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PERFORMANCE VARIATIONS AMONG STRATEGIC GROUP MEMBERS IN THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF INDIVIDUAL SUSTAINABLE GROWTH CAPABILITIES, 1995-1997

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A Thesis
In
The Faculty
of
Commerce and Administration

Presented in Partial Fulfilment of the Requirements
for the Degree of Master of Science in Administration at
Concordia University
Montreal, Quebec, Canada

December 1998

ABSTRACT

Performance Variations Among Strategic Group Members in the Pharmaceutical Industry: An Examination of Individual Sustainable Growth Capabilities, 1995-1997

Zied Guedri

The relationship between strategic group membership and firm profitability has been a central and controversial theme in the strategic management literature. The theoretical foundation for a direct link between strategic group membership and firm profitability has been the notion of mobility barriers. However, the empirical evidence for a direct association between strategic group membership and performance is inconsistent and conflicting. Consequently, this study examines the hypothesis that individual firm sustainable growth capabilities may moderate the effects of member's shared strategy characteristics on performance in the pharmaceutical industry. Four strategic groups based on scope and resource deployments strategic dimensions were identified among forty-two global pharmaceutical firms. Significant differences in performance and sustainable growth capabilities were found within each group. There was also evidence of a significant correlation between sustainable growth capabilities and performance within each group. It is concluded that effects of firms' sustainable growth capabilities should be taken into account to improve the explanatory power of strategic groups in competitive performance.

A mes très chers parents

ACKNOWLEDGMENTS

The author wishes to express his gratitude and appreciation to Dr. Jean McGuire for her precious support in conducting this study.

Special thanks are also extended to Drs. Jerry Tomberlin, Geoffrey Bell and Hamda Guedri for their contribution to this paper.

Finally, I would like to thank my family who more than anyone else has lived this experience with me. This work would not have been possible without their precious support and sacrifice. This paper is dedicated to my parents.

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INTRODUCTION

This paper examines the strategy-capability-performance consequences of strategic group membership for firms in the pharmaceutical industry. Indeed, a central theme in the strategic groups literature is that there is a theoretical relationship between strategic groups and financial performance (Caves & Porter, 1977). In particular, it is argued that profitability may differ systematically among groups in an industry because of mobility barriers and group level effect (Caves & Porter, 1977 and Dranove, Peteraf, & Shanley, 1998). However, the empirical evidence for a direct link between strategic group membership and performance is inconsistent and conflicting. Where the linkage appears absent or equivocal, it has been advanced that this was primarily due to the large number of approaches used, which have generally not captured adequately the differences in the strategies adopted by firms in competitive environments (McGee & Thomas, 1986). While the existence of a direct link between group membership and firm profitability appears questionable, it is proposed that individual firm sustainable growth capabilities, which reflect individual firm's potential to create resources to attain a certain sustainable growth, may moderate the effect of member's shared strategy characteristics on performance. Therefore, it is argued that effects of firm's sustainable growth capabilities should be taken into account to ameliorate the explanatory power of strategic groups in competitive performance.

The first chapter begins with a brief literature review intended to present the different stages in the evolution of research on strategic groups as well as the theoretical foundation of the relationship between strategic groups and financial performance.

In the second chapter, an overall description of the competitive environment of the pharmaceutical industry is proposed. This description will provide helpful understanding of the competitive environment and competitive behavior of firms in the pharmaceutical industry. It will also be useful to identify major distinctive components of strategy among firms. The analysis developed in the second chapter will ultimately permit the identification of significant asymmetries among firm's strategies and thus, the determination of estimates regarding the nature of important mobility barriers.

In the third chapter, the analytical framework, including strategic variable selection, the operationalization of firm sustainable growth capability, the statistical procedure adopted to identify strategic groups, the sampling approach and the data bases employed in this study are developed.

Finally, the results of the procedure adopted to identify strategic groups within the pharmaceutical industry as well as examination of the strategy-growth capabilities-performance relationship are discussed.

CHAPTER I: REVIEW OF LITERATURE

Since it was introduced by Hunt (1972), the concept of strategic groups has attracted notable attention in the strategic management and industrial organization economics literature. Its utilization in various industry settings has demonstrated that the strategic group concept may significantly improve exploration of the nature of strategy-performance relationship (Cool & Schendel, 1987). Although there are no conventional criteria for describing strategic groups, it is commonly accepted that the main characteristics are: (1) each group is composed of firms that follow similar strategies; (2) firms within a group resemble one another more closely than any other firm outside the group; and (3) firms within a group are likely to respond similarly to a market opportunity or threat (Thomas & Venkatraman, 1988).

Potential applications of the concept of strategic groups have been thoroughly developed in the strategic management literature during the last twenty years (Hatten & Hatten, 1987; Mascarenhas & Aaker, 1989; Harigan, 1985 and McGee & Thomas, 1986). Hatten & Hatten (1987) suggested that by capturing the conceptual space between firm and industry, strategic groups represent an exceptional "meeting ground" for strategic management and industrial organisation. Strategic groups concept has the potential to be a precious theoretical tool for strategy researchers and to be a valuable help for managers when analysing competitors, making strategic investment decisions, and developing successful strategies (Mascarenhas & Aaker, 1989). Important benefits of strategic grouping approach for strategic analysts that have been introduced in the strategic management literature includes notably:

- Aaker (1984) and Day (1984) defined strategic groups analysis as the exercise of detecting the major distinctive components of strategy among firms within an industry that justify continuous differences in performance and then exploring groups of firms with similar strategies to provide helpful understanding of the competitive environment and competitive behaviour. Thus, strategic groupings is a pertinent setting for investigating whether or not particular companies in an industry have competitive advantage over their competitors and how firms take advantage of and protect their superiority. Such analysis is important because it helps strategists to evaluate the attractiveness of market opportunities for their firm (and for their rivals), their endowment to exploit industry changes, and therefore their long-term opportunities for profitability within the industry in question (Harigan, 1985). Therefore, strategic groups analysis represent a systematic and comprehensive approach to elaborate a strengths and weaknesses analysis in terms of the framework of relative competitive advantage (McGee & Thomas, 1986).

  In addition, the concept of strategic groups is useful to judge the attractiveness of each group and evaluate the assets and skills necessary to compete successfully over time within each group (Mascarenhass & Aaker, 1989).

- Longitudinal analysis of strategic groups allows a valuable tool for studying a specific industry. The matching of market segment changes with strategic group evolutions may be important to predict the characteristics of competition. As suggested by Mascarenhas (1989), strategic groups analysis permits meaningful perception of the stability and sustainability of competitive advantage and performance in an industry.

- Strategic groups may be of value in studying both the traditional theory of entry and oligopoly theory. Indeed, McGee & Thomas (1986) suggested that the generalisation of entry barriers into mobility barriers allows a more realistic picture of the process of entry and the incentives for diversification (Cross entry) in addition to providing a link with firm-level strategy formulation.
- Strategic groups analysis can be used to preserve information distinguishing individual firms which is generally lost in industry studies using averaged and aggregated data (Hatten & Hatten, 1987).
- Because strategic groups allow investigation of many firms at the same time, they permit evaluation of the effectiveness of their strategic behaviour over a wide range of variations than an individual company's experience affords (Hatten & Hatten, 1987).
- Strategic group analysis facilitates the evaluation of the repercussions of a collective movement by many companies into analogous competitive postures (Hatten & Hatten, 1987).

