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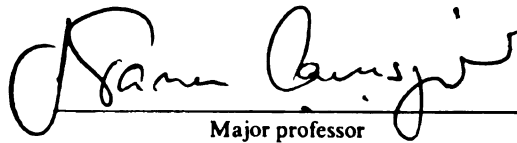
**An Analysis of Competitive Positioning Strategies
in the U.S. Ethical Pharmaceutical Industry :
An EQS Application**

presented by

Poh-Lin Yeoh

has been accepted towards fulfillment
of the requirements for

Doctorate degree in Marketing



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**AN ANALYSIS OF COMPETITIVE POSITIONING STRATEGIES IN THE U.S.
ETHICAL PHARMACEUTICAL INDUSTRY : AN EQS APPLICATION**

By

POH-LIN YEOH

A DISSERTATION

**Submitted to
Michigan State University
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ABSTRACT

AN ANALYSIS OF COMPETITIVE POSITIONING STRATEGIES IN THE U.S. ETHICAL PHARMACEUTICAL INDUSTRY : AN EQS APPLICATION

By

POH-LIN YEOH

To examine the effect of competitive positioning strategies on firm performance, the following research questions were addressed in the context of the U.S. ethical pharmaceutical industry between 1971 to 1989: (1) How are the competitive positioning variables causally related to one another? (2) Which competitive positioning variables have the greatest effect on performance? and (3) How do early and late entrants differ in terms of their competitive positioning variables and overall performance?

The key constructs considered were: (1) R&D intensity; (2) advertising intensity; (3) therapeutic market diversification; (4) therapeutic differentiation; (5) spatial strategy; (6) outlicensing; (7) internal R&D efforts; and (8) new product development efforts. Performance was measured with respect to two indicators: global and domestic market share. Based on a review of the new product development, innovation, and strategic marketing literature, twenty hypotheses were proposed and tested using EQS.

Findings from this study suggest that the timing of entry is not a random or independent variables but rather, is part of the firm's entry strategy. The following factors are fundamental for success in the industry: an emphasis on

product innovation; looking beyond the U.S. market as a source of sales; maintaining strong commitments to R&D; and focusing and exploiting internal R&D competency.

Late entrants must address how they can overcome competitive advantages achieved by early entrants: (1) higher quality and differentiated products; and (2) stronger new product development efforts. Since the direct relationship between new product development efforts and late entrants' performance is negative, electing to concentrate their R&D and marketing efforts on NCE development may be detrimental to this group of firms' performance in the long run. Findings suggest that they should focus instead on less innovative product development efforts. In addition, late entrants also need to commit more resources to their advertising efforts. Superiority in this marketing activity will spell the difference between success and failure for many products in the future as the market continues to be filled with similar chemical entities.

A strategy that is recommended for late entrants is to concentrate R&D efforts on one therapeutic market at a time. This strategy will produce a niche until the resources become available to permit an assault on another niche. This niche-by-niche strategy will allow global exploitation of their products more successfully despite being "technological followers."

Overall, firms identified as early entrants are doing what is necessary to maintain market share advantages; they

offer innovative products which provide further opportunities for product advantages and differentiation. However, they need to be more selective in their choice of therapeutic markets. Since the development of highly innovative products involve greater uncertainties and riskiness, management must ensure that these projects should only be undertaken when there is a good match between the resource base of the firm and the needs of the project. Firms should also identify opportunities in a certain therapeutic market by comparing its relative market size and degree of unmet needs as well as evaluating the competitive intensity and diversity of approaches in the research area. These criteria will help early entrants employ their R&D and marketing resources more effectively.

Although this study was limited to a single industry, insights obtained on the relationship between strategy and performance may have implications for other high technology industries.

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CHAPTER ONE

INTRODUCTION

1.1 Motivation for the Study

In the strategic management literature, strategy often is defined as (1) the set of activities involving the analysis of perceived environmental opportunities and constraints, (2) the development of organizational capabilities, and (3) the evaluation of present and proposed organizational strategies and their potential to create and sustain competitive advantages and economic rents (Cool 1985).

Strategic marketing is very similar to strategic management, that is, it also is concerned with management of the organization-environment interface and with coordination of the marketing mix decisions to create long-run competitive and consumer advantages. There is, however, a fundamental difference between strategic management and strategic marketing (Wind and Robertson (1983, p. 12):

Marketing strategy's difference is that it serves a boundary role function between the firm and its customers, competitors, and other stakeholders. Marketing develops strategy based on analysis of consumers, competitors, and other environmental forces which then should be combined with other strategic inputs (such as financial, R&D, and human resources) to arrive at an integrated business strategy.

Achieving and sustaining competitive and consumer advantages have emerged as the cornerstones of strategic thinking, and a focus on strategic marketing has become a means of attaining these goals. Particularly, the emphasis on competitive advantage raises a variety of questions, for example: (1) What are the firm's core products and markets? (2) What new product markets should the firm enter? (3) Should a firm be in a particular product market? (4) How should resources be allocated among product markets?

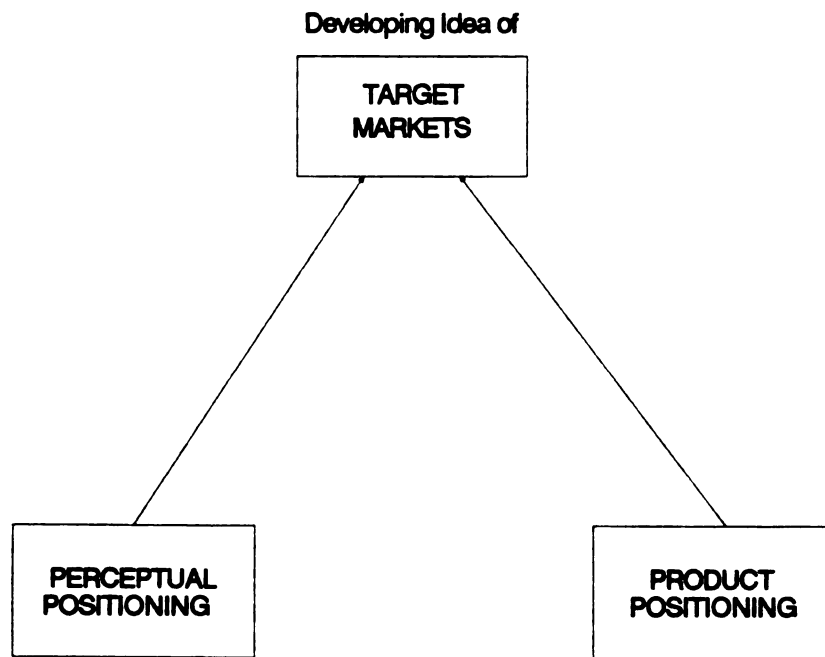
In the pharmaceutical industry, product markets can be classified into different therapeutic categories, such as nutritional, pain control, internal medicine, mental health, topical, antiinfectives, respiratory, and cancer. These major categories can be divided into therapeutic classes and further subdivided into subclasses. Hypertension exemplifies a therapeutic class within the cardiovascular category. To treat hypertension, several subclasses of drugs can be used, such as beta-blockers, calcium-channel blockers, ACE inhibitors, and diuretics. Similar to market segments, therapeutic subclasses can be viewed as a set of products with similarities according to the diseases or conditions treated and the character of treatment. Kemp (1975, p. 257) argues that drugs belonging to a particular subclass [tend to have] "similar therapeutic properties, not similar chemical structures, even though products of the same subclass frequently are chemically similar."

Once the firm has chosen the choice of product markets to serve, it then must decide on how to position itself against other competitors in those markets. In this study, the concept of positioning is different from that which is common in the buyer behavior literature (for example, Aaker and Shansby 1982; Arabie et al. 1981; Shocker and Srinivasan 1979; Wind 1973). Dimingo (1988) notes that the literature often does not distinguish clearly between psychological or perceptual positioning and product market positioning. The schematic difference between the two concepts is shown in Figure 1.1.

Perceptual positioning is often viewed from a buyer perspective. Six approaches to a perceptual positioning strategy are proposed by Aaker and Shansby (1982): positioning by (1) attribute; (2) price-quality; (3) use or applications; (4) product user; (5) product class; and (6) competitor. In general, perceptual positioning is defined as an attempt to move a product/brand to a particular location within a perceptual product space (Dillion, Domzal, and Madden 1986). The key factor is to develop a product/brand positioning program congruent with the psychological meaning that consumers associate with the product or brand. Perceptual positioning is a key concept in marketing and communication strategies, and various quantitative research tools have been employed to provide information about consumers' evaluations of products. Examples include multidimensional scaling (Ness

Figure 1.1

Schematic Difference between Perceptual and Product Positioning



1986) and conjoint analysis (Greene and Nkonge 1989).

Psychological positioning is an outgrowth of product market positioning. In other words, the success of psychological positioning strategies depends on the information uncovered in the market positioning process, that is, a clear identification of the target markets and how they react to various strategies. Psychological positioning "involves forging a distinctive product or corporate identity based on the market positioning factors and then using the tools of communication to move the [consumers] toward a buying decision" (Dimingo 1988, p. 35).

Market positioning is viewed from the perspective of the marketer. It is the process of identifying and selecting target markets with business potential, targeting vulnerable competitors, and devising a strategy to compete with them (Dimingo 1988). As noted by Abell (1975), differences in firms' skills, resources, and historical perspectives as well as differences in product markets require firms to adopt different postures in their positioning strategies. This type of positioning is quite similar to Aaker and Shansby's (1988) discussion of positioning with respect to a competitor, although they were concerned with how this positioning strategy can be exploited in an advertising context. For this study, the following definition of competitive positioning is employed :

Competitive positioning is the pattern of decisions in a company that defines the range of product markets to compete in and in a way that focuses the company's resources to convert distinctive competencies into competitive and buyer advantages.

As such, competitive positioning has a high degree of overlap with business strategy¹ and should be viewed as an integral part of business strategy.

The present study is concerned with competitive positioning strategy within the U.S. pharmaceutical industry. An extensive review of the literature revealed limited empirical research on pharmaceutical firms' competitive positioning strategies. The basic objective of this research is to help fill this gap by addressing three pertinent issues. (1) How do pharmaceutical firms choose to compete in terms of their competitive positioning strategy? (2) Do different market positioning strategies have varying degrees of success? (3) How do these strategies influence firm performance?

The remainder of this chapter is organized into five sections. The first briefly discusses the uniqueness of the pharmaceutical industry and why it offers an opportunity for the study of market positioning strategies. The second highlights the scope of the research. The third reviews the purpose of the research. The fourth discusses the expected contribution of the research from both a managerial and

¹A distinction often is made between corporate strategy and business strategy. The former deals with the line of business in which a firm should participate, while the latter addresses how the firm should compete in each line of business in which it participates.

academic perspective. The final section gives an overview of the organization of the dissertation.

1.2 Uniqueness of the Pharmaceutical Industry

The high level of R&D investment in sophisticated technologies places the pharmaceutical industry among the leading technology-driven industries. All such industries share certain characteristics:

1. A rapidly changing technological environment in which products are sold.
2. Global competition in many areas of product discovery, development, and commercialization.
3. High investments in research and development (R&D), both absolutely and as a percentage of sales.
4. A higher proportion of technical professionals in the workforce, such as scientists, engineers, and technologists, compared to other industries.

Certain other characteristics are unique to the pharmaceutical industry.² First, there is a long lead time for drug discovery and development. Second, significant R&D expenses are incurred. All research-based drug companies depend on new ethical drugs for economic success, and in this area pharmaceutical firms compete vigorously. R&D plays a key role in the drug firm's success because (1) there is a high dependency on a very large cash flow from a small number of drugs, usually three or four, (Thomas 1988; Spilker 1989) to recoup funds spent on unsuccessful drugs; (2) revenue from

²A fuller description of each of these characteristics is provided in Chapter two.

successful drugs is used to offset declining margins on older drugs whose patents have expired and which have been imitated and marketed as low-price generic drugs; and (3) higher R&D allocations may lead to drugs superior to those of the competition (Murray 1989).

Third, the U.S. drug industry is extensively and rigorously regulated by the federal government. The constraints imposed by the Food and Drug Administration (FDA) are a key difference between the pharmaceutical industry and other high-technology industries.

Fourth, the industry supplies its products and technologies in a complex industrial goods market (Roberts 1981) in which medical practitioners serve as intermediaries between the manufacturers and ultimate end-users. Therefore, much of the marketing effort tends to be directed at physicians and pharmacists rather than the customers.

These unique features of the pharmaceutical industry raise a variety of questions pertaining to firms' competitive positioning strategy which have yet to be addressed in the literature. For example, since there is a considerable lead time from drug development to approval, do firms that license-in their drugs perform better than firms that develop their own drugs from internal R&D? Does the stringency of FDA regulations lead U.S. firms to introduce their products overseas? If so, how does this affect firm performance? To the extent that there is high brand loyalty among physicians,

do early entrants consistently outperform later entrants into particular product markets?

Product innovation is universally recognized as a key component in corporate strategy in technology-intensive industries and is assuming an increasing importance (for example, Cooper and Kleinschmidt 1987; Moore 1987; Urban, Hauser and Dholakia 1987). Firms also must decide on the types of product markets to enter and how to compete in those markets. (Day 1986; Roberts and Berry 1987). The research-intensive pharmaceutical industry provides an opportunity to examine these decisions.

1.3 Scope of Research

Once the firm has targeted one or more product markets in which to compete, the next critical step is to identify the distinctive competencies that will allow the company to compete vis-à-vis its competitors in the selected markets. Day and Wensley (1988) identified two areas of potential distinctive competence for an organization: superior skills and superior resources. Superior skills arise from the ability to perform certain functions more effectively than competitors; for example, superior technical skills can allow a firm to produce a better quality product than its competitors. Superior resources are tangible factors that enable a firm to develop an advantage over its competitors such as an established brand name.

To capture the two underlying dimensions proposed by Day

and Wensley (1988), three variables are considered in this research :

- (1) means of competition, that is, the type of approach (internal development versus externalization) and the level of resource commitments;
- (2) market entry timing, that is, whether the firm should attempt to be the pioneer, an early follower, or a late entrant; and
- (3) geographical scope, that is, the location of target markets in which to compete.

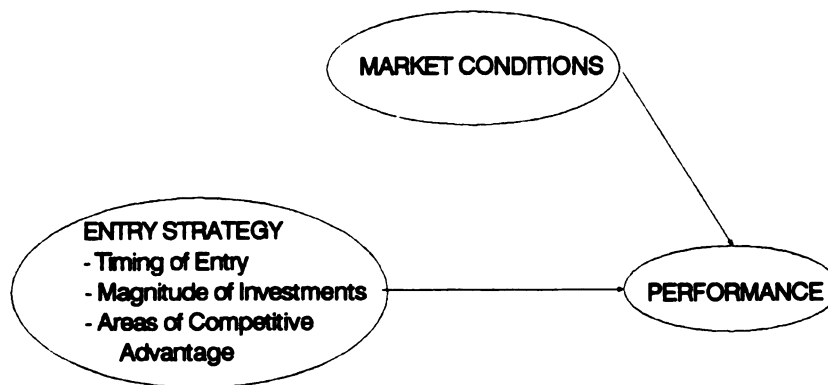
The means of competition reflects the competitive advantage, while the other two variables relate, respectively, to the firm's advantage over competitors by being first in the market and by adopting a global strategy.

The timing of entry and means of competition variables were formally addressed by Day (1986) in his discussion of entry into new markets. Using Day's framework, Green and Ryans (1990) empirically tested the relationship between entry strategy and firm performance using the Markstrat simulation. Their conceptual model is shown in Figure 1.2. In addition to studying the effect of entry strategy on performance, they attempted to study the effects of product-market characteristics on performance. All but one of their hypotheses about the relationship between entry strategy and performance were supported.

1.3.1 Level of Analysis

There are three level of analysis at which this study

Figure 1.2
Basic Entry Strategy Model



Source : Donna H.Green and A.B. Ryans (1990), "Entry Strategies and Market Performance : Causal Modelling of a Business Simulation," Journal of Product Innovation Management, 7 (3), 45-8.

could be conducted. At the product level, the objective would be to determine how firms position their products in specific market segments. Product management studies have tended to concentrate on this unit of analysis (Rubenstein et al. 1976; Maidique and Zirger 1984; Cooper and Kleinschmidt 1987). The most publicized research dealing with product success and failure is the British SAPPHO studies (Rothwell et al. 1974) and NewProd studies (Cooper 1979a, 1979b).

Concentrating on product success or failure does not help explain how firms organize R&D efforts over time. In addition, focusing on individual new products rather than the firm's entire new product program has been criticized by some researchers as myopic (Gold 1980). As argued by Cooper (1985b), "it is conceivable that a firm could have a steady stream of successful new products, but may lack significant new products in its portfolio," thereby jeopardizing the long-run future of a business. Although the product is a useful level of analysis from a strategic marketing perspective, it does not give an overall picture of the competitive positioning strategy pursued by each firm in the industry.

At the division level, the emphasis is on how a certain segment of the firm positions itself in the industry. When a firm has several divisions, however, each competing in the same or different markets within the same industry, the identification of the firm's positioning strategy at this level of analysis is tenuous. It is not uncommon for

pharmaceutical firms to have both ethical and generic drugs that compete in the same therapeutic classes. Since this study is only concerned with ethical drugs, using the division as the unit of analysis could make it difficult or impossible to differentiate results.

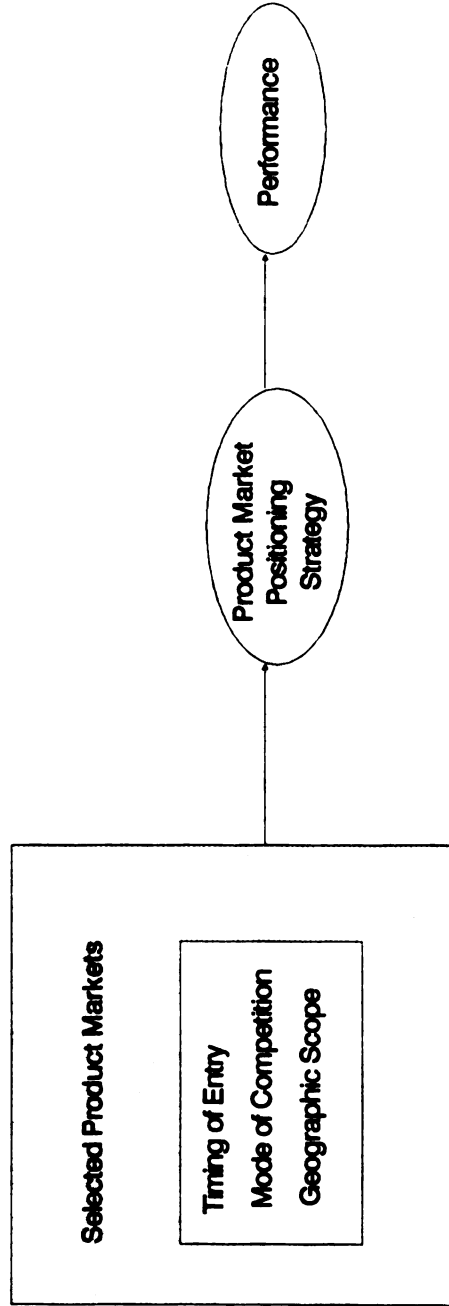
Analysis at the firm level permits a more representative assessment of the strategy pursued by each firm in the industry considered. This is the level of analysis used here. By focusing on this level, consideration can be given to such strategic questions as: (1) Does the firm need to change its positioning strategy? (2) Should the firm increase its R&D and marketing spending? (3) How is overall firm performance affected by its competitive positioning strategy?

1.4 Purpose of Research

This dissertation is concerned with the relationship between competitive positioning strategy and overall performance of firms in the U.S. pharmaceutical industry. A systematic relationship is posited between the two variables. The conceptual framework that guides the research is shown in Figure 1.3.

This study deals only with successful entry by firms into the various therapeutic categories. Given that the standard duration of research on a pharmaceutical product is 10-15 years, high failure rates are not unusual as the drug goes through the FDA approval process (see p.46). Since very few of these product failures are fully documented, it is

Figure 1.3
Product Market Positioning : Conceptual Framework



easier to examine successful products than unsuccessful ones. Therefore, products that have failed to enter product markets for various reasons will not be considered.

Three major research questions are of interest:

- (1) How are the competitive positioning variables causally related to one another?
- (2) Which competitive positioning variable have the greatest effect on performance? What is the relative importance of these direct and indirect effects?
- (3) How do early and late entrants differ in terms of competitive positioning variables and overall performance?

1.5 Expected Contribution of the Research

This dissertation builds on two major studies. The first, an empirical analysis by Bond and Lean (1977) examined two prescription drug markets. It attempted to demonstrate how the order of entry and the circumstances surrounding entry affected brand sales, promotion, and product differentiation in the diuretics and antianginals therapeutic submarkets. The present research attempts to extend their findings to a wider range of therapeutic markets at various stages of maturity.

The second study, by Green and Ryan (1990) developed and tested a model within the simulated Markstrat environment involving only one product market and five firms. One objective of the present research is to assess whether their results can be validated with empirical data. In the Markstrat world, a "controlled" business environment, the lack of variance may not yield meaningful results even though

findings may be theoretically significant. This study examines "actual" data on pharmaceutical firms competing over a broader range of product markets.

By building upon these prior works, this dissertation attempts to make the following contributions: (1) conceptualization of the competitive positioning strategy from a marketing perspective, (2) detailed measurement and longitudinal analysis of strategy, and (3) development of qualified insights into strategy-performance relationships of significant use to managers.

This research approaches the pharmaceutical industry from a marketing perspective. Because of its prominence in the health care sector and its unique characteristics, such as the rapid rate of technological development, reliance on patent protection, and the effects of governmental regulation, the industry has been a popular arena for testing concepts and paradigms in the fields of industrial economics and policy analysis.

Most articles on the marketing aspects of the industry have been descriptive in nature, although there are a few exceptions. Harrell (1972) used the Fishbein Model to determine physicians' prescribing behavior. A maximum likelihood estimation procedure was used by Bearden and Mason (1980) to study how confidence in regulation, potential savings, and effect on drug research represent possible determinants of physician and pharmacist support of generic

drugs. In two studies, Statmand and Tyebjee (1981, 1985) examined, respectively, the extent to which brand loyalty and patent protection influence the market position of an ethical drug and how marketing efforts of pharmaceutical firms have changed in response to the Drug Substitution Laws.

Only recently has the ethical drug industry been studied from a strategic management perspective, using the strategic group paradigm (for example, Cool and Schendel 1987, 1988; Fiegenbaum, Sudharshan, and Thomas 1990); and transaction costs analysis (Tapon 1989). While marketing variables such as product competition, price behavior and advertising were considered in earlier studies, they were mainly viewed from an economic perspective. Some examples include looking at relationships between product competition and monopolistic powers (Steele 1962; Schiffrin 1967); market instability (Comanor 1964), price levels and market shares (Schwartzman 1976), advertising and sales levels (Harrell 1978; Leffler 1981), and the effect of advertising on competition (Walker 1971; Schwartzman 1976; Bond and Lean 1977).

The current research examines several key marketing constructs identified by past researchers as critical in influencing firm level performance. Theoretical and empirical studies from the strategic marketing and innovation literature will be used to identify these key marketing constructs.

The empirical contribution of this dissertation relates

to two major aspects: a longitudinal versus cross-sectional analysis of the data and the methodology used. This study examines the competitive positioning strategy of U.S. pharmaceutical firms from 1971-1989. The 19-year is sufficient for a longitudinal evaluation of shifts in firms' entry strategies and any effects on performance. Due to the lag time effect between implementation of a strategy and the evaluation of how well it worked, cross-sectional analysis may be inadequate for examining strategy-performance relationships.

The methodology used to model the dynamic aspects of competitive positioning strategy on performance is also a contribution of this research. Performance often is influenced by a host of factors and, testing each one is less superior than considering all in their entirety. Structural equation modelling is used here to gain insights into indirect and direct effects of the constructs shown in Figure 1.3. In addition, rather than test a single model against the data, a two-group analysis is conducted to test whether the hypothesized model is invariant between late entrants and early entrants.

Finally, from a managerial perspective, competitive positioning is an important strategic issue as it provides the platform from which competitive advantage can be achieved. Although performance results from the interaction of many variables, this study attempts to identify the competitive

positioning strategy variables that relate significantly to And a longitudinal analysis provides a systematic way to address this task.

Although this study focuses on the U.S. pharmaceutical industry, the findings have implications for strategic marketing in any industry. Any firm needs to understand what strategies are being pursued by competitors. This information enables evaluation of the relative strengths and weaknesses of certain strategic positions and determine of how best to position the firm against its rivals so as to achieve a sustainable competitive advantage.

1.6 Organization of the Research

This dissertation is organized in six chapters. Chapter 2 is an overview of the operating environment of the drug industry. Knowledge of the environment is necessary to understand how the industry dynamics affect firm strategies and performance and also to provide a rationale for the selection of variables in Chapter 4.

Chapter 3 defines the key constructs employed in this study, drawing on relevant theoretical and empirical studies from the strategic marketing and innovation literature. This chapter concludes with a complete statement of research questions.

Chapter 4 develops the research hypotheses. The operationalization of the variables and the data bases used in this study are discussed. The methodology for testing the

hypotheses also is explained.

Chapter 5 discusses the findings from the statistical analysis.

Chapter 6 summarizes the findings and points out their contribution to strategic marketing research and practice. Limitations of the study and suggestions for future research also are outlined.

CHAPTER TWO

THE U.S. PHARMACEUTICAL INDUSTRY

Major changes took place in the U.S. pharmaceutical industry during the 1970s and 1980s, and the strategic management literature suggests that adaptive strategies were a major tool used by firms in dealing with their changing environment. This study assumes that the success of a firm's strategy in the face of environmental challenge and complexity is reflected in its level of performance, although more extensive analysis is undoubtedly needed to establish the complex causal relationships among strategy, performance, and environment.

In this chapter, a brief historical account of the institutional development of the U.S. pharmaceutical industry is provided, along with a review of the major developments in its market and institutional environment. Particular attention is paid to the economic, political, technological, and social events and trends that have been instrumental in shaping the industry. Finally, three major responses in reaction to these environmental shifts are discussed.

2.1 Historical Development of the Drug Industry

In the 1930s, U.S. pharmaceutical firms manufactured a

limited number of unpatented drugs which were marketed without prescription to the consumer. Many of the compounding functions were performed by retail pharmacists rather than manufacturers, and the pharmaceutical industry was essentially a commodity business. According to Harold Clymer (1975),

R&D as such was nonexistent in most firms....it was in 1939 that I joined SmithKline; you can judge the magnitude of their R&D at the time by the fact that I was told I would have to consider the position temporary since they had already hired two people within the previous year for their laboratory and were not sure that the business would warrant the continued expenditure.

Almost all of the minimal advertising was placed in newspapers and quality magazines, stressing the quality and purity of drugs, rather than their therapeutic advantages.

Advances in drug therapy were minimal before the 1930s. "Passive therapy" or the vaccination method dominated until 1910 when Ehrlich's discovery of salvarsan for the treatment of syphilis marked a radical departure. His discovery opened the field of chemotherapy by demonstrating how drugs could act as "magic bullets", that is, how particular chemicals could kill particular organisms without harming the patient. Even though Ehrlich demonstrated the opportunities available for R&D, a quarter of a century passed before the age of the wonder drugs.

The discovery of sulfonamides in 1932 and the demand for drugs during World War II transformed pharmaceuticals from a

commodity business centered around bulk products to a technology-intensive industry characterized by very specialized and differentiated products. Manufacturers began investing in facilities as well as R&D to exploit new opportunities and potential profits. At the same time, power shifted from the retail pharmacist to the manufacturers, who had assumed the compounding functions by the end of the war.

The mass production of penicillin in 1942 further stimulated the development and large-scale production of therapeutic discoveries, particularly broad-spectrum antibiotics, hormones and vitamins. Intensified innovation resulted in the introduction of more than 700 new drugs between 1940 and 1960. These extended to new therapeutic categories as well, such as cardiovascular, steroids, oral contraceptives, and tranquilizers which did not exist prior to the 1950s. Further developments included the discovery of specific chemical agents capable of acting upon certain parts of the body and upon the diseases each part contracted within these therapeutic classes.

Both patent protection and brand name promotion further allowed manufacturers to maximize the commercial exploitation of their discoveries. The period (1940-1960) often is called the Golden Age of Discovery.

2.2 Origin of the Major Drug Firms

As shown in Table 2.1, the major U.S. drug firms originated as pharmaceutical supply houses. In contrast,

Table 2.1 Origins of Selected Pharmaceutical Companies

Date of Origin	Company	Home Country
(1) Original Activity : Pharmaceutical Supplies		
1618	E. Merck	Germany
1715	Glaxo	United Kingdom
1817	Boehringer Mannheim	Germany
1828	SmithKline	United States
1851	Schering A.G.	Germany
1855	Sterling Drugs	United States
1858	Squibb	United States
1860	American Home Products	United States
1866	Warner Lambert/Parke Davis	United States
1876	Eli Lilly	United States
1880	Richardson-Merrell	United States
1885	Upjohn	United States
1885	Boehringer Ingelheim	Germany
1886	Wellcome	United Kingdom
1887	Bristol-Myers	United States
1888	Boots	United Kingdom
1888	Searle	United States
1906	Lederle	United States
1913	Astra	Sweden
1923	Organon	Netherlands
1927	Merck & Co.	United States
1929	Schering Plough	United States
1944	Syntex	(originally Mexico; since 1958, Panama)

(2) Original Activity : Dyestuffs

1758	Ciba-Geigy	Switzerland
1812	Hoechst	Germany
1848	Pfizer	United States
1863	Bayer	Germany
1884	Montedison	Italy
1886	Sandoz	Switzerland
1888	Abbott	United States

Table 4.1 continued

Date of Origin	Company	Home Country
1890	Morton-Morwich	United States
1895	Dow	United States
1896	Hoffman La-Roche	Switzerland
1911	AKZO	Netherlands
1926	ICI	United Kingdom

Source : James Barrie (1977), The Future of the Multinational Pharmaceutical Industry to 1990, New York : John Wiley and Sons, Appendix 4.

their European counterparts, which were established earlier, had origins in organic chemicals and dyestuffs. The first wonder drug, Salvarsan, was developed in 1910 in the laboratories of the chemical group I.G. Farben industries (Bayer division) of West Germany.

2.3. Expansion Strategy

During the 1960s and 1970s, U.S. drug firms began expanding into related areas, such as agricultural chemicals, cosmetics, and medical equipment and diagnostic aids. These businesses provided potential synergies with the firms' traditional products. Because of the transferability of knowledge from the development of chemical drug compounds to chemicals for agricultural purposes, many drug firms entered the agribusiness field. Examples include Eli Lilly, Merck, Pfizer, Syntex, and Upjohn.

Experience in consumer goods marketing also prompted entry into the cosmetics industry. For example, Pfizer bought Coty in 1963, and Eli Lilly purchased Elizabeth Arden in 1971.

The medical equipment and diagnostic aids industry was a likely extension for two reasons. Hospitals, the major customers for these products, were already major purchasers of drugs, and these devices were regulated by the FDA, with which drug firms already had developed extensive experience. Firms active in this line of business include Syntex, SmithKline-Beckman, and the Rorer Group.

Expansions also occurred within the drug industry, mainly through acquisitions and mergers. Table 2.2 lists the major activity from 1960-1990. In the latter part of the 1980s, notable acquisitions were made by Kodak (Sterling Drugs) and American Home Products (Robins). In 1989, there were several large mergers, SmithKline with Beecham, Merrell Dow with Marion and Bristol-Myers with Squibb.

