	n.s.			
H-1b:				
Dependent Variable - Top-performing drugs				
Linear equation				
HPRDEV	n.s.	-	-	.0008
HINLIC	.032	.015	2.140[a]	
Quadratic equation				
HPRDEV	n.s.	-	-	.0000
$HINLIC^2$	n.s.	-	-	

a - denotes significance at the $p < .001$ level



Values reported are adjusted R squares. Non-reported values were statistically or managerially non-significant.

FIGURE 6 STRATEGIC CHOICES

subsequently reduced to .1156 when past in-licensing was dropped from the equation using a backwards stepwise elimination method (probability of F to remove = .05). The linear regression equation provided a slightly higher explanatory power using both variables for an adjusted R^2 of .1305 with an F statistic of 340.12 (significant F = .000).

Two observations are relevant. First, the Beta weights on the linear equation suggests that the past in-house product development variable (HPRDEV) provides approximately ten times the explanatory power of the in-licensing variable (HINLIC). Second, the sign of the Beta weight for past in-licensing is also positive suggesting that some direct relationship between past in-licensing and current in-house product development exists. The positive sign could also be consistent with the left side of an inverted U-shaped relationship as hypothesized. This suggests a longer time period be modelled in subsequent studies if the quadratic curve is to be identified.

Generally accepted practice is to utilize lower order polynomials over higher order polynomials (Cohen and Cohen 1983) for the virtues of simplicity, flexibility, and general descriptive accuracy. This is particularly applicable when two or more variables are used as predictors. Given this practice and its higher R^2, the linear equation is the preferred model. This simpler

explanation implies that the in-licensing strategies have some, but relatively minor, affect upon subsequent product development success. It bears repeating that these past strategy variables reflect a fixed, and perhaps relatively short, nine-year time period. If this time period were lengthened or manipulated in the model, a stronger relationship might be found.

Though the linear model is the generally accepted best fit, the discrepancy in findings relative to the quadratic model bears some attention because this study is concerned with the relationship between in-licensing and future product development success. The hypothesized relationship reconciles Porter's (1990) and Ohmae's (1990) theories concerning strategic alliances and predicts an inverted U-shaped curve.

The effect size, or R^2, associated with both models is relatively small (.130 and .116). However, strategy is a highly complex phenomenon which involves many variables both known and unknown. An effect size of .01 is considered interesting in other highly complex fielded research, psychology for example (Hunter and Schmidt 1991). Therefore, given the complexity of strategy, the significance of the findings, and attribution of the effect to a single variable, an effect size of .13 is of sufficient interest to researchers and managers to merit further investigation of the relationship.

Correlations of past in-house product development to current product development and past in-licensing to current product development by therapeutic class were subjected to a bare bones meta-analysis to detect differences in distribution among classes. Correlations of both variables to current product developments are shown in Table 17. The analysis showed that 5.38% of the past product development and current product development variables among classes is attributable to sampling error. Likewise, analysis of the correlation of past in-licensing and current in-house product development showed that approximately 16.55% of the variance among classes is attributable to sampling error. The homogeneity chi-square in the first meta-analysis (167.22) and the second analysis (54.38) both show that significant ($p < .01$) heterogeneity is present in the samples. This suggests that an unknown moderator variable may account for these differences. Hypothesis 1a is supported but warrants additional research.

Managerial Use of Past Product Acquisition Information

Managers can use information regarding competitors past product acquisition behavior to predict product classes in which competitors are likely to introduce new products. The relationship between past and current strategic behavior was found to be significant but small. However, in-house product development intuitively and statistically represents

TABLE 17

CORRELATIONS OF PAST IN-HOUSE PRODUCT DEVELOPMENT AND PAST IN-LICENSING WITH CURRENT PRODUCT DEVELOPMENT WITHIN PRODUCT CLASSES

PRODUCT CLASS	PAST PRODUCT DEVELOPMENT	PAST IN-LICENSING
Antihistamines	-.0206	.0105
Anti-infectives	.4335[b]	.3174[b]
Anti-cancer	.4750[b]	.2232[b]
Cardiovascular	.3053[b]	.0688
Central nervous system	.4339[b]	.2038[b]
Eye, ear, nose, and throat	-.0127	-.0134
Gastro-intestinal	.2355[b]	.0412
Hormones	.1131[a]	.0000
Skin and mucous membrane	.3370[b]	.1089[a]

a - denotes significance at $p < .05$
b - denotes significance at $p < .01$

a greater commitment to a product market than does in-licensing.

There are two managerial ramifications of this difference in level of commitment to product classes. First, expectations for further product introductions into a particular category should be stronger when products are developed in-house versus externally. This means that research and development activity would be a better indicator of future product introductions than past in-licensing. Second, these findings imply there has been a

relatively small risk of future competition from R&D of firms who in-license products in a particular class.

Caution should be exercised in generalizing these findings to other industries. In particular industries in which the R&D cycle is short may have intense competition using both in-licensing and in-house product development interchangeably. However, it is likely that these findings can be tentatively generalized to other industries with costly and lengthy R&D cycles.

H-1b The number of top sales producing drugs the business markets in a therapeutic class is a function of the number of products a business previously developed and in-licensed.

As in hypothesis 1a, the sample is composed of 4,536 observations by firm and by therapeutic product class, pooled across classes based upon homogeneous findings across classes as determined by meta-analysis. Using a backwards stepwise regression analysis, each of the two independent variables, past in-house product development (HPRDEV) and past in-licensing (HINLIC), was regressed on the independent variable, top-performing drug (TOPDRUG). A summary of model statistics is provided in Table 16.

The linear model was significant with an adjusted R^2 = .0008 and an F = 4.578 (significant F = .032). Past in-house product development was not incorporated into the model. The quadratic model did not load past in-licensing

or reach significance with an adjusted R^2 = .0000. Though statistically significant, the effect size of the linear model is so small as to be of little predictive value.

Two explanations can be offered for the small effect size in the significant linear model. The first is the low number of top-performing drugs relative to the total number of products developed in-house, and therefore few top-performing drugs are available for in-licensing by other firms. Second, the short nine-year time span associated with the in-licensing and product development variables may obscure stronger relationships.

It is interesting to note the significant relationship, though very small, is between in-licensing and top-performing drugs rather than internally developed products and top-performing drugs. However, the low predictive value of this relationship renders additional analysis trivial in a now univariate model. A meta-analysis was done using the correlations of past in-house product development and past in-licensing with top drugs (see Table 18). The analysis revealed heterogeneity in the correlations between past in-house product development and top drug with a non-significant homogeneity Chi-square of 58.09. This indicates that a moderator variable is operating between past in-house drug development and the incidence of top drugs.

However, homogeneity is present with the correlations between past in-licensing and top drugs with a homogeneity Chi-square of 15.49 ($p < .05$). This meta-analysis indicates

TABLE 18

CORRELATIONS OF PAST IN-HOUSE PRODUCT DEVELOPMENT AND PAST IN-LICENSING WITH TOP DRUGS WITHIN PRODUCT CLASSES

PRODUCT CLASS	PAST IN-HOUSE PRODUCT DEVELOPMENT	PAST IN-LICENSING
Antihistamines	.0100	-.0127
Anti-infectives	.1315[b]	.0032
Anti-cancer	.1165[b]	.0020
Cardiovascular	.0015	-.0387
Central nervous system	-.0068	-.0031
Eye, ear, nose, and throat	.0292	.0395
Gastro-intestinal	-.0272	-.0197
Hormones	.0392	-.0222
Skin and mucous membrane	.0121	.3525[b]

a - denotes significance at $p < .05$
b - denotes significance at $p < .01$

that the small effect size between in-licensing and top drugs is not due to sampling error and holds across therapeutic classes. Findings relevant to both independent analyses direct further research to seek additional variables to account for success in producing top-performing drugs. However, hypothesis 1b is partially, but nominally, supported.

Combining the findings of hypotheses 1a and 1b, it is possible to summarize that past in-house product development plays a role in predicting the dependent variable, sales, in some but not all therapeutic classes. However, past in-house product development may or may not play a role in predicting success of producing top-performing drugs. Further research within product classes, or group classes by other relevant criteria, is needed to determine the true relationship.

Past in-licensing plays a small role in predicting sales performance and development of top-performing drugs. This role is consistent in relationship to producing top-performing drugs but varies due to an unknown moderator variable in relationship to sales.

H-1c The number of current products developed by a business is a function of the number of therapeutic classes in which a business previously developed products.

A Spearman Product Moment Correlation was calculated between the independent variable, breadth of product

developments (DEVCLASS), and the dependent variable, current product developments (CPRDEV). The sample is composed of a total of 504 observations with the line-of-business the unit of analysis. A correlation of .1753 (significant at $p < .01$), with an $r^2 = .031$ was observed. This effect size, though significant, is small. The relationship is positive implying that the broader the product developments across classes, the higher the number of top-performing drugs. This is inconsistent with Foxall's (1983) theory of constrained search across product classes. However, a correlation of .1704, $r^2 = .029$ (significant at $p < .01$), was also found between $DEVCLASS^2$ and current product developments. A summary of these models is provided in Table 19.

While the linear relationship is the preferred model because of its simplicity, the quadratic relationship cannot be ignored. This is particularly true because the sign of the Beta weight for the quadratic is positive, which is opposite to the relationship hypothesized. It is possible that the relationship with the quadratic polynomial might be stronger if the element of time is modelled as a variable. Alternatively, observation of any existing quadratic relationship might be curtailed by a limitation in firm resources which prevents an over-broad commitment to product development. Since the relationships tested in hypotheses 1a and 1b showed significant heterogeneity across therapeutic classes, different functions might also be found for

this hypothesis if the data were split using one or more moderator variables as described in the discussion of the first two hypotheses. Hypothesis 1c is partially supported.

TABLE 19

HYPOTHESES 1C AND 1D: SUMMARY OF RESULTS

HYPOTHESIS	CORRELATION	r^2	SIGNIFICANCE
1-c Dependent Variable--Current Products Developed			
Linear			
DEVCLASS	.1753	.032	<.01
Quadratic			
DEVCLASS	.1704	.029	<.01
1-d Dependent Variable--Current Products Introduced			
Linear			
HPRDEV	.2535	.064	<.01

Managerial Implications--Product Acquisition Strategies

Though these findings are inconclusive relative to the question of breadth of search for new products, the relationship between product acquisition strategy and successful product development is of vital importance. Strategic research on an industry scale is difficult because unsuccessful firm strategies remain unstudied due to firm failures and management turnovers. This is an area in which managerial interviews and support of case studies have the

potential to contribute significantly to distinguishing successful from unsuccessful strategies.

If the hypothesized relationship does not hold as these tentative findings suggest, managers should not constrain their search to a few product classes or categories. They imply quite the contrary, that a much broader search for new products yields better results than a moderately broad search.

H-1d The number of current product introductions into that country is a function of the number of products previously introduced to a country market.

The sample is composed of a total of 3,024 observations by country and by firm. 504 observations from each of the six study countries are included. A Spearman Product Moment Correlation was performed with the independent variable, past products introduced (HPRODUCT), and the dependent variable, current product introductions (CPRINTRO). A significant correlation of .2535 (significant at $p < .01$), with an $r^2 = .064$ was determined. This effect size, though significant, is somewhat small. Here again, given the large number of variables which affect market access strategy, the effect size is an interesting basis for further research.

The relationship is linear and positive. That is, the higher the number of products previously marketed, the higher the likelihood of current product introductions into a country. Correlations of past product introductions to

current product introductions across countries were subjected to a bare bones meta-analysis to detect differences in distribution among countries. The analysis showed that 67.67% of the variance in correlation of products previously marketed and current product introductions among countries is attributable to sampling error. The homogeneity chi-square in this meta-analysis (8.87) is not significant ($p < .20$) indicating that this relationship holds true across countries. Therefore hypothesis 1d is supported.

Managerial Implications--Market Access

Although these findings statistically support the notion that existing market relationships are used for subsequent product introductions, from a managerial perspective the correlation is smaller than would be expected for maximizing these relationships. The pharmaceutical industry engages in licensing quite heavily, which provides opportunities to fill existing channels. Given the high cost of developing and maintaining nondomestic market relationships, firms would be well advised to seek additional products to market with their own. This study reveals that these firms utilize in-licensing almost twice as much as other product acquisition strategies. Previous research cautions managers that these products should be chosen to use the same pre- and post-sales support system as their current product line.

Marketing in-licensed products also provides a means for preparing a marketing system for future product introductions.

Summary--Hypothesis Family One

Although all four of the hypotheses in this family are statistically supported, the actual affect sizes are quite small. It seems prudent to further assess the relationships of pairs of past and current strategies.

For this analysis only firms which engage in the current strategy examined were used. Table 20 sets forth Phi statistics (Pearson Chi-square probabilities) for each pair of strategies studied in this family of hypotheses.

These statistics provide a useful historic description of firms which engage in certain strategies. The findings are consistent with the multivariate analysis done earlier. However, a closer examination of significant pairs sheds some additional light on licensing motivations.

First, as is logical, firms which engaged in product development in the past currently develop products in-house. Second, firms which currently market top-performing drugs have acquired in-licensing agreements in the past. Third, firms currently introducing products tend to have introduced products in the past. Further, the relationship of current introductions is more significant with past out-licensing of the firm products than with past self-introductions. However, the relationship between past and current

TABLE 20

RELATIONSHIPS OF PAIRS OF PAST AND CURRENT STRATEGIES

Relates to Hypothesis	Past Strategy	Current Strategy	Phi[1]
1a	HPRDEV	CPRDEV	.338[2]
	HINLIC	CPRDEV	.180
1b	HPRDEV	TOPDRUG	.105
	HINLIC	TOPDRUG	.581[2]
1c	DEVCLASS	CPRDEV	.277
1d	HPRODUCT[4]	CPRINTRO	.722[2]
	HOUTLIC	CPRINTRO	.264[3]
	HPRINTRO	CPRINTRO	.180

Note: Statistics include only firms engaging in the current strategy examined.
1 - Pearson Chi-square probability
2 - Significant @ $P \leq .01$
3 - Significant @ $P \leq .05$
4 - HPRODUCT is the sum of HOUTLIC and HPRINTRO

introductions is stronger with than without past self-introductions.