Hunt (1972) defined a strategic group as a set of firms facing similar threats and opportunities that are different from the threats and opportunities facing other firms in an industry. Another well accepted definition of strategic groups is provided by Porter (1980, p129): "A strategic group is a group of firms in an industry following a similar strategy along a certain number of strategic dimensions". These strategic dimensions are essentially long-term in nature and costly to reverse (McGee & Thomas, 1986). Accordingly, the explanatory power of the strategic group concept is radically dependent

on the strength of the scheme adopted to identify relevant strategic dimensions (Thomas & Venkatraman, 1988). If the objective is to isolate different groups of firms that are maximally similar within a group and maximally different across groups, in terms of their strategies, then operationalization of strategy represents the most important stage. Thomas & Venkatraman (1988) distinguish between studies adopting a 'unidimensional' versus 'multidimensional' view of strategy. On one hand, several studies have operationalized strategy in narrow terms focusing on one functional area or a single dimension (Porter, 1979; Newman, 1978, Hunt 1972). On the other hand, many studies viewed strategy in relatively broader terms encompassing multiple functional areas or dimensions (Dess & Davis, 1984; Fiegenbaum, Sudharsan & Thomas 1987, 1990; Cool & Schendel, 1987). The dimensional difference in operationalizing strategy may be explained, in part, by the objective of the studies. Indeed, research on strategic groups can roughly be divided into three categories. Early work, including studies by Hunt (1972), Newman (1973,1978), Porter (1979) and Caves & Pugel (1980) introduced the strategic groups concept and focused on whether or not it was pertinent to reject the Industrial Organisation (IO) assumption of intra-industry firm homogeneity. Most of the empirical work published between 1980 and 1985 went beyond the investigation of heterogeneity to concentrate on the existence of groups of similar firms within specific industry contexts. Finally, since 1985, strategic groups literature has focused on the importance of developing a dynamic perspective to analyse competition within industries.

Phase I: Introduction of the strategic groups concept

Until the end of the 1970's, the conventional approach used to analyze firm's behaviours was guided by the prevailing assumption of intra-industry homogeneity of the Bain-Mason paradigm. This conventional approach takes firms within an industry as identical in all economically important aspects except for their size (Caves & Porter, 1977). However, Hunt (1972) first challenged the assumption intra-industry homogeneity by recognising the existence of strategic groups, which were adopting distinct strategies in the home appliance industry in the 1960s. Hunt (1972) isolated four strategic groups of competitors in the industry based on three strategic variables: (1) extent of vertical integration, (2) degree of product differentiation and (3) differences in product differentiation. He noticed that even though the industry was remarkably concentrated, the profitability of the industry was low. Hunt justified this situation by the existence of strategic groups, which were implementing "asymmetric" strategies. Using a similar approach, Newman (1973,1978) identified strategic groups in the chemical process industries based on their degree of vertical integration.

Significant differences between firms were also identified in terms of their size (Porter, 1979; Caves & Pugel, 1980). Porter (1979) classified firms in each industry into two groups defined as industry leaders and followers. Caves & Pugel (1980) followed Porter in using firm size as an indicator of strategic group membership. They examined seventy-three U.S. manufacturing industries over the period 1969-1972. Their results indicate that advertising, capital intensity and direct foreign investment increased with firm size and were directly associated with the existence of different groups of firms.

As a summary, the early stage of research introduced the notion of strategic groups. Most studies published during this first phase had as their principal (and in some cases, the only) objective to determine that the selected industry is heterogeneous and that distinct groupings can be identified through clustering in terms of a set of strategic characteristics (Thomas & Venkatraman, 1988). It should be emphasised that almost all of these studies have operationalized strategy in narrow terms using a single dimension such as size (Porter, 1979; Caves & Pugel, 1980), degree of vertical integration (Newman, 1973, 1978) and product line (Hunt, 1972). It is clear that this narrow conceptualisation of strategy does not capture adequately the complexity of the strategy construct.

Phase II: Structuring of the concept of strategic groups

While intra-industry firm heterogeneity is a necessary condition for the existence of strategic groups, it is not a sufficient condition (Thomas & Venkatraman, 1988). Strategic group theory suggests that not only are there dissimilarities between companies in an industry but also that groups of firms in an industry implement similar strategies (Thomas & Venkatraman, 1988). Recognising limitation of the research on firm heterogeneity in an industry, most of the empirical work published between 1980 and 1985 went beyond the investigation of heterogeneity to concentrate on the existence of groups of similar firms within specific industry contexts.

During this second phase, strategic groups have been differentiated along various dimensions. Several authors have used financial strategy variables (Ryans & Wittink,

1985;Baird & Sudharsan, 1983). Ryans & Wittink (1985) applied finance theory and the capital asset pricing model as a basis for group identification in the context of the airline industry. They suggest that if particular firms belong to the same strategic group, then their stock prices should tend to move together. Their results suggest a clear U.S. trunk airline group. Similarly, Baird & Sudharsan (1983) used financial variables such as leverage, current ratio, return on assets, dividend payment ratio and times interest earned to group firms in the office equipment/electronic computing industry. They detected many different and rather stable groups in this industry differing with respect to their financial policies and strategies.

Other authors have used marketing strategy variables such as price, advertising, promotion, display and number of brands to form strategic groups (Hatten & Hatten, 1985; Hawes & Crittenden, 1984; Tassey, 1983). Hawes & Crittenden (1984) identified four distinct strategic groups in the supermarket industry based upon several marketing strategy variables, while Hatten & Hatten (1985) found three groups in the brewing industry. Finally, Tassey (1983) operationalized strategy in technology based industries using firm's investments in marketing and R&D. His empirical results support the existence of a heterogeneous competitive structure in technology-based industries, with the returns-to-scale estimates varying among the industries analysed.

The strategic mapping approach based upon dimensions of firms' strategic posture has also been used to isolate strategic groups in seven declining industries (Harrigan, 1980).

Harrigan (1980) suggested that existence of strategic groups is justified by their strategic postures within the industry.

Different approaches have been utilised to operationalize strategy in the banking industry (Ramsler, 1982; Heyes, Spence, & Marks, 1983). Ramsler (1982) studied strategic groups of non-U.S. banks in the U.S. market. The objective of his study was to determine whether firms within each group adopted similar entry strategies for competing in the U.S market. Findings indicate that banks belonging to the same strategic grouping tended to implement similar strategies in entering the U.S. banking industry. Similarly, Heyes, Spence, & Marks (1983) applied the statistical technique of logit analysis involving match between characteristics of investment bank and characteristics of individual customers to isolate strategic groups. They detected four principal groups, which were quite different from the groupings obtained from conventional industry wisdom. Their results indicate that investment banking is a concentrated industry characterized by substantial competition within groups. In contrast, competition between groups was much less vigorous.

Some studies have attempted to relate the concept of strategic groups to the phenomenon of industry life-cycles (Primeaux, 1985). Primeaux (1985) suggested that investment behaviour (measured by net capital expenditures) might be an important variable by which the life cycle stage of an industry could be detected. He found that leaders were at a different stage than followers and that the stage of the industry life-cycle did not

correspond to the stage of the strategic groups. Primeaux (1985) added that a single strategic group might adopt different generic strategies to compete in different markets.

Few studies viewed strategy in relatively broader terms by focusing on multiple functional areas or dimensions (Frazier & Howell, 1983; Dess & Davis, 1984).

For example, Frazier & Howell (1983) utilised three parameters from Abell's (1980) criteria for business definition to produce strategic groups in the medical supply and equipment industry. They suggested that firms within any given industry will variously define themselves and form strategic groups on the basis of their customer groups, the customer needs they serve, and the technologies they employ in meeting customer needs. Frazier & Howell (1983) found that although the technology used in this industry is analogous, consistent differences exist between firms in their choice of customer groups served and customer functions pursued. They concluded that marketing strategy variables have a significant impact on the firm's strategic choices and positioning.

Firms within an industry can be categorized on the basis of their intended generic strategies as identified by Porter (1980): 1. differentiation, 2. overall low cost, and 3. focus. Accordingly, Dess & Davis (1984) examined generic strategies as determinants of strategic group membership. Rather than using investigator-determined economic data to form strategic groups they focused on the perceptions of twenty-two CEOs from non-diversified manufacturing industries (paints and allied products) to identify the important strategic dimensions affecting the competition.

Most of the empirical studies related to strategic groups concept during the second phase (1980-1985) concentrated on investigating the existence of groups of similar firms within specific industry contexts. Some of these studies have operationalized strategy in narrow terms focusing on a single functional area such as finance (Ryans & Wittink, 1985;Baird & Sudharsan, 1983), marketing and R&D (Hatten & Hatten, 1985; Hawes & Crittenden, 1984; Tassey, 1983). On the other hand, few others viewed strategy in relatively broader terms and focused on multiple functional areas or dimensions (Frazier & Howell, 1983; Dess & Davis, 1984).