Another major trend has been the acquisition of U.S. firms by foreign companies. Notable purchases are listed in Table 2.3. The attractive opportunities provided by the U.S. market have made it a favored regional area of expansion for British, German, and Swiss drug firms.

In summary, the 'chemotherapeutic' revolution of the 1940s transformed the drug industry from a commodity business to a technology-intensive industry. Whereas European companies entered the drug industry as chemical concerns, U.S. firms originated as drug supply houses. The significant mergers and acquisitions in recent years suggest that worldwide consolidation may lead to the domination of the industry by a dozen companies by the year 2000.

Different aspects of the operating environment of the pharmaceutical industry are highlighted in the next section. Economic, technological, political, and social aspects are emphasized.

2.4 Environmental Trends in the U.S. Pharmaceutical Industry

2.4.1 Economic Environment

Table 2.2 Mergers and Acquisitions Within the U.S. Drug Industry, 1960-1990

<u>Acquiring Firm</u>	<u>Acquired or merged firm</u>
Abbott	Ross (1964), Sorenson Research (1980)
American Home Products	Robins (1988)
Beecham	SmithKline (1989)
Bristol Myers	Mead-Johnson (1967), Westwood (1969), Squibb (1989)
Dow Chemical	Allied Labs (1960), Richardson-Merrell (1981)
Kodak	Sterling Drugs (1988)
Merrell Dow	Marion (1989)
Procter and Gamble	Norwich-Eaton (1982), Richardson-Vicks (1985)
Schering	Plough (1971)
Warner-Lambert	Texas Pharmacal (1967), Parke-Davis (1970)
3M	Riker (1970)

Source : Annual reports.

Table 2.3 Acquisition of U.S. Drug Firms by Foreign Companies, 1971-1990

<u>Acquirer</u>	<u>Acquired</u>
Bayer (Germany)	Cutter (1973), Dome Labs (1978), Miles Labs (1978), Cooper (1980)
Beecham (UK)	Massingill (1971)
Boehringer-Ingelheim (Germany)	Hexagon (1975), Philips Roxane (1979)
Boots (U.K.)	Riker (1977)
Ciba Geigy (Switzerland)	Alza (1977), Tutag (1978)
Glaxo (U.K.)	Meyer Labs (1977)
Imperial Chemical Industries (ICI) (U.K.)	Stuart Pharmaceuticals (1971)
Nestle (Switzerland)	Alcon (1977), Lafayette Pharmaceuticals (1978)

Source : Annual reports.

Various aspects of the economic environment are reviewed below. To understand competition in the pharmaceutical industry, it is necessary to define different industry segments. The effects of seller concentration on the industry as well as on the various therapeutic classes then are analyzed.

2.4.1.1 Market Sectors in the Drug Industry

The pharmaceutical industry has three major market segments, each with its own form of competition : ethical (prescribed) drugs, proprietary (non-prescribed) drugs, and generic drugs.

Ethical drugs are patented and sold primarily through prescriptions. Advertisements are directed to the medical and pharmacy professions only. Patented drugs were the driving force of the modern pharmaceutical industry and accounted for the spectacular sales growth after 1940. Competition in this segment exemplifies the "creative destruction" described by Schumpeter (1975). The result was revolutionary treatment and prevention of disease through the discovery of new patented therapies to replace existing ones and the application of new technologies to drug discovery processes.

Branded prescription drugs eventually become either proprietary or generic drugs. Proprietary drugs, more commonly known as over-the-counter (OTC) drugs, are sold directly to consumers without prescription and usually are

to OTC status. Advertising and other promotional efforts are key competitive strategies used by the original manufacturers to exploit the advantage of brandname recognition in this segment.

Generic drugs generally are those which have lost patent protection and can be manufactured by any firm. Within the generic class, a further distinction can be made between branded and commodity generics. For example, acetaminophen, the generic name of the drug marketed by McNeil as Tylenol, is no longer protected by patent, can be made by other manufacturers, and can be sold under its generic name, making it a commodity generic. Only McNeil can sell acetaminophen under the branded generic name Tylenol.

Competition in the generic drug segment follows closely the neoclassical model. There are numerous sellers and buyers, and price competition dominates. Unlike primary drug producers, generic manufacturers do not incur heavy R&D or advertising costs and do not engage in the lengthy FDA approval process. The desire to control health care costs has led many governments to encourage substitution of brand name drugs with generics. Specifically, the repeal of ant substitution laws and the passage of the 1984 Drug Price Competition and Patent Restoration Act have encouraged greater generic competition in the United States. The loss of market share of branded drugs by generics occur gradually after the patent of a pioneering brand expired (Statman and Tyebjee

1981), but a recent study found that generics achieve an average unit market share of 49 percent within two years of entry (Grabowski and Vernon 1989).

In addition to the three market segments noted above, two other distinctions made in the industry should be mentioned: whether the drugs are single-source or multi-source and whether drugs are for acute care or for maintenance purposes.

Single-source and Multi-source Drugs. Single-source drugs are those available only from one supplier. Although multi-source drugs generally are equated with generics, a patented holder may license out a drug to other firms, a strategy often used to prevent a competitor's brand from gaining market share dominance.

Acute Care and Maintenance Drugs. A distinction is made in the industry between acute and maintenance drugs. The first type treatment diseases which can be cured within a short period, anti-infective drugs are an example. Maintenance drugs are intended for chronic diseases, examples are cardiovascular and cancer drugs. The upward trend in sales of maintenance drugs is evident in Table 2.4. Since chronic diseases imply a longer period of medication, the market potential for maintenance drugs is much greater, *ceteris paribus* than for acute drugs. In addition, because maintenance drugs are characteristically repeat purchases, a certain sales volume can be achieved on a smaller per capita basis than is the case for acute drugs.

Table 2.4 Sales of Prescription Pharmaceuticals by
Therapeutic Classes, 1976- 1991

Therapeutic Classes	1976	1981	1984	1985	1986	1991
Cardiovascular	1,035	2,100	3,565	4,150	4,695	7,550
Antiinfective	1,185	1,770	2,725	3,000	3,510	5,150
Internal Medicine	1,495	2,310	3,095	3,400	4,025	5,400
Pain Control	785	1,560	2,070	2,305	2,610	3,190
Respiratory	480	780	760	900	1,060	1,375
Nutritional	435	725	1,310	1,365	1,480	2,000
Topical	320	590	900	990	1,065	1,250
Mental Health	935	1,150	1,790	2,070	2,275	3,025
Other	380	965	1,735	1,900	2,120	2,850
Total	7,050	11,950	17,950	20,080	22,840	31,790

Source : Arthur D. Little Decision Resources (1988), "Sales of
Prescription Pharmaceuticals to 1991," Spectrum, 1-4.

Note : A full description of the therapeutic classes is shown in Appendix A.

In conclusion, there are several ways to segment the drug market: ethical versus proprietary versus generic drugs, single-source versus multi-source drugs, and acute versus maintenance drugs.

2.4.1.2 Concentration in the U.S. Drug Industry

There are two areas of concentration in the U.S. pharmaceutical industry: among sellers and in various therapeutic classes.

Seller Concentration. The concentration ratio is often used as a summary measure of the size and distribution of firms in an industry. Based on the value of shipments, it is constructed by relating the size of the largest sellers in the market to overall market volume. Statistics collected by the U.S. Bureau of the Census rank the pharmaceutical industry in the bottom 40 percent among a total of 450 industries. Table 2.5 lists the concentration ratios for the four and eight largest pharmaceutical firms. Both indicators show that concentration remained fairly stable and low over 20 years.

Another measure of concentration is the Herfindahl-Hirschman Index (HHI),³ which often is used as an indicator of market power for antitrust purposes. In examining merger activity, a value greater than 1,000 would suggest a high level of market power in an industry. Table 2.6 shows the HHI

³The HHI is computed by squaring the market share for each firm, expressed in percent, and summing the result. The sum is then multiplied by 10,000 to express the HHI index in whole numbers.

Table 2.5 Concentration Ratio for the Pharmaceutical Industry,
Selected Years, 1963 - 1982

Year	Number of firms	Percent of values of industry shipments accounted for by:	
		Four largest companies	Eight largest companies
1963	1,011	22	37
1967	875	24	40
1972	756	25	43
1977	756	25	41
1982	683	26	41

Source : U.S. Bureau of the Census (1986), 1982 Census of Manufacturing, Concentration Ratios in Manufacturing, MC77(SR) -9, Washington, D.C.

Table 2.6 Herfindahl-Hirschman Index Values for the Prescription
Pharmaceutical Industry, 1978-1986.

Year	Index Value
1978	440
1979	453
1980	446
1981	439
1982	414
1983	411
1984	394
1985	368
1986	342

Source : Pharmaceutical Manufacturers Association, internal memorandum

index in the prescription (Rx) pharmaceutical industry for selected years. The figure is less than half the usually accepted value, and the HHI has declined steadily in the last decade.

Concentration in Therapeutic Classes. It has been argued that the use of four- and eight-digit concentration ratios are too broad. Meadsay (1977, p. 279) states :

In short, concentration ratios for the pharmaceutical industry as a whole convey a somewhat misleading impression of the industry, although they are useful in the broad sense of supplying information on the number and approximate size distribution of drug firms. From a standpoint of the influence of industry structure on competitive behavior, it is necessary to go beyond the industry-wide ratios and examine concentration in therapeutically significant categories and in bulk drug production. On this basis, it appears that high concentration in these separate categories, rather than the moderate concentration of the entire industry, is the dominant structural characteristic.

In other words, since substitutability is particular pertinent in the drug industry, a concentration measure should include demand cross-elasticities between or among therapeutic markets. Antiinfective treatments do not intersect with cardiovascular drugs, and sales in these markets should not be combined. Based on this argument, concentration and market share turnover should be gauged at the therapeutic class level.

From Table 2.7 which shows the concentration ratios for the nine major therapeutic classes for selected years, two important observations can be made. First, the four-firm and eight-firm concentration ratios are significantly higher in individual therapeutic classes than when overall firm sales

Table 2.7 Concentration in the Therapeutic Classes, 1963-1982

Therapeutic Classes		Four- and Eight-Firm Concentration Ratios					
Cardiovascular	C ₄	59.2	49.6	47.0	46.9	48.3	43.0
	C ₈	70.9	64.3	65.9	65.8	65.1	60.6
Nutritional	C ₄	29.2	33.2	47.1	48.7	47.5	48.5
	C ₈	42.9	46.2	64.2	62.1	58.9	57.6
Pain Control	C ₄	46.0	53.2	48.0	44.1	52.7	51.4
	C ₈	64.4	70.0	72.4	68.6	74.1	70.5
Internal Medicine	C ₄	36.0	31.2	29.1	28.2	31.1	38.4
	C ₈	50.7	47.1	46.6	44.8	50.8	57.3
Mental Health	C ₄	58.6	60.1	61.6	65.9	60.3	51.1
	C ₈	75.3	78.5	79.5	82.0	80.2	75.4
Topical	C ₄	28.6	35.5	36.8	36.2	31.6	38.8
	C ₈	43.9	52.7	52.5	52.6	44.6	52.4
Antiinfectives	C ₄	39.3	41.7	46.5	46.4	46.6	48.6
	C ₈	60.2	66.6	68.7	66.0	63.7	65.6
Respiratory	C ₄	35.4	41.9	45.8	43.4	38.2	35.2
	C ₈	51.9	57.9	65.8	65.5	58.2	53.5
Cancer	C ₄	65.7	68.0	76.3	66.8	58.9	61.6
	C ₈	n.a.	n.a.	95.8	78.0	66.7	67.5
Average	C ₄	44.1	46.0	48.7	47.4	46.1	46.3
	C ₈	57.4	60.4	67.9	65.0	62.5	62.3

Source : Karel Cool (1985), "Strategic Group Formation and Strategic Group Shifts : A Longitudinal Analysis of the U.S. Pharmaceutical Industry, 1963-1982," Ph.D. Dissertation, Purdue University, p.226.

are considered. The average four-firm concentration ratio ranged from 44.1 percent in 1963 to 46.3 percent in 1982. The corresponding eight-firm ratio is between 57.4 percent and 62.3 percent.

Second, significant shifts have also occurred among therapeutic classes. As mentioned earlier, more and more firms are pursuing R&D in chronic diseases, resulting in overcrowding in a few therapeutic classes. For example, in the cardiovascular category, concentration ratios (C_4 and C_8) have steadily declined; in the nutritional and antiinfective classes, concentration has steadily increased. Finally, other categories (pain control, topicals, and cancer) have experienced irregular ups and downs over the two decades. Table 2.7 clearly shows the dynamics of competition and illustrates the value of analysis by therapeutic classes rather than by aggregate level.

A further indication of the competitive dynamics of the pharmaceutical industry can be seen by the changes in market share rank turnover in each of the therapeutic classes. Table 2.8 ranks the top ten firms in each class for 1963, 1972, and 1982 and shows the average market share rank changes among the top ten leading firms in each class. Market share turnover obviously is affected by the entry and exit of firms. Entrants into a therapeutic class could be entirely new firms from outside the drug industry or by pharmaceutical firms with new products in that particular market. In either case, the

market position of existing firms is likely to change.

Some interesting patterns can be observed from these two tables. Changes in market share rank turnover caused some instability in certain therapeutic classes vis-à-vis others, as can be seen in Table 2.8. For 1972 compared to 1963, the largest absolute average rank change observed was in the nutrition and topical (8.4) classes and the smallest was in mental health (5.1).⁴ For the second decade, the largest and smallest changes were observed in topical (11.1) and mental health (4.4), respectively. Comparing Table 2.8 with Table 2.7, although one would expect concentration evolution and market share rank turnover to be inversely correlated, opposite patterns are observed for certain therapeutic classes.

Table 2.9 summarizes the comparisons between concentration evolution and market share turnover for the different therapeutic categories between 1963 and 1982. In the mental health category, the four-firm concentration ratio declines, and there is a negative rank turnover. This signals a more entrenched market position among competing firms. In contrast, the topical category was characterized by both growing concentration and a positive rank turnover, suggesting intense competition from new entrants and existing firms.

⁴The average market share rank in each therapeutic category was computed by taking the average of the absolute rank changes of the top ten firms from 1963 to 1972. The same procedure was applied for 1972 to 1982.

Table 2.8 Market Share Rank Turnover of Top Ten Firms in Each Therapeutic Class, 1963-1982.

1. CARDIOVASCULAR

	Rank	I	II	III	IV	V	VI	VII	VIII	IX	X	Average Absolute Change in Ranks
Year												
1963		8	24	15	18	1	7	2	3	10	13	
1972		8	24	3	25	20	13	4	18	15	14	6.7
1982		3	8	24	14	10	15	25	18	13	20	9.4

2. NUTRITION

1963		1	7	15	17	3	2	26	11	22	10	
1972		4	1	15	18	7	17	2	11	3	22	8.4
1982		4	1	24	2	15	18	20	3	11	9	8.1

3. PAIN CONTROL

1963		7	3	23	11	16	24	1	5	8	6	
1972		7	8	3	6	23	16	24	11	1	5	8.2
1982		6	8	17	7	19	10	23	16	3	24	5.3

4. INTERNAL MEDICINE

1963		17	14	13	7	8	22	24	10	2	3	
1972		17	13	3	6	14	18	7	10	15	22	7.1
1982		14	3	6	17	7	13	10	19	15	12	6.1

5. MENTAL HEALTH

1963		26	3	14	24	5	7	10	6	1	8	
1972		26	8	14	10	3	24	18	6	5	7	5.1
1982		26	8	14	12	18	23	15	2	20	3	4.4

6. TOPICAL

1963		23	12	14	3	15	18	6	1	16	8	
1972		18	12	15	23	3	1	6	14	8	16	8.4
1982		6	8	14	12	18	23	15	2	20	3	11.1

7. ANTIINFECTIVES

1963		2	10	15	7	17	26	3	4	16	9	
1972		7	4	10	17	15	3	2	9	1	12	7.5
1982		7	10	4	17	8	2	1	3	26	14	5.4

8. RESPIRATORY

1963		14	12	16	11	18	24	17	7	23	3	
1972		12	11	18	16	14	23	3	4	10	24	6.6
1982		12	11	18	23	4	16	24	14	3	5	8.3

9. CANCER

1963		23	2	7	26	na	na	na	na			
1972		4	7	26	2	23	17	15	10			
1982		4	7	2	23	26	17	3	8			

Source : Karel Cool (1985), Strategic Group Formation And Strategic Group Shifts : A Longitudinal Analysis of the U.S. Pharmaceutical Industry, Ph.D Dissertation, Purdue University.

Table 2.9 Comparison of Concentration Evolution and Changes
in Market Share Rank Turnover in Each Therapeutic
Category between 1963 and 1982

Therapeutic Category	Four-firm concentration	Market share rank turnover
Cardiovascular	Decline	Positive
Nutrition	Increase	Negative
Pain Control	Increase	Negative
Internal Medicine	Increase	Negative
Mental Health	Decline	Negative
Topical	Increase	Positive
Antiinfectives	Increase	Negative
Respiratory	Decline	Positive

In summary, to understand the competitive dynamics of the drugs industry's economic environment, it is necessary to look beyond aggregate firm level data. Although the concentration ratios in Table 2.5 indicate stability over the last two decades, shifts in market share rankings among the largest firms show otherwise. Because concentration levels and trends differ significantly among therapeutic categories, it is more valid and meaningful to conduct a competitive analysis at that level. Comparisons between concentration ratios and market share turnover at the therapeutic level revealed that the two do not always correlate negatively. In the next section, the political aspects of the pharmaceutical environment are discussed.

2.4.2 Political Environment of the U.S. Drug Industry

The drug industry has come under increasingly stringent scrutiny and in the United States, it is extensively and rigorously regulated by the federal government. The constraints imposed by FDA are a key distinguishing feature of the pharmaceutical sector vis-à-vis other high-technology industries. Studies by Ashford et al. (1977), Temin (1979), and Young (1982) indicate the significant link between regulatory constraints and research productivity in this industry.

Government involvement in the control of therapeutic drugs dates to the early twentieth century in the United States. Since it would be impossible to discuss all relevant

laws, only the most significant are noted here.

2.4.2.1 Federal Regulation

Pure Foods and Drug Act (1906). The primary concern of this act was to prevent and control food adulteration and abuse; drug regulation was of secondary importance.

1938 Food, Drug, and Cosmetic Act. This was the first direct drug regulation prompted by the exilir tragedy of 1937. It imposed better procedures for premarketing clearance in order to protect the public from untested and potentially harmful drugs.

Kefauver-Harris Amendments (1962). While the 1938 Law was significant, the testing of new drugs remained unregulated. The birth defects caused by thalidomide prompted the 1962 amendments, which established closer FDA control over the premarket testing of new drugs and altered the criteria for the approval to market new drugs. Specifically, drug manufacturers had to show proof-of-efficacy in addition to the proof-of-safety requirement, and approval hinged on the Investigational New Drug (IND) requirement for clinical testing. The major effect of the IND was to stipulate a comprehensive data on animal tests before the FDA would allow human trials. As a result of the IND procedures, the FDA shifted after 1962 from essentially an evaluator of evidence and research findings at the end of the R&D process to an active participant in the whole discovery and development process.

Figure 2.1 explains the various steps in the drug development and approval process. Industry experts estimate that the course from pharmaceutical research to a marketable drug averages 10-15 years and costs about \$200 million. As can be seen from the chart, the attrition rate is fairly high between the time a drug is filed as an IND to the time it is finally approved by the FDA. A fuller historical description of the process is provided by Wardell (1979).

Waxman-Hatch Act (1984). This legislation made it easier for generic drug manufacturers to market their products by eliminating much duplicated testing and by permitting them to prove that their products were the bioequivalent of existing ethical drugs. In addition, ethical drug manufacturers were given a five-year extension to the 17 years of patent protection.

2.4.2.2 State Regulation

State government actions also have affected the drug industry, most especially by repeal of anti-substitution laws. In the 1960s all states prohibited pharmacists from substituting any drug for the one prescribed by a physician; by 1981 all states, only Indiana and Oklahoma, had not repealed these. Two factors contributed to the repeal: pressure from consumer groups and third-party payers increased as health care costs spiralled, and many pharmacists wanted to assume a greater role in drug selection.

Figure 2.1 Drug Development and Approval Process

Preclinical Testing			Phase I					Phase II			Phase III			FDA		Approval
YEARS	1	2	3			4	5	6	7	8	9		10			
Test Population	Laboratory and Animal Studies		20 to 40 Healthy Volunteers			100 to 300 Patient Volunteers			1,000 to 3,000 Patient Volunteers			Post-marketing safety monitoring				
PURPOSE	Assess safety and biological activity		Determine safety and dosage			Evaluate effectiveness. Look for side effects.			Verify effectiveness, monitor adverse reactions from long-term use.			Review usually takes about 2-3 years		Large-scale manufacturing		
														Distribution		
														Education		
% of all new drugs that pass			70% of INDs			33% of INDs			27% of INDs			20% of INDs				

FILE IND

FILE NDA

FILE IND

FILE NDA

Source: Pharmaceutical Manufacturers association, internal memorandum.

Conclusion. Government regulation are two-fold: removal of ineffective new drugs from reaching the marketplace and has enabled greater participation by consumers and pharmacists in the drug selection process. Regulation has had significant negative effects however, and these are discussed in the following section.

2.4.2.3 The Negative Effects of Regulation on the Drug Industry

The Kefauver-Harris amendments have been controversial since their passage in 1962. Two major negative consequences are cited: (1) a decline in R&D innovation and shortened patent lives; and (2) increased concentration among larger firms.

Decline in R&D Innovation. New chemical entities (NCEs) are drugs characterized by chemical differentiation and have therapeutic advantage over existing products. The development of NCEs is important to society and contributes to the overall growth of the industry. Between 1961 and 1980, 710 NCEs were registered by European firms, 353 by U.S. firms, and 155 by Japanese firms (Burstall, 1985).

Table 2.10 gives an overview of the total number of NCEs introduced in the United States between 1940 and 1986. The pre- and post-1962 average was 47 and 25, respectively. Econometric studies (for example, Baily 1972; Sarett 1974; Wardell 1973) indicate that regulation has depressed drug innovation. Wardell and Lasagna (1975) also found a majority

Table 2.10 New Chemical Entity Drug Introductions to U.S. Markets, 1940-1986

Year	Number of Entities	Year	Number of Entities
1940	14	1963	16
1941	17	1964	17
1942	13	1964	25
1943	10	1966	13
1944	13	1967	25
1945	13	1968	12
1946	19	1969	9
1947	26	1970	16
1948	29	1971	14
1949	38	1972	10
1950	32	1973	17
1951	38	1974	18
1952	40	1975	15
1953	53	1976	14
1954	42	1977	16
1955	36	1978	23
1956	48	1979	15
1957	52	1980	13
1958	47	1981	19
1959	65	1982	26
1960	50	1983	22
1961	45	1984	15
1962	24	1985	20
		1986	24
TOTAL :			1,178

Source : Paul de Haen database, various years.

of U.S. drug companies shifting their research efforts overseas, where regulation was less stringent.

Regulatory practices are not the only factor, however, and the depletion of research opportunities has been offered as another. In a comparative analysis of drug innovation in the United States and United Kingdom (Grabowski, Vernon and Thomas 1976) found that R&D productivity had declined more in the former than the latter, but regulation explained only one-third of the decline. The remaining two-thirds of the U.S. decline was matched by a similar decline in the United Kingdom, where regulation is less stringent, an effect that the researchers state is "consistent with the hypothesis of a worldwide depletion of research opportunities" (p. 36).

Increasing Concentration. Enforcement of the 1982 amendments also seems to have strengthened the position of larger firms and resulted in increased concentration (Peltzman 1974; Vernon and Gusen 1974; Grabowski et al. 1976; Schwartzman 1976). Table 2.11 confirms the trend toward firm concentration in innovational output. Despite a decrease in the number of NCEs and firms since 1962, the four-firm concentration ratio has steadily risen.

One reason for the increasing dominance of large firms is that fewer new, effective drugs are challenging the market position of older drugs. Furthermore, larger firms have an R&D advantage because they have the financial resources to sustain long periods of product development and approval. The

Table 2.11 Concentration of Innovational Output in the U.S. Ethical Drug Industry

Period	Total number of NCEs	Number of firms having an NCE	Concentration ratio innovational output		
			4-firm	8-firm	20-firm
1957-1961	233	51	0.462	0.712	0.931
1962-1966	93	34	0.546	0.789	0.976
1967-1971	76	23	0.610	0.815	0.978

Source : Henry G. Grabowski, John M. Vernon, and Lacy G. Thomas (1976), "The Effects of Regulatory Policy on the Incentives to Innovate : An International Comparative Analysis," in Impact of Public Policy on Drug Innovation and Pricing, S.A. Mitchell and E.A. Link, (eds.), Washington, D.C. : The American University, p.72.

Note : Innovational output is measured as NCE sales during the first three full years after product introduction

costs of drug development have made it increasingly difficult for smaller firms to remain in the "innovation race" (Clymer 1970). The uncertainties in pharmaceutical research also requires large financial investments which small-scale firms lack. Yoshikawa (1989) found that it takes approximately 7,000 compounds to develop one successful pharmaceutical drug in Japan while in the European Community it may take as high as 10,000 compounds to one promising new drug.

Conclusion. Two exogenous factors may account for the decline in drug innovation: stringent regulation and a depletion of research opportunities. Trends in the drug industry support the thesis advanced by Schumpeter (1950) and Galbraith (1952) that larger firms not only are better equipped for rapid technological innovation but also achieve increasing returns to scale. The next section looks at the interface between the regulatory and technological environments.

2.4.3 Trends in the Technological Environment

Three important aspects of the technological environment are: the increasing cost of drug R&D and concentration in drug research, conservatism in R&D, and foreign competition in drug innovation.

2.4.3.1 Increasing R&D Costs

Table 2.12 summarizes the results of six studies that examined the costs of discovering and developing NCEs before

Table 2.12 Research and Development Costs Per NCE Drug,
Before and After 1962 (in millions of 1980 dollars)

1980 Dollars		
	Pre-1962	Post-1962
Baily (1972)	\$16.0	\$ -
Clymer (1972)	-	56.5
Sarett (1974)	3.4	25.9
Schwartzman (1975)	3.7	48.6
Schnee (1977)	3.1	-
Hansen (1979)	-	47.6

and after 1962, excluding the cost of capital. These studies clearly demonstrate the substantial increase, on average about 7 times more. Based on NCEs approved between 1970 and 1985, a study by Wiggin (1987) showed that the total cost for an approved drug had inflated to \$125 million (expressed in 1986 dollars). A study by DiMasi et al. (1990) found that total pharmaceutical costs had escalated to \$231 million by 1989.

The increasing cost of developing a new drug is also the result of the shift in R&D focus to chronic diseases, requiring more R&D time and financial resources. The differential costs of conducting R&D in different therapeutic classes were calculated by Hansen (1980), using an accounting approach, for a sample of 37 NCEs tested on human beings from 1963 to 1975. Because R&D expenditures for a new drug are made over time, they were capitalized in the study. The results are summarized in Table 2.13. The most expensive research category is psychopharmacological (\$70.3 million), and the least expensive is antiinfective (\$19.1 million).

2.4.3.2 R&D Conservatism

The decline in R&D productivity is also attributed to pharmaceutical laboratories. An article in The Economist (1987, p. 67), "Mismanaging Drug Research," about research done at the Harvard Business School of Public Health, notes :

Drug companies pour more of their revenue into R&D than most other industries, but new products reaching the market have declined. The industry blames stringent government controls to ensure drug safety. Critics blame the companies' own bureaucratic habits.

Table 2.13 Average R&D Cost for a Sample of 37 NCEs by Therapeutic Category, 1963-1975 (in millions of 1967 dollars)

Therapeutic category	R&D cost	Number of NCEs
Cardiovascular	30.6	4
Neurologic, Analgesic	36.3	6
Psychopharmacological	70.0	3
Metabolic, Antifertility	65.3	5
Antiinfective	19.1	12
Antiinflammatory	68.3	4
Gastrointestinal, Respiratory, Surgical	28.5	3

Source : Ronald W. Hansen (1980), "Pharmaceutical Development Cost by Therapeutic Category, Working Paper, University of Rochester Graduate School of Management," (March).

Downs (1967, p. 20) summarizes this tendency in his Law of Increasing Conservatism: "All organizations tend to become more conservative as they grow older, unless they experience periods of rapid growth or internal turnover." In an era of "transition and shakeout" (Financial World 1987) and "greater turbulence and interdependence" (The Economist 1987), drug firms are finding that superiority in all aspects of discovery and development of new drugs is difficult to maintain. Technological innovations come so fast and in so many areas that virtually no company can afford the staff to keep abreast of all new discoveries. The riskiness and high cost of R&D also are forcing firms to seek promising innovations from sources outside their own laboratories. The number of licensing agreements, mergers, and joint ventures jumped from six in 1979 to twenty in 1988 (*Wall Street Journal Indices* 1979 and 1988). Some examples of long-term R&D contracts and joint ventures between pharmaceutical firms and university laboratories are summarized in Table 2.14. Drug firms also are collaborating on R&D projects. Table 2.15 provides a few examples.

2.3.4.4 Foreign Competition

Patent activity is another measure of research intensity and indicates the extent of competition from foreign drug firms. Table 2.16 shows the percentages of patents issued for drugs between 1963 and 1986 in the U.S. pharmaceutical industry. Of particular significance is the decline in the relative

**Table 2.14 Selected Examples of Joint Ventures and Long-term R&D Contracts between
Pharmaceutical Firms and University Laboratories**

Year	Company	University	Amount (\$million)	Duration (years)	Area of Research
1988	Squibb	Massachusetts General Hospital	6.4	5	Molecular Neurogenetics
1988	SmithKline	Johns Hopkins	2.2	5	Respiratory Disease
1987	Upjohn	University College, London & Center Paul Broca INSERM, Paris	5.0	5	Central Nervous System
1987	Squibb	Oxford	32.0	12	Central Nervous System
1985	Cynamid	Rice	n.a.	n.a.	Artherosclerosis and Heart Disease
1982	Bristol-Myers	Yale	3.0	5	Anti-cancer drugs
1981	Johnson & Johnson	Scripps Clinic & Research Foundation	30.0	n.a.	Synthetic Vaccines
1975	Monsanto School	Harvard Medical	23.5	12	Tumor, Angiogenesis Factor

Source : Frank Tapon (1989), "A Transaction Costs Analysis of Innovations in the Organization of Pharmaceutical R&D," Journal of Economic Development and Organization, 12, 197-213.

Table 2.15 Selected Examples of R&D Collaborations Between Pharmaceutical Firms

Pharmaceutical Firms	Project Description
Dupont and Merck	Joint development and marketing of blood pressure and heart disease mechanisms
Johnson & Johnson, Chiron and Abbott	Johnson & Johnson and Chiron will develop and do market tests for the hepatitis C virus, while Abbott will license worldwide rights to manufacture and market hepatitis tests from the other two companies
Rorer Group and Bolar	Joint venture to develop and market drugs for the treatment of hypertension
Syntex and Immunex	A research and licensing agreement for a chemotherapy drug; Immunex will acquire the market rights, and Syntex will retain rights to the drug outside the United States.
Boots and Hoechst	A 50/50 venture to manufacture bulk ibuprofen in the United States.
Chemex Pharmaceuticals and Senju Pharmaceuticals	A drug evaluation and licensing agreement for an antiinflammatory drug.
Geritech and Yamanouchi Pharmaceutical	This alliance was motivated to develop and commercialize products aimed at treating many of the health effects of diabetes and aging. The arrangement includes collaboration on R&D and offers Yamanouchi an exclusive license to market Geritech technologies in the Far East.
SmithKline French and Novo-Nordisk	An agreement to develop a calcium channel blocker currently in preclinical trials. Novo-Nordisk will have marketing rights to the drug within Europe, and SmithKline will have rights outside Europe.