The first significant relationship is readily evident. That is, firms with R&D capacity tend to continue to engage in R&D activities and strategies.

The second relationship, between past in-licensing and marketing top-performing drugs, suggests that firms with in-house R&D are more likely to out-license a product than to introduce it themselves. This is important, especially in light of the findings of hypotheses 2a and 2b, which are presented in the next section. The models which follow show a strong relationship between product introductions and performance. It can be extrapolated that to maximize performance, firms which engage in R&D must also develop their channels of distribution.

Finally, firms currently introducing products have a strong history of out-licensing. That is, these firms are either learning that they need to introduce products themselves or they cannot find firms which will introduce their products into key markets.

Hypothesis--Family Two

H-2a: Pharmaceutical business sales revenue is a function of the number of products developed, the breadth of products developed, the number of in-licensed products, product line breadth, the number of product introductions into country markets, the number of out-licensed products, market representation, and the number and breadth of top drugs.

The sample for the second hypothesis family is composed of 504 observations by line-of-business over the study time period (1982-1987). Hypothesized relationships included potential polynomials for six of the independent variables: products developed (TPRDEV), products introduced (TPRINTRO), in-licensed products (TINLIC), out-licensed products (TOUTLIC), product line breadth (BREADTH), and breadth of products developed (DEVCLASS). Two explanations are possible to account for a potentially better model using one or more monomials versus the hypothesized polynomial variables. The first explanation involves successful firm bias. The sample may exclude firms which may represent the

downswing of hypothesized U-shaped relationships. The second explanation involves measurement constraint which holds the element of time to a fixed period of nine years in calculation of variables. For this reason, a modelling approach was used to determine the best fit of combinations of polynomials as both monomial and polynomial variables. This analysis resulted in a possible sixty-four combinations of variables for each of the two models.

In each analysis all nine independent variables are regressed on the dependent variable using a backwards stepwise method. Appendix D reports the adjusted R^2 for each model. The independent variables include products developed (TPRDEV), products introduced (TPRINTRO), in-licensed products (TINLIC), out-licensed products (TOUTLIC), breadth of product line (BREADTH), breadth of products developed (DEVCLASS), breadth of top-performing drugs (TOPTHER), the number of top-performing drugs (TOPDRUG), and market representation (MKTREP). Hypothesis 2a models sales, adjusted for inflation, (ASALES) as the dependent variable and hypothesis 2b models a surrogate measure of market share (SHARE) as the dependent variable.

The best fit model for each hypothesis was subsequently analyzed with a simultaneous model utilizing only the variables which loaded at $p < .05$ in the original stepwise equations. This method provides a more normal distribution of error over the variables included in the model and avoids

over or understatement of Beta weights as a result of order of entry.

Linear Model Predicting Sales

The model predicting sales tested hypothesis 2a and utilized seven of the nine independent variables to obtain an $R^2 = .589$. A summary of this model is provided in Table 21. A graphic representation of both the linear and quadratic model solutions are also provided in Figure 7. The linear model was preferred over the quadratic model because of its slightly higher predictive value and its simplicity. However, it should be acknowledged that many quadratic bivariate relationships are valid, although they did not contribute to the model in the presence of other elements. The following discussion first addresses the variables excluded from the sales model followed by a discussion of the model itself. Relevant bivariate relationships are address along with discussion of independent variables of the model. The model predicting is addressed in the next section of this chapter.

Market representation (Y_9) was not included in the final model predicting sales because it did not add significantly to the equation with the highest predictive value. In preliminary univariate analysis, market representation showed significant correlations with top-performing drugs ($r = .34$, $p < .01$), out-licensed drugs ($r = .27$, $p < .01$), and in-licensed drugs ($r= .09$, $p < .05$)

TABLE 21

HYPOTHESIS 2A: REGRESSION MODEL FOR STRATEGY AND SALES

Quadratic Solution					Independent Variables				
Dependent Variable	Y_1^2	Y_2	Y_3	Y_4	Y_5^2	Y_6^2	Y_7	Y_8	Y_9
ASALES									
R^2= .585									
Beta[a]	n.s.	-.330	n.s.	.860	n.s.	n.s.	.403	n.s.	n.s
T		-2.56		6.671			4.684		
Sig T		.013		.000			.000		

Linear Solution					Independent Variables				
Dependent Variable	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
ASALES									
R^2= .594									
Beta[a]	-.184[c]	.151[c]	.102	.234[c]	n.s.	.107	n.s.	.578[c]	n.s
T	-2.916	2.598	2.716	5.696		2.414		18.700	
Sig T	.004	.010	.007	.000		.016		.000	

a - adjusted R^2
b - standardized Beta weights
c - denotes significance at the $p \leq .001$ level

Y_1 = number of products developed in-house
Y_2 = number of products introduced
Y_3 = number of products in-licensed
Y_4 = number of products out-licensed
Y_5 = breadth of product developments
Y_6 = product line breadth
Y_7 = number of top-performing drugs
Y_8 = breadth of top-performing drugs
Y_9 = market representation market share

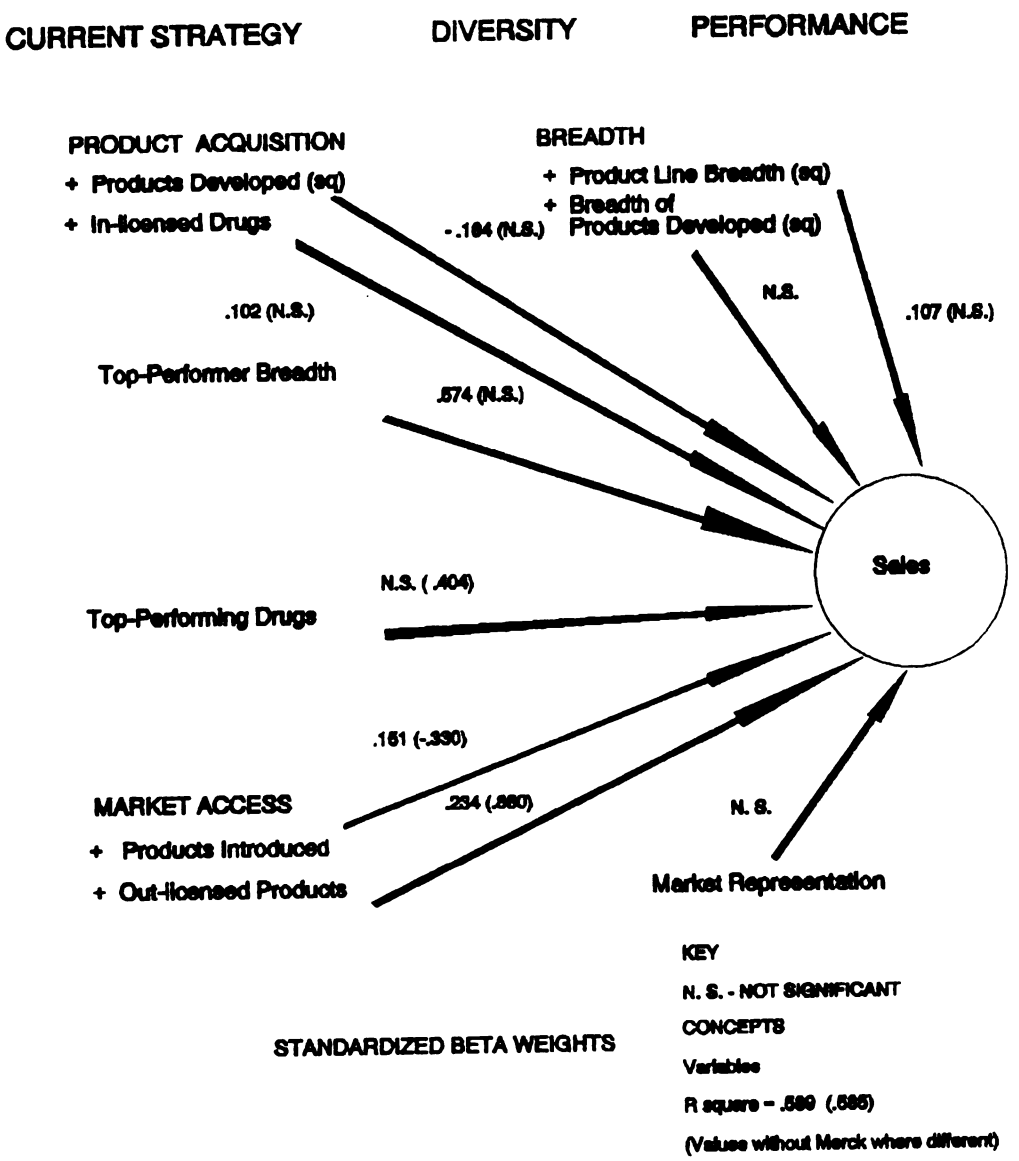


FIGURE 7 LINEAR REGRESSION MODEL PREDICTING SALES

but did not have a significant correlation with sales or market share. There may be a significant correlation if differences in the drug products which are represented in the various markets is also taken into account.

One such difference among these products is age. Forty percent of the observations showed a zero market representation as calculated for this variable. This means that forty percent of the observations represent a year between 1982-1987 in which a firm did not introduce or in-license a product for marketing to any of the six study countries. Since the historic variables were also accounted for in this variable, it also means that these same firms also did not introduce or in-license products in any of the nine years prior to the observation years. The sample firms represent the top 100-150 sales performing firms in the study years. There are three interpretations which might follow from this observation.

First, it is possible that many of the top 100-150 firms primarily market outside of the top six country markets. If this is the case, these firms are giving priority to smaller markets, which is intuitively unlikely. Second, many of those firms that do market within the six countries have not introduced products which are listed in the Paul de Haen data base for the ten-year period observed. Given the thorough and continuous updating procedures used by Paul de Haen International, Inc. and the industry confidence in the databases, exclusion of significant

products or a significant number of products is unlikely. Finally, regardless of age of their products these firms can and do produce sizable sales revenues. Therefore it is more probable that the average age of top sales-performing products is high and that these products had already been introduced into the top six markets before or at the beginning of the study time span.

Breadth of products (Y_5) developed also did not load in the model. This is probably a function of low variation in this variable. Approximately 77% of the sample had a product line breadth of three or fewer product classes. However, it is consistent with the notion of building complementary product lines within markets. Therefore subsequent studies should address product breadth within markets as well as across markets.

The variables which were used to predict sales are discussed in order of relative importance as demonstrated by their Beta weights in the model. Breadth of top-performing drugs (Y_8) has the highest Beta weight (.574) representing a positive linear relationship with sales. This is consistent with the hypothesized relationship and industry criteria as derived from interviews with industry executives. Simply stated, as the number of classes in which a firm has top-performing drugs increases, firm sales increase. Given the skewed distribution in this variable--only Merck has top performers in three or more classes--a second model was run eliminating Merck as an outlier.

With Merck eliminated, the R^2 dropped slightly (from .589 to .585) and top-performing drugs replaced top-performer breadth in the equation (Beta = .404). These findings are consistent with accepted industry success criteria which tie survival to the number and breadth of top performers.

The number of products out-licensed (Y_4) loaded into the model with the second highest Beta weight (.234). In the model excluding Merck, this Beta weight ranked first (.880) indicating that aggressive out-licensing of products is an important part in the sales strategy of most firms. This describes a positive linear relationship between the number of out-licensed products and sales. The hypothesized relationship is an inverted U-shape which is not inconsistent with this finding. However, if the downswing in the hypothesized relationship is to be found, subsequent studies should expand the number of years represented in the sample. This can be accomplished by increasing the number of observed years or the number of years' data used in the calculation of this historic variable. These findings are consistent with Ohmae's (1989) pro-strategic alliance views.

The third largest Beta weight (-.184) describes a negative linear relationship between in-house product development (Y_1) and sales. This is inconsistent with Porter's hypothesis supporting in-house development strategies over external acquisition of products. The simple correlation (.244) between the quadratic variable and

sales defines a U-shaped curve, suggesting a learning curve and/or economies of scale may be present in the sales success of products developed in-house.

The next variable of importance, products introduced (Y_2), carries a Beta weight of .151, which describes a positive linear relationship with sales. Products introduced is the only variable which dramatically changes by remaining significant but reversing its sign (Beta = -.330) with Merck removed from the sample. Though Merck is an outlier in the sample, its success is envied by the industry and its strategy is of particular interest. The reversal of the sign of this Beta weight illustrates the importance of not only introducing new products, but of introducing good products with effective strategy since, for the model without Merck, the impact of product introductions is negative in the presence of other strategies.

The hypothesized relationship is an inverted U-shaped curve. As previously discussed with out-licensing, a negative linear finding is not inconsistent with the hypothesis. Subsequent research should address longer time periods if this relationship is to be found. Constrained firm resources may also prevent manifestation of the downswing in this curve. That is, because product introduction is quite costly, only a limited number of eligible products may be introduced.

Product line breadth ($Y_{6,}$) loaded into the equation with the fifth highest Beta weight (.107), describes a

positive linear relationship to sales. This relationship is not contrary to the hypothesized relationship which predicted an inverted U-shape.

The sixth most important variable, products in-licensed (Y_3), carries a Beta weight of (.102) in this model. The relationship described with sales is positive and linear. As with out-licensing and product introductions, the hypothesized relationship is an inverted U-shape. The argument regarding the time period captured in this model is also relevant to this variable. That is, findings are not inconsistent with the inverted U-shaped relationship which may be found in a model with a longer time frame.