Phase III: Emergence of the concept of strategic groups dynamics

Since 1985, strategic groups literature has focused on the importance of developing a dynamic perspective to analyse competition within industries (Sabourin, 1994). In particular, McGee & Thomas (1986, p157) suggested that a dynamic perspective is notably important to examine:

- The existence and evolution of group structures and their relationship to the evolution of industries,
- The theory of entry, the queue of potential entrants and the alternative entry paths,
- The patterns of rivalry in oligopolistic markets, and
- The growth and evolutionary patterns of firms.

A considerable empirical support for a dynamic perspective on strategic groups was provided by Cool & Schendel (1987), Fiegenbaum, Sudharsan & Thomas (1987, 1990), Mascarenhas & Aaker (1989) and Fiegenbaum & Thomas (1993). The authors criticised

the fact that almost all-previous studies have been limited to the identification of strategic groups at a given point in time, which assumes that groups identified at a given point hold over time. To verify the general validity of this proposition, Cool & Schendel (1987) proposed a statistical procedure to longitudinally identify strategic groups in the U.S. pharmaceutical industry over the period 1963-1982. They identified four stable strategic time periods. These are respectively, 1963-69, 1970-74, 1975-79 and 1980-82. Cool & Schendel (1987) suggested that significant changes which had taken place over the period studied might be related to the observed strategic group changes. The authors identified six primary groups. The first group is composed by large, R&D intensive prescription drugs firms active in many market segments with a broad range of products. The second group consists of large firms differing from the first group on three key dimensions: (1) they are advertising-intensive and not R&D intensive; (2) they compete in the non-prescription as well as the prescription market segments; and finally (3) they serve fewer market segments in the prescription drug market and offer a less comprehensive product range. The third group includes medium-sized firms pursuing principally a "me too" strategy. The fourth group also consists of medium sized firms without real competence in R&D. The fifth group is composed by small prescription drug firms with a narrow product range and a selective participation in market segments. Finally, the sixth group includes only one member, a very small firm, with a very focused product line and a narrow scope.

Cool & Schendel (1987) suggested that the six strategic groups experienced important changes from 1963 to 1982. The 1960s displayed an explicit strategic group structure characterised by high asymmetry. In the early 70's, firms attempted new strategies

motivated by environmental change and their poor performance. In the late 1970s, a consolidation took place, which was in turn broken apart in the early 1980s as new groups formed.

Many subsequent studies adopted the direction suggested by Cool & Schendel (1987). For example, Fiegenbaum, Sudharsan & Thomas (1987, 1990) suggested a need for further refinement of the notion of strategic groups. They advanced that previous strategic group studies generally ignored the influence of time on competitive strategy and assumed homogeneity in strategic conduct for the time period analyzed. Therefore, they proposed a general analytical method to identify stable periods of time called SSTP (stable strategic time periods). A modified method of operationalizing stable strategic time periods (SSTP) incorporating changes in both mean vectors and variance-covariance matrices was also introduced by Fiegenbaum & Thomas (1990).

In addition to pharmaceutical industry, strategic group dynamics have been also examined in the international offshore oil drilling (Mascarenhas, 1989; Mascarenhas & Aaker 1989) and the insurance industry (Fiegenbaum & Thomas, 1993, 1995). Strategic group dynamics over periods of economic stability, growth, and decline in the international offshore oil drilling industry have been investigated by Mascarenhas (1989). The author found that changes in group strategy were related to important environmental transformation involving growth and decline rather than economic stability, which is concordant with the adaptation perspective. Findings also suggested that mobility rates among groups were higher during economic decline than during stability or growth and that mobility was also greater between similar groups than between dissimilar groups.

Similarly, Mascarenhas & Aaker (1989) investigated group membership over the period 1973 to 1982 in the case of oil drilling industry. In particular, their study was based on the assumption that group identification should be based on mobility barriers. Their empirical findings strongly support the hypothesis that mobility barriers explain groupings of firms in the industry.

Fiegenbaum & Thomas (1993) analyzed dynamic aspects of strategic groups in the context of the US insurance industry from 1970-1984. They examined the longitudinal structure of industry strategic groups and discerned the strategic patterns followed by these strategic groups over time. Results indicate that three predominant groups are present throughout the period of the study while other group positions emerge and disappear over time. Findings also show a low level of firm mobility between strategic groups, which is consistent with mobility barriers present in the industry.

More recently, Fiegenbaum & Thomas (1995) proposed a longitudinal, dynamic perspective describing the forces driving strategic group membership and structural evolution in the context of the insurance industry over the 1970-1984 time period. The authors suggested that a strategic group acts as a reference point for group members in developing competitive strategy. Therefore, Fiegenbaum & Thomas (1995) proposed a partial adjustment model of strategic mobility illustrating strategic change in an industry both within and across strategic groups. Their results indicate that strategic groups act as reference points for firm strategies and that predictions of future firm strategies and industry/group structures could also be successfully derived.

The studies discussed above and displayed in table 1 have as their common theme the application of some sort of strategic groups concept. However, differences in terms of the objective of the research and the deployment of the strategic dimensions that lie behind the strategic group concept do exist. The purposes of the studies reported are diverse. Early studies introduced the strategic groups concept and focused on whether or not it was pertinent to reject the Industrial Organisation (IO) assumption of intra-industry firm homogeneity (Hunt, 1972; Newman, 1973,1978; Porter, 1979; Caves & Pugel, 1980). Subsequent studies published between 1980 and 1985 went beyond the investigation of heterogeneity to focus on the existence of groups of similar firms within specific industry contexts (Ryans & Wittink, 1985;Baird & Sudharsan, 1983; Hatten & Hatten, 1985; Hawes & Crittenden,1984; Tassey, 1983). During the first and second phase, most of the studies have operationalized strategy in narrow terms focusing on a single functional area, the only exceptions being Frazier & Howell (1983) and Dess & Davis (1984) studies. Some of the more recent studies focus on issues related to industry and firm evolution and the way in which the dynamics of group membership can improve the understanding of these (Cool & Schendel, 1987; Fiegenbaum, Sudharsan & Thomas, 1987, 1990; Mascarenhas & Aaker, 1989 and Fiegenbaum & Thomas, 1993, 1995). Such studies often adopted a multidimensional view of strategy reflected by a wide range of variables depicting scope and resource deployment decisions. Many of studies cited above focus on the link between group membership and performance. Indeed, a central theme in the strategic groups literature is that there is a theoretical relationship between strategic groups and performance. In particular, it is advanced that profitability may differ systematically among groups in an industry because of mobility barriers (Caves & Porter

1977; Caves 1984; Cool & Schendel 1987; McGee & Thomas 1986; Porter 1979; Cool & Dierickx 1993; Mascarenhas & Aeker 1989).

Table:1 Stages of development of the concept of strategic groups in the literature

Stage 1: Introduction of the strategic groups concept.

Research objective	Illustrate the existence of heterogeneity in the industry substructure.
Contributors	❑ Hunt (1972) ❑ Newman (1973,1978) ❑ Porter (1979) ❑ Caves & Pugel (1980)

Stage 2: Structuring of the concept of strategic groups

Research objective	Examine strategic groups within specific industry contexts.
Contributors	❑ Harrigan (1980) ❑ Ramsler (1982) ❑ Heyes, Spence, & Marks (1983) ❑ Spence, & Marks (1983) ❑ Frazier & Howell (1983) ❑ Tassey (1983) ❑ Baird & Sudharsan (1983) ❑ Hawes & Crittenden (1984) ❑ Primeaux (1985) ❑ Dess & Davis (1984)

Stage 3: Emergence of the concept of strategic groups dynamics.

Research objective	Integration of a dynamic perspective
Contributors	❑ McGee & Thomas (1986) ❑ Cool & Schendel (1987) ❑ Fiegenbaum, Sudharsan & Thomas (1987, 1990) ❑ Fiegenbaum & Thomas (1990). ❑ Mascarenhas (1989) ❑ Mascarenhas and Aaker (1989) ❑ Fiegenbaum & Thomas (1993) ❑ Fiegenbaum & Thomas (1995)

Sources: Adopted from Sabourin (1994) and Thomas & Venkatraman (1988).