Source : The Pharmaceutical News Capsule (1989).

Table 2.16 Patents Issued in the U.S. Pharmaceutical Industry, 1963-1986

	Year														
	1963-1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986
% Total Patents with															
U.S. Origin	65	58	55	57	53	51	52	50	49	51	47	47	51	50	48
Foreign Origin ^a	35	42	45	43	47	49	48	50	51	49	53	53	49	50	52
Foreign Origin :															
U.S. Owned	6	6	8	6	7	7	8	7	6	7	6	4	6	5	6
Foreign Owned	29	36	37	37	40	42	42	43	43	46	47	44	45	47	40
U.S. share of ^b total patents	71	64	63	63	60	59	60	57	55	58	53	51	56	55	54
% of U.S. patents with foreign origin	8	9	13	9	12	12	13	12	11	12	11	8	11	9	11

Source : U.S. Patent and Trademark Office, various years.

^a Foreign origin refers to residence in a foreign country.

^b Percentage of patents issued to U.S. firms, U.S. government, and U.S. individuals residing abroad of total patents of U.S. firms, U.S. government, and U.S. individuals.

share of patents held by firms of U.S. origin; this figure dropped from 66 percent from 1963-1972 to about 48 percent in 1986. Meanwhile, innovational activity abroad grew substantially; the percentage of patents of foreign origin rose steadily from about 35 percent in 1963-1972 to 52 percent in 1986. The stringent demands of clinical trials and toxicology testing by the FDA have forced firms to locate their research facilities overseas.

Conclusion. The decline in pharmaceutical innovation since 1962 has been accompanied by sharp increases in the cost, duration, and risk of new product development. The rise in R&D cost has been more pronounced in certain therapeutic classes than others, and smaller drug firms have been more affected than larger companies. The higher costs per innovation render small-scale research operations relatively less productive per dollar spent and hence less profitable. One response has been collaborative and joint venture arrangements between pharmaceutical firms or with university laboratories. The performance of foreign drug firms has increased over the last two decades, as indicated by their increase in patent activity. In the next section, social trends affecting the pharmaceutical industry are discussed.

2.4.4 Trends in the Social Environment

In general, the social environment strongly influences and is influenced by the political-economic environment. Certain social trends warrant special attention here:

consumer drug use, changing demographics, and the financing of health care services.

2.4.4.1 Consumer Drug Use

U.S. health care expenditures have almost tripled in the past three decades. Health care financing was about \$500 billion in 1987, compared to about \$27 billion in 1960. Despite the decline in drugs as a percentage of national health care expenditures,⁵ consumer use has steadily increased. Table 2.17 shows that the total number of prescriptions, drug expenditures, and the proportion that drug expenditures contribute to health care costs have increased over the last two decades.

One factor contributing significantly to rising drug expenditures is higher drug prices. Over the past twenty years, price inflation has continually outpaced the economy's overall inflation rate. In 1981 and 1982, however, drug expenditures in total and as a percentage of health care expenditures declined slightly. This decrease may have been due to the greater use of generics, particularly by hospitals.

2.4.4.2 The Aging Population

A contributory factor to the increasing use of drugs is the aging of the population. Substantial improvements in

⁵Drugs as a percentage of national health care expenditures have declined from 13.6% in 1960 to 7% in 1987.

Table 2.17 Total Prescriptions, Drug Expenditures, and Drug Expenditures as a Proportion of Total Health Care Costs (in millions of 1967 dollars)

Year	Prescription	Drug expenditure	Drug expenditure as a % of health care costs
1963	4.5	22.2	10.3
1964	4.5	22.9	9.9
1965	5.0	25.2	10.6
1966	5.4	27.0	10.8
1967	5.4	28.2	11.0
1968	5.7	30.9	11.6
1969	5.9	33.1	11.9
1970	6.2	34.1	11.3
1971	6.5	35.6	11.4
1972	6.9	38.6	11.5
1973	7.2	41.5	11.7
1974	7.1	45.3	12.5
1975	7.0	46.3	12.7
1976	6.8	46.8	12.6
1977	6.5	46.8	12.3
1978	6.2	47.2	12.4
1979	6.1	49.8	12.5
1980	6.2	50.5	12.3
1981	6.2	50.0	11.8
1982	6.4	46.6	11.0

Source : U.S. Health Care Financing Administration, Health Care Financing Review, various years.

health care have extended the age-adjusted death rate in the United States. Table 2.18 gives the actual and projected proportion of the U.S. population age 65 and older for selected years.

Older Americans are the most important group of consumers for the pharmaceutical industry, as they are the most susceptible to illness, and thus spend a disproportionate amount on drugs. Being an important source of revenue, this segment has developed "countervailing power" in the industry, particularly with respect to public policy pertaining to health.

2.4.4.3 Third-Party Financing

While demographic trends point toward continued growth, the pace of drug inflation is likely to slow due to tightened third-party reimbursements and as increased competition for the health care dollar controls utilization and restrains pricing. As used here, third-party payment systems refer to government programs, such as Medicare and Medicaid, corporate-financed employee health insurance, and private insurance.

The proportion of drug expenditures accounted for by government programs versus all third-party payers is shown in Table 2.19. It reveals that the rapid rise in health care expenditures has contributed to the increasing portion of drug costs covered by third-party payers. At the same time, the share of health care costs paid directly by consumers dropped from 51.7 percent in 1963 to 31.5 percent in 1982.

Table 2.18 Percentage of U.S. Population Age 65 and Older

Year	Percentage
1963	9.4
1967	9.6
1971	10.0
1975	10.6
1979	11.4
1982	11.5
1995 ^a	13.1
2025 ^a	19.5

Source : U.S. Bureau of Census, Current Population Reports, various years.

^a Estimates by the U.S. Bureau of the Census.

Table 2.19 Contribution of Third-Party Payments to Drug and Total Health Care Expenditures

Year	% of expenditures paid by government programs		% of expenditures paid by all third-party payers	
	<u>Drugs</u>	<u>Total health care</u>	<u>Drugs</u>	<u>Total health care</u>
1963	2.6	17.0	4.1	48.3
1964	2.9	17.9	4.7	47.5
1965	2.9	18.8	4.9	48.0
1966	3.5	24.2	5.9	49.5
1967	4.2	29.8	7.0	56.5
1968	4.8	37.8	7.9	60.2
1969	5.1	37.1	8.7	60.5
1970	6.8	36.0	11.0	60.1
1971	6.6	36.9	11.2	61.3
1972	7.1	36.8	12.0	62.7
1973	7.2	37.3	12.7	63.7
1974	6.9	39.0	12.7	63.7
1975	7.2	42.4	13.4	66.6
1976	8.4	41.6	15.8	68.3
1977	8.3	41.0	16.4	67.2
1978	8.4	42.0	16.8	67.5
1979	8.3	42.1	17.3	67.3
1980	8.5	42.3	18.9	67.1
1981	8.9	42.7	20.1	67.9
1982	8.7	42.4	21.6	68.5

Source : U.S. Health Care Financing Administration, Health Care Financing Review and Social Security Bulletin, various years.

While not shown in the table, increasing per-capita drug outlays currently make up a large portion of drug costs covered by private health insurance. The share of total drug costs for private insurance increased to 14 percent in 1984, up from only 4 percent in 1972. Over the same period, payments by consumers fell from 88 percent to 78 percent, while government's total drug expenditures rose from 6 percent to 8 percent.

A growing cost consciousness on the part of the government and other third-party payers has resulted in the implementation of several cost containment measures. Examples of government initiatives are the Prospective Payment for Medicare Inpatient Services, the Drug Price Competition, the Patent Restoration, and the Medicare Catastrophic Coverage acts. At the same time, insurance companies, employers, and others are raising employee deductibles and co-payments, implementing out-patient incentives, and encouraging employees to join health maintenance organizations (HMOs). The effect of these actions remain uncertain, but it is clear that "attempts to pass the buck on health costs [to the consumer] will give the industry a monumental headache in 1991" (Business Week 1991, p.90).

Conclusion. Transformations in the U.S. health care system are shifting industry policy from indiscriminate expansion to a more conventional, businesslike approach that is more sensitive to the marketplace. While prescription drug

firms should benefit from the growing number of elderly in the population, the initiation of various cost containment measures by the government and other third-party payers is expected to affect the performance of many drug firms unless they continue to develop and market drugs that offer real patient care advantages or that prove more cost effective than alternatives.

So far, discussion of the pharmaceutical industry has focused on the U.S. environment. The next section gives a brief overview of the world pharmaceutical industry.

2.5 Globalization of the Pharmaceutical Industry

Before the 1950s, pharmaceutical competition remained largely national in scope, with the significant exception of the Swiss multinationals. Today, competition in the industry is truly worldwide, and national markets are interdependent. In the face of growing cost pressures and escalating R&D budgets, drug companies must achieve a global presence, supported by more efficient and effective R&D efforts and large detail forces.

2.5.1 Global Presence

Figures for worldwide Rx (prescription) sales, Rx market share, R&D expenditures, and size of detail force for the top 30 pharmaceutical companies are shown in Table 2.20. Sales totaled nearly \$209 billion in 1988 and accounted for 50.95 percent of worldwide sales of all pharmaceutical companies.

Table 2.20. Top 30 Pharmaceutical Companies' Worldwide Sales, Market Shares, R&D Expenditures, and Detail Force, 1988.

Company	Sales		R&D (mil)	R&D as a percentage of sales	Worldwide		
	RX (mil)	Total (mil)			Market share 1988	Market share 1983	Detail force
Merck (USA)	\$4,240	\$5.94	\$615	14.5	3.95%	3.80%	6,200
Glaxo Holdings (UK)	3,160	3.52	405	12.8	3.00	1.40	5,500
Ciba-Geigy (SWZ)	3,020	12.73	440	14.6	2.80	3.20	5,300
Hoechst (GER)	2,700	25.53	330	12.2	2.50	3.00	4,400
American Home Products (USA)	2,420	5.50	250	10.3	2.25	3.10	4,330
Bayer (GER)	2,370	23.65	480	20.3	2.20	2.00	4,000
Johnson & Johnson (USA)	2,350	9.00	385	16.4	2.20	2.30	3,500
SmithKline (USA)	2,200	4.75	285	13.0	2.15	2.80	3,000
Pfizer (USA)	2,260	5.39	380	16.8	2.10	2.90	3,600
Sandoz (SWZ)	2,230	7.26	390	17.5	2.10	2.00	3,400
Eli Lilly (USA)	2,090	4.07	375	17.9	1.95	2.50	3,250
Bristol-Myers (USA)	2,010	5.97	275	13.7	1.90	2.10	4,000
Hoffman La-Roche (SWZ)	1,940	2.79	470	24.2	1.85	2.20	3,500
Squibb (USA)	1,710	2.59	275	16.1	1.60	1.30	3,950
Schering-Plough (USA)	1,670	2.97	300	18.0	1.55	1.60	NA
Upjohn (USA)	1,650	2.70	320	19.4	1.55	1.60	3,500
Warner-Lambert (USA)	1,590	3.91	220	13.8	1.50	1.90	NA
American Cyanamid (USA)	1,560	4.59	190	12.2	1.45	NA	NA
Takeda (JAP)	1,480	5.06	312	12.1	1.40	1.10	1,800
Abbott (USA)	1,450	4.94	250	17.2	1.15	1.10	1,600
Imperial Chemicals (UK)	1,450	21.06	240	16.6	1.35	1.60	NA
Beecham Group (UK)	1,400	4.68	140	10.0	1.35	1.40	NA
Wellcome (UK)	1,340	2.11	205	15.3	1.25	1.10	NA
Rhone-Poulenc (FRA)	1,300	10.72	250	19.2	1.20	1.30	NA
Sankyo (JAP)	1,190	3.25	NA	NA	1.10	1.00	NA
Dow Chemicals (USA)	1,070	16.68	160	15.0	1.00	0.90	NA
Fujisawa Pharmaceuticals (JAP)	1,060	1.52	160	15.1	1.00	0.90	NA
Astra (SWE)	1,050	1.08	200	19.0	0.80	0.70	NA
Sanofi (FRA)	1,046	2.40	200	19.1	0.60	0.50	NA
Yamanouchi Pharmaceuticals (JAP)	1,000	1.48	140	14.0	0.95	0.60	NA
Syntex (PAN)	880	1.27	175	20.0	0.80	0.90	NA

Source : Financial World (1989a)

NA = not available

Judging by the percentages of world market share of individual companies, the global pharmaceutical industry is an oligopoly.

Fourteen of the top 30 companies are located in the United States, four each in Japan and the United Kingdom, three each in Switzerland and Germany, and one each in Sweden and France. Among the top twenty firms, the drug industry is still dominated by U.S. and European multinationals with the exception of Takeda. In general, the major Japanese drug companies (Takeda, Sankyo, Fujisawa, and Yamanouchi) are a fragmented and highly diversified group. While they have traditionally focused on their domestic market (Burdstall 1985), they are increasingly becoming more globally oriented (Yashikawa 1989). Licensing and joint ventures tend to be the most frequent entry modes used by Japanese drug firms.

Because Western Europe, the United States and Japan accounts for approximately 75 percent of total world demand for health care products, most of the leading players seek to establish an insider position in each of these markets. The worldwide distribution of corporate sales for North American-based companies and European-based companies is shown in Table 2.21.

Between 1980 and 1988, the average percentage of sales received outside the home region by all pharmaceutical companies increased slightly, from 37 percent to 40 percent. Over the same period, European-based companies aggressively increased their global presence, while that of North American-

Table 2.21 Leading Pharmaceutical Companies : Worldwide Distribution of Corporate Sales, 1980 and 1988

	Year	
	1980	1988
All Pharmaceutical Companies		
Home Region	63%	60%
Rest of the World	37%	40%
North American-based Companies		
North America	63%	64%
Europe	24%	22%
Asia	7%	9%
Others	6%	5%
European-based Companies		
Europe	57%	50%
North America	18%	29%
Asia	10%	12%
Others	15%	9%

Source : Company reports, various years.

based companies remained relatively stable. European penetration of the U.S. market increased to 29 percent, compared to only 18 percent over the 1980-1989 period.

2.5.2 Detail Force

In an increasingly competitive and globalized health care product industry, marketing plays a critical role. One way to achieve a global presence is to support a critical mass of detail people for the marketing or co-marketing of one's own or other companies' products as well. As was shown in Table 2.20, Merck and Glaxo fielded the largest detail forces in 1985-88. Through extensive international marketing and selling, both Merck and Glaxo managed to turn Vasotec (an ACE inhibitor⁴) and Zantac (antiulcer), respectively, into billion-dollar products. Zantac was sold in the United States through a co-marketing deal with Roche, which "rented out" 800 salesmen to Glaxo.

The detail force is considered essential to the success of a new drug. A typical U.K. pharmaceutical company makes about 17,000 calls to 24,500 physicians at least once a year. The U.S. Pharmaceutical Manufacturers Association estimates that 25,000 detail representatives were employed at a cost of \$25,000 per employee (Silverman and Lee 1974).

2.5.3 Research and Development

Much of the discussion on industry R&D was covered in

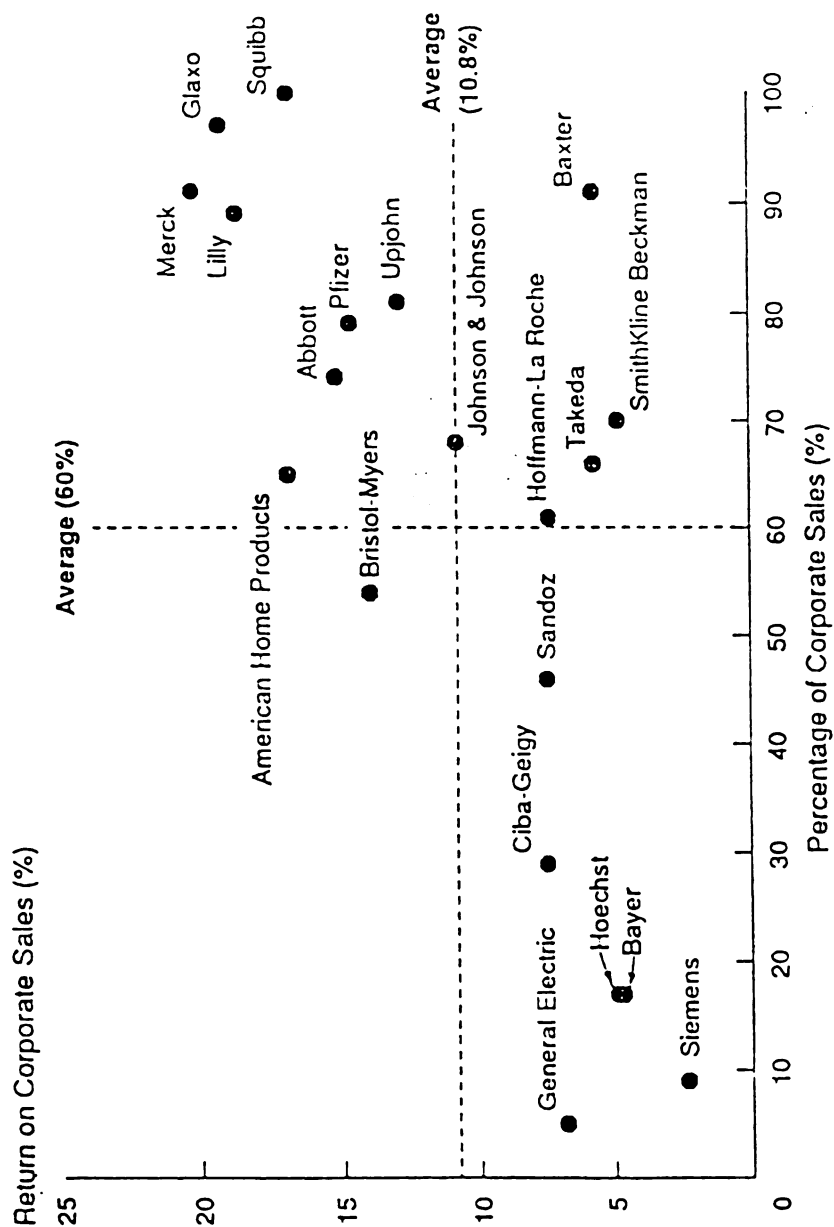
⁴ACE inhibitor is a drug for the treatment of hypertension.

section 2.4.3. Here the focus is on R&D at the firm level. Figure 2.2 compares R&D expenditure and health care product sales from 1985 to 1988 among the major pharmaceutical firms. The similarity in corporate strategies is evident: most increased their R&D investments faster than their sales growth. Exceptions were Hoffmann La-Roche, Merck, and Upjohn, which experienced above-average sales growth and were already either making large R&D investments or allocating a high percentage of health care product sales to R&D.

Leading all companies in R&D expenditure growth was Glaxo, highly dependent on the antiulcer drug Zantac, which attained sales of \$1.7 billion in 1988. To avoid over-reliance on this "cash cow", the company invested heavily in R&D. Two other leading companies, SmithKline Beckman and Squibb, also depended on billion-dollar drugs, Tagamet and Capoten, respectively, for nearly 50 percent of their 1988 ethical pharmaceutical sales. The inability to generate a stream of new drugs and overdependency on a single blockbuster drug led, in part, to the 1989 mergers of SmithKline Beckman with Beecham and of Squibb with Bristol-Myers.

Conclusions. To compete more effectively in the global market, major pharmaceutical firms have made massive investments in R&D and enlarged their detail force. Compared to their North American counterparts, Western European firms have been especially aggressive in establishing their presence in overseas markets. Escalating pressure to develop new

Figure 2.2 Comparison of R&D Expenditure Growth and Health Care Product Sales for 20 Major Pharmaceutical Firms, 1985-1988



products, which requires high-risk and expensive R&D, calls for a worldwide presence to fund such development. This force will drive U.S. companies to seek a broader global reach during the 1990s.

2.6 Conclusion

Major changes in the environment of the U.S. pharmaceutical industry as well as the global context have been analyzed in some detail. Such an analysis is important as it permits identification of the major trends and forces pharmaceutical firms need to consider in planning their strategic posture.

Following is a summary for each environmental domain.

2.6.1. Economic Environment

The pharmaceutical industry can be analyzed along several dimensions: (1) ethical versus proprietary versus generic drugs; (2) single-source versus multisource drugs; and (3) acute versus maintenance drugs. Seller concentration was analyzed on an industry level and for individual therapeutic classes. From the standpoint of the influence of industry structure on competitive behavior, it is necessary to go beyond industry wide ratios and examine concentration in therapeutically significant categories. An analysis of concentration and market share rank turnover at the therapeutic category level reveals certain categories have exhibited more instability than others.

2.6.2. Political Environment

The effects of government regulation since the passage of the Kefauver amendments in 1962 are believed to have contributed to the declining rate of R&D innovation and higher R&D costs. Spiralling health care costs have prompted both federal and state governments to implement several cost containment measures.

2.6.3. Technological Environment

The shift in R&D focus from acute to chronic diseases has contributed to the differential costs of conducting R&D in different therapeutic classes. There is also increasing concentration of R&D among larger firms. The prohibitive cost and risk of pharmaceutical R&D suggest that a certain economy of scale may be necessary to compete in the industry. These same forces are also encouraging firms to form collaborative R&D ventures with other companies and university laboratories. An analysis of the patent activity among U.S. and foreign firms reveals that the latter have increased their share in innovative activity.

2.6.4. Social Environment

Consumer drug use has grown substantially, partly because of an aging population and the dramatic expansion of third-party payments. As third-party payers and governments attempt to control health care costs, generic substitution programs are expected to rise.

2.6.5. Global Environment

The global pharmaceutical industry is dominated by Western Europe and U.S. firms, but Japanese companies are increasing their presence worldwide through licensing and joint ventures. R&D has become the undisputed chief basis of competition in the global pharmaceutical industry. To support new product introductions from these R&D efforts, companies also have increased their detail force size to wring the greatest revenue from new products, as soon as possible, in the maximum number of markets.

The changes that have taken place in these five major environments strongly reinforce the notion that a longitudinal analysis is necessary to capture the dynamics of these changes. In the next chapter, the literature review pertaining to the concepts in Figure 1.3 is discussed.

CHAPTER THREE

REVIEW OF THE LITERATURE

This chapter reviews the literature pertaining to the concept of competitive positioning. The purpose of this review is to assess what has been accomplished in the field to date and to present a synthesis of the empirical and theoretical literature. The review will also cover a discussion of the dependent variable, firm performance.

First, the basic research framework is presented. This is the structure-conduct-performance (SCP) paradigm which has its roots in industrial organization (IO) research. Structure was covered in chapter 2. Both conduct and performance are discussed in this chapter.

Second, while there is general agreement about how to define strategic performance, there is, little consensus about how to measure it. Therefore, it is necessary to define and identify measures of strategic performance that adequately reflect pharmaceutical firms' positioning strategies.

Third, firm conduct is discussed in terms of choice of product markets, timing of entry, mode of competition, and degree of geographical diversification (refer to Figure 1.3).

Since this study is concerned with the relationship not only between competitive positioning strategy and performance

but also among the components of the positioning strategy, research questions relating to these associations are addressed in detail. The research questions provide the basis for hypotheses stated in chapter 4.

3.1 The Structure-Conduct-Performance (SCP) Paradigm

3.1.1. Description

First offered by Mason (1939), the SCP paradigm postulates that market structure influences the firm's conduct which in turn affects performance. This paradigm is widely used by economists and organizational behaviorists to understand and evaluate industry rivalry and performance.

In IO terminology, market structure refers to the stable characteristics of the industry environment that influence the nature of competition among buyers and sellers operating in it (Caves 1982). Market structure is usually assessed by measures such as seller and buyer concentration, barriers to entry and exit, and degree of product differentiation. Firm conduct consists of firm's competitive reactions toward the structural elements and toward rivalry moves made by other firms. Finally, while industry performance has been the central concern in IO research, recent studies have shifted their focus to performance at the firm level.

3.1.2. Studies using the S-C-P Paradigm

Few IO studies simultaneously examine or measure the inter relationships among structure, conduct, and performance.

For example, such "structuralists" as Mason (1939) and Bain (1958) argue that relationships between market structure-conduct and conduct-performance are not necessary for evaluating overall firm performance. Since structure determines conduct, it is sufficient to relate market structural elements to performance to assess the nature of competition. [For an excellent review of empirical research in the area of market structure and industrial performance, see Vernon (1982).]

The structuralist approach has come under attack in recent years, despite the value of this extensive body of research, as inadequate to explain all the variance in performance (Vernon 1972; Phillips 1976). Researchers such as Bass, Cattin, and Wittink (1978) argue that the performance implications of a particular aspect of market structure depend upon the market under consideration. Generalizing structure-performance relationships across different product classes and industries can only lead to erroneous results.

Alternatively, "behaviorists" argue that the linkage between structure and performance appears to be moderated by the relative competitive position of the firm. Early proponents of this view include Hunt (1972), Newman (1972) and Porter (1973).

From the behaviorist school emerged the concept of

"strategic groups" of firms.⁷ Research by Hatten and Schendel (1977), Porter (1977), Schendel and Patton (1978), and Cool and Schendel (1987) suggests that firm performance partially depends upon membership in a particular strategic group and that all firms are not equally able to adapt to changes in competitive conditions and market structural elements. Overall, the relationships among firm performance, conduct, and market structure can be expressed as :

$$\text{Firm Performance} = f(\text{Conduct, Market Structure}),$$

where conduct relates to the controllable variables endogenous to the firm, while market structure relates to the notion of uncontrollable or environmental variables exogenous to the firm. The joint influence of conduct and structure on performance is increasingly recognized and adopted in several disciplines.

In marketing, the PIMS studies (for example, Schoeffler 1977; Schoeffler, Buzzell, and Heany 1974; Buzzell, Gale, and Sultan 1975) attempt to explain performance across a diverse sample of industrial firms by using the concepts of strategy and environment. From this perspective, performance is conceptualized as:

$$\text{Firm Performance} = f(\text{Strategy, Environmental Variables}).$$

⁷For more detailed analysis about strategic groups, readers can refer to studies by McGee and Thomas (1986), and Thomas and Venkatraman (1988).

In strategic management research, several studies have focused on firm performance within one industry. For example, studies in the U.S. brewing industry (Hatten 1974; Hatten and Schendel 1977; Hatten, Schendel, and Cooper 1978; Schendel and Patton 1978), consumer goods industries (Oster 1982; Porter 1973), and banking industry (Hayes, Spence, and Marks 1983; Ramsler 1982) confirm the interdependencies between strategic variables and industry structure in influencing firm performance. Accordingly, performance can be expressed as:

$$\text{Firm Performance} = f(\text{Strategic Conduct, Industry Structure}).$$

This is the formulation adopted in this study. Industry structure will be assessed in terms of the different therapeutic categories in which pharmaceutical firms compete. Strategic conduct will be defined in terms of firms' competitive positioning strategies. Implied in this concept is a focus on how a company competes in the selected therapeutic categories and positions itself among competitors.

In the strategic management literature, action sets and resource allocations or commitments generically characterize strategy. While the variables in this study are not defined in these specific terms, they are somewhat similar in operationalization.

3.2 Action Sets

Action sets refer to directional choices to achieve organizational objectives in light of environmental

opportunities and constraints. Action sets also are known as "scope" choices. According to Walters (1986), the components of these choices are: the range of market segments or customer groups, types of products across the segments, and geographic scope.

Range of Product-Markets. As pointed out in chapter 2, there are several market sectors in which firms compete in the pharmaceutical industry: ethical versus proprietary versus generic drug sales; single-source versus multi source drugs; and acute versus maintenance drugs. This study focuses on the ethical drug sector, where new drug development is greater than in the proprietary or generic sectors.

Types of Products. New drugs can be classified into four categories:

- (1) New Chemical Entity - products that are new, single chemical entities not previously known, including new salts;
- (2) Duplicate Single Products - follow-up marketing of a new chemical entity, previously introduced by another manufacturer;
- (3) Compounded Products - any products having more than one active ingredient;
- (4) Alternate Dosage Forms - products previously marketed in tablets and now offered in ampules, capsules, liquid, and so forth.

NCEs are only considered in this study as they are regarded as "breakthroughs" in the truest sense. Economists concerned with R&D activity in the drug industry generally have argued that NCEs represent the most innovative of the new products developed (Grabowski 1968). The other categories

described above are not "new" products, merely outgrowth of previously marketed chemical entities.

Geographic Scope. As mentioned in chapter 2, maintaining a presence overseas is necessary in an industry undergoing rapid globalization. Pharmaceutical firms may differ in their degree of geographic diversification or concentration and/or their timing of a geographic expansion strategy. Therefore, global marketing efforts of drug firms are investigated in this study.

3.3 Resource Allocations/Commitments

In addition to action sets, strategy is characterized by the allocation of resources, that is the commitment of distinctive resources and the creation and deployment of new resource combinations to pursue intended action sets. Since the types of resources necessary for competitive advantages will vary among industries, it is necessary to identify resource commitments that are unique to an industry. For example, in his study of the international financial services industry, Walters (1986) identifies the following as key contributors to competitive advantage: (1) adequacy of an institution's capital base and risk base; (2) human resources; (3) access to information and markets; and (4) technology base. In the pharmaceutical industry, resource commitments in both marketing and R&D are considered central in attaining and maintaining a position of sustainable competitive advantage. Section 3.5.2 provides a fuller description of these

resources.

3.4 Firm Performance

Firm performance refers to the achievement of a firm with respect to a certain criterion or criteria. The measurement of firm performance always has been problematic. While some researchers adhere to a multidimensional measure (for example, Bagozzi and Phillips 1982; Benson 1974; Chakravarthy 1986; Keats 1983), others assert that various aspects of performance can be captured in a single measure (for example, Kirchoff 1977; Hatten, Schendel, and Cooper 1978). Yet others argue that performance encompasses not only the interests of organizations but also those of society (for example, Parsons 1960; Price 1972; Steers 1975). Some even suggest that the construct be abandoned altogether (Hannan and Freeman 1977).

Although the determination of performance descriptors is complex, a performance measure is necessary. It allows firms to evaluate objectively the quality of their strategic decisions. The next section develops this issue in greater detail and provides the background for the selection of performance measures used in this study.

3.4.1. Measures of Economic Success

This research employs multiple performance indicators as they relate to the firm, not the pharmaceutical industry. Three types of performance measures are discussed: accounting

indicators, financial-market measures, and output market descriptors. The advantages and disadvantages of each are discussed briefly below.

3.4.1.1 Accounting Indicators of Performance

Such accounting indicators as return on investment (ROI), return on sales (ROS), and cash flow to investment are commonly used in assessing firms' profitability. Shrader, Taylor, and Dalton (1986) noted that both ROI and ROS are predominant measures of economic performance in studies relating planning process and strategy content to organizational performance. Despite limitations (see Dearden 1969; Jacobsen 1987; Reece and Cool 1978), Woo and Willard (1983, p. 13) also concluded that profitability measures such as ROI and ROS are important measures of performance:

Despite the problems inherent in ROI, results from [our study] support their continual use.....when properly complemented by other measures, [our study] shows that ROI is essential to the comprehensive representation of performance.

The advantages of using these accounting measures are that, as ratios, they facilitate the comparison of firms of different sizes, and they are often publicly reported. Recent critics (McQuire and Schneeweis 1983) have cited several problems, however: (1) the scope for accounting manipulation; (2) undervaluation of assets; (3) distortions due to depreciation policies, inventory valuation, and treatment of certain revenue and expenditure items; and (4) differences in methods of consolidating accounts.