Managerial Implications--Linear Model Predicting Sales

This section summarizes the sales model with a review of its major components. These three components are product acquisition, market access, and industry portfolio criteria.

First, the two variables relevant to product acquisition, product developments and in-licensed products, were significant predictors in the model. Internal product development shows a much stronger (and negative) relationship than did the external strategy, in-licensing. This is inconsistent with speculation from industry executives, which predicts a lesser sales effort for in-licensed products. The reduced effort is thought to be a result of lack of identity with the product, lower sales commissions, lower profit margins, or a combined effect of all three.

Both product acquisition variables became non-significant when Merck was eliminated from the sample. The variance became more associated with products introduced and out-licensed products.

This is interesting because the shift from strength in in-licensing to strength in out-licensing suggests that Merck's strategies for product introduction are superior to those of the rest of the industry. Furthermore, firms are cognizant of their lack of the necessary ingredients for some successful product launches as is evidenced by their extensive reliance upon out-licensing to produce sales.

Managers and researchers should specifically address product introduction strategies to enhance sales performance. Executives should be particularly cautious against over-reliance upon a narrow product line. This need is illustrated by the difference in contribution of measures of product line breadth between the Merck and no-Merck models. This might be accomplished by building in-country sales forces who can market an increased number of in-licensed products as well as reduce reliance upon out-licensing.

Both products developed and in-licensed products were hypothesized to have an inverted U-shaped relationship with sales. The number of products developed was demonstrated to have the expected curvilinear relationship. The expected relationship of in-licensed products to sales was neither proven or disproved.

Second, the variables relevant to market access, product introductions, and out-licensed products, were also significant predictors. In this case the external strategy, out-licensing, had a stronger relationship with sales than did the internal strategy of product introductions except when outliers were removed.

These two market access variables were also predicted to have inverted U-shaped relationships with sales. In both cases only a positive linear relationship was shown. There is still the potential for this relationship over a longer time frame.

The model failed to provide sufficient evidence to disprove either Ohmae's (1989) hypothesis favoring use of strategic alliances or Porter's (1990) hypothesis against use of strategic alliances. However, there is support for the benefits of using both in-licensing and out-licensing at least in the short run. In fact, out-licensing was found to have a very strong relationship with sales, much greater than does product introductions, which has also been shown to be negative. In the case of product acquisition, product development was shown to be more closely associated with sales than was in-licensing (although negatively) in the short run.

The third component of this model is to examine the relationship of industry-defined criteria to sales. The variables which represent these criteria in the model are market representation, product line breadth, top-performing

drugs, and breadth of top-performing drugs. Market representation failed to load on the model but may be an artifact of the nine-year time frame used for the study. Findings relative to product line breadth supported the expected relationship. Not surprisingly, top-performing drugs also demonstrated a highly positive relationship with sales either directly or through top-performer breadth. The most predictive variable for the entire sample was breadth of top-performing drugs, though out-licensing was far more predictive in the absence of Merck.

The second model addresses the same independent variables to predict market share. The empirical results associated with the model are presented in the following section followed by a comparison of the two models.

Quadratic Regression Model Predicting Market Share

H-2b: Pharmaceutical business market share is a function of the number of products developed, the breadth of products developed, the number of in-licensed products, product line breadth, the number of product introductions into country markets, the number of out-licensed products, market representation, and the number and breadth of top drugs.

The model predicting market share utilized five of the nine independent variables to obtain an $R^2 = .683$. As with the model predicting sales, this model was calibrated a

second time with Merck removed from the sample. This resulted in a somewhat lower R^2 (.612). A summary of both the linear a quadratic solutions to the general model is provided in Table 22. The quadratic model was chosen because of its higher predictive power. A graphic representation of the results of the preferred model is provided in Figure 8. The figure also includes the Beta weights for the solution without Merck noted in parentheses. The following discussion first addresses variables which were excluded from the model, followed by a discussion of the model itself.

Three variables were excluded from the model predicting market share: breadth of top-performing drugs, market representation, and in-licensed products. Three variables (top-performing drugs, breadth of top-performing drugs, and market representation) are industry success criteria. One excluded variable, market representation, was also excluded from the model predicting sales. Two of the excluded variables (top-performing drugs and breadth of top-performing drugs) appear to be predictors of sales and market share either directly or indirectly. Market representation and market share did not correlate significantly ($r = .050$).

The variables which were used to predict market share are discussed in order of relative importance as demonstrated by their Beta weights in the model. As expected,

TABLE 22

HYPOTHESIS 2B: REGRESSION MODEL FOR STRATEGY AND MARKET SHARE

Quadratic Solution							Independent Variables		
Dependent Variable	Y_1^2	Y_2	Y_3	Y_4	Y_5^2	Y_6^2	Y_7	Y_8	Y_9
SHARE									
R^2 = .683[a]									
Beta[b]	-.244[c]	.227[c]	n.s.	.237[c]	-.126[c]	.299[c]	.584[c]	n.s.	n.s.
T	-4.095	3.253		5.165	-1.903	4.941	16.269		
SIG T	.001	.003		.000	.058	.000	.000		

Linear Solution							Independent Variables		
Dependent Variable	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
SHARE									
R^2 = .633[a]									
Beta[b]	-.230[c]	.151[c]	n.s.	.2182[c]	n.s.	.197[c]	n.s.	.645[c]	-.230[c]
T	-3.557	2.720		5.130		4.813		21.868	-3.557
SIG T	.001	.078		.000		.000		.000	.001

a - adjusted R^2
b - standardized Beta weights
c - denotes significance at the $p \leq .001$ level

Y_1 = number of products developed in-house
Y_2 = number of products introduced
Y_3 = number of products in-licensed
Y_4 = number of products out-licensed
Y_5 = breadth of product developments
Y_6 = product line breadth
Y_7 = number of top-performing drugs
Y_8 = breadth of top-performing drugs
Y_9 = market representation

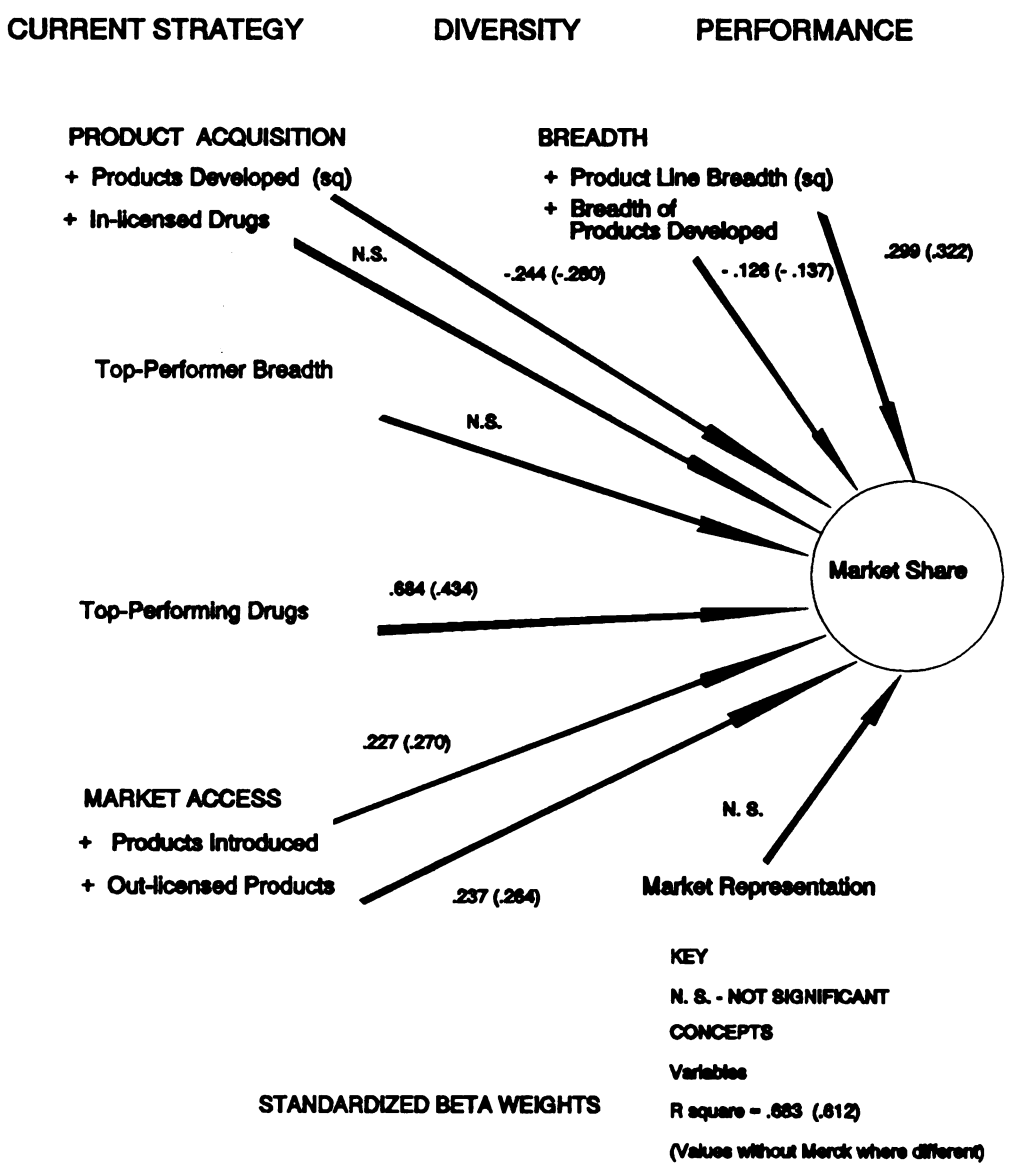


FIGURE 8 QUADRATIC REGRESSION MODEL PREDICTING MARKET SHARE

top-performing drugs were the highest predictor of market share with a Beta weight of .584.

Breadth of product line (Y_6) has the second highest Beta weight (.299), indicating an U-shaped relationship with sales. This relationship is opposite to the inverse U-shape hypothesized. As in the model predicting sales, two explanations for this phenomena are offered. First, as firms begin to offer a greater number of products, they experience a learning curve with respect to managing multiple product categories. As they offer an even greater number of products this experience accumulates and is reflected in higher sales and subsequently higher market share. The second explanation relates to specialization. Initial product line expansion across therapeutic classes may not carry sufficient critical mass to warrant specialized marketing and management. As critical mass is achieved, specialization becomes more feasible. Higher sales and market share then result from specialized marketing and management skills.

The number of products developed (Y_1) loaded into the model with the third highest Beta weight (-.244). This describes an inverted U-shape relationship as hypothesized. This finding is consistent with Foxall's (1983) notion of constrained search resulting in higher in-house development productivity, leading to greater market share. By relating product development to market share, other factors such as promotion, market access, competition and other

idiosyncrasies of management are also implied in the equation. It is very informative that even with several of these (e.g., market access, and licensing strategies) included in this model, this inverted U-shaped relationship is third in importance.

The fourth largest Beta weight (.237) describes a positive linear relationship between the number of out-licensed products (Y_4) and market share. The hypothesized relationship is an inverted U-shape, which is not inconsistent with this finding. Again, if the downswing in the hypothesized relationship is to be found, subsequent studies should expand the number of years represented in the sample. These findings are consistent with Ohmae's (1989) pro-strategic alliance views.

The fifth variable in the model, products introduced (Y_2), carries a Beta weight of .227, which describes a linear relationship with market share. This is not inconsistent with the hypothesized relationship, an inverted U-shaped curve. As discussed with product line breadth in the sales model, this finding can be explained by applying the principles of specialization, positive economies of scale, and the learning curve. As firms introduce a greater number of products they experience reduced effectiveness as they begin a learning curve with respect to the product introduction process. As they introduce more products their effectiveness increases with experience and is reflected in higher market share. With respect to

specialization, initial growth in product introductions may not carry sufficient critical mass to warrant specialized marketing and management. As critical mass is achieved, specialization becomes more feasible. Higher market share then results from specialized in-country marketing and management skills.

The sixth and final variable in the model, breadth of product developments (Y_5), with a negative Beta weight (-.126) has a negative relationship with market share. The hypothesized relationship is an inverted U-shape. That is, as the number of classes in which products are developed increases, the firm's market share increases. The findings are contrary to the hypothesized relationship.

Summary of Strategy Models

To summarize, a review of model elements relative to product acquisition, market access, and industry criteria is presented. This summary is accompanied by a comparison of the sales and market share models developed in testing this second family of hypotheses.

The market access variables which denote internal strategy (product introductions) and external strategy (out-licensed products) were both significant in the market share model. As in the sales model, out-licensed products loaded more heavily than product introductions, indicating advantages to out-licensing strategies at least in the short run.

Both of the product acquisition variables which represent internal strategy (product developments) and external strategy (in-licensed products) did not load into the market share model as they did in the sales model. In-licensed products, while correlating significantly with market share, did not add significantly to the model. Product developments demonstrated the hypothesized inverted U-shaped relationship with market share, as with sales. Breadth of product development loaded only on the market share models with an inverted U-shaped curve. Breadth of product line also displayed a similar relationship with market share, as with sales. In both the sales and market share models the relationship was found to be a U-shaped relationship, which might be explained by the learning curve, positive economies of scale, and/or specialization.

Findings of these models can also be summarized as they relate to use of external versus internal resources. The models showed similar rankings within product acquisition and market access. That is, product development was consistently more important than in-licensed products and out-licensing was consistently more important than product introductions. In an overall sense with respect to external and internal strategy, out-licensing ranked first relative to sales, and product development ranked first relative to market share. Product introductions and in-licensing retained third and fourth strategy ranks respectively across the two models. Taken as a whole, these findings seem to

indicate that internal product acquisition and external market access are the stronger strategies in a sales producing and a competitive sense. These relationships may shift if studied over a longer period, but do have managerial implications which are discussed in Chapter VI.