Strategic group membership as a predictor of firm performance

The relationship between strategic group membership and firm profitability has been a central and controversial theme in the strategic groups literature (Caves & Porter 1977; Caves 1984; Cool & Schendel 1987; McGee & Thomas 1986; Porter 1979; Cool & Dierickx 1993; Mascarenhas & Aeker 1989). Porter & Caves (1977) were the first to consider potential effects of strategic group membership on firm performance (Cool & Dierickx, 1993). The theoretical foundation for a direct link between strategic group membership and firm profitability has been the notion of mobility barriers. In traditional industry organisation theory, firms in an industry are assumed to be identical in all economically important dimensions except for their size and are supposed to be equally protected by entry barriers (Caves & Porter, 1977). Caves & Porter (1977) challenged this assumption and suggested that entry barriers are specific to groups and do not protect all firms in an industry equally. They argue that mobility barriers between groups rest on the same structural features as barriers to entry into any group from outside the industry (Caves & Porter, 1977). According to Caves & Porter (1977), profits rates may differ systematically among groups constituting an industry, the differences stemming from competitive advantages that a group may have against others.

Several different but harmonious definitions of mobility barriers were introduced in the strategic management literature. Indeed, McGee (1985) defined mobility barriers as either the absolute costs of transiting from one group to another or as the operating or variable cost penalty relative to the incumbents that the strategic group entrant must face. Cool &

Schendel (1988) described mobility barriers as structural forces obstructing firms from freely changing their competitive position. Mascarenhas & Aeker (1989) stated that barriers to entry could be assets such as brand name, loyal customer base, distribution channels, or an automated factory. They added that entry barriers could also be skills such as the ability to design simple products that are reliable and inexpensive. Assets and skills are considered as entry barriers because they are generally difficult to acquire or neutralise (Mascarenhas & Aeker, 1989). The authors describe exit barriers as including specialised assets, long-term contracts with supplier or labour, customer or distributor commitments and managerial pride. Accordingly, Mascarenhas & Aaker (1989) present mobility barriers as much more 'who you are" or resource dependent than "what you do" or action dependent.

McGee & Thomas (1986) defined mobility barriers as group specific entry barriers that afford protection to group members. They suggested that mobility barriers fall into three categories: market-related strategies, the characteristics of supply in the industry, and features specific to the ownership and management of the individual firm. These categories correspond to differentiation strategies and cost-based strategies at the business unit level, and to characteristics of strategy at the corporate level (McGee & Thomas, 1986). According to McGee & Thomas (1986) Market-related strategies comprise:

1. The product line, its width and scope;
2. The geographical coverage of the market and the nature of market segments targeted;
3. The channels of distribution employed and the relationships with buyers;
4. The technologies embodied in the product; and

5. The nature and type of branding and product differentiation in general.

These variables represent strategic choices requiring a risky initial investment cost and some elapsed time before competition on equal terms becomes possible.

Similarly, the characteristics of supply include the scale economies resulting from size (in production or in marketing or in administration); and the range of assets that could be invested in supply (manufacturing capability, technological capability, marketing and distribution systems, and R&D expenditures). McGee & Thomas (1986) suggested that the investment options in supply-side assets for a firm can be difficult to define with precision (what is a R&D capability?) and thus can be hard to copy at least in the short run.

Finally, firm specific sources of mobility barriers include organisational structure and control systems, management skills and capabilities, the nature and extent of diversification and of vertical integration, and the nature of the firm's ownership and its connections with other power groups such as unions, consumer groups and regulators (McGee & Thomas, 1986).

McGee & Thomas (1986) stated that " a firm within a group makes strategic decisions which cannot readily be imitated by firms outside the group without substantial costs, significant elapsed time, or uncertainty about the outcome of those decisions". This statement seems to imply that barriers to entry are high around all groups (Hatten & Hatten, 1987). In other words, it assumes that mobility barriers are symmetric. Hatten & Hatten (1987) suggested that although this assumption may hold in particular industries, it does not hold in all. Accordingly, Hatten & Hatten (1987) introduced the concept of

asymmetrical mobility barriers. Strategic group asymmetry refers to inter-group differences, and the distances between strategic groups are indicated in part by dissimilar mobility barriers heights. The authors argued that barriers to the most profitable markets within an industry are high, whereas those to the less successful markets are low. Large or efficient firms may be able to imitate smaller niche players within their niches at low cost, while it is much more risky and expensive for smaller firms to attack larger industry members directly (Hatten & Hatten, 1987). This asymmetry is confirmed by Caves & Porter (1977) who stated that "entry can be blockaded into one of an industry's strategic groups and easy into another". Thus, when a firm attains an asymmetrical position, it is likely that its market share will increase at the expense of others (Olusoga, Mokwa & Noble 1995). Indeed, Bain (1956) and Oster (1982) have hypothesised that profitability is positively related to the size of the entry barrier.

In stable industry environments, mobility barriers may protect a group's competitive advantage from forces outside the group over long period of time while in highly dynamic environments, effective mobility barriers typically take the form of a series of temporary barriers (Dranove, Peteraf & Shanley, 1998). However, Hatten & Hatten (1987) suggested that belonging to a strategic group whose members enjoy high mobility barriers is not always profitable for a firm. Hatten & Hatten (1987) suggested that high mobility barriers might become traps in changing environments, even for industry leaders. He cited the example of Timex company which faced a real threat when Texas Instruments penetrated the low priced watch industry with a new technology whose costs were lower than Timex's. Timex's competitive strengths as a manufacturing assembler,

an important mobility barrier against traditional watch industry competition, was changed by the outsider into a weakness, and essentially a mobility barrier to exit.

To summarise, mobility barriers preserve profitability differentials for two reasons. First, they inhibit imitation from competitors outside the group, which maintains the imperfectly competitive conditions needed for strategic groups to affect prices and profits (Dranove, Peteraf & Shanley, 1998). Second, mobility barriers delineate the boundaries of the group and increase the stability of the group over time (Dranove, Peteraf & Shanley, 1998).

More recently, Dranove, Peteraf & Shanley (1998) suggested that strategic groups might have a constant effect on profits if and only if there are mobility barriers restraining entry into the group as well as strategic interactions within the group (group-level effect). These strategic interactions alter the conduct of members from what they would be in the absence of the group. Such interactions take various forms including market power, efficiency and differentiation effects. Market power interaction may take the form of explicit collusion within a group to increase prices or restrict output. Efficiency effects may result from strategic alliances among group members to pool production, reap shared economies of scale in manufacturing, and develop new technologies. Finally, the third form of group-level effect on profitability may result from interactions on differentiation. For example, group members may engage in jointly sponsored or congruent advertising that produces synergistic increases in product demand. In addition, firms belonging to the same strategic group may interact to ameliorate their reputation. It should be noticed

however, that these types of interactions are only implications of mobility barriers notion. In fact, Caves & Porter (1977) suggested that firms within a strategic group are sensitive to their interdependency and are likely to react identically to the same stimuli. They added that because their interdependency is easily perceived, tacit agreements among group members develop rapidly, which maintain superior performance and deter entry.

As developed earlier, a central theme in the strategic management literature is that strategic group membership has performance repercussions. However, the empirical findings on this differential performance hypothesis are conflicting. Porter (1979) contrasting the performance of 'leaders' and 'followers' strategic groups stated that leader group outperformed followers. However, the difference found was not statistically significant. Frazier & Howell (1983) found no difference in profitability among strategic groups in the medical supply and equipment industry, while Dess & Davis (1984) concluded that generic strategic groups in the paint and allied products industry differed on some performance indicators while not on others. Similarly, Cool & Schendel (1987) studying the U.S. pharmaceutical industry detected performance differences in terms of market share but differences in profitability between groups were not observed. Johnson & Thomas (1988) found, in the U.K brewing industry, that within-group variations in performance are greater than between-group variations. On the other hand, Oster (1982) found that heavy advertisers outperformed low advertisers in those industries where advertising spending has permanent effects. Similarly, Mascerenhas & Aaker (1989) found that performance differences exist across strategic groups in the oil-drilling industry.

Clearly, there is no consistent, uniform support from empirical studies for a direct strategic group membership→performance relation. However, these findings do not imply that strategic groups have no performance implications at all.

According to Lawless, Bergh & Wilsted (1989), individual firm attributes have been underspecified or missing in previous strategic group studies. Thomas & Venkatraman (1988) proposed that absence of performance differences across groups indicates that more attention should be concentrated on within-group differences in performance and on differential sets of skills and assets of different actors. Porter (1979) suggested that the concept of mobility barriers alone is insufficient to explain performance differences among firms, including companies within the same strategic group. He proposed that potential moderator variables such as market factors, as well as firm-specific factors (risk profiles, scale, asset endowment, and ability to execute a chosen strategy) would enhance performance prediction more than those based on mobility barriers alone.