3.4.1.2. Financial Market Measures of Performance

Accounting indicators record only the historical performance of the firm. Monitoring a firm's strategy requires measures that will capture future performance, that is, a long-term valuation rather than the short-term perspective characteristic of accounting measures.

The most popular financial market measure of performance is the M/B ratio, or the spread between the market and book value of the firm. This indicator has been shown to measure the perceived ability of the firm to return to its shareholders an amount in the future in excess of expected return (Rappaport 1981). Peters and Waterman (1982) also used this indicator as a performance screen to evaluate the long-term wealth creation potential of a firm.

The M/B ratio, however is not without problems. It is not entirely free from accounting manipulation, that is, the book value of a firm can be distorted. Financial market measures also are not equipped to deal with changes in business performance over time. Although they may provide a good estimate of the performance effect of an event at the time it occurs, subsequent effects are difficult to identify. For this research, financial market measures were deemed inappropriate for this longitudinal study.

3.4.1.3. Output Market Success Indicators

These indicators which refer to the operational performance of the firm in its markets, include such measures

as market share, market share growth, market share rank, and sales growth. Venkatraman and Ramanujan (1986) argue that there are two separate domains, financial accounting measures, which reflect "fulfillment of the economic goals of the firm" (p. 803), and operational measures, which reflect "key operational success factors that might lead to financial performance" (p. 804).

The relationship between market share and profitability is widely recognized in the PIMS research (Gale 1972; Buzzell, Gale, and Sultan 1975). Under most circumstances, businesses that achieve a high share of the markets they serve are also considerably more profitable than their small share counterparts. As empirically demonstrated by Woo (1979) and Rumelt and Wensley (1981), the positive relationship between market share and profitability is far from universally valid and is mediated by various firm and market characteristics. Therefore, the market share indicator should not be taken as an absolute indicator of performance and its relationship to profitability is not clearly established.

Nevertheless, market share indicators will continue to hold a central place in marketing studies as measures of performance. The relationship between marketing effort and market share is specified in attraction models (Lilien and Kotler 1983; Moriarty 1975; Weiss 1968) and is monitored closely in the measurement of a firm's performance against those plans (Wind and Mahajan 1981). In developing a dynamic

model of a marketing system, Lambkin (1989) employed market share as a factor preceding profits. Since market share plays a central role in strategic marketing, and given its frequent use as a key objective in the strategic planning process, this measure of performance will be examined here. The lack of information pertaining to depreciation rates excludes the consideration of accounting indicators for this study (see p. 92).

3.5. Competitive Positioning Components

This section discusses the antecedents of firm performance. Three key components of the competitive positioning strategy will be discussed: (1) timing of entry, (2) means of competition, and (3) geographic scope. From a strategic marketing perspective, the initial positioning of a product in a particular market is an important factor in success or failure.

The literature has focused mainly on the individual components of the competitive positioning strategy. It is argued here that a full understanding of performance over time in relation to positioning strategies requires an analysis of all dimensions.

In this study, attention is restricted to firms which had success with their positioning strategy. Although some researchers such as Glazer (1985) maintain that "successful" firms should not be studied in isolation from firms that "failed," it is often difficult to collect information about

failures.

Furthermore, since the pharmaceutical industry tends to be dominated by large firms, this study excludes the experiences of small, independent ventures. The large and established pharmaceutical companies very often possess organizational capabilities in "downstream" functions, such as bringing new drugs from the laboratory to the market, economies of scale, and political clout over smaller firms. This selection bias limits the generalizability of the study's findings to firms of all sizes.

3.5.1. Timing of Entry

The choice of market entry strategy has been found to influence product failure and success (Urban et al. 1986; Schnaars 1986). Whether to be a pioneer or follower is an important strategic question. The decision to enter a market balances the risks of "sinking the boat" or "missing the boat." Abell (1978, p.21) states that "there are only limited periods in which the 'fit' between the key requirements of a market and the particular competency of a firm competing in the market is at an optimum." If the firm enters a new and emerging product market early, it can push an underdeveloped product into the marketplace and gain customer acceptance. If entry is delayed too long, the firm may sacrifice the benefits of being first with a new product or technology.

In analyses of market entry, different aspects of the issue have been emphasized. One set of studies has stressed

the sources of advantage of early entrants. A second set has focused on timing of entry and performance.

3.5.1.1. Barriers to Entry

While timing of entry is an important factor, studies have shown that it is not the order of entry per se that determines market position. More important are the entry barriers that the pioneer builds (see Robinson and Fornell 1985; Lieberman and Montgomery 1988; Fershtman, Mahajan, and Muller 1990). Theoretical arguments in the literature illustrate how entry barriers can provide pioneers with sustainable advantage. Bain (1956), who was the first to study this issue, cited economies of scale, product differentiation, and absolute cost advantages as barriers to market entry.

Entry barriers can be both structural (exogenous) and behavioral (endogenous). Examples of the former include market concentration (King and Thompson 1982); seller concentration (Crawford 1975; Mann 1966); number of competitors (Harrigan 1981); and government policy (Grabowski and Vernon 1986; Porter 1980a). The following discussion focuses on firm-specific actions that influence endogenous barriers.

Mechanisms or forms of entry barriers leading to first-mover advantages and disadvantages are provided in an excellent review by Lieberman and Montgomery (1988). They define first-mover advantages in terms of the ability of

pioneering firms to earn positive economic profits. First-mover advantages can be attained through: (1) leadership in product and process technology; (2) development of buyer switching costs ; and (3) preemption of assets. Potential disadvantages include: (1) free-rider problems; (2) shifts in technology or customer needs; and (3) a tendency toward inertia by established incumbents. Only the mechanisms leading to first-mover advantages are discussed here.

Technological Leadership. For firms in high-technology industries, the ability to protect intellectual property through patents is an important entry barrier when the product technology is a function of R&D expenditures.⁸ In a research using the PIMS data base, Robinson (1988) found that pioneer firms benefit from patents to a greater extent than do followers (29 percent versus 13 percent). In a study involving 48 patented product innovations in pharmaceuticals, chemicals, and electronic products, Mansfield et al. (1981) found that, on average, imitators could duplicate patented innovations for about 65 percent of the innovator's cost. Imitation appears more costly in the pharmaceutical industry, however, because imitators must go through the same regulatory procedures to get their drugs approved.

A study by Kemp (1975) of the diuretics drug market showed contrary to traditional economic theory on market

⁸Because product patents rather than process patents offer more protection in the pharmaceutical industry, they are considered here.

imperfections, patent holders did not have total monopolistic power during the period of patent protection. Very often, economic theory does not take into explicit consideration the effect of entry in situations in which replication of the product is possible. Therefore, what has not been appreciated is that the development of additional products in the same subclass makes entry possible when it otherwise would be barred by the patent of the pioneering drug. As indicated by Table 3.1, in the diuretics subclasses,⁹ follow-on drugs had a minimal effect on market shares in carbonic anhydrase inhibitors and fast-acting diuretics, while follow-ons in the other two sub classes had a marked effect on physicians' prescribing patterns and on market share. Judging from this example, follow-ons may be as attractive a form of entry as pioneering a breakthrough product.

Switching Costs. Switching costs refer to supplier-specific learning by the buyer over time. First-mover advantages that arise from buyer switching costs are particularly strong for high-involvement products such as prescription drugs. Over time, the buyer adapts to the characteristics of these products and their suppliers and finds it costly to change to another brand (Wernerfelt 1985). For example, Porter (1980b) found that nurses were reluctant

⁹The four sub-classes are : carbonic anhydrase inhibitors, fast-acting diuretics, thiazides and related compounds, and potassium-conserving compounds.

Table 3.1. Postmarketing Experience in Diuretics : Number of Single Entity Follow-on Brands Marketed and Their Market Share in 1969

Subclass	Number of follow-on brands marketed		Share of market of breakthrough, (percent)	Share of market of single entity follow-on products marketed (percent)	
	Breakthrough company	Out-siders		Breakthrough company	Out-siders
Carbonic anhydrase inhibitors	1	2	97.9	0.0	2.1
Fast-acting diuretics	0	1	90.9	-	9.1
Thiazides and related compounds	1	15	27.2	25.2	40.9
Potassium-conserving compounds	1	2	11.6	40.3	48.1

Source : Bernard Kemp (1975), "The Follow-on Development Process and the Market for Diuretics in Drug Development and Marketing," Robert Helms, (ed.), pp.255-76.

to switch to other suppliers' intravenous solution delivery systems once they were accustomed to a certain supplier's brand. Thus, switching costs can enhance the value of market share obtained early in the evolution of a new market *ceteris paribus*.

Under conditions of uncertainty about product quality, buyers may rationally stick to the first brand that performs the job satisfactorily. As suggested by Comanor and Wilson (1974, p. 24), "much brand loyalty is a device for reducing the risks of consumer decisions."

A consumer behavior study by Carpenter and Nakamoto (1986) found that order of entry influences the formation of consumer preferences. The first product introduced tends to capture significant attention, which may yield an asymmetric competitive advantage for the pioneering firm. Products such as Coca-Cola and Kleenex are classic examples. In another study by Carpenter and Nakamoto (1990), it was found that later entrants can increase profits by differentiating their products with a high advertising budget and high price if the dominant brand has a powerful asymmetric competitive advantage. Attempts to position near the dominant brand with a "me-too" strategy, however, led to relatively poor performance.

These perceptual effects have been confirmed in other research. In a study of two therapeutic submarkets in the ethical pharmaceutical industry, diuretics and antianginals,

Bond and Lean (1977) found support for Bain's (1956) hypothesis of consumer-based information advantages. Physicians tend to ignore "me-too" products even if offered at lower prices and with substantial marketing support.

Considering the environment in which physicians dispense drugs to their patients, Thomas (1988) noted the following three characteristics: (1) physicians are time conscious and thus attempt to reduce their search time for alternatives beyond satisfactory therapies; (2) physicians are price insensitive, as they do not pay for the products; and (3) physicians are highly concerned about the therapeutic quality of drugs.

The last factor points to the importance of asymmetry of consumer acceptance between existing and entering brands. In such an environment, when physicians become convinced that the first brand is performing satisfactorily, that brand becomes the standard against which subsequent entrants are judged. It becomes harder for follow-on entrants to persuade consumers to invest in learning the qualities of their products.¹⁰ Loyalty also is strong for branded ethical drugs after patents expire (Statman and Tyebjee 1981). The loyalty created through experience with existing brands is a disadvantage for later entrants (Comanor and Wilson 1974).

The lack of economic incentives on the part of the

¹⁰In addition, for certain therapeutic subclasses, the physician may be faced with a bewildering array of alternatives. Physicians have a limited processing information capacity, so they learn about and work with only a few (U.S. Senate 1972), which reinforces brand loyalty.

physician to prescribe cheaper alternatives also amplifies brand loyalty. According to the FTC (1979, p. 2), "the basic problem is the economic forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay." This point was confirmed by Gagnon (1983), who also found that physicians were unaware of price differences among competing brands.

In a similar study, Kemp (1975) hypothesized that follow-on brands were unsuccessful in capturing market share from the breakthrough product because of the promotional activity by the pioneering company and the difficulty of overcoming the first-of-a-type syndrome.

In one case, that of fast-acting diuretics, the company that introduced the breakthrough, Hoechst, was new and small in the U.S. market, although not small internationally. Its successful promotional campaign enabled it to obtain and maintain its market position. (Kemp 1975, p. 270).

Preemption of Assets. First movers can gain advantage by controlling physical assets or can deter entry through strategies of spatial preemption. The most relevant strategy for this study is preemption in product characteristics space or niches in product differentiation. The theory of spatial preemption (Prescott and Visscher 1977; Schmalensee 1978; Rao and Rutenberg 1979) argues that first movers can establish positions in product space such that latecomers find it unprofitable to occupy the interstices.

A PIMS study by Robinson and Fornell (1985) found that new consumer product pioneers initially held product quality superiority over imitators and subsequently developed advantages in the form of a broader product line. This suggests that pioneers attempt to reinforce their early lead by filling product differentiation niches.

Conclusion. In summary, three major forces act as important first-mover advantages in the pharmaceutical industry. First, the ability to protect the firm's technology through patents may limit the number of entrants into the market and allow a firm to market a product superior to that of competitors. Second, drugs have high switching costs and, therefore, higher brand loyalty. Third, pioneering firms that offer products with distinct advantages can extend their brand advantage to their other product lines.

3.5.1.2. Entry Timing and Performance

Theoretical and empirical work on the order of entry suggests long-term market share rewards for pioneering brands. Studies have concentrated on the consumer and industrial goods industry. The PIMS database often has been used as the main source of data to test hypotheses.

In a study involving the PIMS data base, Biggadike (1976) examined 40 industrial product entries into new markets by large firms. After four years, the average market share of these entrants was 15 percent, but the largest share of the

largest existing competitor in each of the 40 businesses decreased from 47 percent to 28 percent when new entrants came into the market. Similar results were obtained by Dillion, Calantone, and Worthing (1979) in their study of 174 industrial products; they found that pioneering was a major determinant of the long-term success of a new product.

Robinson and Fornell (1985) found a significant market share penalty for late entry. Using the PIMS data, they sampled 371 consumer goods units in the mature stage of the life-cycle. The average market share for pioneer firms was 29 percent, compared to 16 percent for early followers and 11 percent for late entrants. In comparing these results with those found in a study involving a cross-section of industrial goods businesses, Robinson (1988) again showed that market pioneers tend to have higher market shares than late entrants.

A recent study by Lambkin (1989) strongly supports the relationship between order of entry and competitive performance. Propositions were tested on a sample of new business ventures from the PIMS start-up data base and were validated on a hold-out sample of adolescent business from the main PIMS data base. A multidimensional measure of performance was considered. Overall, order of entry loaded significantly on market share, relative market share, return on sales, and return on investment but insignificantly on cash flow/investment.

Another study using the PIMS data to test the effects of entry order, by Miller et al. (1989), analyzed 119 nonservice businesses (consumer and industrial). It found that pioneers had significantly higher market shares than followers and that little "degree of lateness effect" existed between early and late followers.

An empirical analysis by Urban et al. (1986) found that the order of entry of a brand into a consumer product category is inversely related to its market share. This study differed from similar research in two respects: (1) brands were chosen as the unit of analysis instead of firms; and (2) market share was constructed by evoking consumers' evaluation of the product. Consumer preferences and rating data were later used in product positioning and differentiation. Nevertheless, similar results in terms of pioneering advantages were found in this study. Second entrants obtained on average only about three-quarters of the market share of pioneers, and later entrants garnered progressively smaller shares.

Longitudinal studies in the ethical pharmaceutical and cigarette industries also confirm the order of entry effects. From their examination of two related prescription drugs (diuretics and antianginals), Bond and Lean (1977, p. vi) concluded that "the first firm to offer and promote a new type of product received a substantial and enduring sales advantage." Research on trends in seven cigarette submarkets by Whitten (1979, p. 41) led to the finding that the "first

entry brand received a substantial and enduring sales advantage" in six of the seven segments."

The effect of entry timing on performance also was identified in the Markstrat study by Green and Ryans (1990). Since the Markstrat environment is "controlled," it could be argued that the results may be an artifact of the simulation. However, their findings found support in "real world" studies (for example, Biggadike 1976; Bond and Lean 1977; Whitten 1979; Dillion et al. 1979; Robinson and Fornell 1985; Urban et al. 1986; Robinson 1988; Lambkin 1989; Miller et al. 1989).

Despite the strong empirical support, several researchers have questioned the validity of the premises underlying the order of entry hypothesis (Aaker and Day 1986). Study of a sample of 100 new product failures and successes found no real advantages for pioneering brands (Cooper 1979b). This contention was supported by Dillion et al. (1979). Despite the advantages of being a market pioneer, a follower strategy can pay (Haines et al. 1989). Besides those identified by Lieberman and Montgomery (1988), other advantages of a follower strategy are knowing the market is really there, learning from the pioneer's experience, introducing superior manufacturing techniques, introducing products with superior design attributes, and fine-tuning the marketing mix.

The ability to compete with a superior product and creative positioning of the marketing mix has been extensively studied. Since these factors pertain to "how" firms compete,

and is discussed in detail in Section 3.5.2., only a brief mention is made here.

One way later entrants can "leapfrog" pioneering business is to develop an innovative product with superior features and/or lower price (Urban et al. 1986). Follow-on brands of the potassium-conserving compounds were successful because of firms' market research to "discover and counteract the effect of promotional strategies of rivals" (Kemp 1975, p. 27). The competition also led to an improved understanding by physicians and pharmaceutical manufacturers of the modes of action, therapeutic properties, and side effects of the drugs on the market.

Bond and Lean (1977) found that later entrants offering drugs with distinct therapeutic benefits can overcome first-entrant advantages through heavy promotional expenditures. Neither these outlays nor low price alone dislodged the pioneers, however, which led the authors to conclude that "large-scale promotion of brands that offer nothing new is likely to go unrewarded" (p. vi).

Although "me-too" entries are unlikely to be successful, a well-conceived "second-but-better" entry, backed by aggressive advertising and superior positioning, may gain competitive advantage over the pioneer's products (Urban et al. 1986). This is the strategy recommended by Carpenter and Nakamoto (1990) for late entry into a market dominated by an entrenched competitor.

Conclusion. The basic premise that order of entry is systematically related to performance is strongly supported, although studies have shown the moderating influence of variations in firm strategy in different entrant categories.

A basic limitation of prior studies on timing of entry should be recognized, namely they tend to be cross-sectional. As noted by Bass, Cattin, and Wittink (1978), a cross-sectional study can be affected by sample heterogeneity, often resulting in misleading conclusions. Even though some research has focused specifically on the consumer or industrial goods industries, the broad range of businesses studied within each sector does not eliminate the possibility of alternative explanations. This ambiguity is avoided here by looking at only major firms in the ethical pharmaceutical industry. Heterogeneity is reduced because one industry and firms of the same size are considered.

Past research findings about the timing of entry and firm performance lead to the following research question:

Question 1 : How is timing of entry related to firm performance?

3.5.2. Means of Competition - Competitive Position in R&D and Marketing

This section discusses the two resource deployment areas most important in achieving economic success in the pharmaceutical industry: R&D and marketing.

In many situations, it is reasonable to assume that the greater the investment the firm makes in its product-

positioning strategy, the more likely it will be to succeed. For example, MacMillian and Day (1987) split their sample of new corporate ventures into "high" and "low" investment groups. For most of the strategic options considered such as plant size, relative sales promotion, size of salesforce, and advertising expenditures, relative price, relative quality, the higher the level of investment, the higher was the return on investment and the larger the market size.

The fundamental theorem of "market share determination" holds that the market shares of various competitors are proportional to their shares of total marketing effort (Kotler 1984). This relationship is also pivotal in the market share attraction models (Little, Bell, and Keeney 1975).

The major resource commitments that capture the bases of competition and competitive advantage in the ethical pharmaceutical industry are research and development (R&D) and marketing (Cool and Schendel 1987). The application of these resources is discussed in the next two sections, along with the relationship between timing of entry and resource commitments.

3.5.2.1. Competitive Position in R&D

To ascertain a firm's competitive position with respect to the R&D function, two factors will be evaluated: the degree of commitment to R&D and the effectiveness of R&D efforts.

Commitment to R&D (R&D Intensity). Expenditures on research and development constitute an important form of non price competition in high-technology industries. Macro studies on economic growth in industrialized nations have accepted technological innovation (and, by extension or proxy, business investments in R&D) as the leading determinant variable (Schumpeter 1934; Denison 1967; Harberger 1984). Similarly, micro studies have attempted to show the causal link between R&D investment and growth of individual industrial firms. This causal relationship has been strongly supported (Mansfield 1968; Scherer 1976; Jarrell 1983; Comanor 1986; Morbey 1988; Franko 1989). In a cross-sectional examination of various industries, Franko (1989) argued that the R&D intensity of individual firms is positively and significantly related to subsequent relative worldwide corporate sales growth and hence to global market share.

Many studies show that R&D intensity positively affects corporate performance in terms of five measures :

1. **Valuation measures**, such as stock market value, P/E and investment value (for example, Elia 1980; Pakes 1985);
2. **Profit measures** such as profitability, gross margins, earnings per share, earnings per sales, return on investment (for example, Grabowski and Mueller 1978; Parasuraman and Zeren 1983; Reynard 1979; Wagner 1984);
3. **Returns versus other investments** (for example, Grabowski and Mueller 1978);
4. **Technical output parameters**, such as patents, papers, patents per employee, patents per sales, product quality (for example, Cooper 1984; Hambrick and Macmillain 1985; Kamien and Schwartz 1975); and

5. **Size and growth measures**, such as sales growth, market share, new product sales, and diversification (for example, Buzzell, Gale, and Sultan 1975; Hambrick et al. 1983; Schoeffler, Buzzell, and Heany 1974).

Performance in the pharmaceutical industry has been largely evaluated from a profitability perspective. Some of the major findings on the returns to R&D in the industry are shown in Table 3.2. As mentioned on p. 93, for the purpose of this research, corporate performance will be evaluated using size and growth measures (that is, market share).

Effectiveness of R&D Efforts - (Product Development Efforts).

Studies of new product development have shown that equal R&D commitments do not necessarily translate into effective R&D efforts. Effectiveness is considered to reflect the differential competencies of firms to convert R&D resources into actual product developments, that is their success in converting New drug Applications (NDAs) to New Chemical Entities (NCEs) and in concentrating on NCEs versus other new products. Both these measures capture a firm's commitment to new product development efforts through R&D.

3.5.2.2. Competitive Position in Marketing

Organizational behavior studies lend preliminary support to the view that the mean level of marketing effort increases from the "reactor" to "defender" to "analyzer" to "prospector" strategy types. According to Miles and Snow (1978), prospectors are often pioneers into new markets, while analyzers are often "second-in" after prospectors, and

Table 3.2. Returns to Pharmaceutical R&D

Author/Year	Major Findings
Baily (1972)	Econometric analysis showed that nominal pretax returns to pharmaceutical R&D dropped from more than 30 percent before 1962 to less than 15 percent after 1962.
Statman (1983)	Nominal after-tax returns on pharmaceutical R&D declined from 20 percent in the mid-1950s to about 10 percent in the late 1970s.
Joglekar and Patterson (1986)	Real after-tax return on R&D pharmaceutical was approximately 6 percent for a new drug compound beginning in the mid-1970s.
Grabowski and Vernon (1990)	Average new product introductions in the 1970s earned an after-tax return of 9 percent, which was in line with the industry's cost of capital.

frequently achieve above-average new product success rates.

McDaniel and Kolari (1987) found that the mean marketing effort was higher for analyzers than for defenders for 15 of the 16 marketing variables, and the reported mean was higher for prospectors than for analyzers for 14 of the 16 marketing variables. Similar results were found by Meyer (1982) and Hambrick (1983). The higher R&D and marketing effort expended by prospectors supports the image of these organizations as active in the development of new products (Hambrick 1983).

The development of NCEs that are true blockbusters is extremely rare today. Most new products are incremental improvements over existing therapies (The Economist 1987; Financial World 1987), and companies must promote these products into a market already using those therapies.

The importance of marketing as a success factor in the pharmaceutical industry is illustrated by Zantac, which was the largest selling drug in 1988. When it was first introduced by Glaxo, it was only marginally different from the previous world leader, Tagamet. There was relatively little medical incentive to use Zantac rather than Tagamet and many physicians continued to prescribe Tagamet. Without a creative and powerful market effort, Zantac probably would have been another "me-too" product. Glaxo's aggressive marketing efforts made the difference.

To capture a firms' competitive position with respect to the marketing function, the level of advertising expenditure

is considered here.

3.5.2.4. Relationship between Entry Timing and Resource Commitments

To obtain a complete picture of a firm's past and current strategic investments, Day and Wensley (1988) proposed linking the firm's effort level to the value of first-mover advantages. Timing of entry should be consistent with the firm's capabilities on the point in time that the market is observed. A firm with strong R&D capabilities would find it advantageous to be a first mover. A firm with strong marketing skills would find it advantageous to enter later (Lieberman and Montgomery 1988).

In analyzing twelve case histories from various industries, Schnaars (1986) found that firms with strong marketing skills tend to engage in later entry. For example, IBM entered mainframes after Sperry-Rand and personal computers after Apple; in both cases, IBM was able to gain a commanding market share over the earlier entrants. In the consumer goods industry, Procter and Gamble relies heavily on later entry to dominate markets opened up by pioneers.

Miller, William, and Wilson (1989) explored not only the extent to which entry order determines market share but also competitive factors that later entrants might employ to overcome a pioneer's advantages. Their results showed that pioneers invest heavily in product R&D and are relatively more competitive in terms of superior product quality and

differentiation. Overall, followers had few successful competitive options other than promotion for gaining market share. This was confirmed in the study by Urban et al. (1986).

Conclusion. In the ethical pharmaceutical industry, new product development occupies a central role in strategic resource deployment. The extent of a drug firm's commitment to this activity can be assessed with respect to its R&D function. Marketing commitments also are key in influencing firm performance. Finally, the literature also suggests that the level of commitment to strategic resources and timing of entry can affect performance.

The theoretical and empirical findings related to R&D and marketing commitments and performance suggest the following research questions :

Question 2 : How is a firm's new product development effort related to its commitment to R&D?

Question 3 : How does a firm's commitment to R&D affect performance?

Question 4 : How does a firm's commitment to marketing affect performance?

Question 5 : What is the relationship between new product development efforts and firm performance?

3.5.3. Source of Innovation and Firm's Competitive Position in R&D

In the discussion of the firm's competitive position in R&D, a factor that should be considered is whether the products are developed internally or obtained externally.

While a firm's internal R&D often is viewed as a critical determinant of technological leadership, this is not the only source of technical know-how. A firm that trails in product technology still may still be competitive by borrowing ideas from external sources and developing them for their market segments (Abell and Hammond 1979; Porter 1985). Transaction cost analysis provides a theoretical perspective for explaining how pharmaceutical firms organize for R&D.

3.5.3.1. Transaction Cost Analysis

Transaction cost analysis (Williamson 1975, 1981, 1985) is increasingly used to explain how firms organize for activities along the value-added chain. This theory has been applied in the empirical analyses of production and supply activities (Monteverde and Teece 1982a, 1982b; Balakrishnan and Wernerfelt 1986); the personal selling function (Anderson 1985); and channels of distribution (Klein 1986; Anderson and Coughlan 1987).

With respect to R&D activities, the application of transaction cost analysis has been limited (Williamson 1975; Teece and Armour 1977; and Teece 1988) and only recently has it been tested in the pharmaceutical industry (Tapon 1989; Pisano 1990). Tapon (1989) argues that transaction costs are lower when firms negotiate contracts with outside laboratories for certain steps in the R&D process, particularly basic research, that is, these costs are higher when firms conduct the same activities internally. Therefore, transaction costs

vary according to institutional arrangement and, it is the differences between transaction costs, rather than their magnitude, which determines the choice of arrangement.

Transaction costs arise from three factors (Williamson 1985): (1) the frequency of transactions; (2) uncertainty surrounding the transactions; and (3) whether transactions are supported by any transaction-specific assets.

R&D projects in the pharmaceutical industry run for several years, and relevant transactions do not occur frequently. Therefore, the first factor is not applicable to the pharmaceutical industry.

Uncertainty may have different effects. For example, in an uncertain environment, firms may desire greater flexibility and consequently avoid internationalization (Leifer and Huber 1977). Technological uncertainty may have the same effect (Balakrishnan and Wernerfelt 1986; Walker and Weber 1984), that is the greater the level of technological uncertainty, the greater the disincentive to make versus buy. Walker and Weber (1984) found, however, that volume uncertainty provides an incentive to internalize.

An empirical study of pharmaceutical firms (Pisano 1990) found that higher uncertainty, expressed in small numbers of R&D suppliers, leads firms to internalize biotechnology R&D in areas in which R&D capabilities are concentrated in a few suppliers. Technological uncertainty has the most relevance for this study. As mentioned in chapter 2, the risks and

costs of pharmaceutical research are forcing firms to be more innovative and selective. As pharmaceutical innovation becomes more complex and dependent on increasingly sophisticated scientific investigation, firms increasingly will seek promising drug innovations from outside their own laboratories.

Transaction-specific assets are defined as durable investments undertaken to support particular transactions and whose opportunity cost is much lower in other transactions, in other uses, or by other users should the original transaction be terminated prematurely (Day and Klein 1987). Asset specificity can be expressed in terms of specific physical assets, specific sites, specific human assets, and specific dedicated assets. Higher transaction-specific assets arising from the latter three will encourage firms to R&D (Tapon 1989).

3.5.3.2 Sourcing of Innovation Patterns in the Pharmaceutical Industry

One distinguishing feature of firms that successfully manage technology is a balanced strategy of both internally and externally developed technologies (Mansfield 1987).

The discussion on how pharmaceuticals firms organize for R&D (Section 2.4.3.2) suggests that an increasing number of firms are moving toward external acquisition. Tapon (1989) proposes three major factors driving pharmaceutical firms to form long-term R&D projects with other firms and university

laboratories; the effectiveness of patent protection, the rising importance of basic research in the innovation process, and the relative failure of traditionally organized, in-house laboratories. According to industry experts, two major forces are: (1) cost reduction, when outside services are cheaper, including avoiding investment in large, expensive operations, and (2) the inability to maintain a pipeline of successful drugs.

Since many costs are related to product development and sales, external procurement means the firm need not maintain high fixed-cost operations in either facilities or salesforce, (that is, it can avoid transaction-specific assets). Since technological innovations come so fast and from such diverse origins, it would be impossible for a company to be adequately staffed internally to keep abreast of all new discoveries. A successful strategy is to harvest discoveries from the myriad innovative research locations.

The external strategy chosen for examination in this study is licensing; it is a more rapid mode of entry than other alternatives such as joint ventures and it is the most widely used mechanism in the pharmaceutical industry. Marion Laboratories exemplifies a firm that has successfully used a licensing strategy for product market expansion. By licensing products with therapeutic value from foreign competitors, Marion has gained a strong foothold in the cardiovascular therapeutic category with the drug Cardizem, licensed from a

Japanese company. As suggested in the literature (see Crawford 1985; Killing 1978; Lowe and Crawford 1983; Shahrohki 1987) the need to ensure speedy market introductions, reduce or avoid high R&D investments, reduce new product failures, diversify product range, and keep abreast of external technology are powerful internal motivators for technology acquisition through licensing.

For this study, a distinction is made between outlicensing and inlicensing. The former refers to the external licensing of a drug for another overseas firm to market, while the latter refers to drugs acquired from another firm.

Table 3.3 shows the cumulative number of drugs developed in-house and licensed-in by the top 50 pharmaceutical firms in 1989. An earlier study by the National Academy of Sciences (1983) found that almost one-third of new drug introductions into the U.S. market have been sold under a patent license (see Table 3.4).