Major differences in the importance of the industry success criteria were found between the sales and market share models. Both the sales and market share models did not incorporate the market representation variable. An explanation for this lack of importance may be an artifact of the time span studied. That is, the high age of top-performing drugs may have reduced the variation in the market representation variable within the observed sample.

Top-performing drugs showed a surprisingly negative linear relationship to sales and are observed to be relatively unimportant in the market share model. Breadth of top-performing drugs was the best predictor in the sales model, yet did not add significantly to the market share model. This may be the case since a sufficiently broad product line is necessary to appropriately develop and maintain distribution channels in several country markets. A well developed distribution network is a necessary precursor to exploiting sales potential of top drug products.

Concurrent Strategies

Correlations between pairs of licensing strategies is also interesting (see Table 23). The single most frequently used strategy in the sample was product out-licensing (401), followed by the number of products developed in-house (299). These two strategies are complementary and logically occur together the most frequently and logically have the highest correlation (.655). The third most frequently occurring strategy is in-licensing (139). The least frequently used strategy is product introduction (89). In-licensing and product introductions are also logically highly correlated (.521).

These sample frequencies, when compared to Merck's strategies, are consistent with the earlier observation that Merck seems to manage product introductions better than other firms. In fact, other firms as a whole are not attempting introductions as a major strategy.

These correlations raise the question of multi-collinearity in the predictive models. The effects of collinearity as a potential problem in marketing research has been recently examined by Mason and Perreault (1991). Using exhaustive Monte Carlo experiments they concluded that the effects of collinearity are over-represented in the literature, they found the danger of Type II errors are more problematic than Type I. "Any combination of small sample size, low overall model fit, or extreme intercorrelation of predictors precludes confidence in inference (p 277)."

TABLE 23

CORRELATION MATRIX--HYPOTHESIS FAMILY TWO

	Y_1	Y_1^2	Y_2	Y_2^2	Y_3	Y_4	Y_5
Y_1	1.000						
Y_1^2	.8496*	1.0000					
Y_2	.8656*	.7704*	1.0000				
Y_2^2	.7189*	.8625*	.8722*	1.0000			
Y_3	.5424*	.3951*	.5207*	.4200*	1.0000		
Y_4	.6550*	.5003*	.6328*	.5239*	.5415*	1.0000	
Y_5	.7349*	.4305*	.5827*	.3578*	.5071*	.6377*	1.0000
Y_6	.6851*	.3918*	.5973*	.3853*	.6099*	.6323*	.8910*
Y_6^2	.7402*	.4863*	.6834*	.4746*	.6497*	.6531*	.8264*
Y_7	.3088*	.1441*	.2782*	.1403*	.3096*	.2486*	.3249*
Y_8	.3416*	.1628*	.3119*	.1585*	.2953*	.2603*	.3439*
Y_9	-.0184	-.0341	.0814	.0892#	.1016#	.3654*	.1608*
SALES	.4262*	.2402*	.4372*	.2867*	.4438*	.4829*	.4439*
MARKET SHARE	.4004*	.2050*	.4043*	.2452*	.4098*	.4340*	.4333*

	Y_6	Y_6^2	Y_7	Y_8	Y_9	SALES	SHARE
Y_6	1.0000						
Y_6^2	.9334*	1.0000					
Y_7	.3556*	.3355*	1.0000				
Y_8	.3647*	.3496*	.9816*	1.0000			
Y_9	.2128*	.1259*	-.0279	-.0357	1.0000		
SALES	.4924*	.5044*	.6880*	.6923*	.7048	1.0000	
MARKET SHARE	.4903*	.4958*	.7300*	.7442*	.0554	.9703*	1.0000

* - Significant $\leq$ LE .01 (2-tailed)
\# - Significant $\leq$ LE .05
Y_1 = number of products developed in-house
Y_2 = number of products introduced
Y_3 = number of products in-licensed
Y_4 = number of products out-licensed
Y_5 = breadth of product developments
Y_6 = product line breadth
Y_7 = number of top-performing drugs
Y_8 = breadth of top-performing drugs

to their Monte Carlo runs ($n \leq 300$) and the overall fit of both models, it can be reasonably concluded that collinearity is not a problem.

Hypothesis--Three

H-3: The number of products a business introduces into a country market is a function of regulations concerning compulsory out-licensing, generic substitution, national formularies, national health plans, acceptance of nondomestic clinical testing, and pricing incentives.

The original sample includes 101 top-performing global pharmaceutical firms during the period 1982-1987. Of the potential 606 observations (101 firms by six years), 504 were constructed at the line-of-business level. This resulted in 3,024 observations by line-of-business, by year, and by country of product introduction.

A stepwise backward analysis was performed regressing six of the dummy regulation variables on the number of product introductions. The regulation variables were lagged by three years (1979-1984) to allow for the average length of time between application and approval of drugs for marketing. Variables found significant in the stepwise regression were rerun using a simultaneous method to distribute any sampling error equally. Since there was no variation in patent protection among the sample countries

during the study period, that factor was not included in the study.

The regressions found a relationship for only two of the independent variables: acceptance of nondomestic clinical testing and national health plans (R^2 = .006 [$p < .001$]). Though statistically significant, these findings do not provide meaningful policy implications from the hypothesis as stated. To restate, these findings do imply that firms choose to enter markets regardless of generic substitution plans, national formulary systems, compulsory out-licensing, and pricing incentives. A summary of standardized Beta weights for the analysis is presented in Table 24.

A second multiple regression was run with compulsory out-licensing recoded "0" for France, Italy, and Japan because they reportedly seldom enforce this regulation. Four regulatory variables were retained in this equation--generic substitution, national formularies, national health plans, and compulsory out-licensing--which still yields an R^2 = .006 ($p < .001$). The explained variance remains unchanged from the first regression, yet the four variables which loaded significantly did change. A third regression analysis was done to determine whether country market had an impact on the number of product introductions. This regression was also significant ($p < .001$); however, it provided only R^2 = .004.

TABLE 24

STEPWISE REGRESSION ANALYSES PREDICTING PRODUCT INTRODUCTIONS BY REGULATIONS AFFECTING THE GLOBAL PHARMACEUTICAL INDUSTRY

	Independent Variables					
Dependent Variable	GENERIC SUBSTI-TUTION	NATIONAL FORMULARY	NATIONAL HEALTH PLAN	ACCEPTS NONDOMESTIC CLINICAL TESTING	R&D PRICING INCENTIVES	COMPULSORY OUT-LICENSING
First Model						
CPRINTRO						
R^2=.006[a]	n.s.	n.s.	- .043	- .052	n.s.	n.s.
Beta[b]			-2.232	-2.682		
T			.026	.007		
Sig T						
Second Model						
CPRINTRO						
R^2=.006[a]	- .041	- .072	- .055	n.s.	n.s.	.054
Beta[b]	-1.798	-2.836	-2.837			1.863
T	.072	.005	.005			.063
Sig T						

a - adjusted R^2
b - standardized beta weights
c - denotes significance at the $p \leq .001$ level

First, it is notable that the regulations showing any relationship are anti-competitive in nature. Except for compulsory out-licensing and product introductions, each of these slight relationships was negative, as expected. In a purely competitive environment, initial use of such constraints would be likely to deter market introduction. The actual environment, however, has a long history of regulation, and this may have upset balance of the market. The country sample in this study represents considerable purchasing power for pharmaceuticals (approximately three-fourths of the world market). In the last two or three decades, buyer power has exerted itself to such an extent that pharmaceutical firms cannot avoid these regulations and must comply to access the largest markets. This is consistent with the definition of an industry with a high degree of globalization drive, that is, subject to forces which encourage the firm to operate across many national boundaries (Yip 1991).

It is also interesting to examine differences among firms' strategy relative to regulation. Table 25 reports these same regulations regressed, in six stepwise equations, upon product introductions grouped by firm's home country. Adjusted R^2s range from .030 for national health plans to .136 for generic substitution. These are all considerably more predictive than the general regulatory equation with a predictive power of .006.

TABLE 25

STEPWISE REGRESSION ANALYSES PREDICTING PRODUCT INTRODUCTIONS BY REGULATIONS AND COUNTRY OF ORIGIN

Dependent Variables

	FRENCH FIRMS	ITALIAN FIRMS	GERMAN FIRMS	ENGLISH FIRMS	USA FIRMS	JAPANESE FIRMS
Independent Variables - Standardized Beta Weights						
GENERIC SUBSTITUTION						
Adjusted R^2 = .136	-.141	-.130	n.s.	n.s.	n.s.	-.372
NATIONAL FORMULARY						
Adjusted R^2 = .110	-.098	.194	n.s.	.095	n.s.	-.216
NATIONAL HEALTH PLAN						
Adjusted R^2 =.030	n.s	n.s.	.179	n.s.	n.s.	n.s.
ACCEPTS NONDOMESTIC CLINICAL TESTING						
Adjusted R^2 =.094	n.s.	.114	.117	.084	n.s.	-.213
R&D PRICING INCENTIVES						
Adjusted R^2 =.030	n.s.	n.s.	.075	n.s.	n.s.	.186
COMPULSORY OUT-LICENSING						
Adjusted R^2 =.051	-.084	n.s.	n.s.	.106	n.s.	-.184

Note: Beta weights are significant @ $p \leq .001$ level.

French, Italian, and Japanese firms all behave somewhat adversely relative to generic substitution (R^2 = .136). Japanese product introduction behavior is over twice as strong (-.372 Beta weight) as French and Italian firms. All significant relationships were negative, which is consistent with the study hypothesis.

The second strongest relationship is with national formularies (R^2 = .110). As with generic substitution, French and Japanese firms had negative Beta weights (-.098 and -.216 respectively). However, Italian and English firms showed positive Beta weights (.194 and .095 respectively). The study hypothesis is partially supported with regard to national formularies. That is, at least for French and Japanese firms, national formularies are negatively related to product introduction strategies.

Acceptance of nondomestic clinical testing was hypothesized to have a positive relationship with product introduction behavior. In relationships which were significant, three of the four were positive. Italian, German, and English firms all introduced more products into countries which accepted nondomestic clinical testing. Japan, on the other hand, had a Beta weight of close to double the other three but with a negative valence. This can be rather easily explained by a general strategy of Japanese firms, which has kept them operating primarily domestically until very recently (Yashikawa 1989).

Compulsory out-licensing appears to affect product introductions by some of the study country firms (R^2 = .051). As hypothesized, the predicted relationships were negative with French and Japanese firms. English firms did, however, introduce products significantly more often under compulsory out-licensing. This is easily explained because their domestic market was the only country in which the regulation has been consistently enforced.

National health plans were expected to have a negative relationship with product introductions. This is not the case. German firms appear to introduce more products into countries with than those without national health plans. The United States is the only study country not to have such a plan. Since German firms are not introducing as many products into the United States or Japan (see Table 26), this could be a function of a Europe based strategy rather than aversion to countries without national health plans.

TABLE 26

STEPWISE REGRESSION ANALYSIS PREDICTING PRODUCT INTRODUCTIONS BY COUNTRY OF ORIGIN

Independent Variables	FRENCH FIRMS	ITALIAN FIRMS	GERMAN FIRMS	ENGLISH FIRMS	USA FIRMS	JAPANESE FIRMS
Dependent Variable - Total Firm Product Introductions						
Adjusted R^2 = .082						
Beta weights	-.178	-.116	n.s.	n.s.	-.093	-.323

Note: Beta weights are standardized and significant @ $p \leq .001$ level.

Descriptive product introduction statistics by regulatory condition are provided in Table 27. Table 28 sets forth a breakdown of product introductions into country markets by country of origin.

R&D pricing incentives appeared to be related to strategies of Japanese and German firms, both countries' firms had positive Beta weights. The stronger relationship with Japanese firms (.186) can be explained by its strong domestic marketing strategy and the Japanese R&D incentive price program. German firm strategy has less than half the strength relationship (.075). Though this relationship is significantly positive, with an R^2 of only .030, existing R&D pricing incentives cannot be considered a success in attracting pharmaceutical product introductions into country markets.

Finally, the potential for sales of drug products over-the-counter (OTC)--that is, without a physician's prescription--might also affect product introduction regression analysis was run using three conditions as dummy variables: CNS drugs introduced into the United States, all categories of drugs introduced into France, and all others. The study sample of 504 firm-level observations over six years yielded 27,218 observations when split by country of introduction and nine therapeutic classes. As expected,

TABLE 27

PRODUCT INTRODUCTIONS INTO REGULATORY CONDITIONS

	Generic Substitution	National Formulary Systems	National Health Plans	Acceptance of Nondomestic Clinical Testing	R&D Pricing Incentives	Compulsory Outlicensing
Regulation in Effect						
Products Introduced	129 (75%)	138 (80%)	44 (25%)	132 (76%)	104 (60%)	77 (45%)
Observations by firm and year	72	111	33	105	88	49
Regulation Not in Effect						
Products Introduced	44 (25%)	35 (20%)	129 (75%)	41 (24%)	69 (40%)	96 (55%)
Observations by firm and year	28	32	110	38	45	84
Total Products Introduced	173 (100%)	173 (100%)	173 (100%)	173 (100%)	173 (100%)	173 (100%)
Chi-square	35.26	50.99	48.86	35.26	88.5	88.5

Note: Chi-squares are significant @ $p \leq .001$ level.

TABLE 28

STEPWISE REGRESSION ANALYSES PREDICTING PRODUCT INTRODUCTIONS INTO COUNTRY MARKETS BY COUNTRY OF ORIGIN

Independent Variables - Product Introductions into countries:	FRANCE	ITALY	GERMANY	ENGLAND	USA	JAPAN
Adjusted R^2 =	.037	.136	.112	.051	.114	.107
Dependent Variables/ Country of Introduction - Standardized Beta Weights						
FRENCH FIRMS	n.s.	-.094	n.s.	-.083	-.164	n.s.
ITALIAN FIRMS	n.s.	.294	n.s.	n.s.	-.122	n.s.
GERMAN FIRMS	.104	n.s.	.247	n.s.	-.114	n.s.
ENGLISH FIRMS	n.s.	n.s.	n.s.	.106	n.s.	n.s.
USA FIRMS	n.s.	-.101	n.s.	n.s.	n.s.	n.s.
JAPANESE FIRMS	-.130	-.208	-.182	-.184	-.351	.330

Note: Beta weights are significant @ $p \leq .001$ level.

behavior. The study countries have very little variation in regulations which govern introduction of new chemical entities as OTC products.