The emerging resource-based view of the firm intrinsically suggests an explanation for the firm effects on strategies and performance outcomes within the same industry (Mauri & Michaels, 1998). The resource-based view concentrates on firm effects as the foundation for sustainable competitive advantage (Wernerfelt, 1984; Barney, 1991; Petraf, 1993). The proponents of the resource-based view argue that the most important dimension of differences in strategies and performance level among competitors within an industry is the existence of valuable, rare and non-substitutable firm characteristics capable of producing core resources that can provide competitive advantage when

protected from imitation and effective isolating mechanisms (Wernerfelt, 1984; Petraf, 1993; Mauri & Michaels, 1998).

These core resources can be classified as financial, physical, human, technological and organizational (Grant, 1991). They can be refined internally, through sustained investments in hard-to-copy attributes of managers committing to irreversible strategic actions (Mauri & Michaels, 1998). The heterogeneity of firms results in systematic differences in performance within the same industry and probably within the same strategic group (Mauri & Michaels, 1998). Indeed, Lawless, Bergh & Wilsted (1989) suggest that even when firms adopt similar strategies, the idiosyncrasy in their resources (capabilities in their terminology) produces heterogeneous performance outcomes.

Lawless, Bergh & Wilsted (1989) concluded in a multi-industry study that firm's capabilities (defined as the capacity to implement or change strategy), moderate the effect of members' shared strategy characteristics on performance and that it should be taken into account to increase the explanatory power of strategic groups in competitive performance. Additionally, they suggested that the closer a strategic group's strategy fits an individual member's existing capabilities, the greater is the probability for successful implementation and profitability. They also pointed out that individual members might not realize similar returns to the extent that differences exist in their stock of assets. In addition to resource configuration, capability also includes resources in place reflected in actual tangible and intangible assets, like plant, equipment and skilled personnel, with which a firm can implement its strategy and survive market changes (Lawless, Bergh & Wilsted 1989). They also demonstrated, based both on prior instance in the strategy

literature and the logic of capability-strategy fit that financial resources could be accurate indicators of capability. According to Chatterejee & Wernerfelt (1988) a firm's financial position critically affects its ability to invest in new strategies. Therefore, a firm's financial capabilities reflect its ability to grow and to respond to market disturbances (Bettis & Mahajan, 1985). In the short term, a firm's financial assets (cash position and degree of leverage) may have important strategic implications since cash cannot always be raised from external markets without the disclosure of sensitive information to potential investors (Teece, Pisano & Shuen, 1997).

Following this line of thought, it is suggested that the effect of strategic group membership on profitability should be weighed against each member's unique financial capabilities, in particular, firm's sustainable growth capabilities. Sustainable growth is defined by Higgins (1977) as the increase in sales that is consistent with the firm's established financial policies. In other words, firm's sustainable growth capability is the individual firm's potential to create resources to attain a certain sustainable growth. Lawless, Bergh & Wilsted (1989) suggested that if capability differences confound the strategic group membership-performance association, then adding them to the model may clarify persistent intra-group performance differences suggested by previous empirical strategic group studies. Therefore, the following revised model is proposed:

Performance = f (group membership, firm sustainable growth capabilities)

Dependent variable Independent variable + moderator variable

The objective of this study is then to test the model proposed in the pharmaceutical industry context using appropriate strategic group identification, and correct definition of performance and growth capability indicators.

The arguments presented would be tested as follows:

The first hypothesis addresses the assumption of existence of distinct strategic groups in the pharmaceutical industry.

***H1**: Distinct strategic groups exist in the pharmaceutical industry.*

Next, it is essential to determine if there is substantial and continuous within-group variation in sustainable growth capability and performance. If both growth capability and performance variations are found among strategic group members, it can be tested whether there is a relationship between the two. Therefore it can be proposed that:

***H2**: Performance is positively correlated with growth capabilities for members of the same strategic group.*

CHAPTER II STRATEGIC GROUPS IN THE PHARMACEUTICAL INDUSTRY

The World's Pharmaceutical Industry: A Global Map

The pharmaceutical industry is a research-intensive industry composed by a collection of companies that discover, develop, manufacture, and market medicines for the treatment and prevention of human diseases (Spinkler, 1994). The pharmaceutical industry includes both the prescription or ethical industry – which provides products only to the medical profession - and the non-prescription or over-the-counter (OTC) drug industry- which advertises its products directly to the public (Schnee & Caglarcan, 1978). Prescription or ethical drugs constitute by far the most lucrative segment of the industry and accounted for 77.4 percent of the U.S. industry sales in 1996 (IMS Health, 1998). The actual products which fall into this category are determined by national health officials and the purchaser may or may not be reimbursed through the public health care programme (Ballance, Pogany & Forstner, 1992). Non-prescription or over-the-counter (OTC) drugs have a small share of the market but their importance is growing. Because OTCs are used for self-treatment of minor ailments, they must be safe to use without a doctor's advice and supervision.

The pharmaceutical industry is comprised of several markets, which are essentially therapeutic end-use categories. Pharmaceutical preparations for cardiovascular diseases constitute the leading therapeutic category in the developed markets holding an average

market share of 20.4 percent in 1997. Following in second place is alimentary tract and metabolism group with a market share of 16.2 percent and in third position central nervous system with 14.8% of the market (IMS Health, 1998).

The pharmaceutical industry is increasingly multinational in scope. Most major research-based corporations market their products throughout the world. The United States constitute the largest pharmaceutical market in the world accounting for 33.2 percent of worldwide pharmaceutical sales estimated at $296.4 billion in 1996 (IMS Health, 1998). Other major markets include Europe with 29.4 percent and Japan with 17.9 percent (IMS Health, 1998). Thus, more than 80 percent of all pharmaceuticals are sold in developed market economies.

Historically, the centers of global research have been in developed countries that encourage free markets and thus innovation. Approximately 36 percent of pharmaceutical R&D conducted by companies worldwide in 1995 was performed in the United States, followed by Japan with 19 percent of global R&D, Germany (10 percent), France (9 percent), United Kingdom (7 percent) and Switzerland (5 percent) (PhRMA, 1998).

Although there are thousands of pharmaceutical firms worldwide, only a few companies are considered as key players. Of the world's top ten firms by sales in 1995, five are located in the U.S., two in Switzerland, two in the United Kingdom and one in Germany (IMS Health, 1998).

Despite the fact that the pharmaceutical industry shares some attributes with many other high technology industries, it is unique in some other characteristics (Spilker, 1994). The principal factors that distinguish pharmaceutical companies from other companies are essentially the following:

- The long period of time necessary to develop and market a newly discovered drug;
- The extreme degree of risk and uncertainty of a drug's future, even after it is marketed;
- The highly restrictive regulations that rule all aspects of a drug's development, production, and marketing;
- The difficulty to predict at what time the next important drug discovery will happen;
- The significant number of variables and factors intervening in biological experiments, technical development, and particularly clinical trials;
- The perceived value of a drug to stockbrokers and to stockholders in terms of potential profits raises and falls quickly based on information, which may or may not be correct or pertinent to the drug's real value.

The pharmaceutical industry emerges as an industry characterized by vigorous competition at several levels. Data on entry into various therapeutic markets, market share instability, and price flexibility suggests that market rivalry is tremendous (Schnee & Caglarcan 1978). The evidence that supports the view that there is significant competition in the pharmaceutical industry includes:

- Price flexibility on specific products;

- Instability of market share over a period of a few years. The pharmaceutical industry has the second highest rate of market share instability of all industries in the U.S.A. (Schnee & Caglarcan 1978);
- High rates of corporate mergers, buyouts, bankruptcies and licensing arrangements (Spilker, 1994; and Bogner & Thomas, 1996).

In general, the ability to differentiate allows a considerable source of nonprice competition. In pharmaceuticals, competition within narrower therapeutic classes relies on the ability of the firm's sales force to differentiate the firm's products (Bogner & Thomas, 1996). This take place on two levels: multisource drugs and patent-protected drugs.