There are advantages and disadvantages to product market entry through either internal R&D or licensing. For the former, the major advantage is the use of existing resources, while the major drawbacks are the long time lag to breakeven and unfamiliarity with new markets which may lead to financial errors. The two key advantages to licensing are rapid access to proven technology and reduced financial exposure. As Killing (1978) points out, licensing avoids the risks of Table

Table 3.3. Cumulative Number of Drugs, Developed Both In-house and by Licensing, Top 50 Pharmaceutical Firms, 1989

Position in 1989	Position in 1988	Company	Drugs		
			Total drugs	In- house	License
1	(4)	Bristol-Myers	103	79	24
2	(1)	Merck & Co.	98	75	23
3	(9)	Ciba-Geigy	96	62	34
4	(3)	Rhone-Poulenc	94	58	36
5	(2)	Johnson & Johnson	92	62	30
6	(8)	Lilly	91	78	13
7	(5)	Elan	90	90	0
8	(6)	Roche	90	65	25
9	(10)	Hoechst	88	71	17
10	(7)	SmithKline	81	54	27
11	(18)	American Home Products	64	46	18
12	(15)	Upjohn	64	45	19
13	(12)	Fujisawa	62	45	17
14	(17)	Erbamont	60	46	14
15	(13)	Sandoz	60	41	19
16	(11)	Warner-Lambert	56	44	12
17	(28)	Roussel Uclaf	56	29	27
18	(26)	American Cyanamid	55	34	21
19	(22)	Wellcome	53	39	14
20	(27)	Pfizer	52	37	15
21	(37)	Genetech	50	44	6
22	(19)	Merrell Dow	50	42	8
23	(21)	Boehringer Ingelheim	50	36	14
24	(29)	Eastman Kodak	49	29	20
25	(16)	Schering AG	48	40	8
26	(20)	Sanofi	48	37	11
27	(36)	Yamanouchi	48	29	19
28	(35)	Schering-Plough	47	35	12
29	(14)	Takeda	46	42	4
30	(43)	Abbott	46	28	18
31	(39)	Mitsubishi Kasei	44	36	8
32	(42)	Akzo	44	35	9
33	(38)	Squibb	41	34	7
34	(41)	Kyowa Hakko	41	34	7
35	(24)	Glaxo	40	21	19
36	(62)	Rorer	39	31	8
37	(25)	Syntex	39	27	12
38	(32)	Monsanto	39	26	13
39	(31)	Beecham	38	32	6
40	(40)	Yissum	36	36	0

Table 3.3. continued

41	(49)	Sumitomo	36	23	13
42	(34)	Astra	36	19	17
43	(23)	Sankyo	35	26	9
44	(50)	Pharmaetec	34	33	1
45	(44)	ICI	34	28	6
46	(48)	Dupont	34	26	8
47	(30)	Bayer	34	22	12
48	(45)	Meiji Seika	34	21	13
49	(51)	Shionogi	34	21	13
50	(-)	Fisons	33	27	6

Source : Scrip (1989), World Pharmaceutical News, (January 20), pp.1 - 20.

Table 3.4. Licensed versus. Self-Originated Drugs Sold by U.S. Firms, Stratified by Firm Size

	1963-1968	1969-1974	1975-1980
% Self Originated			
Small	50.00	51.72	41.67
Medium	55.56	26.67	52.63
Large	77.27	80.00	83.33
% Licensed from U.S. Sources			
Small	20.59	17.24	22.22
Medium	0.00	26.67	21.05
Large	4.55	0.00	0.00
% Licensed from Foreign Sources			
Small	29.41	31.03	36.11
Medium	44.44	46.67	26.32
Large	18.18	20.00	16.67

Source : National Academy of Sciences (1983), Competitive Status of the U.S. Pharmaceutical Industry, Washington, D.C. : National Academy Press.

product development by exploiting the experience of firms that have already developed and marketed the product. This access to technology is particularly important to firms that want to establish a broad product portfolio of drugs to treat a broad spectrum of interrelated ailments.¹¹

Licensing is not a substitute for internal technical competence, however, and the acquired technology will not be proprietary. Another drawback is that licensing agreements is they restrict sales to certain areas such as only the U.S. market. Marion, for example, had to limit its sales of Cardizem to the United States. For long-term sustained growth, an increasing market penetration or a steady stream of new drugs is necessary.

Conclusion. Although internal research and development capabilities often are viewed as critical determinants of competitiveness, these are not the only possible source of technical know-how. Through a variety of licensing agreements, an increasing number of major pharmaceutical firms are tapping into the R&D capabilities of competitors and other organizations to supplement their own R&D. Transaction cost analysis was used to explain firms' choices between in-house and external sources of R&D. The above discussion leads to the following research questions:

¹¹An example is the treatment for cancer. Because cancer patients have to go extremely painful chemotherapy, which increases their anxiety while lowering their immunity, both tranquilizing and antiinfective drugs are given. Supplemental nutritional products are also necessary to maintain the health of cancer patients.

- Question 6 : Is there a relationship between a firm's internal R&D and its new product development efforts?
- Question 7 : How is performance influenced by a firm's internal R&D?
- Question 8 : Do firms that develop drugs internally also engage in greater outlicensing?
- Question 9 : Do firms with strong new product development efforts also engage in more outlicensing?
- Question 10 : Does high commitment to R&D affect the firm's outlicensing behavior?
- Question 11 : Does a firm's outlicensing behavior affect performance?

3.5.4 Therapeutic Market Diversification

The decision by pharmaceutical firms to develop drugs depends largely on how they perceive their strengths and weaknesses. Marked differences among companies often are based on their relative strengths in different therapeutic markets and on whether the market is in the growth, maturity, or decline stage.

Previous research on technological innovation (Nelson and White 1977) suggests that when technical advance is cumulative, a firm's efficiency in performing a particular type of R&D project depends on its experience with similar projects. This learning curve effect allows the firm to build in-house expertise, thereby reducing transaction costs for subsequent projects undertaken internally. This line of argument also is supported by Porter (1990) and Foxall (1983). Porter strongly advocates the continual replacement of old

products with improved or new ones. Foxall suggests that by concentrating efforts on established patterns of product development, the search for new products is facilitated.

Some pharmaceutical firms commit themselves to many therapeutic areas and spread their resources too thin. In other firms, the diversification into many therapeutic subclasses is indicative of both their manufacturing and their R&D mobility and implies some basic knowledge of several classes of products. This may enable the firm more readily to transfer or add manufacturing resources in yet another therapeutic area. In other words, the firms have some basic knowledge in several areas of chemotherapy and can build on this knowledge as scientific opportunities become evident (Cocks 1975). This leads to the following research question:

Question 12 : How is therapeutic market diversification related to a firm's new product development efforts?

3.5.5 Therapeutic Differentiation

The FDA drug classification scheme provides a basis for distinguishing drugs that are first to offer some new therapeutic advantage from drugs that merely duplicate existing therapies. This scheme classifies three types of drugs.

Type A : Important Therapeutic Gain - the drug may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential).

Type B : Modest Therapeutic Gain - the drug has a modest but real potential advantage over other available marketed drugs, such as greater patient convenience, elimination of a significant adverse reaction, less frequent dosage schedule, usefulness in specific subpopulation of those with the disease (for example, those allergic to other available drugs), and so forth.

Type C : Little or No Therapeutic Gain - the drug essentially duplicates in medical importance and therapeutic usage one or more drug already marketed.

The first drug to be marketed, even if not a blockbuster, generally earns significant market recognition. Factors that lead to first-mover advantages were discussed earlier in this chapter. Followers must differentiate themselves from the first product in order to gain market share. There is a concern among industry analysts that much of the increased NCE activity in the late 1980s simply produced "me-toos"¹² rather than major breakthroughs. According to the industry, however, products that are launched later generally do better because they are based on more recent scientific discoveries. Since drugs differentiated as Type A and Type B offer firms a stronger advantage over competitors, it is of interest to determine what factors influence the ability of the firm to develop highly differentiated drugs. Therefore :

Question 13 : Are firms that are successful in their new product development efforts also likely to have higher therapeutically differentiated drugs?

¹²A "me-too" is generally a product which has been developed by modifying the structure of an existing product. In some cases, however, research paths converge, and similar products are introduced into the market within short periods of each other.

- Question 14 : How is a firm's internal R&D related to its ability to produce therapeutically differentiated drugs?
- Question 15 : Does diversification into many therapeutic markets encourage the development of highly therapeutically differentiated drugs?
- Question 16 : What is the relationship between therapeutic differentiation and firm performance?
- Question 17 : How is outlicensing influenced by therapeutic differentiation?

3.5.6 Spatial Strategy

The rapid rate of technological change and lengthy approval process shorten the commercial period in which R&D investment must be recovered. As a consequence, firms must operate globally to maximize the sales potential of new products (Burstall 1985).

A firm's spatial strategy can be assessed by looking at where NCEs are first marketed. It was mentioned in chapter 2 that a successful product must be introduced simultaneously into each of the three major regions: the United States, Europe, and Japan. These markets currently account for at least 60 percent of worldwide pharmaceutical sales. Ohmae's (1986) "triad view" states that, to be successful, firms must simultaneously begin marketing new products in these three major developed regions. Although this is the conventional wisdom in the industry, no empirical research has attempted systematically to determine whether the firm's spatial strategy influences performance.

When a drug is developed, it is not necessarily introduced in the home country. Countries that attract NCEs are likely to have a strong demand for pharmaceuticals, tend to have higher levels of real prices and GDP growth, and are likely to have consumers who spend a higher proportion of their income on medical expenses. In chapter 2, discussion of the U.S. health care industry pointed to increasing drug prices and household expenditures on health care. This suggests that the United States should be an attractive first market for drugs, but the strict regulatory approval (considered the most costly in terms of time and resources) may mean that other countries are more attractive first markets. Therefore :

- Question 18 :** Does therapeutic market diversification influence whether a firm markets drugs first in the United States?
- Question 19 :** Are firms that are strong in new product development efforts likely to market drugs first in the United States?
- Question 20 :** What is the relationship between internal R&D and a firm's marketing of drugs first in the United States?
- Question 21 :** What is the relationship between drugs that are first marketed in the United States and firm performance?

3.6 Conclusion

The above discussion centered on proposed relationships among (1) each component of the competitive positioning strategy variable and performance; and (2) the competitive positioning strategy components. The purpose of this chapter

was to provide a theoretical framework for studying the competitive positioning strategy conceptual framework developed in chapter 1. A summary of the research questions is provided in Table 3.5. In the next chapter, a discussion of the specific hypotheses to be tested will be addressed.

Table 3.5 Summary of Research Questions

1. Timing of entry

Q1. How is entry timing related to performance?

2. R&D and Marketing Commitments

Q2. How is a firm's new product development efforts related to its commitment to R&D?

Q3. How does a firm's commitment to R&D affect performance?

Q4. How does a firm's commitment to marketing affect performance?

Q5. What is the relationship between new product development efforts and firm performance?

3. Source of Innovation and Outlicensing

Q6. Is there a relationship between a firm's internal R&D and its new product development efforts?

Q7. How is performance influenced by a firm's internal R&D efforts?

Q8. Do firms that develop drugs internally also engage in greater outlicensing?

Q9. Do firms with strong new product development efforts also engage in greater outlicensing?

Q10. Does high commitment to R&D affect on the firm's outlicensing behavior?

Q11. Does a firm's outlicensing behavior affect performance?

4. Therapeutic Diversification

Q12. How is therapeutic market diversification related to a firm's new product development efforts?

5. Therapeutic Differentiation

Q13. Are firms that are successful in their new product development efforts also likely to have higher therapeutically differentiated drugs?

Q14. How is a firm's internal R&D related to its ability to produce therapeutically differentiated drugs?

Q15. Does diversification in many therapeutic markets encourage the development of highly therapeutically differentiated drugs?

Table 3.5 (cont)

Q16. What is the relationship between therapeutic differentiation and firm performance?

Q17. How is outlicensing influenced by therapeutic differentiation?

6. Spatial Strategy

Q18. Does therapeutic market diversification influence whether a firm markets drugs first in the United States?

Q19. Are firms that are strong in new product development efforts likely to market drugs first in the United States?

Q20. What is the relationship between internal R&D efforts and a firm's marketing of drugs first in the United States?

Q21. What is the relationship between drugs that are first marketed in the United States and firm performance?

CHAPTER FOUR

HYPOTHESES AND RESEARCH DESIGN

The focus of this study is on the relationship between competitive positioning strategy and performance. The research questions addressing this association were presented in chapter 3.

This chapter reviews the measurements of competitive positioning and defines and operationalizes the performance criteria employed to evaluate the effectiveness of a firm's strategic actions. The databases used and the sample selection procedure are discussed. The statistical hypotheses then are presented, and the chapter concludes with a discussion of the statistical methodology.

4.1 Variable Definition

4.1.1. Competitive Positioning Variables

In this section, the components of the competitive positioning strategy are defined and measured. The specific manifest variables are: (1) timing of entry; (2) competitive position in R&D; (3) competitive position in marketing; (4) source of innovation; (5) therapeutic market diversification; (6) therapeutic differentiation; (7) outlicensing behavior; (8) spatial strategy; and (9) new product development efforts. Each construct is presented below; their measurement and data

bases are summarized in Table 4.1.

4.1.1.1. Timing of Entry

Many studies of first-mover advantages have tested their propositions on either the PIMS data (for example, Robinson and Fornell 1985; Robinson 1988; Lambkin 1988; Miller et al. 1989) or on primary data (Urban et al. 1986).

In the PIMS data, entry timing is based on the time a business entered its market. A *pioneer* is first in developing products or services, an *early follower* then enters the still growing and dynamic market, and a *late entrant* arrives in a more established market (Robinson 1988; Lambkin 1988). The timing of entry variable will be used here to differentiate firms as early or late entrants, a dichotomous classification supported in the Urban et al. study (1986) which suggests that entry order can best (most parsimoniously, at least) be considered a dichotomy: early and late.

There is a consensus in the literature that timing of market entry is the appropriate criterion for first-movership (Lieberman and Montgomery 1988). Here, for the order of entry, 1 = first, 2 = second, and so forth. This measurement also was used by Urban et. al. (1986) and by Green and Ryans (1990). To differentiate a firm as an early or late entrant, three figures are considered: the total number of therapeutic markets in which a firm competes in, the number of times a firm enters first (=1) or second (=2) in different therapeutic

Table 4.1 Measures Used in the Study

CONSTRUCTS	MEASURES	DATA SOURCES
Product Market Positioning Variables		
1. Competitive Position in Research and Development		
1a. Commitment to R&D		
R&D intensity (R&DINTENSITY)	(Total firm R&D)/(Worldwide health care sales)	Annual Reports 10-K reports
1b. R&D effectiveness (New Product Development Efforts)		
(i) R&D orientation (R&DORIENT)	(Cumulative number of NCEs approved)/(Cumulative number of NDAs submitted)	FDA, Paul de Haen Drug Product Index/New Drug Analysis
(ii) Firm's commitment to NCE development (PRODUCT)	(Cumulative number of NCEs introduced)/(Cumulative number of all products introduced)	Paul de Haen New Product Analysis/ New Product Survey
2. Competitive Position in Marketing		
Advertising intensity (ADVERTISE)	(Total advertising dollars)/(Worldwide health care sales)	Annual Report, COMPUSTAT
3. Source of Innovation		
Internal R&D efforts (HISTORY)	(Cumulative number of own R&D drugs in development)/(cumulative R&D products in development)	SCRIP
4. Therapeutic Market Diversification		
Diversity in therapeutic markets (DIVERSIFY)	(Number of therapeutic markets in which the firm has sales)/(Total number of markets)	Annual reports, Paul de Haen New Drug Survey/New Product Survey

Table 4.1 (con't)

5. Therapeutic Differentiation		
Therapeutic Differentiation (DIFF)	(Cumulative number of drugs given a Type A and B rating)/(Cumulative number of NCEs)	FDA
6. Outlicensing		
Outlicensing behavior (LICENSE)	(Cumulative number of NCEs licensed)/ (Cumulative number of internally developed new drugs)	Paul de Haen Drug Product Index
7. Spatial Strategy		
Marketing of drugs first in the United States (ORIGIN)	(Cumulative number of NCEs introduced in the United States)/(Cumulative number of internally developed new drugs)	Paul de Haen Drug Product Index
Performance Variables		
8. Performance		
(i) Domestic market share (DOMESTIC)	(Total domestic RX sales/Total U.S. market volume of all ethical drug sales)	Annual Reports, 10-K Reports
(ii) Global market share (GLOBAL)	(Total foreign RX sales/Total global market volume of all ethical drug sales)	Annual Reports 10-K Reports

markets, and the ratio of the number of times a firm enters first and second to the total number of therapeutic markets it competes in. Firms that compete in fewer than 35 therapeutic markets, have fewer than 20 first and second entries, and have a ratio of less than 0.5 are classified as late entrants.

4.1.1.2. Competitive Position in R&D

The importance of both R&D and marketing in the pharmaceutical industry was covered in chapter 3. Discussed below is the R&D strategy measurement, followed by the marketing strategy measurement.

To determine a pharmaceutical firm's competitive position with respect to R&D, its degree of commitment to R&D activity and the effectiveness of its R&D efforts should be considered.

Commitment to R&D. This variable also reflects a firm's R&D intensity and is measured by the R&D-to-sales ratio (RDINTENSITY). Wall Street analysts use an absolute (gross R&D spending) and a relative measure (R&D as a percentage of sales) to quantify R&D productivity among pharmaceutical firms (Financial World 1989b). Absolute measures of R&D are plagued with problems, however, as they do not offer evidence of how effectively one company spends its research dollars relative to its competitors. When firms are of equal size, the R&D-to-sales ratio is a good descriptor of the relative emphasis firms place on R&D. When the size distribution has a high

variance, this ratio fails to capture one important aspect of differences in R&D commitment: the absolute amount of resources allocated to R&D. Since absolute R&D spending increased dramatically among some firms during the 1980s, the size factor needs to be taken into account.

R&D Effectiveness. A real challenge in the pharmaceutical industry is introducing a steady stream of drugs from R&D efforts. To measure firms' competency at turning R&D resources into actual new products, a latent variable, New Product Development Efforts, is captured by two variables: R&D orientation and Commitments to NCE Development.

R&D orientation (R&DORIENT) is the ratio of cumulative NCEs approved to the cumulative NDAs submitted. To ascertain a firm's commitment to NCEs versus other types of new product introductions (PRODUCT), the ratio of cumulative NCEs introduced to cumulative new product introductions is used. This measure reflects the firm's commitment to developing NCEs rather than imitative products, such as combination or modified products.

Obviously, compared to "me-toos" or combined products, NCEs are more rare and require substantially larger resource commitments, but their potential for competitive differentiation and profit is much greater. Substantially more duplicate products need to be introduced to achieve the same sales level, and often these products are unsuccessful.

Cumulative figures for the two measures of R&D effectiveness were considered between 1971 and 1989. The use of cumulative rather than annual figures was necessary to smooth out short-term fluctuations and to account for the lags between NDA filing and NCE approval. This is the method recommended by Cool (1985).

Due to a lack of systematic data on firms' submission of Investigational New Drugs (INDs), this study cannot directly determine a firm's competency in converting INDs to NDAs. Since only about 3 percent of IND filings reach the NCE approval stage, the two measures used here, R&DORIENT and PRODUCT, provide stronger measures of a firm's R&D effectiveness.

4.1.1.3 Competitive Position in Marketing

In this study, a firm's competitive position in marketing is reflected in the firm's advertising strategy. Advertising is a key marketing tool in the pharmaceutical industry. This study focuses on advertising efforts to the medical and paramedical professions. Here, advertising intensity is determined by taking the ratio of total advertising dollars to worldwide health care sales (ADVERTISE).

In summary, the key variables used to capture a firm's competitive position in R&D and marketing are as follows.

Research and Development

Commitment to R&D

1. R&D intensity (RDINTENSITY) =

$$\frac{\text{(Total firm R\&D)}}{\text{(Worldwide health care sales)}}$$

R&D Effectiveness (New Product Development Efforts)

2. R&D Orientation (R&DORIENT) =

$$\frac{\text{(Cumulative number of NCEs approved)}}{\text{(Cumulative number of NDAs submitted)}}$$
3. Firm's commitment to NCE development (PRODUCT) =

$$\frac{\text{(Cumulative number of NCEs introduced)}}{\text{(Cumulative number of all products introduced)}}$$

Marketing

Commitment to Marketing

- Advertising intensity (ADVERTISE) =

$$\frac{\text{(Total advertising dollars)}}{\text{(Worldwide health care sales)}}$$

4.1.1.4. Source of Innovation

As discussed in chapter 3, the ability of firms to develop and exploit technological know-how internally is an important dimension of competition. Many factors, however, may prompt firms to consider external sourcing of R&D. Decisions about which technical capabilities to develop internally and which to access through licensing arrangements with external sources will affect a pharmaceutical firm's viability in an evolving technological environment.

A firm's tendency to rely on external sources for R&D also depends on the firm's historical pattern of R&D procurement. For example, firms with experience in licensing arrangements are likely to continue engaging in this form of

external sourcing. Firms lacking that experience are more likely to find in-house R&D more attractive.

The historical propensity (HISTORY) of a firm to procure R&D ideas internally or externally is operationalized by taking the ratio of the cumulative number of "own R&D products" in development to the "cumulative number of R&D products" in development where, the former refer to the drugs that originated in the firm's laboratories, and the latter refer to the total number of drugs developed both internally and externally. The difference between the numerator and denominator gives the total number of drugs sourced externally. To summarize, the source of innovation construct is measured by :

$$\text{Internal R\&D Efforts (HISTORY)} = (\text{Cumulative number of own R\&D drugs in development}) / (\text{Cumulative number of R\&D products in development})$$

4.1.1.5. Therapeutic Market Diversification

The degree of therapeutic market diversification is indicated by the variable DIVERSIFY, that is, the ratio of the number of therapeutic markets in which the firm has sales to the total number of markets considered for this study. As mentioned in Section 3.5.4. market diversification is indicative of the R&D and manufacturing mobility within pharmaceutical firms. In addition, this index also shows the extent to which a firm follows a "focused" strategy, targeting efforts on only a few therapeutic markets, or a

"differentiated" strategy, spreading resources over several markets. Therefore,

$$\text{DIVERSIFY} = (\text{Number of therapeutic markets in which the firm has sales}) / (\text{Total number of markets}).$$

4.1.1.6 Therapeutic Differentiation

Therapeutic differentiation is measured by the ratio between the cumulative number of drugs given a Type A and B rating by the FDA to the cumulative number of NCEs. Therefore :

$$\text{Therapeutic differentiation (DIFF)} = (\text{Cumulative number of drugs given a Type A and B rating}) / (\text{Cumulative number of NCEs}).$$

4.1.1.7 Outlicensing Behavior

The outlicensing behavior of the firm is measured by the ratio of cumulative number of NCEs licensed overseas to the cumulative number of new product introductions:

$$(\text{OUTLICENSE}) = (\text{Cumulative number of NCEs licensed overseas}) / (\text{Cumulative number of internally developed new products}).$$

4.1.1.8. Spatial Strategy

In order to determine a pharmaceutical firm's commitment to the United States as a key market, the variable ORIGIN is considered in this study. Therefore,

$$\text{Marketing of drugs first in the United States (ORIGIN)} = (\text{Cumulative number of drugs that are marketed in the U.S.}) / (\text{Cumulative number of internally developed new products})$$

4.1.2. Variables Measuring Performance

In chapter 3, a distinction was made among financial accounting indicators, financial measures, and output market success indicators of performance. The latter, it was concluded, best captured strategic performance for the purpose of this study.

The importance of market share earned by pioneering brands has been established in chapter 3. Two market share measures will be used here: domestic market share (DOMESTIC), and global market share (GLOBAL). Both are based on sales volume, the most common way to define market share (Spilker 1989).

Domestic market share is determined by dividing the firm's total U.S. market ethical drug sales volume by total U.S. market ethical drug sales volume. Global market share is computed similarly by dividing the firm's total worldwide ethical drug sales volume by total global market sales volume of all ethical sales. Therefore:

1. Domestic Market Share (DOMESTIC) =

$$\frac{\text{(Total domestic RX sales)}}{\text{(Total U.S. market sales volume of all ethical drugs)}}$$
2. Global Market Share (GLOBAL) =

$$\frac{\text{(Total worldwide RX sales)}}{\text{(Total global market volume of all ethical drug sales)}}$$

4.2. An Overview of Data Bases Used in the Study of Competitive Positioning Strategy

4.2.1. Data on NDAs

Data on the effectiveness of each firm's R&D efforts was obtained from the FDA. Under the Freedom of Information Act, the author requested annual data on the number of NDAs submitted by firms between 1971 and 1989. The request was made in January 1991 and the information was received in April 1991.

4.2.2. New Product Introductions and Order of Entry

Paul de Haen data bases provided much of the information for the study. His periodical publications include *New Drug Analysis*, which surveys all NDCs introduced nationally, and *New Product Survey*, which covers all new drug products introduced. These data bases were consulted to obtain information on firms' new product introductions between 1971 and 1989.

Paul de Haen also publishes *Drug Product Index* in an international and a U.S. edition, covering eight countries and the U.S. market, respectively. Both currently span the years 1950-1989 and focus on: nonproprietary drug name; trade name; therapeutic subclass; manufacturer; country of manufacturer; originating firm; originating country; date of beginning marketing in country; and country market.

Paul de Haen International, Inc., is now a division of Micromedia, Inc., headquartered in Englewood, Colorado.

4.2.3. Source of Innovation

Data on the source of innovation variables was collected from *Scrip World Pharmaceutical News*, 1971-1989. At the end of every year, Scrip reviews the global pharmaceutical industry and ranks the top 100 firms based on the number of drug products a firm has in development. This number includes new products originating from both internal and external R&D sources.

4.2.4. Performance Measures

Measures of performance were mainly extracted from company annual reports and 10-K statements.

This concludes the overview of the major databases used in the study. Besides these databases, other information sources were made available by Upjohn. The next section discusses the issues involved in the sample selection for this study.

4.3. Sample Selection

4.3.1. Selection of Firms

Several factors had to be considered in selecting a suitable sampling frame for this study.

First, foreign firms were excluded due to the unavailability or unreliability of data on some of the strategic and performance dimensions.

Second, firms had to be operating as separate entities from 1971-1989. This criterion was adopted to reduce any bias that might result from a changing sample. Therefore, firms that were acquired or merged during this time were eliminated.

Third, only firms with a significant commitment to the ethical drug business were chosen. That commitment was defined as as more than 50 percent of sales from ethical drugs. Therefore, firms with a large percentage of sales from either proprietary or generic drugs were excluded.

The companies that met the criteria are listed in Table 4.2.

4.3.2. Selection of Therapeutic Markets

There are ten major therapeutic categories in which a pharmaceutical firm may compete. Each can be further differentiated into subclasses. Since it was not possible to analyze all these subclasses, the study was limited to a few within each. Therapeutic categories dominated by OTC drugs were eliminated. Given the nature of competition in the OTC sector, these categories were eliminated to avoid possible confounding effects. This consideration also eliminated drugs from the nutritional and topical categories. As shown in Table 4.3, these two therapeutic categories contributed insignificantly to the sales of all prescription pharmaceuticals (about 11 percent) between 1976 and 1991.

The subclassess chosen for examination in this study are

Table 4.2 Drug Firms in the Study Sample

<u>Firm</u>	<u>Divisions^a</u>
1. Abbott Laboratories	Abbott Laboratories
2. American Cyanamid	Lederle
3. American Home Products	Ayerst Wyeth
4. Bristol-Myers	Bristol Laboratories
5. Carter-Wallace	Wallace Laboratories Wampole Laboratories
6. Johnson and Johnson	Johnson and Johnson McNeil Laboratories Ortho Pharmaceutical Corp.
7. Eli Lilly and Company	E. Lilly Dista
8. Marion Laboratories	Marion Labs
9. Merck and Company	Merck and Co. Merck, Sharpe and Dohme
10. Pfizer Laboratories	Pfizer Roerig
11. A.H. Robins	Robins
12. Rorer Group	William H. Rorer, Inc.
13. Schering-Plough	Plough Schering
14. G.D. Searle	Searle
15. SmithKline Beckman	SmithKline and French
16. E.R. Squibb and Sons	Squibb
17. Sterling Drugs	Breon Winthrop
18. Syntex	Syntex Borden
19. The Upjohn Company	Upjohn
20. Warner-Lambert	Lambert Parke Davis Warner-Chilcott

^a Only the ethical division is considered.

Table 4.3. Sales of U.S. Prescription Pharmaceuticals by Therapeutic Categories, 1976-1991,
in Millions of Dollars

Therapeutic Category	1976	1981	1984	1985	1986	1991
Cardiovascular	\$1,035	\$2,100	\$3,565	\$4,150	\$4,696	\$7,550
Antiinfective	1,185	1,770	2,725	3,000	3,510	5,150
Internal Medicine	1,495	2,310	3,095	3,400	4,025	5,400
Mental Health	935	1,150	1,790	2,070	2,275	3,025
Total	\$4,650	\$7,330	\$11,175	\$12,620	\$14,506	\$21,125
Percentage of Total Drug Market	66	61	62	63	64	66
Pain Control	785	1,560	2,070	2,305	2,610	3,190
Respiratory	480	780	760	900	1,060	1,375
Nutritional	435	725	1,310	1,365	1,480	2,000
Topical	320	590	900	990	1,065	1,250
Total	2,020	3,655	5,040	5,560	6,215	7,815
Percentage of Total Drug Market	29	31	28	28	27	25
Other	380	965	1,735	1,900	2,120	2,850
Total Drug Market	\$7,050	\$11,950	\$17,950	\$20,080	\$22,840	\$31,790

Source : Adapted from Arthur D. Little (1988).

cardiovascular, mental health, antiinfective, and internal medicine markets, which consistently have accounted for more than 60 percent of total prescription sales in the last two decades. In Appendix A, each drug is allocated to a therapeutic category according to its primary function in therapy for a certain body system, rather than in terms of the drug's chemical compound. Paul de Haen's classification system is useful in this respect.

This concludes the discussion of the sampling frame and the therapeutic markets that are considered for this research. The next section looks at the research hypotheses that are tested in this dissertation.

4.4. Research Hypothesis

At the end of the literature review in chapter 3, a number of research questions were raised. Specific research hypothesis will now be developed to reflect the basic research questions underlying this study.

4.4.1 Timing of Entry

The discussion on the timing of entry effects tends to conclude that there is a negative relationship between timing of entry and performance. That is, pioneers tend to earn higher market shares relative to early followers, and early followers tend to have higher market share than late followers. To answer research question 1, that is,

the extent to what timing of entry is related to firm performance, the sample of firms is classified into two groups, early entrants and late entrants. Although no formed hypothesis was developed for research question 1, implied in the distinction between early and late entrants is the effect of entry timing on performance.

4.4.2 Competitive Position in R&D and Marketing

As mentioned earlier, a firm's competitive position in R&D and marketing is determined by its R&D intensity and advertising intensity, respectively. Therefore, the following research hypotheses were posited. For early and late entrants:

Research Question 2. How is a firm's new product development effort related to its commitment to R&D?

Hypothesis (H1). High commitment to R&D has a positive effect on new product development efforts.

Research Question 3. How does a firm's commitment to R&D affect performance?

Hypothesis (H2). There is a positive relationship between a firm's commitment to R&D and performance.

Research Question 4. How does a firm's commitment to marketing affect performance?

Hypothesis (H3). There is a positive relationship between a firm's commitment to marketing and performance.

Research Question 5. What is the relationship between new product development efforts and firm performance?

Hypothesis (H4). There is a positive relationship between new product development efforts and firm performance.

4.4.3 Source of Innovation

While licensing and collaborative research are expected to increase in the pharmaceutical industry, the discussion on the internalization of R&D strongly suggests that a firm's long-term economic success depends on its ability to develop and exploit internal technological know-how. Hence, for both early and late entrants:

Research Question 6. Is there a relationship between a firm's internal R&D and its new product development efforts?

Hypothesis (H5). There is a positive relationship between internal R&D and new product development efforts.

Research Question 7. How is performance influenced by a firm's internal R&D?

Hypothesis (H6). There is a positive relationship between internal R&D and firm performance.