England, West Germany, Japan, and Italy all require that new products be classified as prescription-only for the first five years after introduction. France is slightly more lenient in requiring prescription-only status for a minimum of only two years. The United States has the most flexible categorization laws on the books; however, in effect these laws are as or more restrictive than five years. In addition, central nervous system drugs and other drugs with a high potential for consumer abuse may never be reclassified to OTC status. Nevertheless, a multiple even with the statistical power of this enormous sample size, neither product introductions into France or CNS

introductions into the United States loaded into the equation.

Though a multivariate model is unable to substantially predict product introduction strategies, a comparison of introduction frequencies with respect to presence or absence of each regulation does provide some insights. The differences between the number of product introductions with and without each regulation in effect and without were significant (Chi-square significant @ $p < .01$). Policy makers should note three specific results. First, the strong positive relationships between product introductions and generic substitution and national formularies is contrary to the negative impact hypothesized. Second, the other anti-competitive regulations, national health plans, compulsory out-licensing, and non-acceptance of foreign clinical trials do relate negatively to product introductions as hypothesized. Third, when controlling for domestic activity, fewer product introductions were made into countries with R&D incentives.

Table 29 provides frequencies of introductions into country markets by country of origin. It is interesting to note that the largest block of introductions are generally into domestic markets. However, firms from three countries of origin did introduce a larger percentage of products into foreign markets: German (60%), US (61%), and English (82%).

TABLE 29

FREQUENCIES OF PRODUCT INTRODUCTIONS INTO COUNTRY MARKETS BY COUNTRY OF ORIGIN

	FRANCE	ITALY	GERMANY	ENGLAND	USA	JAPAN
Total Number into country	24	13	33	22	44	39
FRENCH FIRMS foreign - 1 (33%) total - 3	2	-	1	-	-	-
ITALIAN FIRMS foreign - 0 total - 0	-	-	-	-	-	-
GERMAN FIRMS foreign - 18 (60%) total - 30	5	5	12	4	3	1
ENGLISH FIRMS foreign - 28 (82%) total - 34	3	2	8	6	14	1
USA FIRMS foreign - 43 (61%) total - 70	11	5	12	11	27	4
JAPANESE FIRMS foreign - 3 (8%) total - 36	1	1	-	1	-	33

A larger sample or different research design probably would not yield a stronger effect for several reasons: (1) the statistical power of the research is high; (2) a portion (76 percent) of the world market is represented the sample; (3) The sample size is large; (4) six countries have been sampled; (5) nine therapeutic classes are included; (6) the secondary databases are widely accepted; (7) the sample period is long (1982-1987); and (8) an exaggeration effect is created by the dummy coding of regulation variables. For all these reasons, if an effect does exist, it should have been apparent in a study such as this one. The fact that the study hypothesis generally was not supported by these findings suggests interesting implications for macromarketers and public policy makers.

This lack of the expected relationships between regulation and behavior in the pharmaceutical industry in these countries supports the notion that regulators have been able to exercise a free hand over the industry with respect to anti-competitive legislation without impacting availability of drugs. It is still possible, however, that if this free-hand approach continues, especially in terms of increased compulsory out-licensing, it may affect future product introductions. The current state of regulation and enforcement has not impacted strategic product introduction decisions. This may be because they are based upon contribution margins, not sunk R&D costs. Compulsory out-licensing, however, may have the potential to impact future

product introductions by reducing profit potential for the industry and influencing R&D investment decisions.

Summary

This chapter has provided a discussion of the analysis and results of this dissertation. In summary, the three objectives of this study have been fulfilled by empirical testing of three families of hypotheses. The first hypothesis, to relate past product acquisition and market access strategies to current strategy, was partially supported. The second was to examine the relationship between product acquisition and market access strategies and performance. Specifically, the effect of licensing strategies versus internal strategies were related to sales and market share and produced two models with reasonably good predictive values (R^2 = .602 an .632 respectively). The third, to examine the relationship between regulatory issues and product introduction, was not supported. A summary of study findings is presented in Table 30.

The first objective was met with an empirical analysis of four hypotheses. Hypothesis 1a was partially supported with a positive linear relationship between past in-house product development and current product development within a therapeutic class. Test of hypothesis 1b provided nominal support in a statistical sense but provides little support for the relationship between past in-licensing and top-performing drugs. Hypothesis 1b showed no relationship

between past in-house product development and top-performers.

The third hypothesis in this first family (1c) was empirically tested to study the relationship between past breadth of product development and current product development success. The relationship was expected to be an inverted U-shaped curve and was found to have a positive linear relationship, partially supporting this hypothesis.

The last hypothesis of this family (1d) showed a significant positive relationship between past and current product introductions to a country. Hypothesis 1d was fully supported.

The second objective was met with two models predicting performance. Performance measures used are sales and market share. The predictors used in both models are product acquisition, market access, licensing strategies, and industry success criteria. Internal product acquisition strategy, product development, was found to be more important in predicting sales and market share than in-licensed products. At the same time, external market access strategy (out-licensing) was found to be more predictive than product introductions.

TABLE 30

SUMMARY OF STUDY FINDINGS

HYPOTHESIS	SUPPORT	KEY FINDINGS
1-a	$R^2 = .130_b$	Past in-house product development and past in-licensing have positive linear relationships with current in-house product development.
1-b	$r^2 = .001^c$	Past in-licensing has a very small, positive linear relationship to incidence of top drugs.
1-c	$r^2 = .032^a$	The breadth of products developed has a positive linear relationship to the number of products currently developed. A positive quadratic relationship is also significant.
1-d	$r^2 = .064^a$	The number of products previously introduced into a country is positively related to the number of current product introductions.
2-a	$R^2 = .594$	In the multivariate model, sales is a significant linear function of total products developed (negative), breadth of product development (negative) and product line breadth, products introduced, products in-licensed, products out-licensed, top drugs (negative), and breadth of top drugs.
2-b	$R^2 = .683$	In the multivariate model, market share is a significant quadratic function of total products developed (negative), breadth of product development, and breadth of product line, plus a linear function of out-licensed products and products introduced.
3	$R^2 = .004^c$	Regulatory issues were found to be non-significant in relationship to product introductions. Compulsory out-licensing was the exception with a slight (Beta = .004) relationship. When compulsory out-licensing was recorded to reflect enforcement the same R^2 was obtained using three variables: generic substitution, national health plans, and compulsory out-licensing.

a = significant at $p < .01$
b = significant at $p < .001$
c = statistically significant but not managerially significant

Breadth of product development showed a consistent relationship with sales and market share. Its inverted U-shape relationship is consistent with Foxall's (1983) notion of success with constrained search for new products. Product line breadth in both models and product introductions in the market share model showed U-shaped relationships which suggest presence of learning curve effects, positive economies of scale, and/or specialized management and marketing.

Industry success criteria did not predict sales and market share in the same manner. Market representation failed to be predictive in either model. Breadth of top-performing drugs was very important in the sales model but did not add significantly to the market share model.

The third objective was met with an empirical test of hypothesis 3, which related regulatory issues to product introductions in a country. Compulsory out-licensing was the only regulatory issue found to have a significant overall relationship with product introductions. However, when product introductions were analyzed by firm home country it was found that some countries' firms introduce fewer products into countries with generic substitution (France, Italy, and Japan) and countries with compulsory out-licensing (France and Japan). In general France introduced fewer products into countries with anti-competitive regulations. Italy introduced somewhat fewer into countries with generic substitution and Japan

introduced fewer to all non-domestic countries than at home. This hypothesis was partially supported in a statistical sense but provided nominal explanation for product introduction behavior.

Chapter VI addresses the managerial, public policy, and methodological implications, as well as limitations of the study, and recommendations for further research.

CHAPTER VI

CONCLUSIONS AND IMPLICATIONS

Introduction

International business literature has been missing a balanced and empirical approach to the study of licensing strategies and its relationship to performance. The relationships conceptualized by Foxall (1983), Meyer and Roberts (1988), Ohmae (1989), and Porter (1990) were synthesized and adopted to develop models for such an empirical analysis. The models incorporated internal strategies of product development and introduction and external strategies of in-licensing to obtain products and out-licensing to access markets. First, past in-house product acquisition and market access behaviors were related to current strategies. Then, past and current strategies where related to two performance measures, sales and market share. Finally, since international business must access numerous country markets, product introduction strategies were examined as a function of relevant regulatory issues.

This study has provided an empirical analysis of the strategy-performance relationships reviewed above. Based upon the findings presented in Chapter V, this chapter

presents a revised global strategy framework, a revised global pharmaceutical product portfolio, research and public managerial implications of the study followed by public policy implications and recommendations. The conclusion of this chapter summarizes study limitations and contributions.

Research Implications

This section will relate each of these families of hypotheses to the literature. A summary of key study findings as they relate to the literature can be found in Table 31.

Past and Current Strategies

The four hypotheses in the first family were all supported to varying degrees. The first, which relates past in-house product development and past in-licensing to current product development, was fully supported. The stronger relationship is between past and current product development. The weaker relationship is between past in-licensing and current product development. Both relationships are positively linear, logically indicating that increased product development success evolves from an increase in interest in the product class both by development activity and, to a lesser extent, indirectly by in-licensing. This is very similar to Meyer and Roberts' (1988) notion of technology focus, using a product category rather than a type of technology. It is also consistent with the portion of Foxall's theory (1983), which positively

TABLE 31

FINDINGS IN CONTRAST TO PREVIOUS LITERATURE

PROPOSITION	AUTHOR (year)	THIS STUDY
Products are currently selected for country markets without regard to product complementarity.	Anderson and Coughlan (1983)	consistent
A constrained search for innovation is positively related to performance.	Foxall (1983)	consistent
Technology focus is important relative to performance.	Meyer and Roberts (1988)	consistent
Strategic alliances enhance firm performance.	Ohmae (1989)	consistent
Strategic alliances lead to mediocrity.	Porter (1990)	consistent (4-6 years)
Networking, or strategic cooperation, contributes to achievement of firm goals.	Thorelli (1990)	consistent
Strategic alliances lead to mediocrity.	Porter (1990)	inconsistent (short-run)

relates search within a limited number of categories to success. This study shows in-licensing to have a negative impact on market share during the later portion of the study period. These results may also be consistent with Porter's (1990) theory which associates long term success with internal rather than external product acquisition strategies.

The second hypothesis is partially, but nominally, supported with a linear relationship between past in-licensing and producing top-performing drugs. These results did not show a significant relationship between product development and producing top-performing drugs. This is inconsistent with Foxall (1983), Meyer and Roberts (1988), and Porter (1990). However, the product categories samples have been determined to have heterogeneous relationships in the models for both hypotheses 1a and 1b.

Differences in the sample across therapeutic classes suggests that a moderator variable is at work between product development and in-licensing, and the two dependent variables (current product developments and top-performing drugs). Further studies should address this issue. The moderator(s) may be related to stage of the life-cycle associated with the therapeutic class, presence or absence of top-performing drugs within the therapeutic class and/or complementarity across product classes. Other variables may be less easily quantified; e.g., competition within the class, existence of related technologies within the firm,

strategic partnerships, and corporate mission statements. Further research is also needed both in technology-intensive and less technology-intensive industries. Similar findings might be expected in high-technology industries. However, industries which do not require an extensive financial and time commitment for product development may differ significantly. The relationship between in-licensing and product development and top-performing products is likely to be much stronger in low-end technologies because these types of products can be more readily copied or improved upon.

These first two hypotheses (1a and 1b) both predicted a negative quadratic (inverted U-shaped) relationship between past in-licensing and both dependent variables. Findings of this study should not be construed to be inconsistent with these hypotheses. This is because the past variables were calculated with a time constraint which may limit variation in this relationship to less than what is needed to determine the relationship over the long term. Further studies should direct efforts towards studying a lag period in excess of nine years to detect the downswing in the hypothesized relationship.

The third hypothesis in this family relates past breadth of product development to current product development and was partially supported. The findings showed a small but significant linear relationship as well as a slightly smaller but significant positive quadratic relationship. As with the first two hypotheses, further

studies should investigate this relationship over longer time periods and split the data using one or more moderator variable.

The fourth and final hypothesis in this family relates past products marketed to current product introductions. This hypothesis was fully supported across country markets. However, variance between therapeutic classes within country markets was not examined and may provide additional insights. It also would be valuable and interesting to marketers to study this relationship in other industries and other countries.

There are two reasons to explore these relationships in other industries. The first is to test whether a similar relationship exists in industries with similar globalization drivers. That is, are other high-technology, long term R&D, and rapidly changing industries behaving in the same manner? Second, is there a difference in behavior when the globalization drivers affecting an industry are different? For example, a globalization driver operating on the information industry is favorable logistics: for instance, electronic data transmission capability. Would the behavior of firms in the information industry differ significantly from the behavior of pharmaceutical firms? Also in terms of globalization drivers, it would be interesting to study behavior of firms with lesser globalization drivers. Multiple studies might contribute to a methodology for

measuring globalization drive and determine thresholds which stimulate firms to attempt access to global markets.

The relationship between products marketed in the past and current products introduced should also be studied in countries other than the largest markets available to the firm or industry. Country markets may be attractive to firms and industries for reasons other than size. Proximity to manufacturing, home office, or raw materials may mitigate sheer size and warrant inclusion and/or control in further studies. Competitive strength and strategic alliances may also play a part in market access strategies.