Typology of pharmaceutical products

The ethical drug market is primarily structured into specialized *innovative* supply and broad-line *generic* supply. Consequently, drugs are generally classified in terms of their market availability, which is a function of each individual product's patent life cycle (James, 1982).

On introduction into the market by global research-driven pharmaceutical companies, a new chemical entity has a period of protection afforded by its patent. Depending upon whether the product has been completely developed by one company or is licensed to or from another company, or is part of a joint research program, the product is available from one firm, *single source*, or two firms, *dual source*.

The market structure of innovative products may in turn be divided into three sub-components, each of which represents a number of strategic opportunities (Spilker, 1994):

1. ***Superior technology***: offer superior social and economic benefits over all existing drugs.
2. ***Marginal technology***: offer some, more limited, advantages over existing technology.
3. ***'Me too'***: similar products, which offer no notable benefits over existing technology.

A generic drug is a product formerly a single or dual source product, which is no longer protected by patent, where the original branded drug is starting to lose market share as a result of increased competition.

The term *multi-source* is utilized to indicate that a drug is available on the lapse of its patent from different sources. Not all drugs become multi-source on the lapse of a patent due to barriers to market entry. The manufacturing process may be difficult or expensive to replicate economically, the FDA may not approve the interchangeability of multi-source drugs on the basis of important pharmacological differences and raw material costs may be high or limited to the original innovator (Spilker 1994).

Multi-source products competing with the original innovator are usually of two types: branded generics and commodity generics (James, 1982):

1. ***Branded generics*** are generally carefully chosen and marketed as a limited line of products at prices below that of original products but above those of commodity

generics. Branded generics reflect an effort by some marketers to differentiate their generic products and create brand loyalty among physicians and pharmacists. To attain this objective, they identify their range of generic products by a common trademarked name followed by the generic name.

2. ***Commodity generics*** are generic drugs sold by different categories of companies at low prices. These companies range from large pharmaceutical firms, to chain drugstores marketing under private labels, to specialty generic drug companies.

It would appear that both 'Me too' and marginal technology are the most vulnerable market areas for the research-intensive pharmaceutical firms to generic competition (Spilker, 1994). Generic competitors operate without large research and development expenses and costs of conducting medical information about the product to the medical community performed by innovative firms (Bogner & Thomas, 1996). Moreover, the Food & Drug Administration (FDA) approval process exempts generics from costly and lengthy clinical trials to prove their safety and efficacy, and allows generic manufacturers to rely on the safety and efficacy of the original branded drug. Generic firms need only to demonstrate that their generic drug is *therapeutically equivalent* to the branded version (Griliches & Cockburn, 1996). This means that after massive investments initiated by the innovative firm associated to discovering, developing and testing a medicine for safety and efficacy, obtaining regulatory approval and informing the medical community about its therapeutic benefits, generic competitors can charge much less for a competing version and still be profitable.

It is important to emphasize that unlike many other commodities, government agencies, such as Food & Drug Administration in United States, certifies generic drugs as being *therapeutically equivalent* to the branded version in their "orange book" publication: Approved Drug Products with Therapeutic Equivalence Evaluation (Griliches & Cockburn, 1996). Therefore, the generic version differs only in packaging, in labeling, and in provenance (Griliches & Cockburn, 1996).

Products certified as "therapeutically equivalent" by the FDA are (Griliches & Cockburn 1996):

1. Pharmaceutically equivalents, meaning that they contain the same active ingredient(s), are of the same dosage form, are identical in strength and route of administration, and meet applicable standards of purity and quality.
2. Bioequivalent, in that in vivo or in vitro tests indicated that a drug fulfils statistical criteria for equivalence to the reference drug in the rate and extent of absorption of the active ingredient and its availability in the site of action.
3. Adequately labeled.
4. Manufactured in compliance with Current Good Manufacturing Practice (GMP) regulations.

Examination of the typology of pharmaceutical products indicates that technology intensive pharmaceutical companies and generic producers pursue different business strategies. These different business strategies suggest that brand name drug companies

face a number of strategic threats and opportunities that are virtually a mirror image of those for generic companies.

Competitive trends in the pharmaceutical industry

Competitive advantage for research-intensive pharmaceutical firms depends principally on their ability to introduce technologically advanced new drugs. (James, 1982). Leading pharmaceutical firms invest massively in research and development, which managers believe is crucial to long-term competitiveness in the pharmaceutical industry. Nowadays, the search for competitive advantage by innovation is being challenged by increasing innovative costs, higher levels of regulatory control and technological complexity (James, 1982). The most recent estimate-by The Boston Consulting Group, (1993)- indicates that the pretax cost of developing a drug introduced in 1990 was US.$500 million, including the cost of research failures as well as interest costs over the entire period of the investment. In contrast, manufacturers of generic products invest far less in research and development than research-based pharmaceutical companies and accordingly are able to price their products significantly lower than branded products. The cost of demonstrating the bioequivalence of a generic product is estimated at $1 million (Barfield & Beltz, 1985). Consequently, upon patent expiration, branded products often confront intense price competition from generic forms of the drug. Moreover, in many countries outside the United States, patent protection is weak or nonexistent (PhRMA, 1998).

A) Reduction in profitable lifetime for drugs

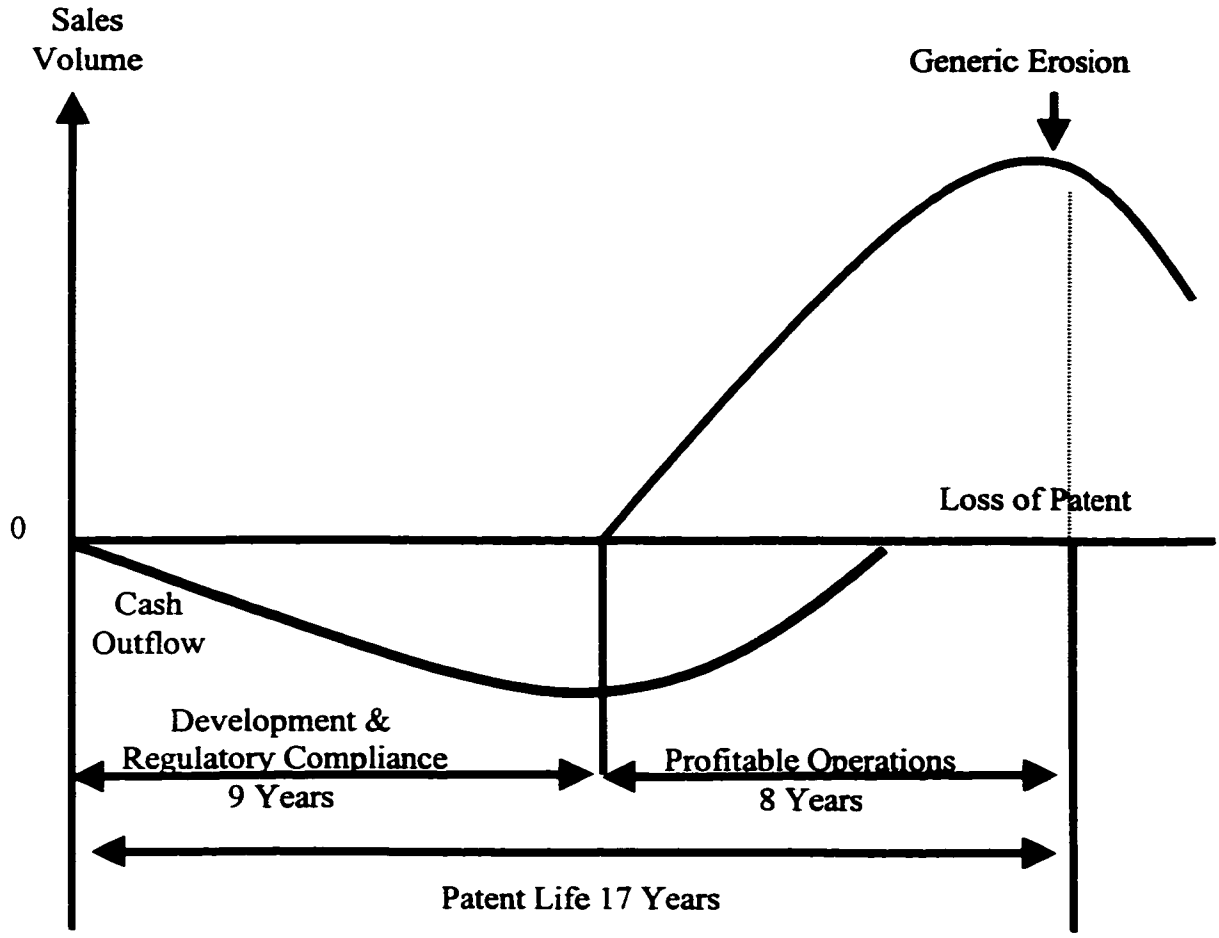
Prior to the repeal of the anti-substitution laws and the decline of barriers to market entry, the research intensive firms could expect considerable sales to continue for a brand name product past the lapse of patents. The only danger for these persisting sales coming from the introduction of higher new technology and/or close substitutes developed and marketed by other innovative companies (James, 1982).