4.4.4 Outlicensing

Although U.S. pharmaceutical firms continue to derive much of their net income from domestic sales, the increasing globalization of the industry requires U.S. firms to expand to overseas markets as more and more European and Japanese firms make inroads into U.S. markets. The next three hypotheses are concerned with the factors that influence outlicensing behavior; the fourth hypothesis investigates the relationship

between outlicensing and performance.

Research Question 8. Do firms that develop drugs internally also engage in greater outlicensing?

Hypothesis (H7). Internal R&D has a positive effect on outlicensing for the late entrants. This relationship is negative for the early entrants.

The expected direction for the next three hypotheses are expected to be the same for both early and late entrants.

Research Question 9. Do firms with strong new product development efforts also engage in greater outlicensing?

Hypothesis (H8). There is a positive relationship between new product development efforts and outlicensing.

Research Question 10. Does a high commitment to R&D affect the firm's outlicensing behavior?

Hypothesis (H9). High commitments to R&D lead to greater outlicensing.

Research Question 11. Does a firm's outlicensing behavior affect performance?

Hypothesis (H10). There is a positive relationship between outlicensing activity and firm performance.

4.4.5 Therapeutic Diversification

In chapter 2, it was argued that competition in the pharmaceutical industry is best examined at the individual therapeutic level. The subclasses considered in this study are at different growth stages; in particular, the mental health, antiinfective, and internal medicine subcategories are experiencing greater competition as they approach the mature

stages. Consequently, one way to reduce risks is to diversify into emerging and growing markets is. A firm's level of therapeutic market diversity can positively influence its competitive position in R&D. As argued on pp. 117/118, this diversity reflects the firm's mobility in R&D resources.

Therefore, a high degree of diversification would be positively reflected in a firm's product development efforts, that is:

Research Question 12. How is therapeutic market diversification related to a firm's new product development efforts?

Hypothesis (H11). There is a positive relationship between therapeutic market diversification and new product development efforts.

4.4.6 Therapeutic Differentiation

A drug's therapeutically differentiated properties are expected to covary positively with the firm's product development efforts and internal R&D and negatively with a high level of therapeutic market diversification. In the pharmaceutical industry, specialization is often necessary to acquire in-depth knowledge of particular diseases before developing drugs with highly differentiated properties to treat them. Therefore, for both groups:

Research Question 13. Are firms that are successful in their new product development efforts also likely to have higher therapeutically differentiated drugs?

- Hypothesis (H12). Strong new product development efforts lead to higher therapeutically differentiated drugs.
- Research Question 14. How is a firm's internal R&D efforts related to its ability to produce therapeutically differentiated drugs?
- Hypothesis (H13). There is a positive relationship between internal R&D and therapeutic differentiation.
- Research Question 15. Does diversification into many therapeutic markets encourage the development of highly therapeutically differentiated drugs?
- Hypothesis (H14). High therapeutic market diversification is negatively related to therapeutic differentiation.
- Research Question 16. What is the relationship between therapeutic differentiation and firm performance?
- Hypothesis (H15). There is a positive relationship between therapeutic differentiation and firm performance.

The relationship between therapeutic differentiation and outlicensing activity is expected to be positive for early entrants and negative for late entrants. Because of first-mover advantages associated with early entrants, these firms are able to exploit their development of highly differentiated drugs on a global basis more effectively than late entrants. Therefore:

- Research Question 17. How is outlicensing influenced by therapeutic differentiation?
- Hypothesis (H16). Therapeutic differentiation is positively associated with the

outlicensing activity of early entrants. This relationship is negative for late entrants.

4.4.7 Spatial Strategy

A high degree of therapeutic market diversification can affect the firm's spatial strategy. Although some countries still have a high demand for acute drugs (such as antiinfectives), in industrialized countries demand has shifted increasingly to maintenance drugs (such as medication for AIDS and cancer). This shift was illustrated in Table 4.3. Therefore, firms that have diversified into these therapeutic categories are in a better position to exploit opportunities in the growing U.S. market.

Research Question 18. Does therapeutic market diversification influence a firm's marketing of drugs first in the United States?

Hypothesis (H17). There is a positive relationship between therapeutic market diversification and the marketing of drugs first in the United States.

New product development efforts and internal R&D are expected to have a positive effect on the firm's spatial strategy. This is because of the firm's need to exploit economic opportunities in the U.S. market. Therefore:

Research Question 19. Are firms that are strong in new product development likely to market drugs first in the United States?

Hypothesis (H18). There is a positive relationship between new product development and the marketing of drugs first in

the United States.

Research Question 20. What is the relationship between internal R&D and a firm's marketing of drugs first in the United States?

Hypothesis (H19). There is a positive relationship between internal R&D and the marketing of drugs first in the United States.

The effect of the firm's spatial strategy for product introduction on performance is expected to be negative for both late and early entrants. The global nature of the industry requires all firms to be major players in the the global market rather than concentrate on the U.S. market as their key source of sales. Therefore:

Research Question 21. What is the relationship between drugs that are first marketed in the United States and performance?

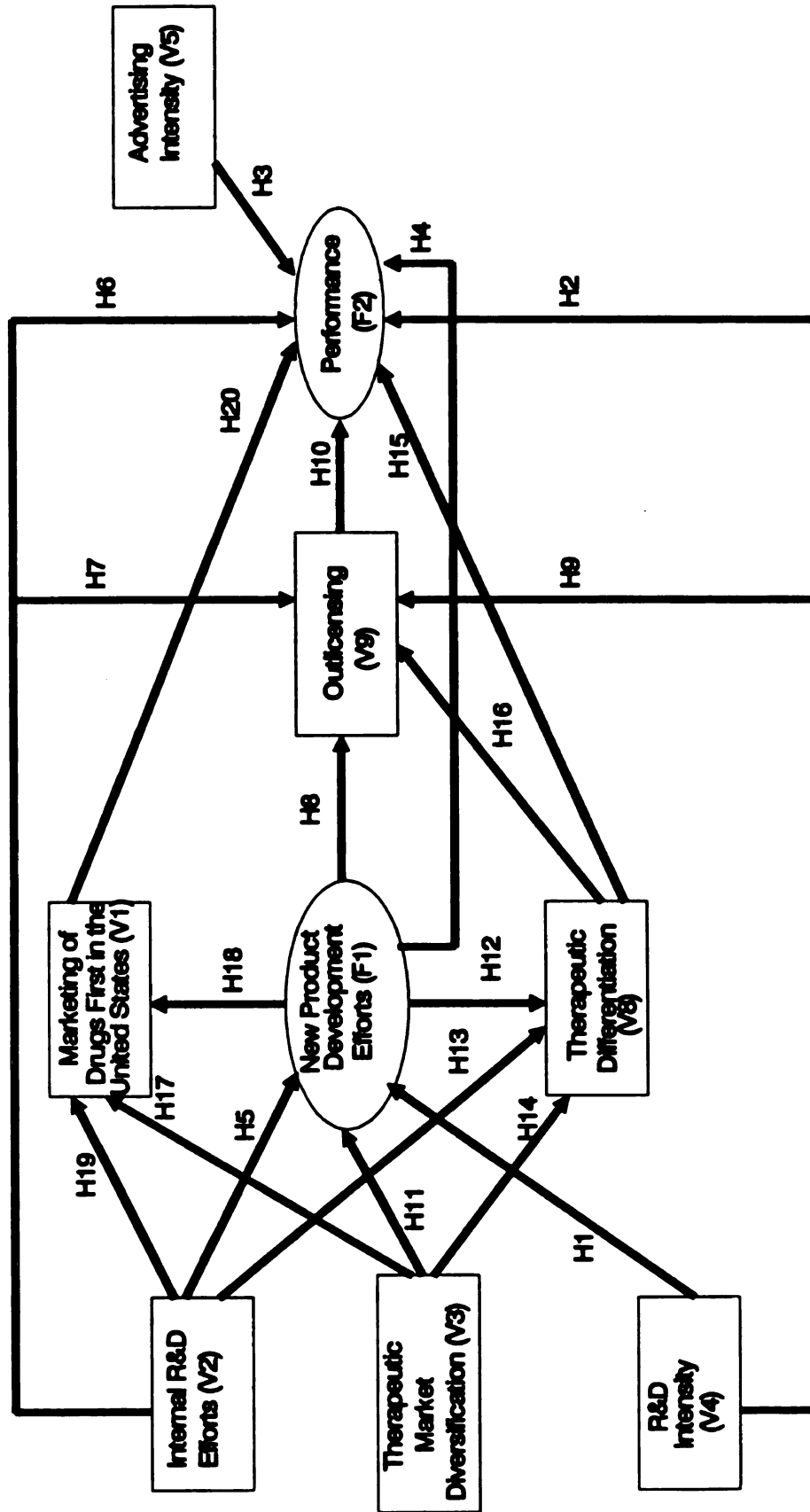
Hypothesis (H20). There is a negative relationship between drugs that are first marketed in the United States and firm performance.

The causal relationships among the variables are shown in Figure 4.1; Table 4.4. summarizes the expected direction of the twenty hypotheses for both early and late entrants. The next section discusses the methodology used to test the statistical hypotheses.

4.5 Methodology

To test the hypothesis in a simultaneous manner, covariance structure modelling was used. It merges the logic

Figure 4.1 Proposed Structural Model



For simplicity purposes, covariances [(v2,v3), (v4,v3), (v4,v2), (v4,v5)] are not shown.

Table 4.4 Expected Direction of Hypothesis for Early and Late Entrants

Hypothesis	Early Entrants	Late Entrants
H1. High commitment to R&D has a positive effect on new product development efforts.	+	+
H2. There is a positive relationship between a firm's commitment to R&D and performance.	+	+
H3. There is a positive relationship between a firm's commitment to marketing and performance.	+	+
H4. There is a positive relationship between new product development efforts and firm performance.	+	+
H5. There is a positive relationship between internal R&D and new product development efforts.	+	+
H6. There is a positive relationship between internal R&D and firm performance.	+	+
H7. Internal R&D has a positive effect on outlicensing for the late entrants. This relationship is negative for the early entrants.	-	+
H8. There is a positive relationship between new product development efforts and outlicensing.	+	+
H9. High commitments to R&D lead to greater outlicensing.	+	+
H10. There is a positive relationship between outlicensing activity and firm performance.	+	+
H11. There is a positive relationship between therapeutic market diversification and new product development efforts.	+	+
H12. Strong new product development efforts lead to higher therapeutically differentiated drugs.	+	+
H13. There is a positive relationship between internal R&D and therapeutic differentiation.	+	+
H14. High therapeutic market diversification is negatively related to therapeutic differentiation.	-	-
H15. There is a positive relationship between therapeutic differentiation and firm performance.	+	+

Table 4.4 (cont)

Hypothesis	Early Entrants	Late Entrants
H16. Therapeutic differentiation is positively associated with the outlicensing activity of early entrants. This relationship is negative for late entrants.	+	-
H17. There is a positive relationship between therapeutic market diversification and the marketing of drugs first in the United States.	+	+
H18. There is a positive relationship between new product development efforts and the marketing of drugs first in the United States.	+	+
H19. There is a positive relationship between internal R&D and the marketing of drugs first in the United States.	+	+
H20. There is a negative relationship between drugs that are first marketed in the United States and firm performance.	-	-

of confirmatory factor analysis, multiple regression, and path analysis within a single analytical framework (see Bentler 1980), selling (Aaker and Bagozzi 1979; Churchill and Pecotich 1982), 1980). Recent textbooks on multivariate analysis have included chapters on covariance structure modelling (Bernstein 1988; Pedhauzer 1982), and several textbooks have been devoted to this topic (for example, Hayduk 1987; Loehlin 1987). Applications of covariance structure modelling are now popular in such marketing fields as consumer behavior (Arora 1982; Burnkrant and Page 1982; Droge 1989; Ryan 1982), personal product adoption (Bagozzi 1983; Bearden and Shimp 1982), and marketing strategy and distribution channels (Gaski 1986; John and Reve 1982).

Fornell (1987) regards covariance structure modelling as one of the "second-generation multivariate analysis" that allows a more theory-based approach to research.¹³ In fact, a fundamental feature of second-generation multivariate methods is their ability to integrate both theory and data. Specifically, covariance structure methods combine theoretical and empirical knowledge by: (1) modelling errors in observation (measurement or nonsampling error); (2) incorporating both theoretical (unobservable) and empirical (observable) variables in the analysis; (3) confronting theory

¹³First-generation methods include multiple regression, multiple discriminant analysis, factor analysis, principal components, multidimensional scaling, and cluster analysis.

with data (hypothesis testing); and (4) combining theory and data (theory building).

Although covariance structure methods often are used for causal analysis, they are not methods for determining causes; rather, they are techniques applied to a "causal model formulated by the researcher on the basis of knowledge and theoretical considerations" (Kerlinger and Pedhauzer 1982, p. 305). Therefore, these techniques are useful in testing rather than generating a theory by requiring the analyst to be *explicit* about the theoretical knowledge, or lack thereof, s/he wishes to bring to bear on the analysis. Since causal modelling forces one to make explicit the assumptions, variables, and hypothesized relationships in a theory, a degree of certainty and precision is added to the theory and the research effort.

In summary, covariance structure modelling rests on the logic of confirmatory analysis. "Confirmatory" implies that the analyst must make some *explicit*, substantive (theoretical), and measurable assumptions or hypotheses that can be tested statistically. When the observed data structure (as measured by the covariances) is closely reproduced by the set of estimated parameters, the model is confirmed, that is, the proposed theoretical model is judged to be consistent with the data.

4.5.1 Description of EOS

Several models for the analysis of covariance structure have been developed, and most applications use the LISREL (*Linear Structural RELations*) representation (Jöreskog and Sörbom 1978, 1981, 1984, 1988). A more recent program, EQS (Bentler 1985), is gaining popularity because it is easy to learn and apply to new modelling situations.

LISREL can only be applied to standard models, while EQS is equally robust for both standard and nonstandard types of models. An illustration of standard and non-standard models is provided by Bentler (1989, Chapter 5). In LISREL, errors of measurement must be taken into account by the use of latent variables. In addition, key variables of relevance to the structural system must not have been omitted, and conditions and times of measurement must be correctly specified to obtain the hypothesized effects. These considerations often lead to standard types of designs characteristic of latent variable models, with repeatedly measured constructs, and each construct having multiple indicators.

In this respect, Bentler (1986) describes the LISREL program as a factor analytical simultaneous equation model (FASEM), highly analogous to canonical correlations. Various types of effects of interest, such as direct paths between the measured constructs and paths from residuals to latent factors, are not permitted. In addition, when the latent factor has only one indicator, the relationship between the

factor (F) and its measured construct (V) is set up as $F \rightarrow V$, whereas careful study will show that a single measured variable cannot create a factor. Despite this limitation, this technique is often used in LISREL to allow the program to run (for example, Jaworski and MacInnis 1989).

EQS overcomes some of the limitations identified in the LISREL program by allowing both measured and latent variables to be used as criteria in the model. That is, the Fs and Vs are allowed to correlate. In addition, the Es and Vs are allowed to covary which is inadmissible in the LISREL program. In EQS terminology, observed or measured variables are called Vs. Hypothetical constructs or unmeasured latent variables are called factors or Fs. Residuals in measured variables are errors, or Es. Finally, the corresponding residuals in factors are called disturbances, or Ds.

As in most model-building efforts, covariance structure analysis begins with the identification of relevant variables and hypothesizes which are exogenous and endogenous. For the former, variability is assumed to be determined by causes outside the causal model. In path analysis, no attempt is made to explain the variability of an exogenous variable with other exogenous variables. For *endogenous* variables, variation is explained by exogenous or other endogenous variables.

In Figure 4.1, internal R&D efforts (V2), therapeutic market diversification (V3), R&D intensity (V4), and

advertising intensity (V5) are exogenous variables; the remaining variables (V1, V8, V9) and latent factors (F1, F2) are endogenous variables. Although not shown in Figure 4.1, relationships among the exogenous variables in the model are represented by curved lines with arrowheads at each end, indicating that one variable is not conceived as a cause of the other. This allows the exogenous variables to be correlated. The remaining relationships are causal, as indicated by the unidirectional arrows. The structural equation model set for Figure 4.1 is summarized in Table 4.5.

4.5.2 Assumptions

Since covariance structure analysis is similar to multiple regression, several key assumptions underlying multiple regression also hold true for covariance structure modelling.

- (1) The relationships among the variables are linear, additive, and causal. Consequently, curvilinear, interactive, or multiplicative relationships are excluded.
- (2) The model is recursive, that is, reciprocal causation between variables is ruled out.
- (3) The variables are measured on an interval scale.
- (4) Residuals are not correlated with the variables that precede them in the model. This assumption creates, for each endogenous variable, a causal path that is a weighted function of variables prior to this variable and an error term (the residual) that is unrelated to other system variables or other residuals.

TABLE 4.5

THE STRUCTURAL EQUATION MODEL SET

V_1 = Marketing of drugs first in the United States (endogenous)

V_2 = Internal R&D (exogenous)

V_3 = Therapeutic market diversification (exogenous)

V_4 = R&D intensity (exogenous)

V_5 = Advertising intensity (exogenous)

V_6 = R&D orientation (endogenous)

V_7 = Commitments to MCE development (endogenous)

V_8 = Therapeutic differentiation (endogenous)

V_9 = Outlicensing (endogenous)

V_{10} = Domestic market share (endogenous)

V_{11} = Global market share (endogenous)

F_1 = New product development efforts (endogenous factor)

F_2 = Performance (endogenous factor)

The structural equations corresponding to the model are as follows.

$$(1) \quad V_1 = \beta_1 F_1 + \beta_2 V_2 + \beta_3 V_3 + E_1.$$

$$(2) \quad V_6 = \beta_4 F_1 + E_2.$$

$$(3) \quad V_7 = \beta_5 F_1 + E_3.$$

$$(4) \quad V_8 = \beta_6 F_1 + \beta_7 V_2 - \beta_8 V_3 + E_4.$$

$$(5) \quad V_{10} = \beta_9 F_2 + E_5.$$

$$(6) \quad V_{11} = \beta_{10} F_2 + E_6.$$

$$(7) \quad V_9 = \beta_{11} F_1 + \beta_{12} V_2 + \beta_{13} V_4 + \beta_{14} V_8 + E_7.$$

$$(8) \quad F_1 = \beta_{15} V_2 + \beta_{16} V_3 + \beta_{17} V_4 + D_1.$$

$$(9) \quad F_2 = -B^*V_1 + B^*V_2 + B^*V_4 + B^*V_5 + B^*V_8 + B^*V_9 + B^*F_1 + D_2.$$

In these equations,

B = standardized partial regression coefficients, which represent the path coefficients;

V = variables defined in Figure 4.1;

F = latent factors defined in Figure 4.1;

E = error terms in the V variables; and

D = disturbance terms in the F variables.

- (5) The variables have a multivariate normal distribution.

To determine whether any of the assumptions are violated, several statistical analyses are used. These are discussed in the following section.

4.5.3 Statistical Validation of the Assumptions

Linearity. To determine whether relationships between or among variables are linear, a scatterplot of the residuals is examined. If nonlinearity is suggested by the scatterplots, three alternatives in correcting this problem are proposed.

- (1) The significance of nonlinear relationships can be determined by computing the correlation ratio; called eta squared (Hayes 1973),
- (2) Exponential terms can be added to the equation and tested for significant increases in variance for which they account for (Kerlinger and Pedhauzer 1973),
- 3) The predictor may be treated as a categorical variable by using either dummy coding or exponential terms in the path analysis (Kerlinger and Pedhauzer 1973).

Recursivity. One way causality is assumed. Models involving reciprocal causation can be handled through two-stage-least squares (Duncan 1975). Whether a certain model is recursive or nonrecursive can be determined only on the basis of knowledge, theoretical formulations, assumptions, and logical analysis of the research.

Interval Scales. Billings and Wroten (1978) argue that the assumption of interval scale property is often

questionable, given the primitive state of measurement of many variables in the industrial/organization literature. Even though the data may not satisfy the requirement of interval scales, Bohrnstedt and Carten (1971) argue that multiple regression is still the recommended technique in the presence of ordinal data.

Uncorrelated Residuals. The presence of autocorrelation has several effects on the analysis.

- (1) Least-squares estimates are unbiased but are not efficient, that is, they do not have minimum variance,
- (2) The estimate of δ^2 and standard errors of the regression coefficients may be seriously understated, thereby giving a spurious impression of accuracy, and
- (3) Tests of significance may be invalid.

The Durbin-Watson d statistic is used to determine whether the residuals of the endogenous variables are autocorrelated (Dillon and Goldstein 1984). The test is based on the assumption that the errors constitute a first-order autoregressive series, that is,

$$u_t = pu_{t-1} + \epsilon_t \quad |p| < 1,$$

and the statistic is defined as :

$$d = \frac{\sum (e_t - e_{t-1})^2}{\sum e_t^2}$$

The closer the d statistic is to the value of 2, the stronger the evidence that there is no autocorrelation in the

error. Evidence of autocorrelation is indicated by the deviation of d from 2 (Johnston 1984).

Multivariate Normal Distribution. Besides estimating parameters and testing models with the traditional multivariate normal theory, EQS also allows the use of distribution-free estimation procedures, such as the elliptical and arbitrary distribution theories. When the raw data are available, the EQS (Bentler 1985) computer program also will calculate the Mardia (1974) coefficient for testing this assumption.

For the normalized estimate of multivariate kurtosis, an objective is to have values close to zero; large values indicate a presence of positive kurtosis, while negative values indicate significant negative kurtosis. Highly skewed data and excessive kurtosis can affect parameter estimates, standard errors, and overall fit. The problem of data not meeting the normal distribution assumptions has received attention in the psychometric literature. Jöreskog and Sörbom (1984) warned that standard errors must be interpreted with caution when the normality assumption is violated. Boomsma (1983) recommends using Maximum Likelihood (ML) estimation with caution when the skewness of the observed variables is larger than 1.00. Muthen and Kaplan (1985) found that both ML and GLS estimators have inflated chi-square values when the skewness of the observed variables is approximately 2.00 in

absolute value.

4.5.4 Evaluation of Structural Models

The framework for evaluating structural equation models follows closely the one proposed by Bagozzi and Yi (1988). When the assessment of input data and statistical assumptions are adequately met, the next two steps involve the assessment of the overall model fit and the internal structure of the model consecutively.

4.5.4.1 Assessment of Overall Model. A popular indicator of the overall goodness-of-fit of any model is the χ^2 test. Essentially, the chi-square statistic compares the goodness-of-fit between the covariance matrix for the observed data and the covariance matrix derived from a theoretically specified structural model. Well-fitting models tend to produce a small chi-square value, or fail to reject the null hypothesis.

Researchers such as Fornell and Larcker (1981), Satorra and Saris (1985), and Bearden et al. (1982) have identified several problems associated with the chi-square test and have recommended the use of multiple fit criteria rather than reliance on a single statistic. For example, the chi-square test can be sensitive to small differences between observed and estimated data, especially when the sample size is large. Several supplemental fit indices have been proposed. For example, Bentler and Bonnett (1980) have developed normed and

nonnormed indices to indicate the fit of a theoretical model relative to the worst case (null) model. The normed fit index (NFI) is a measure of the percentage of total variation explained by the proposed model versus the null model. The authors argue that an $NFI \geq 0.90$ indicates adequate fit. The nonnormed fit index (NNFI) takes into account the degrees of freedom in the model, and it can exceed the normed index in magnitude and can be outside the 0-1 range.¹⁴

4.5.4.2 Assessment of Internal Structure of Model. Concerns regarding the internal assessment of fit include looking at: (1) composite reliabilities for the latent variables; (2) normalized residuals; and (3) the significance of the parameters.

The composite reliability is defined as :

$$p_c = \frac{(\sum \lambda_i)^2 \text{ var}(T)}{(\sum \lambda_i)^2 \text{ var}(T) + \sum \theta_{ii}}$$

where λ = factor loadings;
 T = underlying true score; and
 θ = error of measurement.

the summation of the items comprising the composite variable (that is, the underlying latent variable). Composite reliabilities ≥ 0.6 are desirable.

Normalized residuals greater than two indicate that significant amounts of variances are left unexplained by the

¹⁴ The mathematical derivation of the NFI and NNFI is presented in Appendix B.

model and, hence a specification error is likely.

The evaluation of the fit of individual equations within a model involves computing (1) a squared multiple correlation for each structural equation and (2) t-values for individual parameter estimates. The squared multiple correlations indicate the proportion of variance in each variable/latent factor accounted for by the equation. A t-value ≥ 1.96 indicates that the parameters are significantly different from zero.

4.5.4.3. Assessment of Validity

The criteria discussed so far have focused on issues of model fit. In addition, Bagozzi and Yi (1988) proposed broadening model evaluation criteria to include questions of validity. One way to assess validity is through a multiple group analysis.

The need to perform a multiple group analysis can best be understood by considering two extremes. At one extreme, the populations differ with respect to the variables being measured. One then would expect the covariance structures in the various groups to be different. This in turn implies that the structural models which generate the corresponding covariance matrices also would be completely different. In such a case, doing a multiple group analysis is unnecessary; one could propose and test a different structural model for each group.

At the other extreme, assume that the covariance structures of the different groups are indistinguishable as far as the measured variables are concerned. In this case, one would like (1) to verify that one structural model describes each of the populations and (2) obtain a single set of parameter estimates for the model. Finding this single model is difficult if one analyses the data from each sample separately since parameter estimates would be less precise than if all the samples were analyzed simultaneously. Hence, a multiple group analysis should be able to verify whether a model that is invariant across all groups reproduces the sample data of each group to within sampling accuracy.

Symbolically, assume m populations. Each has a covariance matrix, $\Sigma_1, \Sigma_2, \dots, \Sigma_m$. If all the populations are identical, then $\Sigma_1 = \Sigma_2 = \dots = \Sigma_m$. If they differ, that is, a covariance matrix of a population differs from the others (such as Σ_q), then multiple group analysis can be used to investigate such similarities and differences.

The goodness-of-fit χ^2 is used to assess the adequacy of the model across the groups. On the one hand, a significant χ^2 test points to the rejection of the hypothesis of invariance, suggesting that there is an interaction between population membership and structural model. In other words, the resulting covariance matrices are different, and the various samples must be treated from different populations.

On the other hand, a non-significant χ^2 leads to a failure to reject invariance. This means that the model having identical parameters in all groups fit acceptably and the resulting covariance matrices are identical. One can then conclude that the samples can be treated as arising from the same population.

Hypotheses of equality across groups can be conducted anywhere along a continuum ranging from all parameters or testing a single parameter of interest. Hypotheses that are often tested across multiple populations include:

- ▶ **Equal Factor Loadings** -- to determine whether the observed variables are measuring the same factors in each of the groups, that is, whether the factor loadings are the same;
- ▶ **Equal Factor Variances and Covariances** -- if these are equal across groups while factor loadings are also equal, then the factors are more specifically similar in the various groups;
- ▶ **Equal Factor Regression Coefficients** -- to determine whether path coefficients among latent factors are the same across groups;
- ▶ **Equal Factor Residual Variances and Covariances** -- to determine whether, in a model with latent dependent variables, the variances and covariances are equal across groups; and
- ▶ **Equal Unique or Error Variances and Covariances** -- except in special models, equality of error variances or covariances is the least important hypothesis to test. This is because if the prior hypotheses are accepted, then all of the parameters of the model are equal across groups.

4.6 Conclusion

In this chapter, an overview of the variables used in the study was followed by discussion of the data bases employed to construct the variables. The selection of pharmaceutical firms and therapeutic subclasses also was considered. It was pointed out that covariance structure modelling is used here to test whether the hypothesized structure model (Figure 4.1) is consistent with the data. It was noted that the EQS program will be used to estimate the structural model. The research findings are presented in the next chapter.

CHAPTER FIVE

RESULTS

This chapter is divided into five sections. First, the firms are categorized into early and late entrants using the three criteria discussed on p. 129. Second, a comparison is made between the early and late entrants using the t-test difference of means. Third, the equivalence of the structural model across the two groups is demonstrated. The purpose is to show whether the model proposed in Figure 4.1 describes adequately the two groups and whether there are differences in structural paths between early and late entrants. Hypotheses one through twenty are examined for the two groups at this stage. Fourth, the findings from the two group are analyzed. Finally, the results are summarized. Implications are discussed in the following chapter.

5.1 Identification of Early and Late Entrants

Table 5.1 indicates how early and late entrants are identified in the study. The first column shows the total number of therapeutic markets in which each firm competes. The second column shows the number of times a firm entered those markets either first or second, which reflects the technological superiority of the firm. That is, a first

Table 5.1

Identification of Early and Late Entrants

Firm	# therapeutic markets markets in which competed	# First or second entry	Column 2 Column 1
Abbott	42	22	.524
American Cyanamid	44	24	.545
American Home Products	48	32	.667
Bristol Myers	41	22	.536
Carter Wallace	24	9	.375
Eli Lilly	46	28	.609
Johnson & Johnson	48	20	.417
Marion Laboratories	20	12	.600
Merck	43	30	.698
Pfizer	42	22	.524
Robins	35	16	.457
Rorer	28	10	.357
Schering-Plough	34	12	.353
Searle	20	7	.350
SmithKline	45	34	.756
Squibb	42	22	.524
Sterling Drugs	30	10	.300
Syntex	26	11	.423
Upjohn	40	28	.700
Warner Lambert	44	28	.636

Note: Data from 1971 to 1989 were used for the identification procedure.

entrant is usually a leader in research and development while a second entrant may lag in research but has strong development capability. The third column is the ratio of the second to the first column. At one extreme, a firm entering first and/or second in all therapeutic markets would have a ratio of one. Ratios close to one suggest that the firm is an early entrant. At the other extreme, a ratio of zero indicates late entry in all therapeutic markets.

A firm was classified as a late entrant if it: (1) competed in ≤ 35 therapeutic markets; (2) had ≤ 20 first and second entries; and (3) had a ratio ≤ 0.5 . Firms identified as early and late entrants are shown in Table 5.2. Only Marion Laboratories and Johnson and Johnson did not satisfy all three criteria. Although the former had a ratio of 0.6 and the latter competed in 48 therapeutic markets, they were classified as late entrants because they satisfied the other two criteria. The other seven firms in the late entrant category satisfied all three criteria.

5.2 Comparison between Early and Late Entrants

Table 5.3 presents the t-tests of differences between means of all the variables for early and late entrants. The significant t-values ($p < 0.001$) for all eleven variables strongly suggest that early and late entrants differ considerably in all the competitive positioning constructs. Since these constructs are contingent on timing of entry, this factor is appropriate as a discriminatory construct for this

Table 5.2

Firms Identified as Early and Late Entrants

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

Table 5.3

T-TESTS of DIFFERENCE in MEANS between EARLY and LATE ENTRANTS

Variable	Early Entrants		Late Entrants		t-value [*]
	Mean	S.D.	Mean	S.D.	
Marketing of drugs first in the United States (ORIGIN)	0.5717	0.096	0.4578	0.118	10.39
Internal R&D efforts (HISTORY)	0.5183	0.084	0.3900	0.089	14.30
Therapeutic market diversification (DIVERSIFY)	0.6639	0.080	0.3274	0.063	44.85
Outlicensing (LICENSE)	0.5231	0.093	0.1799	0.108	33.30
R&D intensity (RDINTEN)	0.2332	0.031	0.1861	0.046	11.97
Advertising intensity (ADVERTISE)	0.1828	0.031	0.1449	0.032	11.48
R&D Orientation (RDORIENT)	0.4127	0.106	0.2815	0.050	14.84
Commitment to NCE development (PRODUCT)	0.3110	0.094	0.1796	0.037	17.15
Therapeutic differentiation (DIFF)	0.3577	0.081	0.2139	0.089	16.26
Global market share (GLOBAL)	0.0619	0.024	0.0289	0.018	14.80
Domestic market share (DOMESTIC)	0.0599	0.024	0.0246	0.017	16.08

^{*} All t-values have $p < 0.001$.

study. In addition, the significant differences between the two groups suggest that analyzing the data in terms of samples belonging to two different populations is an appropriate method of analysis.