Strategy and Performance Goals

The results of this study indicate need for further research relative to the strategy performance models developed for the pharmaceutical industry. First, the time frame should be expanded to include information beyond the ten-year scope of the strategy variables used in this study. Second, differences between product categories should be addressed in subsequent models. These differences may be reflected in product complementarity, relative product importance, product quality, and stage in product life-cycle. Third, additional predictive information should be sought. For example, differences in managerial focus and marketing programs may provide important information.

A more sophisticated model for the pharmaceutical industry would incorporate moderator variables as suggested

in this study and identified in other research. A longitudinal path-analytic or structural equation model would be well suited to this purpose.

The findings of this study are not generalizable without further research in both similar and dissimilar industries. The single industry design of this study offers a measure of control over regulation and globalization drivers. Subsequent studies should also address industry specific variables which maximize the opportunity to identify moderator variables which operate between strategy and performance. It is suggested that future samples address variation in technology, regulatory influence, and globalization drivers to further illuminate their role in the strategy-performance relationship.

Regulation and Product Introductions

As with the research implications for the strategy-performance relationship, future research relating regulation to market entry decisions should address other levels of technology and various globalization drivers. Research implications specific to the pharmaceutical industry relate to compulsory out-licensing and R&D incentives.

First, compulsory out-licensing has the potential to impact a large portion of global pharmaceutical volume with a single stroke through EC regulation. An understanding of the nature and extent of negative externalities which may

accrue to other countries the long-term ramifications on the industry are worthy and complex research goals.

Second, signs of industry consolidations may be reflective of extraordinary and growing pressure on the industry. The nature, the extent, and the reach of such pressure needs to be determined to protect social welfare interests.

A Revised Global Strategy Framework for Pharmaceuticals

The global strategy framework initially proposed in Chapter II has been revised to reflect the findings of this dissertation and is presented in Figure 9. Market representation has been eliminated from the framework since it was not shown to significantly impact sales and market share.

Another interesting facet of the revised model is presence of three quadratic variables: products developed, product line breadth, and breadth of products developed. All three variables have been shown to have an inverted U-shaped relationship with the performance measures. It is possible that they are also similarly moderated by other variables. Subsequent studies will require specific attention to the ceiling effect present in each of these quadratic variables so that separate path analytic models can be studied for each condition of the variable: that is, at a low value during the upswing, at higher values accompanied by the downswing, and especially at the mid-range as associated with acceptable and desirable

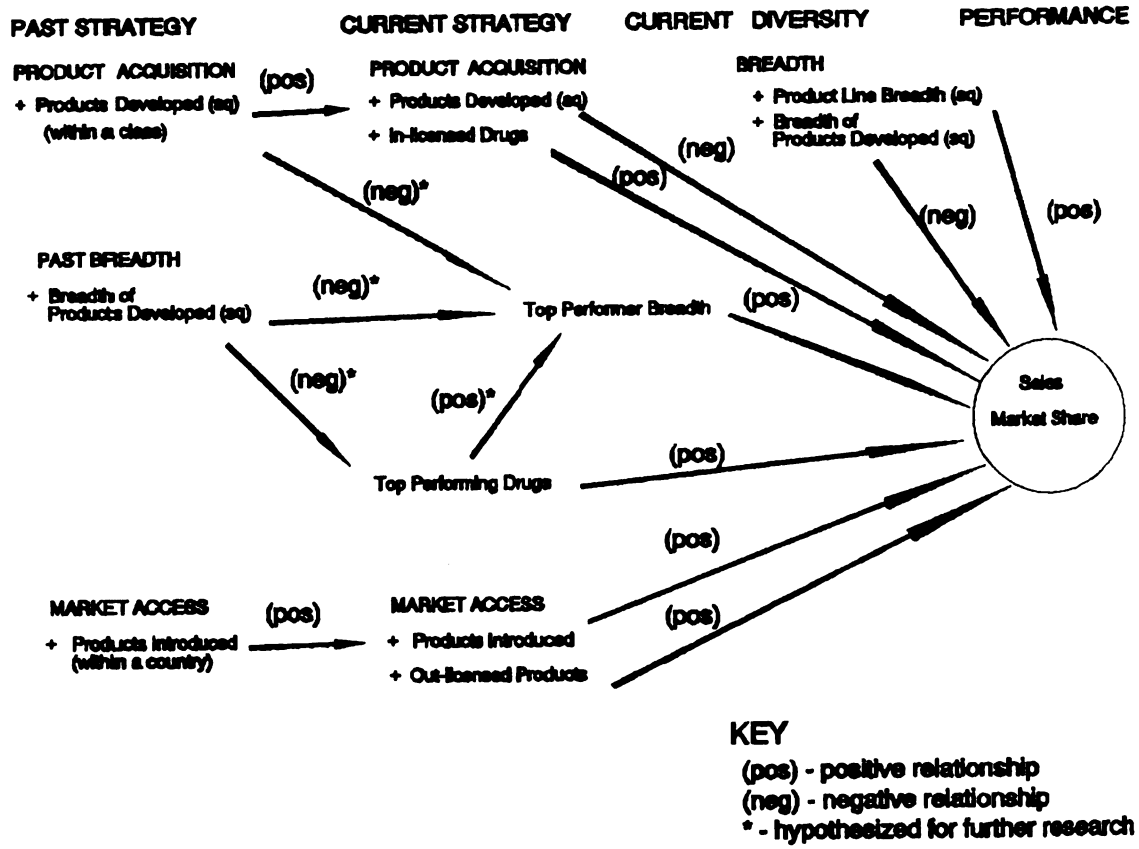


FIGURE 9 REVISED GLOBAL STRATEGY FRAMEWORK FOR PHARMACEUTICALS

performance outcomes. Empirical studies can assist researchers in identifying firms and groups of firms for case level investigation for each of these quadratic variables.

The next section discusses managerial implications and presents a revised pharmaceutical global product portfolio based upon the study findings.

Managerial Implications

Past and Current Strategies

There are several managerial implications of the first family of hypotheses. First, the relationship between past and current strategies has competitive implications. Second, the relationship between past breadth of product development and current product development has R&D management and in-licensing strategy implications.

Past product development and in-licensing predict only about thirteen percent of the variance in current product development. Although this study does not bring to light alternative predictive sources, it does provide a relative weight for managerial knowledge of past strategy information. Observing competitors' product acquisition strategies is not sufficient to predict their future product development strategy. In the pharmaceutical industry, and possibly other industries with costly and lengthy R&D, product development appears to be considerably more predictive of sales and market share than in-licensing. This seems to be

the case over a time period approximately equal to the effective patent life in the pharmaceutical industry. There are also differences in this relationship between therapeutic classes which may be attributable to other, as yet unidentified, variables such as contribution margins and availability of product substitutes.

The relationship of past in-licensing to current strategies is also of interest to firms planning internal versus external market access strategies. That is, choosing to introduce a product directly or out-license it to gain market access. The small degree of the relationship between in-licensed products and future developments within that product class should provide reasonable assurance that out-licensing to a firm will not in itself result in subsequent product competition in the short term. However, this relationship has only been tested over a nine-year period and shows some indication of strengthening slightly beyond that time frame. The nature of this relationship may be different in industries with shorter product development cycles.

Unlike product acquisition strategies, a strong relationship between past and current market access strategies does not exist. This is consistent with Anderson and Coughlan's (1987) notion of pyramiding products within established international channels without regard to product complementarity. The relationship is significant, but very small. Therefore, in scanning the competition, very little

value can be placed on predicting where a particular firm will market products based upon past market access strategy. This has reverse implications which lead to questions regarding the reason for lack of a stronger relationship. One reason may be under-utilization of established global channels. That is, existing distribution channels should support a greater number of products to maximize the benefits of maintaining these channel relationships. Managers should evaluate country channels with an eye to maximizing their potential. Complementary products should be sought (through internal development or in-licensing) to more efficiently utilize these channels.

Strategy and Performance Goals

The strategy-performance model developed and revised in this study suggest three sets of managerial implications. The first set is concerned with product acquisition strategies; the second is concerned with market access strategy; and the third is concerned with industry success criteria. The last set is used to revise the pharmaceutical global product portfolio initially presented in Chapter III.

Internal product development appears to have a stronger relationship with subsequent product development, sales performance, and market share than in-licensing does with product development. In-licensing does contribute to sales and market share. However, firms with a diverse, but not over-broad, base of product development have a competitive

edge over firms who do not. Managers may wish to plan product acquisition strategies to augment rather than replace product development for a few product categories. These findings also suggest that multiple-product category firms perform better than single-category firms in terms of both sales and market share. The relationship holds whether products are in-licensed or developed in-house. However, products developed in-house are considerably more predictive of sales and market share. The major implication is that product diversification is highly desirable whether by internal or external means.

External market access through out-licensing appears to have a stronger relationship with sales and market share than direct product introduction. This relationship is strong in the short-run for pharmaceuticals and likely to hold true in other highly technical or highly regulated industries. Managers should out-license products where and when necessary to reach key markets. This is applicable when goals are short term sales oriented and when market share is the goal.

Finding and maintaining the appropriate degree of product diversification involves selecting a few strong categories for product development and in-licensing to fill out the existing product line. The number of product categories should be limited because performance increases with the number of categories up to a point and then drops off. The number of products actually in-licensed shows a

positive relationship. Together these findings suggest that a critical mass is necessary to enable specialization to occur. To this end, firms should in-license products to fill out their product line, thereby justifying specialization. This also implies that appropriate selection of in-licensed products which augment the current product line is more important than the number of in-licensed products.

Market access by out-licensing seems to be consistently associated with improved performance in the pharmaceutical industry. On the other hand, direct product introductions seem to behave in a manner similar to product line breadth, first decreasing and then increasing relative to performance. Here again, it appears that a critical mass is preferable. This may be due to the opportunity to specialize. Market access by either out-licensing or product introduction is important in predicting sales and market share. However, the percent of market representation was not predictive, which is consistent with a mature industry.

The most interesting and valuable implication of this study is that there are strong differences, possibly managerial, in <u>how</u> products are introduced. In the majority of firms, product introductions have a distinctly negative relationship with performance. The industry leader, Merck, has an equally strong <u>positive</u> relationship between product introductions and performance. Additionally, firm reports refute the myth of aging drugs pulling down performance.

Much to the contrary, Merck is enjoying a considerable profit contribution from older products (Mayer 1990). As a whole, this information paints a picture of superior channel and licensing management by Merck.

In summary, managers must strive for selective diversification into each of the major country markets. Channels in each country should be filled with complementary products. These products may be developed internally or externally. Firms with inadequate resources to support the learning curve associated with managing a critical mass of multiple product categories should not pursue a diversification strategy. Also, firms which choose to diversify should plan a sufficiently broad product line to maximize channel efficiency.

Pharmaceutical industry criteria which were used to develop the product portfolio in Chapter II were found to be more useful in predicting sales versus market share. Top-performer breadth was not predictive of market share, probably because only one firm had top performers in three or more product categories. Top performers remained predictive however, and top-performer breadth can be considered as a benchmark indicating success in both market access and product development. Managers should strive for a balanced line of products which maximize utilization of market channels. Top-performing drugs alone do not produce high level performance. They also require well developed specialized market channels. Continuous, well managed

product development and specialized marketing channels are required for consistently high firm performance. The next section presents a revision of the global product portfolio to reflect the managerial implications of this study.

Revised Pharmaceutical Global Product Portfolio

As originally developed, the global product portfolio incorporated two industry decision rules. The first rule suggested the necessity of a firm marketing three top-performing drugs. The second rule suggested that a firm must market its products in the three key markets: Japan, the United States, and West Germany. The results of this research have shown that both top-performing drugs and market representation are directly or indirectly predictive of sales or market share in the pharmaceutical industry.

The portfolio model has been revised to incorporate additional study findings directly associated with high sales performance and market share in the industry (see Figure 10). First, top-performing drug sales were replaced in the left bar with sales accumulated by several high-performing drug products. This enables a firm to evaluate the breadth of its product line both within a therapeutic class and, by comparing drug sales bars, across therapeutic classes. The portfolio also encourages strategists to evaluate current utilization of their distribution system by therapeutic specialty. Use of the portfolio to design

product lines, rather than simply track top performers, is useful to managers.

The right bar continues to indicate market presence in the six largest pharmaceutical markets. Access to these markets should reflect a concerted effort to manage channels necessary to market both existing products and those under development. An imbalance between market representation and marketable products in a therapeutic class will point management towards an appropriate strategic remedy. It is important to evaluate each product line relative to all markets.

The portfolio can also be used to evaluate use of marketing channels within country markets. This could be done by using separate portfolios for each country market with a product sales bar to record sales of individual products. This would to enable managers to visualize both product line depth and breadth within the country market.

Insufficient market representation associated with large sales may indicate lost sales volume opportunity in ready markets for these proven performers. Insufficient product sales may indicate a need to enlarge a product line with in-licensing, train detail personnel in marketing the therapeutic class, or a need to redirect firm resources to other therapeutic classes.