The combined effect of the repeal on the anti-substitution laws and the Drug Price Competition and Patent Term Restoration Act of 1984 (presented in details in page 63) has been the decline in the period of patent protection afforded to brand name innovative products (PhRMA, 1998). Passage of the Drug Price Competition and Patent Term Restoration Act of 1984 allowed quick approval of generic copies of brand name drugs. Although this law increased the time between FDA approval of a drug and patent expiration, it practically eliminated the period separating patent expiration and generic entry into the market (PhRMA, 1998). Consequently, the profitable lifetime for drugs—the time necessary to recoup development costs and set up reserves for future drug development was severely shortened (James, 1982). Time available for research-based drug companies to recoup R&D investment has been reduced to less than 12 years (PhRMA, 1998, see figure1). James (1982) suggests that the most vulnerable brand name products to generic competition are successful ones. This is explained by the already-created large-scale acceptance by physicians. Therefore, volume brand name products are

the most economically attractive to generic producers since they operate with high costs and low margins. Volume sales are then crucial to preserve their viability (James, 1982).

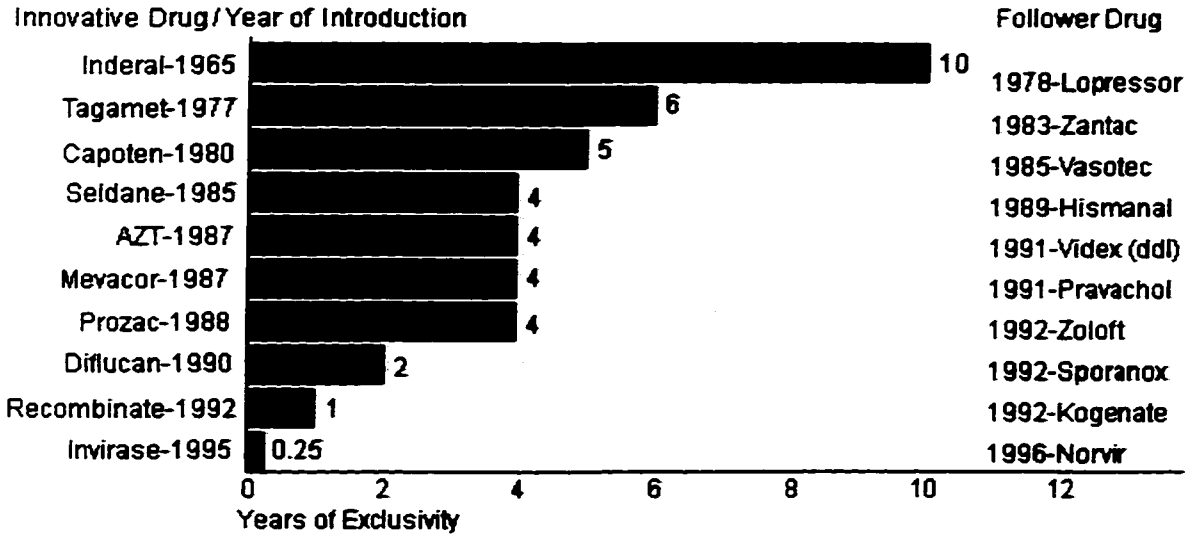
In addition to generic competition, competition coming from new superior technology or close substitutes introduced by another innovative competitors has been significantly increased. This fact is illustrated by the diminishing period during which the first drug in a therapeutic class is the exclusive drug in that class (see figure 2).

Figure 1: The Product Life Cycle for Specialty Drugs
Under conditions of generic substitution, relaxed regulatory compliance and controlled pricing



Source: The marketing of generic drugs (James, 1982).

Figure 2: Diminishing Period of Market exclusivity



Source: PhRMA Industry profile, 1998

In addressing the problem of reduction in the profitable lifetime for drugs, innovative firms have been more or less successful using the following methods (Spilker, 1994):

1. Develop backup drugs: which is a similar chemical structure possessing some benefits over the original drug like fewer dosages per day in order to improve compliance, smaller size capsules to enhance convenience and compliance, any safety improvement, availability in an important, previously unavailable (in the original) dosage form.
2. Develop second generation drug.
3. Develop a new formulation including sustained released capsules or tablets.
4. Create new delivery systems by chemical modifications of physical insertion or dissolution.

5. Develop line extensions: physicians are more likely to recall seeing advertisements that show 20 to 30 dosage forms, dosage strengths, and package size of the brand name than only few dosage strengths and dosage forms of the generic competition.
6. Demonstrate differences between brand and generic products.
7. Switch the product, when it is possible, from prescription to OTC status.
8. Lobby to modify patent laws.
9. Discover a new patentable use for the drug.
10. Develop a rational combination medicine: certain medically rational combinations are preferred by physicians and their patients. A drug whose patent is expiring may be an adequate aspirant for combination development and the resulting combination may be patentable.
11. Secure raw materials: in certain cases, a company may conclude an arrangement with their supplier to acquire all available supplies. This agreement might make it complicated (if not impossible) for a potential generic producer to enter the market and to compete with the brand name product.
12. Increase the standards of technical specifications: certain drugs require a high degree of purity, or narrow technical specifications that are difficult to obtain. Therefore, producers of such drugs generally attempt to raise those specifications. If national pharmacopoeias approve the increased standards, then competitors may be discouraged from entering the market.
13. Reduce prices sufficiently to discourage other producers from entering the market.
14. Exchange exclusivity for profits: in some cases, the patent owner permits generic producers to market the patented product for certain period of time (e.g., six to twelve

months) while the product is still protected by patent. In exchange, the generic company gives a portion of their profits to the patent holder for a longer period of time. The benefit for the generic firms is to attain a large market share during the period of their generic exclusivity.

15. Create a generic company that manufactures exclusively its own previously patented products or additionally of other products as well.

B) The growth of Managed Care Organizations (MCOs)

The growth of Managed Care Organizations (MCOs) has been a major factor in the competitive structure of the health care marketplace. Health maintenance organizations (HMOs) reported 58.8 million members in 1996, up from 33.6 million in 1990 (PhRMA, 1998). MCOs include medical insurance companies, medical plan administrators, health-maintenance organizations, alliances of hospitals and physicians and other physician organizations. It is estimated that more than 90 percent of people registered in HMOs have access to prescription drug advantages (PhRMA industry profile 1998).

In addition to the growing number of enrolled patients, the power of MCOs has increased as a result to their consolidation into fewer and larger entities. Consequently, marketing of prescription drugs to MCOs and to the Pharmacy Benefit Managers (PBMs) that serve many of those organizations has become important to pharmaceutical companies (PhRMA, 1998).

A principal objective of MCOs is to contain and, when possible, reduce health care expenditures. They usually use volume purchases and long-term contracts to negotiate low prices from pharmaceutical and medical device providers. They exercise their purchasing power to bargain for lower supplier prices. In addition, MCOs frequently use a variety of cost-containment techniques particularly for pharmaceutical expenditures.

The widespread use of cost-containment techniques in Managed Care Organizations (MCO) is notable given their growing share of total prescription-drug payments. According to IMS Health, third-party sources- comprising Medicaid, HMOs, and other insurance plans- represented 71 percent of all retail outpatient prescription drugs in 1997, up from 37 percent in 1990 (PhRMA, 1998).