5.2.1 Equivalence of the Structural Models - Assessment of Input Data and Statistical Assumptions

The first step in evaluating structural equation models is to assess input data and the statistical assumptions underlying the estimation method. The assessment will reveal five important findings.

(1) An examination of scatterplots of the residuals indicated that the residuals were randomly dispersed and that the relationships proposed are most likely to be linear. (2) The scatterplots showed few problems with outliers, which suggests that the model has no misspecification problem. (3) All the variables in the model are measured on ratio scales. (4) The model is recursive in that the causal flow is unidirectional. (5) The Durbin-Watson statistic for early and late entrants is 2.079 and 2.021, respectively. Since these values are close to the value of 2 proposed by Johnson (1984), the problem of autocorrelation is not severe in this study. The first autocorrelation is -0.046 for early entrants and -0.010 for late entrants.

The method of estimation used, Generalized Least Squares (GLS), assumes multivariate normality of the observed indicators. As mentioned in Chapter 4, the objective is to

have estimates of multivariate kurtosis close to zero. Tables 5.4 and 5.5 present results on the skewness and kurtosis for the eleven variables in the model for early and late entrants, respectively. With the exception of domestic market share (DOMSH) for the late entrant group, all other variables have reasonable kurtosis and skewness (that is, < 1.00). Thus, the data for the two groups suggest that GLS, a normal theory based estimation procedure, poses no problem for this study since all the observed variables, with the exception of one, possess skewness of less than 1.00 in absolute value.

As suggested by Bagozzi and Yi (1988), any further anomalies in the output should be identified such as negative error variances, nonsignificant error variances, and correlations greater than one. These often point to problems with model specification errors and/or identification problems. For example, since the square of the regression parameter is the variance of the reparameterized residual, error variances must be positive (Rindskopf 1983). Nonsignificant error variances suggest specification problems, since it is unreasonable to expect the absence of random error. Finally, correlations that do not fall within the ± 1 range imply theoretical or empirical underidentification.

In both groups, error variances were positive and significant given the sample size. Bivariate correlations among the variables were between ± 1 . For the data analyzed in the present research, none of the anomalies identified were

Table 5.4
SKEWNESS AND KURTOSIS (EARLY ENTRANTS)

Variable	ORIGIN	HISTORY	DIVERSIFY	LICENSE	RDINTEN	AD	RDORIENT	PRODUCT	DIFF	GLOSE	DOMSH
Skewness	0.3659	-0.1587	0.4056	0.5608	0.3291	-0.0309	0.2283	0.1159	0.4682	0.7440	0.2282
Kurtosis	-0.2206	-0.1989	-0.4318	-0.3610	0.0300	-0.6039	-0.3721	-0.1233	-0.4164	-0.0529	-0.6644

Table 5.5
SKEWNESS AND KURTOSIS (LATE ENTRANTS)

Variable	ORIGIN	HISTORY	DIVERSIFY	LICENSE	RDINTEN	AD	RDORIENT	PRODUCT	DIFF	GLOSE	DOMSH
Skewness	-0.9459	0.7435	0.2728	-0.4319	-0.6937	0.2259	-0.2715	0.0443	-0.8420	0.9784	1.2503
Kurtosis	0.0792	0.2345	-0.2639	-0.8514	-0.1625	-0.5443	-0.4225	-0.4311	0.4765	0.3181	0.8184

Tables 5.6 and 5.7 present the correlation matrix for early and late entrants, respectively.

5.2.2 Assessment of Overall Model Fit

The overall goodness-of-fit indices for early and late entrants are presented in Table 5.8 and Table 5.9, respectively. The p-values for the chi-square tests indicate a good fit of the overall model for both groups. The p-values for early and late entrants are 0.07787 and 0.19152, respectively. Using a p-value of 0.05, the models are not rejected for the two groups. Therefore, there is strong statistical evidence to suggest that the covariance matrix for the observed data and the covariance matrix derived from the theoretically specified structural model are similar to each other. The high normed fit index (NFI) and non-normed fit index (NNFI) verify the goodness-of-fit and indicate that a large percentage of the variation is accounted for by the model in both groups. The high values for these indices suggest that no further statistically significant improvement in fit is possible by adding structural paths to the model.

5.2.3 Assessment of Fit of Internal Structure

Although goodness-of-fit indices address the overall adequacy of a model, they do not explicitly provide information on the nature of individual parameters and other aspects of the internal structure of a model.

Table 5.6 Correlation Matrix for Early Entrants

Variable	ORIGIN	HISTORY	DIVERSIFY	LICENSE	RDINTEN	AD	RDORIENT	PRODUCT	DIFF	GLOSE	DOMSE
ORIGIN	1.0000										
HISTORY	.4528	1.0000									
DIVERSIFY	.5943	.5311	1.0000								
LICENSE	.6727	.6121	.5699	1.0000							
RDINTEN	.4271	.5121	.1191	.5694	1.0000						
AD	.1916	.1391	.0427	.0262	.0047	1.0000					
RDORIENT	.7107	.6404	.7152	.8580	.4892	.0234	1.0000				
PRODUCT	.6582	.6919	.6932	.8295	.5038	.0875	.8778	1.0000			
DIFF	.3212	.5851	.4500	.6152	.3482	-.0802	.4759	.6241	1.0000		
GLOSE	.3340	.6531	.2919	.4901	.4487	.1605	.5489	.5063	.0496	1.0000	
DOMSE	.1288	.5757	.1659	.3537	.4154	.1431	.3865	.4222	.0037	.8693	1.0000

Table 5.7 Correlation Matrix for Late Entrants

Variable	ORIGIN	HISTORY	DIVERSIFY	LICENSE	RDINTEN	AD	RDORIENT	PRODUCT	DIFF	GLOSE	DOMSH
ORIGIN	1.0000										
HISTORY	.5732	1.0000									
DIVERSIFY	.5700	.6310	1.0000								
LICENSE	.6202	.5342	.6373	1.0000							
RDINTEN	.1811	.1346	.3853	.5573	1.0000						
AD	.1249	-.0493	.0384	.2879	.3905	1.0000					
RDORIENT	.7830	.5649	.5477	.6636	.3129	.1167	1.0000				
PRODUCT	.6219	.6780	.7619	.6827	.3052	.1490	.8087	1.0000			
DIFF	.6191	.4881	.6318	.4547	.2849	.1081	.5705	.6315	1.0000		
GLOSE	.5551	.7599	.6944	.6301	.3960	-.0397	.4823	.5535	.5277	1.0000	
DOMSH	.4515	.7715	.5768	.4478	.2264	-.1919	.4051	.4451	.4482	.8952	1.0000

Table 5.8

GOODNESS-OF-FIT INDICES FOR EARLY ENTRANTS

$$\begin{aligned}X^2 &= 25.816, \text{ d.f. } = 18 \\p &= 0.07787\end{aligned}$$

$$\begin{aligned}\text{NFI} &= 1.000 \\ \text{NNFI} &= 0.999\end{aligned}$$

Table 5.9

GOODNESS-OF-FIT INDICES FOR LATE ENTRANTS

$$\begin{aligned}X^2 &= 20.671, \text{ d.f. } = 18 \\p &= 0.19152\end{aligned}$$

$$\begin{aligned}\text{NFI} &= 1.000 \\ \text{NNFI} &= 1.000\end{aligned}$$

The composite reliabilities for the latent constructs, new product development efforts and performance, are 0.8716 and 0.9345, respectively, for late entrants and 0.9314 and 0.9301, respectively, for early entrants. All construct reliabilities are high in value ($p_c \geq 0.6$) for both groups, indicating that the measurement parameters are satisfactory.

The internal quality of a model also can be assessed by examining the normalized residuals. For the late entrant group, the highest normalized residual was 0.116; for early entrants, the corresponding value was 0.126. These indices point to a good model fit for both groups, as normalized residuals greater than 2 indicate that significant amounts of variance remain unexplained and that a specification error is likely.

To determine the significance of the structural parameters of the model, an investigation of the signs of the parameters and their standard errors using the t-test is required. The structural parameter estimates for the early entrant model are shown in Table 5.10; results for the late entrant model are reported in Table 5.11. Both the nonstandardized and standardized parameter estimates are provided. Within the context of an appropriate model, the test statistic in the nonstandardized solution is the univariate Z test, where the null hypothesis is that a given parameter is zero in a given population. Large values (exceeding ± 1.96 for $\alpha = 0.05$) suggest that the null

Table 5.10

STRUCTURAL PARAMETERS FOR EARLY ENTRANTS

Unstandardized Solution

$$\begin{array}{lcl} \text{NEW PRODUCT} & = & .264*V2 + .749*V3 + 1.125*V4 \\ \text{DEVELOPMENT (F1)} & & (.064) \quad (.060) \quad (.149) \\ \text{EFFORTS} & & 4.107^{***} \quad 12.488^{***} \quad 7.568^{***} \end{array}$$

$$\begin{array}{lcl} \text{MARKETING OF (V1)} & = & .427*F1 - .038*V2 + .209*V3 \\ \text{DRUGS FIRST IN} & & (.025) \quad (.083) \quad (.083) \\ \text{THE U.S.} & & 17.080^{***} \quad -.456 \quad 2.503^{\dagger} \end{array}$$

$$\begin{array}{lcl} \text{THERAPEUTIC (V8)} & = & .453*F1 + .178*V2 - .055*V3 \\ \text{DIFFERENTIATION} & & (.091) \quad (.077) \quad (.078) \\ & & 4.981^{***} \quad 2.322^{\dagger} \quad -.704 \end{array}$$

$$\begin{array}{lcl} \text{OUTLICENSE (V9)} & = & .0675*V8 + .907*F1 - .198*V2 + .447*V4 \\ & & (.0596) \quad (.076) \quad (.066) \quad (.113) \\ & & 1.149 \quad 11.894^{***} \quad -2.984^{**} \quad 3.948^{***} \end{array}$$

$$\begin{array}{lcl} \text{PERFORMANCE} & = & -.111*V1 + .174*V2 + .091*V4 + .025*V5 + .207*V8 + .095*V9 + .096*F1 \\ & & (.017) \quad (.017) \quad (.039) \quad (.028) \quad (.016) \quad (.023) \quad (.023) \\ & & -6.662^{***} \quad 10.295^{***} \quad 2.341^{\dagger} \quad .904 \quad 12.646^{***} \quad 4.122^{***} \quad 3.330^{***} \end{array}$$

$\dagger$ $p < 0.05$
 $**$ $p < 0.01$
 $***$ $p < 0.001$

Standardized Solution

$$\begin{array}{lcl} \text{NEW PRODUCT} & & \\ \text{DEVELOPMENT (F1)} & = & .218*V2 + .612*V3 + .351*V4 + .503*D1 \quad (R^2 = .747) \\ \text{EFFORTS} & & \end{array}$$

$$\begin{array}{lcl} \text{MARKETING OF DRUGS (V1)} & = & .333*F1 - .033*V2 + .199*V3 + .703*E1 \quad (R^2 = .506) \\ \text{FIRST IN THE U.S.} & & \end{array}$$

$$\begin{array}{lcl} \text{THERAPEUTIC (V8)} & = & .557*F1 + .181*V2 - .055*V3 + .756*E4 \quad (R^2 = .428) \\ \text{DIFFERENTIATION} & & \end{array}$$

$$\begin{array}{lcl} \text{OUTLICENSE (V9)} & = & .059*V8 + .986*F1 - .178*V2 + .152*V4 + .430*E7 \quad (R^2 = .815) \end{array}$$

$$\begin{array}{lcl} \text{PERFORMANCE (F2)} & = & -.479*V1 + .650*V2 + .128*V4 + .038*V5 + .760*V8 + .395*V9 \quad (R^2 = .775) \\ & & +.432*F1 + .474*D2 \end{array}$$

Table 5.11

STRUCTURAL PARAMETER ESTIMATES FOR LATE ENTRANTS

Unstandardized Solution

$$\begin{array}{lcl} \text{NEW PRODUCT} & .176*V2 & + .364*V3 & + .074*V4 \\ \text{DEVELOPMENT (F1) =} & (.030) & (.047) & (.050) \\ \text{EFFORTS} & 5.790^{***} & 7.674^{***} & 1.481 \end{array}$$

$$\begin{array}{lcl} \text{MARKETING OF DRUGS (V1) =} & .441*F1 & + .399*V2 & + .271*V3 \\ \text{FIRST IN THE U.S.} & (.040) & (.090) & (.146) \\ & 11.025^{***} & 4.449^{***} & 1.854 \end{array}$$

$$\begin{array}{lcl} \text{THERAPEUTIC (V8) =} & .828*F1 & + .032*V2 & + .417*V3 \\ \text{DIFFERENTIATION} & (.248) & (.085) & (.143) \\ & 3.339^{***} & .378 & 2.924^{\dagger} \end{array}$$

$$\begin{array}{lcl} \text{OUTLICENSE (V9) =} & -.157*V8 & + 1.415*F1 & + .199*V2 & + .930*V4 \\ & (.074) & (.223) & (.086) & (.118) \\ & -2.132^{\dagger} & 6.346^{***} & 2.314^{\dagger} & 7.865^{***} \end{array}$$

$$\begin{array}{lcl} \text{PERFORMANCE (F1) =} & -.037*V1 & + .210*V2 & + .076*V4 & - .148*V5 & + .046*V8 & + .022*V9 & - .185*F1 \\ & (.190) & (.022) & (.023) & (.027) & (.012) & (.013) & (.042) \\ & -.195 & 9.560^{**} & 3.294^{***} & -5.404^{***} & 2.492^{\dagger} & 1.682 & -4.315^{***} \end{array}$$

$\dagger$ $p < 0.05$
 $**$ $p < 0.01$
 $***$ $p < 0.001$

Standardized Solution

$$\begin{array}{lcl} \text{NEW PRODUCT} & & \\ \text{DEVELOPMENT (F1) =} & .367*V2 & + .531*V3 & + .078*V4 & + .538*D1 & (R^2 = .711) \\ \text{EFFORTS} & & \end{array}$$

$$\begin{array}{lcl} \text{MARKETING OF DRUGS (V1) =} & .312*F1 & + .329*V2 & + .210*V3 & + .718*E1 & (R^2 = .484) \\ \text{FIRST IN THE U.S.} & & \end{array}$$

$$\begin{array}{lcl} \text{THERAPEUTIC (V8) =} & .400*F1 & + .032*V2 & + .295*V3 & + .731*E4 & (R^2 = .466) \\ \text{DIFFERENTIATION} & & \end{array}$$

$$\text{OUTLICENSE (V9) =} -.129*V8 + .562*F1 + .165*V2 + .386*V4 + .575*E7 \quad (R^2 = .669)$$

$$\begin{array}{lcl} \text{PERFORMANCE (F2) =} & -.011*V1 & + .965*V2 & + .176*V4 & - .238*V5 & + .136*V8 & + .120*V9 & (R^2 = .775) \\ & & & & & & & -.408*F1 & + .474*D2 \end{array}$$

hypothesis can be rejected. This implies that the structural coefficient is significantly different from zero.

The magnitude of the structural coefficients is easier to interpret in standardized solutions since all variables in the equations, including errors, are standardized. In addition, one can estimate the squared multiple correlation coefficient associated with each individual standardized equation, where $R^2 = (1 - \text{error}^2)$. The standardized solutions for the early and late entrants are summarized at the end of Chapter 5 (see Table 5.13). The next section discusses the results of the hypothesis testing for early and late entrants.

5.2.3.1 Analysis of Unstandardized Solution - Early and Late Entrants

Nonsignificant findings and any observed findings that contradict hypothesized effects are noted. As discussed in Chapter 4, hypotheses H_1 , H_2 , and H_{11} address the relationship between a firm's new product development efforts and three exogenous variables: R&D intensity, internal R&D efforts, and therapeutic market diversification, respectively. All three paths are significant and in the expected direction for the early entrants. Therefore, H_1 , H_2 , and H_{11} are supported for this group. Only two exogenous variables, internal R&D efforts ($t = 6.242$, $p < 0.001$) and therapeutic market diversification ($t = 8.746$, $p < 0.001$), have significant effects on late entrants' new product development efforts. The effect of R&D intensity was nonsignificant. Therefore,

only H_2 and H_{11} are supported for the late entrants.

The firm's spatial strategy of drug introductions is theorized to be positively influenced by the firm's therapeutic market diversification (H_{17}), new product development efforts (H_{18}), and internal R&D efforts (H_{19}). Mixed results were obtained for these variables. Specifically, the relative emphasis of these three independent variables differed between early and late entrants. For early entrants, new product development efforts ($t = 17.080$, $p < 0.001$) and therapeutic market diversification ($t = 2.503$, $p < 0.05$) were important predictors of this group's spatial strategy. The relationship between internal R&D efforts and spatial strategy was nonsignificant. For late entrants, new product development efforts ($t = 11.025$, $p < 0.001$) and internal R&D efforts ($t = 4.449$; $p < 0.001$) predicted spatial strategy but therapeutic market diversification had no effect. Therefore, H_{18} was supported in both groups, H_{17} found support among early entrants, and H_{19} was only supported in the late entrant group.

The therapeutic differentiation of a drug is influenced by the firm's new product development efforts (H_{12}), internal R&D efforts (H_{13}), and therapeutic market diversification (H_{14}). As theorized, H_{12} was positive and significant in both groups (early entrants: $t = 4.981$, $p < 0.001$; late entrants: $t = 3.339$, $p < 0.001$). The influence of the other two constructs was mixed. Internal R&D efforts ($t = 2.322$, $p <$

0.05) had a positive influence on early entrants' ability to develop highly therapeutically differentiated drugs but had no effect for late entrants. Diversification into many therapeutic markets had a nonsignificant effect ($t = -.704$) for early entrants but a significant and positive effect ($t = 2.924$, $p < 0.05$) for late entrants. In summary, H_{12} was supported in both groups, but H_{11} and H_{13} found mixed support.

Four variables were hypothesized to influence the firm's outlicensing behavior: the therapeutic differentiation of the drug as indicated by internal R&D efforts (H_7), new product development efforts (H_8), R&D intensity (H_9), and therapeutic differentiation as indicated by the FDA's therapeutic ratings (H_{14}). H_7 , H_8 , and H_9 were supported in both groups. As hypothesized, early entrants did not tend to outlicense their internally developed drugs ($t = -2.984$, $p < 0.01$), while the effect of internal R&D efforts on late entrants' outlicensing behavior was positive ($t = 2.314$, $p < 0.05$). Strong new product development efforts led to greater outlicensing: (early entrants: $t = 11.894$, $p < .001$; late entrants: $t = 6.346$, $p < .001$). The effect of R&D intensity on outlicensing was also in the hypothesized direction for both groups (early entrants: $t = 3.948$, $p < .001$; late entrants $t = 7.865$, $p < .001$). Therapeutic differentiation, however, was found to have a significant and negative effect on the outlicensing behavior of late entrants ($t = -2.132$, $p < 0.05$), whereas this relationship was nonsignificant for the early entrants.

Finally, performance is hypothesized to be a function of the firm's R&D intensity (H_2), advertising intensity (H_3), new product development efforts (H_4), internal R&D efforts (H_5), outlicensing behavior (H_{10}), therapeutic differentiation (H_{15}), and spatial strategy (H_{20}). H_2 , H_5 , and H_{15} were supported in both groups. R&D intensity had a positive effect on performance for both groups: (early entrants: $t = 2.341$, $p < 0.05$; late entrants: $t = 3.294$, $p < 0.05$). The effect of internal R&D on performance for early entrants was $t = 10.295$, $p < 0.001$, and for late entrants $t = 9.560$, $p < 0.001$. The support found for H_{15} (early entrants: $t = 12.646$; $p < .001$; late entrants $t = 2.492$; $p < .05$) suggests that highly differentiated drugs have a positive influence on firms' performance. The other four hypotheses found mixed results. Advertising intensity (H_3) was nonsignificant for early entrants but was in the unexpected direction for late entrants ($t = -5.404$; $p < .001$). Although the effect of new product development efforts (H_4) was significant for both groups, it was in the unexpected direction for late entrants ($t = -4.315$, $p < .001$; early entrants: $t = 3.330$, $p < .001$). The effect of outlicensing on performance (H_{10}) was nonsignificant for late entrants but positive and significant for early entrants ($t = 4.122$, $p < 0.001$). Finally, the relationship between firms' spatial strategy and performance, H_{20} , (which concentrates on the United States as the origin of drug introduction) was supported for early entrants ($t = -6.662$; $p < 0.001$) but

nonsignificant for late entrants.

5.2.3.2 Analysis of Standardized Solution - Early and Late Entrants

Of particular interest in interpreting the standardized solution is the amount of variance accounted for in each structural equation. As was shown in Tables 5.10 and 5.11, the variances accounted for in the five structural equations were fairly high for both groups of firms ($R^2 > 0.42$). With the exception of the licensing construct, all the equations for the early and late entrant groups had similar R^2 . For the licensing construct, the variance accounted for in the late and early entrant groups was 0.669 and 0.815, respectively. While the independent variables better explained licensing in the early entrant group, the fact that nearly half the variance was accounted for by these same variables in the late entrant group suggests a relatively good fit for this construct.

5.2.3.3 Effects Decomposition for Early and Late Entrants

The direct, indirect, and total effects for early and late entrants, respectively, are shown in Table 5.12. These decomposed effects only pertain to the correlations between the seven variables and firm performance. The analysis of decomposed effects is useful in certain situations: when indirect effects outweigh direct effects and when these two effects assume opposite directions, thereby canceling each other's impact to yield a trivial zero-order correlation.

Table 5.12

Direct, Indirect and Total Effects for Performance

Independent Variable	Early Entrants			Late Entrants		
	Direct	Indirect	Total	Direct	Indirect	Total
Internal R&D Efforts (V2)	.650 ^{***}	.102 ^{***}	.752 ^{***}	.965 ^{***}	-.088	.877 ^{***}
Therapeutic Diversification (V3)		.048	.048		-.121 ^{**}	-.121 ^{**}
R&D Intensity (V4)	.128 ^{***}	.116 ^{***}	.244 ^{***}	.176 [*]	.023	.199 [*]
Advertising Intensity	.038	-	.038	-.238 ^{***}	-	-.238 ^{***}
New Product Development Efforts (F1)	.432 ^{***}	.179 ^{***}	.611 ^{***}	-.408 ^{***}	.112 ^{**}	-.293 ^{***}
Therapeutic Differentiation (V8)	.760 ^{***}	.025	.735 ^{***}	.136 [*]	-.016	.120
Outlicensing (V9)	.395 ^{***}	-	.395 ^{***}	.120	-	.120
Marketing of Drugs First in the U.S. (V1)	-.479 ^{***}	-	-.479 ^{***}	-.011	-	-.011

^{***} p < .001
^{**} p < .01
^{*} p < .05

Important managerial insights can also be gained from analyzing the relative impact of the total effect of each variable on firm performance. Going by the direct impact alone is insufficient.

With the exception of therapeutic differentiation (V8) and new product development efforts (F1), there are differences between the early and late entrants in terms of the magnitude and direction of their indirect effects. In particular, therapeutic diversification (V3) has a nonsignificant indirect for early entrants. This variable, however, had a significant but negative indirect effect for late entrants. Indirect effects of internal R&D efforts (V2) and R&D intensity (V4) were significant and nonsignificant for early and late entrants, respectively.

In terms of the relative impact of the total effect of each independent variable, the three most significant variables that positively impact early entrants' performance are internal R&D efforts, therapeutic differentiation, and new product development efforts. While R&D intensity and outlicensing also had significant total effects on firm performance, they are marginally less important.

Internal R&D efforts had the most significant total effect on late entrants' performance, followed by R&D intensity. Findings from Table 5.12 suggest that late entrants suffer from less successful new product development efforts, less effective advertising efforts and therapeutic

diversification efforts. In addition, the total correlation between therapeutic differentiation and firm performance became nonsignificant in the presence of indirect effects, although the direct effect of the independent variable was significant. Going by the direct impact alone would lead one to expect gains in market share from therapeutic differentiation.

5.2.4 Multiple Group Analysis

Discussion thus far has centered on model adequacy with respect to whether the data are consistent with the hypotheses. The t-tests (see Table 5.1) strongly suggested that it is appropriate to analyze the data as samples from two different populations rather than a single population. Yet to be considered is whether the proposed structural model is equivalent across these two groups.

Three paths are hypothesized to be equal between the two groups: new product development efforts and therapeutic market diversification as related to the firm's marketing of drugs first in the United States ($V_1 \rightarrow F_1$; $V_2 \rightarrow V_1$), and therapeutic market diversification as related to new product development efforts ($V_2 \rightarrow F_1$).

The Lagrange Multiplier (LM) test was used to evaluate whether cross-group constraints on the equality of parameters were appropriate or not. A univariate LM test was provided for each cross-group constraint. If the probability of the LM statistic for a constraint is small ($p < .05$), then this

particular constraint should be released. A high probability value suggests that the constraint cannot be rejected.

The overall goodness-of-fit for the multiple group analysis with the three constraints was $X^2 = 86.585$ (d.f. = 35; $p < 0.001$). The univariate test statistics, cumulative multivariate statistics, and univariate increment for the three constraints are shown in Table 5.13.

The univariate test results suggested that constraints #2 and #3 ($p < .05$) are not consistent with the data, that is, the null hypotheses that these two constraints are zero should be rejected. These conclusions were confirmed in the multivariate analysis. The multivariate test is a forward stepwise procedure, and the constraint with the largest univariate chi-square is entered first. In this case, it yielded the same statistic as in the univariate analysis. Constraint #3 then was added, since it contributed most to the chi-square statistic. This yielded an increment of 6.951 chi-square points for a total 2 d.f. multivariate test of 21.504. Constraint #1, however, added marginally to the chi-square; its p value of 0.738 was not significant at the .05 level, which suggested that this constraint cannot be rejected.

Releasing constraints #2 and #3 yielded an overall X^2 fit of 50.458 (d.f. = 37; $p = 0.05545$). When the model was reestimated with constraint #1, the probability for the LM test was 0.246. This suggested that this cross-group constraint is equal in both the early and late entrants.

Table 5.13
Lagrange Multiplier Results

Univariate Test Statistic		
Constraint	Chi-square	Probability
1. (F_1, V_1)	0.558	0.445
2. (V_3, V_1)	14.553	0.000
3. (V_3, F_1)	6.951	0.008

Cumulative Multivariate Analysis			
Parameter	Chi-square	d.f.	Probability
Constraint 2	14.553	1	0.000
Constraint 3	21.504	2	0.000
Constraint 1	21.615	3	0.000

Univariate Increment	
Chi-square	Probability
14.553	0.000
6.951	0.008
0.111	0.738

Since the model with three constraints is a nested version¹⁵ of the model with one constraint, it is possible to test for statistical significance with a X^2 difference test (X^2_d). The X^2_d was 36.127 (d.f. = 2, $p < .001$), which implies that the constraints imposed in the first model (constraints #2 and #3) should be rejected. Because the significant difference in the X^2_d may be due to nonsignificance of either or both paths ($F_1 \rightarrow V_1$ and $V_1 \rightarrow V_2$), these paths were evaluated independently. For both early and late entrants, the path $F_1 \rightarrow V_1$ was significant; the path $V_1 \rightarrow V_2$ was significant in the early entrant group ($t = 2.503$) but nonsignificant in the late entrant group ($t = 1.854$).

5.3 Summary of Findings

Table 5.14 summarizes observed results regarding the 20 hypotheses for early and late entrants.

For early entrants, five findings are notable.

- (1) New product development efforts are influenced by internal R&D efforts, therapeutic market diversification, and R&D intensity.
- (2) New product development efforts and therapeutic market diversification lead firms to introduce drugs first in the United States.
- (3) Therapeutic differentiation is influenced by both new product development efforts and internal R&D efforts.
- (4) R&D intensity, new product development efforts, and therapeutic differentiation are positively related to outlicensing activity.

¹⁵Nested models are special cases of more general models; the former is obtained from the latter by restricting parameters to equalities or constants, usually zero.

- (5) Performance is significantly influenced by direct effects from outlicensing activity, internal R&D efforts, R&D intensity, therapeutic differentiation, and new product development efforts. Concentrating on the United States as the key market for drug introductions has a negative effect on performance. Internal R&D efforts, R&D intensity, and new product development efforts also had positive and significant indirect effects on firm performance.

Four hypotheses were not supported for early entrants: the effect of internal R&D efforts on the marketing of drugs first in the United States, therapeutic differentiation on outlicensing, of therapeutic market diversification on therapeutic differentiation, and of advertising intensity on firm performance.

For late entrants, the following five findings are of particular interest.

- (1) Product development efforts are only influenced by internal R&D efforts and therapeutic market diversification.
- (2) New product development efforts and internal R&D efforts tend to encourage drugs to be first marketed in the United States.
- (3) Two variables only influenced these firms' ability to develop highly therapeutically differentiated drugs: new product development efforts and therapeutic market diversification. The effect of the latter was positive.
- (4) Outlicensing activity is positively influenced by new product development efforts, internal R&D efforts, and R&D intensity. Therapeutic differentiation is negatively related to outlicensing activity, suggesting that FDA ratings are not that important for late entrants.
- (5) Performance is positively influenced by direct effects from internal R&D efforts, therapeutic differentiation, and R&D intensity. Late entrants are less successful than early entrants in new

product development and advertising efforts. These variables have a negative effect on late entrants' performance. However, in the presence of indirect effects, the total effect of therapeutic differentiation on firm performance became nonsignificant. The indirect effect of new product development efforts was positive and significant, while that of therapeutic diversification was significant but negative.

Five hypotheses were not supported for late entrants: the effect of therapeutic market diversification on the marketing of drugs first in the United States, of internal R&D efforts on therapeutic differentiation, of R&D intensity on new product development efforts, of marketing of drugs first in the United States and outlicensing on firm performance.

5.4 Conclusions

In this chapter, the twenty hypotheses in Figure 4.1 were tested. Findings indicate several similarities as well as differences between early and late entrants in terms of how the competitive positing variables are causally related to one another and the relative impact of the seven variables on firm performance. This suggests that early and late entrants have different differential advantages and distinct performance characteristics. Implications of these findings are discussed in Chapter 6.