It is especially important when top-performing drugs are in the R&D pipeline. Good product line and channel

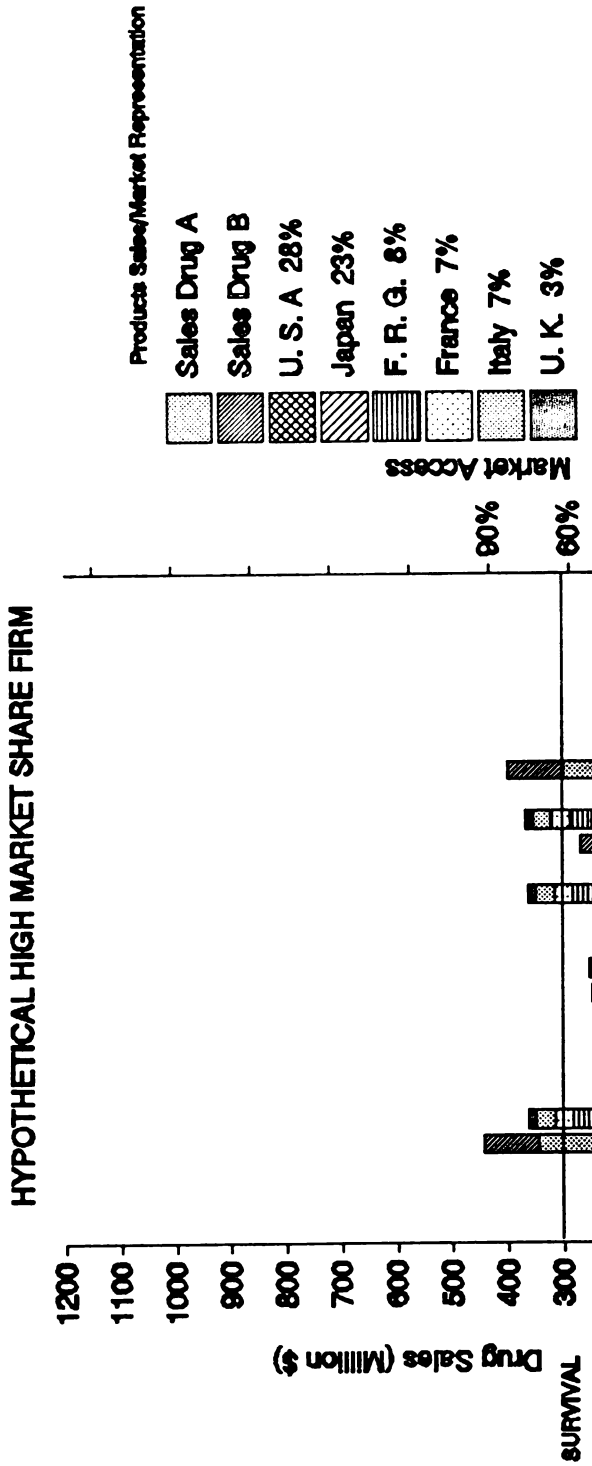


FIGURE 10 REVISED PHARMACEUTICAL GLOBAL PRODUCT PORTFOLIO

management also assure the firm of a functioning system when top performers are added to the product line.

Regulation and Market Decisions

This study also relates product introductions to regulatory issues which affect pharmaceutical product introductions into six country markets: France, Great Britain, Italy, Japan, the United States, and West Germany. While there is variation in regulatory issues across countries, product introductions appeared not to vary widely with regulations. The significant relationship is with compulsory out-licensing and is surprisingly small. The implication to managers (and policy makers) in the pharmaceutical industry is that there appears to be profit potential regardless of regulatory condition.

However, since Great Britain and Italy are the only countries to consistently enforce compulsory out-licensing regulation the situation has the potential for considerable change. If all the countries with existing regulations (France, Italy, and Japan) begin to enforce out-licensing, the portion of the global market under this anti-competitive regulation would increase from 4% to 41%. If the EC adopts a similar regulation, over 26% of the world market would be affected by a single regulatory change. With this competitive pressure the profit potential for the industry would inevitably decrease, at least in the short run,

because contribution margins may decrease substantially. However, as long as there are contribution margins available and significant barriers do not arise from regulation and competition, existing products are likely to be introduced. In the long run, lower pricing induced by compulsory out-licensing will render R&D investments more risky and less rewarding. Managers should direct research efforts towards understanding the short- and long-run ramifications of compulsory out-licensing. The following section discusses the public policy ramifications of these findings.

Public Policy Implications

There are also implications for public policy makers in Western Europe, Japan, and the United States. The first implication concerns the choice of short- and long-term strategies. The second is more specific to regulations affecting the pharmaceutical industry, yet has more general implications as well.

The goal of policy in regulating the ethical drug industry has been to provide safe, effective, accessible products to the public. To this end, numerous special regulations have been imposed upon the industry. These may have the effect of reducing profit potential for the industry and increasing the risk of subsequent R&D investment. Despite the current high degree of regulation, the industry appears relatively unaffected in its product introduction behavior. The only relationships, though

slight, are with anticompetitive regulations. This suggests either that the industry was able to meet product introduction criteria during the period studied or that it has no choice about which markets to access. Findings support the notion that policy makers in the context of this study have had a free hand in the industry because high contribution margins induce product introductions even under the most stringent of regulatory environments.

As discussed in the managerial implications section, this situation could change dramatically with increased enforcement of compulsory out-licensing. Current firm strategies would no longer yield the same ROI. This might not affect product introduction strategy for up to fourteen years (the average product development time frame). This is because firms will continue to seek returns on sunk R&D costs. However, future product introduction strategies may include a reduction in R&D investment (and new product development) to reflect lower industry ROI. Policy makers thus should carefully consider the potential impact of compulsory out-licensing before enforcement. As much as 41 percent of the global market would be affected if existing regulations were enforced. Countries which do not require out-licensing may experience higher pharmaceutical pricing as firms continue to maintain profit margins. If the percentage of the market enforcing this regulation changes substantially the social impact in non-enforcing countries may be as dramatic as in those which do enforce

compulsory out-licensing. The long-term effects might be to stifle R&D thereby reducing the availability of new and improved drug products.

Another regulatory issue, incentive pricing for firms engaging in R&D, was also studied. In the context of other regulations affecting the industry, no significant connection to product introduction was found, with the exception of German and Japanese firms. This suggests either that the industry does not significantly alter strategic behavior in response to this incentive, or that present R&D investment is so far removed from the incentive as to leave current behavior unaffected. The strongest relationships were with firms whose home country has pricing incentives. Thus, this incentive appears to be an inadequate motivator for foreign industry R&D and requires rethinking if future R&D is to be induced on a global scale. When examined without other regulations and controlled for domestic activity, significantly fewer product introductions were made into countries with existing R&D incentives.

The study sample represents the largest country markets (76 percent of global volume) but does not address the smaller markets. Smaller country markets, e.g. those of South America and Africa, tend to have few, if any, regulatory restrictions on the industry. These countries may not have the resources, the sophistication, or the desire to regulate the industry. Furthermore, if these smaller markets were regulated, they may detract product entries

because the cost of satisfying regulatory requirements may exceed potential profit margins. As a result, pharmaceutical products would not be available to consumers in such countries.

The single industry nature of this study has provided an opportunity to closely examine the regulatory issues which impact product introduction. The industry has been characterized as subject to numerous globalization drivers. These include high R&D costs, a rapid rate of technological change, and an increasing rate of technological change. By definition, these factors force an industry to seek global markets in order to survive. Therefore, firms must and do comply with whatever regulations are imposed.

One consequence of noncompliance in an industry with high globalization drivers is attrition due to insufficient market access. Attrition can also result from insufficient product development due to inadequate or poorly managed resources. Evidence of this has been noted recently with respect to aging patents (SmithKline's Tagamet) and the increasing incidence of mergers. Three mergers between major players have occurred in the last three years: (1) SmithKline and Beecham, (2) F. Hoffman-LaRoche & Co., and (3) Bristol-Myers Squibb. This suggests that high costs of R&D, including those imposed by regulatory bodies, may actually have had a negative impact upon long-term availability of drugs. Policy makers need to consider the long-term implications of loss of competition in the

pharmaceutical and other industries in which R&D commitment is of vital public concern.

To restate the potential problem, anti-competitive regulation may have little effect on industries with a high globalization drive, at least in the short run. However, if enforcement of compulsory out-licensing increases, fewer new products may eventually reach the market as the industry attempts to maintain profits. The net long-term affect upon industry R&D may also be negative, resulting in a negative social impact. This is a fertile area for further research.

A second point revolves around the long-run effect of anti-competitive regulation, particularly for industries with an emphasis on R&D. The high cost of continuous R&D is one of the more compelling globalization drivers because it must be covered by profits from one or more market. If ROI is insufficient, the long-run effect is a reduction in R&D.

If firms must seek critical markets to survive, continued product introductions in these markets do not necessarily indicate a healthy industry. On the contrary, continued marketing in countries which require out-licensing may significantly affect future industry health because competitive pressures would reduce profitability and decrease capital available for R&D. To monitor unproductive or counter-productive regulatory effects upon the industry, academicians and policy makers may wish to develop measures for determining cross-country effects of compulsory out-licensing on pricing and profit contributions. Furthermore,

the current incentive programs should not be construed as global stimulators for future R&D. Instead, they appear to operate more in the domestic sphere. The danger here is the potential for policy makers to over-rely on these incentives to outweigh the effect of progressive enforcement of compulsory out-licensing.

In summary, the lack of relationship between the number of product introductions and these regulatory issues suggests that either (a) the industry is obtaining sufficient profits to support any regulatory demands thus far imposed; or (b) the industry health may be failing if these firms have no choice but to introduce products into anti-competitive regulatory environments to achieve contribution margin goals. Given the number of major mergers which have occurred in the past three years relative to the lack of previous mergers, the second explanation may be the more plausible one. The current industry situation may be attributable to the stiff regulatory environment and/or to lack of management expertise. If the explanation is either the regulatory environment or lack of management expertise, the problem is widespread.

The implication to policy makers in the six study countries is that during the study period pharmaceutical product availablity was not affected at least in the short-run. However, the long-run effects are not yet fully understood. This research is consistent with the notion that the long-term effects of stiff regulatory intervention

may eventually decrease availability of pharmaceutical products as a result of reduced industry-wide ROI and R&D investment. This decrease would be considered a negative social impact. Additionally, findings of this study also indicate that regulation is probably not the primary determinant of product introduction behavior.

Conclusion

This dissertation is limited in terms of its single industry nature, relatively short time frame, and the secondary nature of the data. Numerous unresolved issues remain for further research. These issues concern product acquisition strategy differences between product classes, the effects of licensing in the long run, differences in the strategy-performance relationship across industries, and potential ramifications of compulsory out-licensing on the pharmaceutical industry.

This study has, however, contributed to the academic literature statistically powerful, longitudinal, empirical tests of the relationships between (a) past and current product acquisition and market access strategies, (b) licensing strategies and firm performance, and (c) regulation and global strategy of pharmaceutical firms.

Existing literature has also been strengthened by the findings of this dissertation. First, Foxall's (1983) hypothesis concerning the positive relationship between a constrained search for new products and firm success was

supported in the pharmaceutical industry. Meyer and Roberts' (1988) technology focus was adapted to focus on product function and was supported. Porter's (1990) hypothesis concerning positive performance outcomes of internal innovation were supported.

Study results also indicated past strategic behavior consistent with Anderson and Coughlan's (1987) findings with respect to a disregard for product complementarity in utilization of international channels. Furthermore, these results showed superior sales and market share performance in firms which have accomplished product complementarity within their international pharmaceutical channels.

Contributions to the pharmaceutical industry include an empirical test of its commonly used success criteria and a synthesis of these criteria into an industry-specific product portfolio. The study empirically showed a relationship between these criteria and market share and sales. The global product portfolio has been revised for to increase its managerial value by incorporating additional predictive criteria for the industry.

It is hoped that academicians will find this dissertation useful as a basis for further research in global licensing strategies, and that pharmaceutical executives will find these results insightful.

APPENDICES

APPENDIX A

LITERATURE REVIEW MATRIX

TABLE A-1

LITERATURE REVIEW MATRIX

	INDUSTRY	MARKETING STRATEGY	ECONOMICS	INT'L BUSINESS
STRUCTURE	Burstall 1985 Comanor 1986 Egan, Higinbotham & Weston 1982 Faro 1990 Gabowski, Vernon & Thomas 1978 Schnee 1979 Sherer 1985 Schwartzman 1976 Slatter 1977 Silverman & Lee 1974 Temin 1980	Aaronson 1986 Hofer & Schendel 1987 Hutt, Mokwa & Shapiro 1985 Wu 1988	Brada 1980 Caves 1982 Carlson 1983 Comanor 1986 Glennie 1971 Goedde 1983 Grabowski & Vernon 1978 Hartley, Lavers & Maynard 1986 Heiduk 1982 Kirim 1985 Moran 1986 Scherer 1985 Scott & Reekie 1985 Tesler, Best, Egan & Higinbotham 1975 Vernon 1971	Brastow 1988 Cocks 1973 Schnee 1979
CONDUCT General Strategy	Koenig & Lublin 1989	Aaronson 1986 Davidson 1985 Porter 1980, 1986 & 1990		Douglas & Craig 1989 Schnee 1979 Williams 1984 Yoshikawa 1989

TABLE A-1 (cont'd)

	INDUSTRY	MARKETING STRATEGY	ECONOMICS	INT'L BUSINESS
Product Innovation	Beckhaus 1983 DiMasi et al 1990 Gorecki 1986	Carlson 1983 Cool & Schendel 1988 Foxall 1983 Park & Smith 1990 Porter 1990 Tushman & Anderson 1986 Wu 1988	Grabowski 1968 Hartley, Lavers & Maynard 1986	
Product Portfolio Management		Bitondo & Frohman 1981 Bennet & Cunningham 1985 Capon & Glazer 1987 Carlson 1983 Cardoza & Smith 1983 Cardozo & Wind 1985 Cummings & Daley 1981 Devinney & Stewart 1988 Guiltinan & Donnelly 1983 Hambrick, MacMillan & Day 1982 Hambrick & MacMillan 1982 MacMillan, Hambrick & Day 1982 Meyer & Roberts 1988 Sherden 1983 Wind & Mahajan 1981		Harrell & Kiefer 1981 Wind & Douglas 1981

TABLE A-1 (cont'd)

	INDUSTRY	MARKETING STRATEGY	ECONOMICS	INT'L BUSINESS
Place/ Market Entry		Cohen 1985 Kaminiski & Rink 1984 Lilien 1985		Ayal & Ziff 1978 Anderson & Gatignon 1986 Anderson & Coughlan 1987 Buzzel 1965 Cavusgil 1980 & 1990 Cavusgil & Nevin 1981 Devlin & Bleakley 1988 Ghauri 1986 Goodnow 1980 Goodnow & Hansz 1972 Hamel & Prahalad 1985 Harrigan 1987 Johanson & Wiedersheim-Paul 1975 Kale & Sudharshan 1987 Ohmae 1986 a & b, 1989, 1990 Porter 1986 Reid 1980 Robinson 1978 Simmonds 1985 Thorelli 1990 Yip 1989
PERFORMANCE Firm	Curtis 1985 Miller 1988 Noss 1989	Cool & Schendel 1988 Puetz 1987	Buzzell & Gale 1987	
Social		Fisk 1982 Nason 1986 Nason et al 1986	Bodenheimer 1984 Brada 1980 Bradfield 1989 Edner 1986 Laidlaw 1981 Pelzman 1982 Price 1988 Squire 1980	Wells 1982

APPENDIX B

SUMMARY OF VARIABLES

Paul de Haen Variables Used

Single Chemical Entity (SCE)

The non-proprietary drug name uniquely associated with a chemical compound regardless of product form, dosage, or brand name.