Table 5.13 Observed Results for Early and Late Entrants

Hypothesis	Early Entrants (standardized sol.)	Late Entrants (standardized sol.)
H1. High commitment to R&D has a positive effect on new product development efforts.	.351 ^{***}	.078 (nonsig.)
H2. There is a positive relationship between a firm's commitment to R&D and performance.	.128 [†]	.176 ^{***}
H3. There is a positive relationship between a firm's commitment to marketing and performance.	.038 (nonsig.)	-.238 ^{***}
H4. There is a positive relationship between new product development efforts and firm performance.	.432 ^{***}	-.408 ^{***}
H5. There is a positive relationship between internal R&D and new product development efforts.	.218 ^{***}	.367 ^{***}
H6. There is a positive relationship between internal R&D and firm performance.	.650 ^{***}	.965 ^{***}
H7. Internal R&D has a positive effect on outlicensing for late entrants. This relationship is negative for early entrants.	-.178 ^{**}	.165 [†]
H8. There is a positive relationship between new product development efforts and outlicensing.	.986 ^{***}	.562 ^{***}
H9. High commitments to R&D lead to greater outlicensing.	.152 ^{***}	.386 ^{***}
H10. There is a positive relationship between outlicensing activity and firm performance.	.395 ^{***}	.120 (nonsig.)
H11. There is a positive relationship between therapeutic market diversification and new product development efforts.	.612 ^{***}	.531 ^{***}
H12. Strong new product development efforts lead to higher therapeutic differentiation.	.557 ^{***}	.400 ^{***}
H13. There is a positive relationship between internal R&D and therapeutic differentiation.	.181 [†]	.032 (nonsig.)
H14. High therapeutic market diversification is negatively related to therapeutic differentiation.	-.055 (nonsig.)	.295 [†]

Table 5.12 (cont)

Hypothesis	Early Entrants (standardized sol.)	Late Entrants (standardized sol.)
H15. There is a positive relationship between therapeutic differentiation and firm performance.	.760 ^{***}	.136 [†]
H16. Therapeutic differentiation is positively associated with the outlicensing activity of early entrants. This relationship is negative for late entrants.	.059 (nonsig.)	-.129 [†]
H17. There is a positive relationship between therapeutic market diversification and the marketing of drugs first in the United States.	.199 [†]	.210 (nonsig.)
H18. There is a positive relationship between new product development efforts and the marketing of drugs first in the United States.	.333 ^{***}	.312 ^{***}
H19. There is a positive relationship between internal R&D and the marketing of drugs first in the United States.	-.033 (nonsig.)	.329 ^{***}
H20. There is a negative relationship between drugs that are first marketed in the United States and firm performance.	-.479 ^{***}	-.011 (nonsig.)

[†] p < 0.05
^{**} p < 0.01
^{***} p < 0.001

CHAPTER SIX

CONCLUSIONS

The data were analyzed in relation to the theoretical structural model discussed in Chapter 5. This chapter begins with a discussion of the results, then notes the limitations of the study. Next, the theoretical contributions and managerial implications of the findings are discussed. Finally, suggestions for future research are proposed.

6.1 Discussion of Results

The three research questions guiding this research are :

- (1) How are competitive positioning variables causally related to one another?
- (2) Which competitive positioning variables have the greatest effect on performance? What is the relative importance of their direct and indirect effects?
- (3) How do early and late entrants differ in terms of competitive positioning variables and overall performance?

The answers to each of these questions are addressed below.

6.1.1 Relationships among the Competitive Positioning Variables

6.1.1.1 Product Development Efforts

For both early and late entrants, internal R&D efforts and therapeutic market diversification are significant predictors of firms' new product development efforts. This

suggests that a firm's ability to develop and exploit technological know-how internally are important dimensions of competition in the pharmaceutical industry (Thomas 1988). While external sourcing of R&D ideas will continue for established firms confronted with broad and rapid changes in their core technologies, the long-term success of a firm requires the development and successful exploitation of their internal R&D capabilities.

Diversification into many therapeutic markets is indicative of manufacturing and R&D mobility for both early and late entrants (Cocks 1975). This suggests that these technology-intensive firms have the ability to adapt their R&D and manufacturing processes so that they can produce drugs in several therapy areas.

The relationship between R&D intensity and new product development efforts is significant for early entrants but not for late entrants. Acs and others (1988) found that the total number of innovations is positively related to R&D, while Cooper (1982) found no direct link between R&D spending and effectiveness of firms' new product programs. Cooper noted that how the research dollar was spent and how the product was subsequently marketed were more important determinants of success than how much was invested. Therefore, the positive relationship between R&D intensity and new product development efforts of early entrants suggest that this group of firms manage their R&D resources more effectively than late

entrants.

6.1.1.2 Spatial Strategy: Marketing of Drugs First in the United States

Findings suggest that firms with strong new product development efforts tend to introduce their drugs in the United States. Both early and late entrants view the United States as a key market for drug introductions. Between 1940 and 1988, domestic firms accounted for about 62 percent of new drugs introduced in the United States while West European firms accounted for 27 percent. Grabowski (1990) concludes that in terms of both ownership and location, the United States will continue to be a leading source of consensus drugs (those that gain worldwide acceptance).

Therapeutic market diversification has a positive influence on early entrants' introduction of drugs in the United States; this relationship is nonsignificant for late entrants. As discussed earlier, pharmaceutical firms are shifting from acute to chronic disease therapy. In 1929 almost 70 percent of illnesses were acute, but by the 1980s, the figure was 20 percent (Levin 1982). Chronic diseases have become a major concern and a major drug market. Over the past few years, companies increasingly have shifted research priorities from infection-fighters, such as antibiotics, to maintenance drugs, such as cardiovascular drugs, central nervous system products, and antineoplastics. These three therapeutic categories represent key growing product areas in

the United States; "because so many companies are working on these same [therapeutic areas]" (United States International Trade Commission 1991), it is economically advantageous for U.S. firms to exploit these product categories first in the United States and then overseas.

Strong internal R&D efforts encourage late entrants to market their drugs first in the United States, but this relationship is nonsignificant for early entrants. There are two possible explanations for this finding. First, the internal R&D efforts of early entrants may already be captured by another variable, new product development efforts. The magnitude of the indirect effect of internal R&D efforts was large (.121) and significant ($p < .001$). Second, although the hypothesis was not supported for this group, the negative finding suggests a strong likelihood that early entrants, because of their technological superiority, will attempt to exploit their internal know-how on a global basis, whereas late entrants find the domestic market more attractive for launching new products.

6.1.1.3 Therapeutic Differentiation

The therapeutic differentiation of a drug as indicated by the FDA ratings can be thought of as a dimension of product quality. Perceived product quality in the pharmaceutical industry is a function of its intrinsic quality as well as a number of intangibles, such as corporate image and reputation, and the effectiveness of a firm's promotional efforts in

communicating superior product quality.

Findings suggest that new product development efforts may lead to drugs that represent important therapeutic gains or only modest gains. This variable has a greater influence on early entrants (.557) than late entrants (.400), reflecting the higher technological sophistication and orientation of early entrants. Link (1987) found that high technology/innovative firms are more successful at developing products with higher quality and significant user benefits.

This technological superiority is also reflected in the positive effect of internal R&D efforts on therapeutic differentiation for early entrants. As noted by Capon and Glazer (1987), one reason for enhancing the firm's technology portfolio through internal R&D development is to encourage learning on the part of the firm. That is, firms invest in internal R&D to generate and gain proprietary access to technologies in specific products and to the more general know-how related to these products. An R&D project that yields a specific therapeutic compound also may create knowledge and build R&D capabilities that are valuable for discovering other drugs for the same disease. The effect of internal R&D efforts on therapeutic differentiation is nonsignificant for late entrants. Therefore, the prior argument that early entrants are more successful in converting their "learned" internal know-how into more highly differentiated drugs is supported.

For late entrants, therapeutic market diversification or the breadth of product-market scope enhances their ability to develop therapeutically differentiated drugs. This suggests that late entrants' diversification in product markets that are closely related to their areas of technical expertise facilitate the development of highly differentiated drugs. This relationship is nonsignificant and negative for early entrants which suggests that they have "overdiversify." The negative relationship found for early entrants suggests that a smaller range of product market scope is recommended. While an expansion in the scope of product-market activities is driven by management's desire for effective use of the firm's financial, human, and material resources, the direction of diversification is also important. Researchers such as Rumelt (1974), Salter and Weinhold (1978), and Varadarajan and Ramanujam (1987) suggest that diversification into product markets in which a company can use its existing functional skills and resources leads to greater synergy.

6.1.1.4 Outlicensing

The effect of new product development efforts on outlicensing is significant and in the predicted direction for both groups. The needs to recoup R&D costs, expand geographical reach, and exploit sales from new drugs are significant motivators for firms to license out.

The direct effect of therapeutic differentiation on outlicensing was nonsignificant for early entrants but

negative for late entrants. This suggests that FDA ratings are unimportant for the former in their outlicensing of drugs overseas. As for the latter firms, despite having differentiated products which provide significant therapeutic advantages over competing drugs, this advantage was not significant to overcome first mover advantages established by early entrants in overseas markets. For example, early entrants may have established captive relationships with their overseas licensees such that switching costs increase for the latter. As argued by Wernerfelt (1985), over time, buyers adapt to the characteristics of products and their suppliers and find it costly to change to another brand.

The effect of R&D intensity and internal R&D efforts on early and late entrants' outlicensing activity is supported. Firms that are R&D intensive engage in greater outlicensing. While internal R&D efforts have a positive effect on late entrants' outlicensing activity, this relationship is negative for early entrants. In general, a firm licenses a drug for sale in a country where the licensor does not have an adequate sales force to compete in the market. Table 2.20 showed that most of the early entrant firms in this study have a large worldwide detailforce, which would decrease their reliance on outlicensing as an entry strategy into foreign markets. This explains the negative relationship between internal R&D efforts and outlicensing for early entrants.

6.1.2 The Influence of Competitive Positioning Variables on Performance

Prior findings suggest that market share advantage of early entrants is derived from their deployment of strategic resources. Firms strong in technological R&D are first to the market with products based on new technologies. How do R&D expenditures translate into barriers to entry for late entrants? The positive effect of R&D intensity on firm performance for late entrants suggests that if they invest heavily in R&D they can perform as well as early entrants. Therefore, even though late entrants are followers in research, they can recover through strong development capabilities.

The relationship between advertising intensity and performance was found nonsignificant for early entrants and negative for late entrants. The latter finding was unexpected, as researchers such as Lieberman and Montgomery (1988) suggest that a firm strong in marketing skills will find late entry to be in its interest. Miller et al. (1989) and Urban et al. (1986) also concluded that promotion for late followers was one of the few competitive options available for gaining market share. Their findings were confirmed within the consumer and industrial goods industry of the PIMS study. The negative finding for late entrants in this study suggests that they need to invest more in advertising to overcome the brand and firm loyalty created by early entrants.

Total self-sufficiency in new product discovery and development is unrealistic, and many pharmaceutical firms will continue to concentrate on both internal and external R&D for drug procurement purposes. Of course, from a control and profitability standpoint, the ideal is an internal R&D organization so creative and productive that it provides a steady flow of competitively superior products. The results of this study show that internal R&D efforts are significant predictors of firm performance, more so for late entrants (0.965) than early entrants (0.650). This finding confirms a recent study by the U.S. International Trade Commission (1991), which found that higher global market shares are associated with firms that develop a larger portion of their own R&D compounds, since there is higher probability of developing an innovative drug from one's own internal R&D efforts.

The effect of the firm's spatial strategy on performance is supported; it is negative for early entrants but nonsignificant for late entrants. The negative finding for early entrants strongly suggests that a policy of simultaneously introducing NCEs in several major countries should lead to better performance. Another explanation for the negative finding is that, although drugs produced in the United States have a worldwide reputation for quality, U.S. firms are likely to be at a disadvantage because of the significantly longer U.S. regulatory reviews. This stringent

regulation should encourage firms to introduce their drugs abroad, pending marketing approval of the new drugs in the United States.

Therapeutic differentiation has a greater effect on early entrants' performance (0.760) than late entrants' performance (0.136). As noted by Abernathy and Utterback (1978), early entrants may be viewed as offering improved differentiated products simply because their products are technologically new. As proposed by Porter (1980b), product differentiation is the second business-level strategy. Therefore, early entrants may attempt to differentiate their products to facilitate entry into foreign markets as well as to deter other firms from entering these markets.

As hypothesized, outlicensing is proactively used by early entrants to broaden their geographic scope, and this variable has a significant effect on their performance. For late entrants, the effect of outlicensing on firm performance is nonsignificant.

Finally, new product development efforts significantly affect early entrants' performance. Unexpectedly, this effect is negative for late entrants. This suggests that the product innovative abilities of early entrants tend to outperform those of late entrants. Cooper (1985) stressed the strong connection between the firm's new product strategy and performance. A firm needs a clear defined new product strategy as a central and integral aspect of its corporate

strategy.

Among the twenty hypotheses tested, sixteen and fifteen structural paths were significant for early and late entrants, respectively. Paths which are significant across both groups are summarized below. These paths suggest fundamental bases of competition in the industry.

Significant Findings - Fundamental Bases for Competition*

- | | | |
|--|---|--|
| 1. Internal R&D efforts (V2) | [| New product development efforts (F1) |
| 2. Therapeutic market diversification (V3) | | |
| 3. New product development efforts | → | Marketing of drugs first in the United States (V1) |
| 4. New product development efforts | → | Therapeutic differentiation (V8) |
| 5. New product development efforts | [| Outlicensing (V9) |
| 6. R&D intensity | | |
| 7. Internal R&D efforts | | |
| 8. Internal R&D | [| Performance (F2) |
| 9. R&D intensity | | |
| 10. Therapeutic differentiation | | |

Nonsignificant Findings

Early Entrants

1. Internal R&D efforts (V2) → Introduction of drugs first in the United States (V1)**
2. Therapeutic differentiation (V8) → Outlicensing (V9)**

Late Entrants

1. R&D Intensity (V4) → New Product Development Efforts (F1)**
2. Internal R&D efforts (V2) → Therapeutic differentiation (V8)**

* Structural paths which are significant and in the hypothesized direction across both groups.

** Significant in other group.

- | | |
|--|---|
| 3. Therapeutic market diversification (V3) → Therapeutic differentiation (V8)*** | 3. Therapeutic market (V3) diversification → Marketing of drugs first in the United States (V1)** |
| 4. Advertising intensity (V5) → Firm Performance (F2)*** | 4. Outlicensing (V9) → Performance (F2)** |
| | 5. Marketing of drugs first in the United States (V1) → Performance (F2)** |

Unexpected Direction (Late Entrants)

- | | |
|---|-------|
| 1. New product development efforts (F1) → Performance (F2) | [-] |
| 2. Advertising intensity (V5) → Performance (F2) | [-] |
| 3. Therapeutic market diversification (V3) → Therapeutic differentiation (V8) | [+] |

Among the late entrants, two major weaknesses are evident: insufficient spending on advertising and a lack of product innovative abilities. Findings for this group indicated, however, that internal R&D efforts, high commitments to R&D, and therapeutic differentiation positively influence performance. The new product development strategies of late entrants are characteristic of firms belonging to the two clusters proposed by Cooper (1985a): the technologically deficient strategy and the low-budget, conservative strategy.

Cooper found that firms pursuing the former strategy lacked technological sophistication, orientation, and innovativeness (their products were mainly "me-toos"), lacked

** Significant in other group.

*** Paths are significant but in unexpected directions for other group.

an R&D orientation, and were technologically proactive. Firms adopting this strategy, however, had focused new product programs that employed related development technologies and production methods aimed at related markets. Firms pursuing a low-budget, conservative strategy tended to have the lowest R&D spending and also tended to launch products with the least differential advantage. Similar to firms pursuing technologically deficient strategies, low-budget firms tended to balance their technological and product deficiencies with a conservative or "stay close to home" approach. New development efforts were chosen that had the highest technological and production synergy.

As for early entrants, it appears that they seem to have "overdiversify" into therapeutic categories that share little synergistic fit with their internal R&D capabilities. They also need to increase their advertising efforts. Positive effects on performance, however, are derived from their emphasis on : (1) development and exploitation of internal technological know-how; (2) high investments in R&D; (3) development of highly differentiated drugs; (4) successful outlicensing arrangements; and (5) strong new product development efforts. In terms of new product development efforts, many of the early entrants in this study are characteristic of firms with technologically driven strategies and a balanced strategy (Cooper 1985a). Cooper found that both groups of firms are high-technology, high-risk,

innovative firms that emphasize the development of technologically complex products featuring state-of-the-art know-how. They also have a strong R&D- oriented and proactive new product program. While firms pursuing technologically driven strategies lack market synergy with their existing market resource base, balanced strategy firms differ from them in the degree of product fit and focus as well as in market orientation.

6.2 Limitations of the Study

The first limitation to be noted is the focus of this study on a single industry. The competitive positioning variables proposed in the structural model were specifically identified as key strategic variables in the ethical pharmaceutical industry. Whether the research findings and the structural model can be generalized to other high-technology industries requires an in-depth understanding of the variables that uniquely describe competitive advantages for those industries. This may mean a reconceptualizing of the structural model to describe more adequately the competitive positioning strategies used in other industries.

A second limitation relates to the sample selection procedure. Due to data constraints, foreign pharmaceutical firms (particularly those from Japan and Western Europe) competing in the United States were deleted. These firms have made significant inroads into the U.S. market over the last few years and have changed the domestic competitive

environment for U.S. firms. Future research will have to develop ways to capture the effect of foreign competition on domestic markets.

A third limitation relates to the assumption that changes in and adaptations to the external environment are captured in the firm's strategic variables. How firms strategically adapt to environmental changes in the pharmaceutical industry and the consequent effect on performance need to be researched.

A fourth limitation concerns the selection and measurement of the performance indicators. Profitability measures were not included in the study because of their substantial measurement error. Since many of the pharmaceutical firms are diversified, and frequently change their patterns of diversification, constructing consistent sales and income figures poses formidable problems. In addition, accounting measures are likely to be distorted by price level changes, especially in times of high inflation. The United States, where price controls have yet to be implemented, is considered by many to be the last free pricing country (U.S. International Trade Commission 1991). Therefore, to capture the true profitability of U.S. firms, accounting return measures have to be restated for inflation-adjusted depreciation expense.

A fifth limitation relates to the grouping of firms into two major groups: early and late entrants. This study adopted the view of Urban et al. (1986) that timing of entry can be

parsimoniously considered as early and late. Robinson and Fornell (1985), however, found a significant degree of lateness effect: Early followers had significantly higher market shares than late followers, although the difference was much smaller than the difference between pioneers and early followers. A different operationalization of timing of entry into pioneers, early entrants, and late entrants might yield a different set of findings.

6.3 Contributions of Research

6.3.1 Theoretical and Empirical Contributions

In terms of theory, this study has shown that timing of entry is systematically related to competitive performance and that this relationship is likely to be moderated by variations in the strategy of firms. Specifically, it seems that underlying sources of competitive advantages are enjoyed by early entrants over late entrants (for example, Lambkin 1988; Robinson and Fornell 1985; Robinson 1988). These sources of competitive advantages are analogous to entry barriers created by early entrants. Specifically, in this study, product differentiation (Bain 1956; Schmalensee 1982; and Porter 1980b) and strong new product development efforts (Cooper 1985a; Johne and Snelson 1988) were found to be important sources of competitive advantage for early entrants.

Contributions to the New Product Development Literature

The new product development literature has rarely dealt with the distinction between internally developed and

licensed-in technologies. This issue is critical for many firms in high technology industries when they are being confronted with broad and rapid changes in their core technologies and lack the capabilities to deal with new technologies. The results of this research show that internal R&D efforts have a positive influence on firms' new product development efforts. Therefore, even though corporations have many reasons for acquiring technology, rarely are these purchases a substitute for technical competence (Oliver 1982). In addition, as noted by Capon and Glazer (1987), one reason for enhancing the firm's technology through internal R&D development is to encourage learning on the part of the firm. That is, firms invest in internal R&D to generate and gain proprietary access to technologies in specific products and to the more general know-how related to these products. An R&D project that yields a specific therapeutic compound also may create knowledge and build R&D capabilities that are valuable for discovering other drugs for the same disease. Findings show that early entrants are more successful in converting their "learned" internal know-how into more highly differentiated drugs.

Diversification is also an area rarely treated in the new product development literature. Either as a means of spreading overall risk and/or expanding the base of the firm's business, diversification is found to have a positive influence on firm's product innovativeness. Similar to other

findings (Cooper and Kleinschmidt 1987; Link 1987), this study confirms the importance of diversification into many therapeutic markets that are synergistic with the firm's marketing and technical capabilities.

An emphasis on internal R&D efforts also necessitates high R&D spending. As noted by Cooper (1982, 1983), how the research dollar is spent and how the product is marketed are more important determinants of success. It seems that technological leaders (early entrants) are able to convert their R&D spending into successful new products that are of high quality and which offer distinctive therapeutic advantages to customers.

Factors Leading to Outlicensing

For both early and late entrants, high R&D spending and strong new product development efforts lead to greater outlicensing. Since new products are usually backed by large R&D investments, manufacturers need to recover their development costs; increasing overseas sales through outlicensing arrangements is one way to achieve this objective. Maintaining a strong global presence is also necessary because of heightened generic competition and increasing drug substitution practices. As expected, early entrants tend to use their worldwide salesforce to distribute their internally developed products overseas. This finding is consistent with Anderson and Coughlan's (1987) argument that firms tend to erect a protective, restrictive governance

structure around the distribution of complex, sophisticated products that require an investment in learning. The effect of therapeutic differentiation on late entrants' outlicensing was negative. Early entrants may already have established captive relationships with licensees in certain markets thus making it more difficult for late entrants to gain access to these distribution channels. In addition, the nature of the product also encourages high switching costs which prevent the licensees from changing from one licensor to another.

Factors Leading to Marketing of Drugs First in the United States

The high demand for pharmaceuticals encourages U.S. firms to exploit their new product development efforts in the domestic market. However, the negative relationship between this variable and firm performance strongly suggest negative consequences for firms who continually focus on the U.S. market as their key source of sales. Findings from this study also point to the importance of differentiating between the types of therapeutic markets that pharmaceutical firms compete in. Since demand for chronic drugs are much higher in the United States than other developed nations, firms who have diversified into these therapeutic categories are in a strong position to exploit sales from these categories in the U.S. Finally, the high costs from internally developed drugs compel firms to look beyond the U.S. market in an attempt to maximize sales from their internal efforts.

6.3.2 Managerial Implications

It is of central importance for firms to understand what strategies are being pursued by their competitors. This knowledge is necessary to evaluate the relative strengths and weaknesses of certain strategic positions and to determine how defensible these positions are. A competitive positioning framework has been proposed to examine this matter in detail. Success factors for competition in the industry are summarized below.

Emphasize Product Innovativeness

First, the importance of developing and exploiting internal know-how as well as diversifying into related therapeutic markets is crucial for enhancing product innovativeness. Second, increasing product innovativeness can lead to important payoffs -- drugs that are therapeutically differentiated and which offer significant benefits over competing brands. Cooper and Kleinschmidt (1991) argued that product innovativeness have a central role and impact in new product success. Innovative products tend to be more unique, differentiated, and patentable. The innovative firm thus achieves a differentiated and proprietary position, and has a higher likelihood of success than the follower.

Strong new product development efforts also enhance firms' ability to outlicense. Since licensees' size of income is tied to the economic potential of a drug, they are more likely to enter into contractual arrangements with firms that can offer innovative and differentiated products for

outlicensing.

Look Beyond the U.S. Market

Firms who emphasize drugs introductions first in the United States are in a disadvantaged position in the long run. The increasing presence of Western Europe and Japanese firms as well as increasing competition from generics compels U.S. firms to adopt a strong commitment to other foreign markets. "Think globally."

Do Not Neglect Internal R&D Competency

Increasing domestic and global competition together with higher new product development costs suggest that for firms in many technologically advanced industries to succeed, they need to develop "better" new products and to do it faster. Many pharmaceutical firms have entered into product licensing alliances to supplement and accelerate product development. However, this study stresses that internal R&D efforts is a critical determination of long-term competitiveness in the pharmaceutical industry. A recent study by the U.S. International Trade Commission (1991) found that higher global market shares are associated with firms that develop a large portion of its own R&D compounds since the probability of developing an innovative drug is higher from one's internal R&D efforts.

Maintain Strong Commitments to R&D

The importance of R&D as a key strategic resource to the development of distinctive competency has been stressed in

earlier studies (e.g., Cool 1985). Harrigan (1981) and Schmalensee (1983) argued that although incumbent firms may prevent the entry of new firms by investing effectively in R&D, thereby increasing technological scale economies, this barrier is usually short-lived. The positive total effect of R&D intensity on late entrants' performance suggests that if they make significant commitments to R&D, they can perform as well as early entrants.

Late Entrants - How Can We Improve Our Competitive Positions?

The two most significant variables that affect late entrants' performance are internal R&D efforts and R&D intensity, respectively. However, late entrants must address how they can overcome competitive advantages achieved by early entrants: (1) higher quality and differentiated products; and (2) stronger new product development efforts. A recent study by Cooper and Kleinschmidt (1991) found that non-innovative products, namely modifications and revisions, also perform well in terms of return-on-investment and domestic market share. One reason for their success is they "stick close to their knitting." Non-innovative products also tend to do well because of high levels of marketing and technological synergies.

Hence, for late entrants, electing to concentrate on NCE development versus other types of new product developments can be a negative factor. Although they should concentrate their marketing and R&D resources on less innovative product

development efforts, they should not ignore attempts to develop NCEs that are therapeutically differentiated. In these efforts, a recommendation for late entrants is to focus efforts on one therapeutic market at a time. This approach will produce a niche until the resources become available to permit an assault on another niche. This niche-by-niche strategy will allow global exploitation of their products more successfully despite being "technological followers."

In addition, late entrants also need to commit more resources to advertising efforts. Superiority in this marketing activity will spell the difference between success and failure for many products in the future as the market continues to be filled with similar chemical entities.

Jain (1981) suggests that late entrants may come into the market as "me-too" competitors. Pharmaceutical experts claim that even a less effective me-too drug (for example, a "C" drug) can do well in the market, depending on the way it is promoted and marketed (Bond and Lean 1977; U.S. International Trade Commission 1991).

Early Entrants - How Do We Maintain Our Competitive Positions?

Overall, early entrants are doing what is necessary to maintain market share advantages; they offer innovative products which provide further opportunities for product advantages and differentiation. However, they need to be more selective in their choice of therapeutic markets. Since the development of highly innovative products involve greater

uncertainties and riskiness, management must ensure that these projects should only be undertaken when there is a good match between the resource base of the firm and the needs of the project. Firms should also identify opportunities in a certain therapeutic market by comparing the relative market size and its degree of unmet needs as well as evaluating the competitive intensity and diversity of approaches in the research area. These criteria will help early entrants employ their R&D and marketing resources more effectively.

6.4 Suggestions for Future Research

In addition to replicating this study in other industries, several questions require further research.

First, an attempt should be made to include foreign firms in the analysis. Since the pharmaceutical industry operates in a global market, it would be interesting to examine how Japanese and Western European firms differ in their competitive positioning strategies. Since Japanese pharmaceutical companies are traditionally smaller and are less innovative when compared to Western European and U.S. firms, what strategies do they employ to enhance their new product development efforts and performance?

Second, because some of the firms in the sample have merged with or been acquired by other pharmaceutical firms, a follow-up study is necessary. The merger of SmithKline and Beecham created one of the largest ethical drug companies in the world in terms of research budget and worldwide detail

force. In Europe, the merger between Rhone-Poulenc and Rorer gave the French firm access to the U.S. market. Given that these merged firms have economies of scale in R&D and distribution, how does this change the competitive structure of the pharmaceutical industry for other pharmaceutical firms?

Third, although this study looked at a wide range of therapeutic markets, it did not distinguish them by their stage in the technology life cycle (TLC). Timing of entry at the technology level within the product market has not been extensively studied. Most research on entry issues has concentrated on either mature or new/start-up businesses. Studying the timing of entry variable over a broad range of therapeutic markets at various stages of technological growth can offer better insights to several questions. (1) Are firms identified as early entrants in mature therapeutic markets also likely to be early entrants in growing therapeutic markets? (2) How do the competitive positioning variables vary across stages of the TLC? (3) What competitive positioning variables are associated with performance at each stage of the TLC?

Finally, the performance effect of the environment-strategy linkage needs to be addressed. Current regulation and changes in the drug selection process are expected to affect significantly on a firm's R&D efforts and marketing mix. For example: (1) How are pharmaceutical firms responding to the U.S. government's health policies and various cost-

containment measures? (2) Will product liability exposure affect the industry's R&D efforts? (3) Since physicians will become less influential in the drug selection process compared to other major buying groups, such as HMOs, how will pharmaceutical firms' marketing mix change in response to the needs of major buying groups?

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APPENDICES

APPENDIX A

SUB-CATEGORIES OF DRUGS*

Antiinfectives

- Cephalosporins
- Macrolides
- Penicillins
- Tetracyclines
- Sulfonamides
- Antifungals
- Antibiotics
- Aminoglycosides
- Urinary Germicides

Antineoplastics

- Antimetabolites
- Antibiotics
- Hormones
- Antineoplastics

Antihistamines

- Antihistamine

Autonomics

- Autonomics

Cardiovascular

- Antilipemics
- Antianginals
- Beta-blockers
- Antiarrhythmics
- Antihypertensives
- Vasolidators
- Calcium Channel Blockers

Central Nervous System

- Antiparkinson
- Benzodiazepines Anxiolytics
- Anorexics
- Tranquilizers
- Tranquilizers Phenothiazines
- Sedative Hypnotic

- Psychotherapeutics
- Antidepressants
- Respiratory and Cerebral Stimulants
- Analgesics Non-narcotic
- Analgesics and Antipyretics
- Antidepressants Tri and Tetracyclines

Gastro- Intestinal

- Antiucler
- Cathartics
- Antidiarrheal

Hormones and Synthetic Substances

- Adrenals
- Insulins
- Progestrones

Musculo-Skeletal

- Anti-inflammatory (non-steriods)
- Anti-inflammatory

Biologicals

- Vaccines

Skin and Mucous Membrane

- Antiinflammatory
- Fungicides
- Keratolyt-antiacne
- Antibiotics

Spasmolytics

- Respiratory

* Extracted from Paul de Haen Modified American Formulatory Service Therapeutic Classification System.

APPENDIX B

MATHEMATICAL DERIVATION OF NORMED AND NON-NORMED FIT INDICES

The normed and nonnormed fit indices proposed by Bentler and Bonnett (1980) are essentially comparative fit indices. These indices evaluate the adequacy of a particular model M_k in relation to a continuum models ranging from M_1 to M_s where M_1 is the most restricted model and M_s is the least restricted or saturated model. In practice, this is done by evaluating where the goodness-of-fit index T_k falls in relation to T_1 and T_s . If T_k is close to T_1 , M_k is hardly an improvement over M_1 , and the fit index is close to zero. If T_k is close to T_s , M_k is almost as good as the saturated model, which corresponds to the data, and the fit index is close to one.

Bentler and Bonnett (1980) proposed to evaluate model M_k by comparing T_k to T_1 via

$$NFI = \frac{T_s - T_k}{T_s - T_1}$$

which equals zero when $T_1 = T_k$, equals 1.0 when $T_k = T_s$, and is in the 0-1 range. Because of the 0-1 range, this index is called the normed fit index. A disadvantage of the NFI is that it is affected by the sample size (Bearden, Sharma, and Teel 1982). In small samples, it may not reach 1.0 when the model is correct. This can occur because the expected value of T_k may be greater than 0, for example, when T_k is a $\chi^2(d_k)$ variate ($T_k) = d_k$. This difficulty of range was resolved by

the modification index.

$$\text{NNFI} = \frac{T_1 - d_1 d_k^{-1} T_k}{T_1 - d_1}$$

called the nonnormed fit index. The degrees of freedom adjustment in this index was designed to improve its performance near 1.0, not necessarily to permit the index to reflect other model features such as parsimony. When $T_k = (T_k) = d_k$, the $\text{NNFI} = 1.0$, thus obviating a major difficulty with NFI. However, the NNFI can fall outside the 0-1 range. It will be negative when $d_1 d_k^{-1} T_k > T_1$, since usually $T_1 \gg d_1$. It will exceed 1.0 when $T_k < d_k$. In fact, the index can be anomalously small, especially in small samples, implying a terrible fit when other indexes suggest an acceptable model fit (Anderson and Gerbing 1984). As a consequence, the variance of NNFI is substantially larger than the variance of NFI. Despite this negative feature, the NNFI has the major advantage of reflecting model fit very well at all sample sizes (Anderson and Gerbing 1984).

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