Therapeutic Class (THERAPY)

The therapeutic class of the single chemical entity as recorded by the American Hospital Formulary System. This study uses the two digit codes associated with the therapeutic classes in Table 2.

Marketing Firm (MARKETER)

The manufacturer and marketer of a single chemical entity for a country market.

Country Market (COUNTRY)

The country in which this single chemical entity is marketed under the brand name specified.

Year Introduced in Country (YEAR)

The year in which this single chemical entity was introduced in this country market.

Originating Manufacturer (INNOVATR)

The firm which developed this single chemical entity in-house.

Pharmaceutical Line-of-Business Data

Pharmaceutical Line-of-Business (PLB)

Designates the line(s)-of-business of a firm which are engaged in ethical drug manufacturing. The same codes are use for INNOVATR and MARKETER in the merged Paul de Haen data base.

Year (YEAR)

The year for which case data is recorded.

Products Developed within a Therapeutic Class (PRDEV)

Innovative efforts are measured by a count of SCEs, within a therapeutic class, which are self-innovated and marketed by a business. The historic variable is a moving count of SCEs introduced during the nine previous years. The nine year time period corresponds to the average effective patent life of pharmaceutical products during the study time frame. The therapeutic classes examined in the study are summarized in Table 2. Count {SCEs within THERAPY for nine previous years (historic)} and {SCEs within THERAPY for YEAR (current)} where INNOVATOR = PLB and PLB = MARKETER}.

Total Products Developed across Therapeutic Classes (TPRDEV)

This variable is the sum of current and historic PRODDEV across therapeutic classes for each business and represents ten years of information.

Breadth of Product Development (DEVCLASS)

This variable is the number of classes in which a business has developed product during the current year or previous nine years.

In-licensed Products Within a Therapeutic Class (INLIC)

In-licensing arrangements are measured by a count of new SCEs introduced. The historic variable is a moving count of SCEs introduced during the nine previous years. The nine year time period corresponds to the average effective patent life of pharmaceutical products. The current variable is a count of SCEs introduced in the case year. Count {SCEs for nine previous years within THERAPY (historic)} and {SCEs for YEAR within THERAPY (current)} where MARKETER = PLB AND MARKETER not = INNOVATR}. In this study, INLIC is used only as an intermediate variable to calculate PRODNO.

Total Number of In-licensed Products (TINLIC)

The total number of drugs a firm has acquired by in-licensing is the sum of current and historic INLIC.

Total Number of Drugs Marketed within a Therapeutic Class (PRODNO)

The number of drugs a business markets within a therapeutic class is the sum of TPRDEV and TINLIC.

Number of Classes in which Products are Developed (DEVCLASS)

This variable is a count of the number of therapeutic classes in which the PRODEV variable is a non-zero value.

Product Line Breadth (BREADTH)

Breadth of product line is the sum of the number of therapeutic classes marketed in the current year or previous nine years.

Product Introductions within a Country Market (PRINTRO)

This variable is a count of the number of SCEs a business introduces in a country. The historic variable is a moving count of the SCEs introduced in the previous nine years. The current variable is a count of self-innovated and marketed product introductions within a country. This is a measure of a business's commitment to a country market. To calculate: Count {SCEs where YRINTRO = YEAR - 1 to YEAR - 9 (historic)} and {SCEs where YRINTRO = YEAR within a country (current)} and MARKETER = case PLB.

Total Product Introductions across Country Markets (TPRINTRO)

This variable is the sum of current and historic (nine previous years) product intrudoctions across country markets for each business.

Out-licensing (OUTLIC)

Products innovated but not marketed by a business are out-licensed to access markets. The historic variable is a moving count of SCEs innovated by a business and licensed to another business for marketing in a specific country during

the previous nine years. The current variable is a similar count for the case year. To calculate: Count (SCE where YEAR = YRINTRO and PLB = INNOVATR and INNOVATR not = MARKETR. In this study, OUTLIC is used only as intermediate variable to calculate MKTNO.

Total Out-licensing (TOUTLIC)

This variable is the sum of current and historic (nine previous years) products out-licensed across country markets.

Number of Drugs Marketed within a Country (MKTNO)

The number of drugs marketed within a country is the sum of TOTINTRO and TOTOUTLIC for that country.

Marketing Representation across Country Markets (MKTREP)

Marketing representation is measured as the percent of world market accessed by a business. This variable is calculated by multiplying the percent weight for each country market in which the firm markets a therapeutic class times the number of products marketed in that class, and summing across countries. This product is then divided by the total number of drugs marketed in that country. The highest value for this study variable is 66 which means that the business markets in sixty-six percent of the world ethical pharmaceutical market. Values used to weight country markets are provided in Table 1. To calculate: Σ (MKTNO + TPRDEV) x country market weight.

Product Marketing Success (TOPDRUG)

Market-winning innovations for the current year are represented in this variable. Single chemical entities which ranked in the top thirty global sales performers during the year are counted.

Breadth of Market-Successful Products (TOPTHER)

This variable captures top product performer breadth. The information is recorded as the number of therapeutic classes in which the pharmaceutical line-of-business has a top-performing drug during the year. This variable provides a measure of the pharmaceutical line-of-business against industry criterion one which is discussed on page 49.

Pharmaceutical Line-of-Business Sales (SALES)

Revenue of each pharmaceutical line-of-business is recorded in current year dollars and deflated using Gross National Product deflators (U.S. Bureau of the Census 1983 and 1990) prior to analysis across time periods.

Pharmaceutical Line-of-Business Market Share (SHARE)

The size of the world pharmaceutical market is not easily determined nor readily available. Therefore a surrogate market share measure is computed relative to the sales volume of the entities which consistently appear in every study year. Summed sales of these businesses is used as the denominator for the entire study period. To compute: SALES + {Σ SALES of the firms which are represented in each study year}.

The Regulatory Environment

Country (COUNTRY)

The study is conducted across six countries. This categorical variable represents one of the following: France, Great Britain, Italy, Japan, the United States, or West Germany.

Compulsory Out-Licensing (COMPLIC)

COMPLIC records the presence or absence (1,0) of mandatory out-licensing within a country during the year.

Regulation Encouraging Generic Substitution (GENERIC)

GENERIC records the presence or absence (1,0) of a regulation which encourages generic substitution within a country during the year.

Country National Formulary System (FORM)

FORM records the presence or absence (1,0) of a national formulary system within a country during the year.

National Health Plan (PLAN)

PLAN records the presence or absence (1,0) of a nationally funded health care plan within a country during the year.

Country Acceptance of Non-domestic Clinical Trials (CLINIC)

CLINIC records the presence or absence (1,0) of a country's acceptance of other non-domestic clinical trials during the year.

R&D Pricing Incentives (INCENT)

INCENT records the presence or absence (1,0) of pricing policies which provide an incentive for R&D investment.

APPENDIX C

DEFINITION OF TERMS

In-licensing - is the practice of obtaining contractual relationship to market a drug innovated by another firm.

Industry criteria - are rules of thumb for gauging potential for marketing success. These originate from the expertise of industry managers.

Innovating firms - are firms where marketable products are researched and developed.

Out-licensing - is granting contractual permission for another firm to market products which were innovated within the granting firm.

Performance - is measured using annual sales in current year U.S. dollars, normalized to 1985 dollars prior to analysis.

Pharmaceutical line-of-business - is the group or groups within a firm which are engaged in the pharmaceutical line of business. This may be an entire company or one or more strategic business units.

Product portfolio - is a tool or model for analyzing an array of products with which a firm works.

Single chemical entity - is the non-proprietary name of a unique chemical compound which may be marketed for clinical use under one or more trade names by one or more manufacturers.

Top performing drugs - are year-specific and are those thirty drugs with the highest reported revenue in a given year. This closely approximates 1990 sales levels of above $300 million.

APPENDIX D

SUMMARY OF RESULTS--STRATEGY PERFORMANCE MODEL

TABLE D-1

SUMMARY OF RESULTS--STRATEGY PERFORMANCE MODEL

Independent Variables									Adjusted R^2	
Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	ASALES	SHARE
-	-	-	-	-	-	-	-	-	.59446	.63236
sq	-	-	-	-	-	-	-	-	.59297	.62455
-	sq	-	-	-	-	-	-	-	.58136	.61675
-	-	sq	-	-	-	-	-	-	.57917	.61198
-	-	-	sq	-	-	-	-	-	.56841	.60456
-	-	-	-	sq	-	-	-	-	.59270	.62964
-	-	-	-	-	sq	-	-	-	.59233	.61133
sq	sq	-	-	-	-	-	-	-	.58611	.62111
-	sq	sq	-	-	-	-	-	-	.57526	.61031
-	-	sq	sq	-	-	-	-	-	.57895	.62114
-	-	-	sq	sq	-	-	-	-	.57895	.62455
-	-	-	-	sq	sq	-	-	-	.59851	.62276
sq	-	sq	-	-	-	-	-	-	.58561	.61832
sq	-	-	sq	-	-	-	-	-	.57844	.61330
sq	-	-	-	sq	-	-	-	-	.59683	.63096
sq	-	-	-	-	sq	-	-	-	.59683	.63096
-	sq	-	sq	-	-	-	-	-	.56634	.60317
-	sq	-	-	sq	-	-	-	-	.59683	.63096
-	sq	-	-	-	sq	-	-	-	.59810	.61696
-	-	sq	-	sq	-	-	-	-	.59002	.62964
-	-	sq	-	-	sq	-	-	-	.58652	.60615
-	-	-	sq	-	sq	-	-	-	.57884	.59903
sq	sq	sq	-	-	-	-	-	-	.57982	.61280

TABLE D-1 (cont'd)

Independent Variables									Adjusted R^2	
Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	ASALES	SHARE
-	sq	sq	sq	-	-	-	-	-	.55502	.59349
-	-	sq	sq	sq	-	-	-	-	.57691	.61951
-	-	-	sq	sq	sq	-	-	-	.58873	.61424
sq	sq	-	sq	-	-	-	-	-	.56955	.60613
sq	sq	-	-	sq	-	-	-	-	.59553	.63236
sq	sq	-	-	-	sq	-	-	-	.59382	.61288
sq	-	sq	sq	-	-	-	-	-	.57171	.60534
sq	-	-	sq	sq	-	-	-	-	.58440	.62379
sq	-	-	-	sq	sq	-	-	-	.58526	.68299
-	-	sq	sq	-	sq	-	-	-	.57164	.59214
-	sq	sq	-	-	sq	-	-	-	.58190	.60277
sq	-	sq	-	sq	-	-	-	-	.57719	.59733
sq	-	sq	-	-	sq	-	-	-	.59134	.61262
sq	-	-	sq	-	sq	-	-	-	.58598	.60707
-	sq	-	sq	sq	-	-	-	-	.57568	.61922
-	sq	-	-	sq	sq	-	-	-	.59446	.62072
-	sq	-	sq	-	sq	-	-	-	.57719	.59733
-	-	sq	-	sq	sq	-	-	-	.59542	.62276
sq	sq	sq	sq	-	-	-	-	-	.55780	.59555
-	sq	sq	sq	sq	-	-	-	-	.57345	.61744
-	-	sq	sq	sq	sq	-	-	-	.58511	.61424
sq	-	sq	sq	sq	-	-	-	-	.58014	.62218
sq	-	-	sq	sq	sq	-	-	-	.58769	.61665
sq	-	sq	sq	-	sq	-	-	-	.58014	.62218
sq	-	sq	-	sq	sq	-	-	-	.59643	.62443
-	sq	-	sq	sq	sq	-	-	-	.58761	.61181
-	sq	sq	-	sq	sq	-	-	-	.59115	.62072
-	sq	sq	sq	-	sq	-	-	-	.56701	.58798
sq	sq	-	-	sq	sq	-	-	-	.58166	.63236
sq	sq	sq	-	-	sq	-	-	-	.58663	.60623
sq	sq	sq	-	sq	-	-	-	-	.59297	.63236
sq	sq	sq	sq	sq	-	-	-	-	.57953	.62228
sq	sq	sq	sq	-	sq	-	-	-	.57015	.59041

TABLE D-1 (cont'd)

Independent Variables									Adjusted R^2	
Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9	ASALES	SHARE
sq	sq	sq	-	sq	sq	-	-	-	.59823	.62540
sq	sq	-	sq	sq	sq	-	-	-	.59117	.61741
-	sq	sq	sq	sq	sq	-	-	-	.58314	.61181
sq	sq	sq	sq	sq	sq	-	-	-	.58775	.61665
sq	sq	-	sq	-	sq	-	-	-	.58063	.60021
sq	-	sq	sq	sq	sq	-	-	-	.58769	.61665
-	-	sq	-	sq	sq	-	-	-	.59542	.62276

sq denotes variable is squared.
- denotes variable is not squared.

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