About 90 percent of MCOs develop formularies to reduce their cost for medications and medical devices (PhRMA, 1998). A formulary is a list of prescription drugs authorized for insurance coverage based on the prices and therapeutic advantages of the available drugs. The scope of the products included in formularies can vary notably from one MCO to another, and many formularies include alternative and competitive products for treatment of a specific medical problem. Formularies vary from "open," where both listed and non-listed drugs are reimbursed, to "closed," where only listed drugs are reimbursed (PhRMA, 1998). In 1996, approximately 31 percent of HMOs utilized closed formularies, up from 27 percent in 1995 (Horn & al 1996). Closed formularies may exclude new, more expensive, or experimental drugs regardless of their effectiveness.

Exclusion of a product from a formulary can lead to decreasing usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their products included. Where possible, companies compete for inclusion based upon unique characteristics of their products, such as higher efficacy, better patient ease of use or insignificant side effects. A lower overall cost of therapy is a very important factor. Thus, due to their lower cost, generic drugs are usually favored.

Besides formularies, HMOs also apply other techniques to restrain expenditures on prescription drugs (see figure 3):

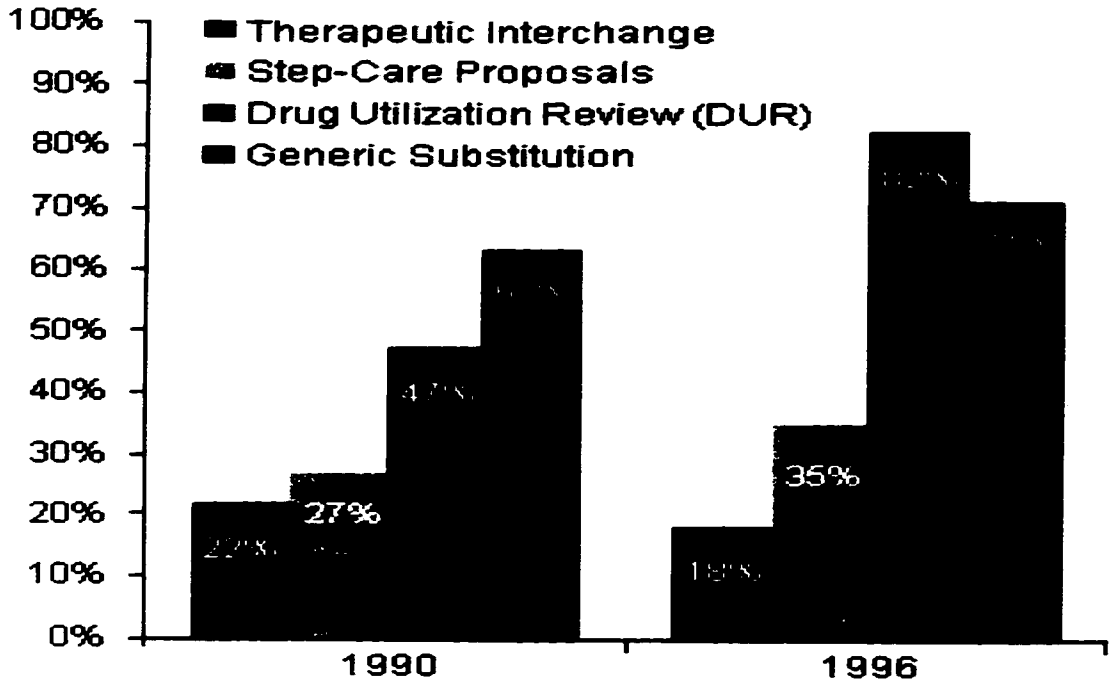
- **Therapeutic Interchange:** This practice consists of giving a different drug having a chemical composition different from the one prescribed. Approximately 18 percent of HMOs use therapeutic interchange in 1998, down from 22 percent in 1990 (PhRMA, 1998).

- **Step-Care Therapy:** This practice implies that physicians pursue a sequence of therapies, generally starting with the lowest-cost treatment and advancing to higher-cost treatments only if prior therapies are not effective. The percentage of HMOs using step-care therapy increased from 27 percent in 1990 to 35 percent in 1996 (PhRMA, 1998).
- **Drug Utilization Review (DUR):** This practice uses retrospective supervision of physicians' prescribing patterns. More than 80 percent of HMOs now require DUR

(PhRMA, 1998). The potential danger of this practice is the continuing focus on cost savings rather quality and patient safety.

- **Generic Substitution:** consists of replacing a brand-name drug with a generic copy. The percentage of HMOs applying generic substitution increased from 63 percent in 1990 to 71 percent in 1996 (PhRMA, 1998).

Figure 3: HMO Plans Utilizing Drug Cost Containment Techniques

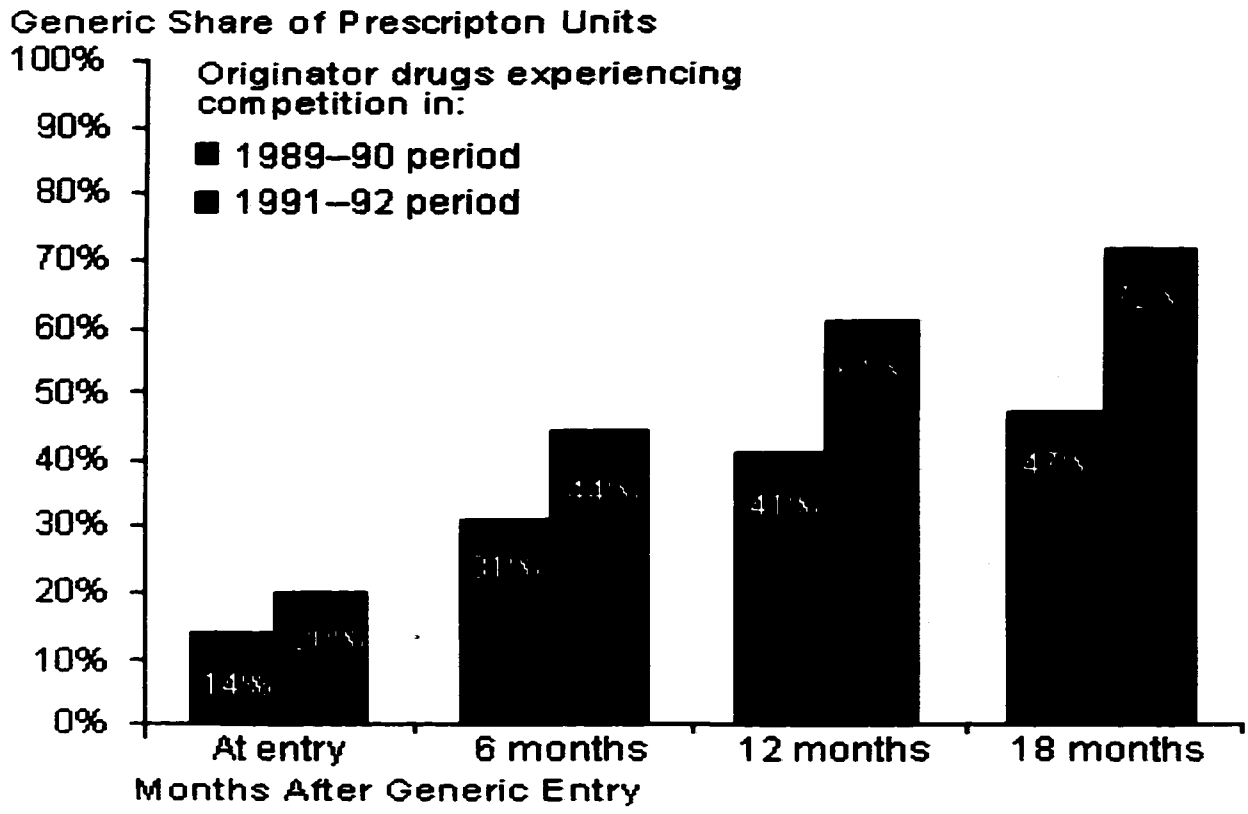


Source: PhRMA Industry Profile, 1998

Frequent utilization of generic substitution by Managed Care Organizations generated faster market share erosion for originator drugs once their patents expire. Generic drugs market share increases from 47 percent 18 months after patent expiration of originator drug in the 1989-1990 period to 72 percent of prescriptions in the 1991-1992 period (PhRMA, 1998, see figure 4). Generic drugs increased their share of the U.S. prescription

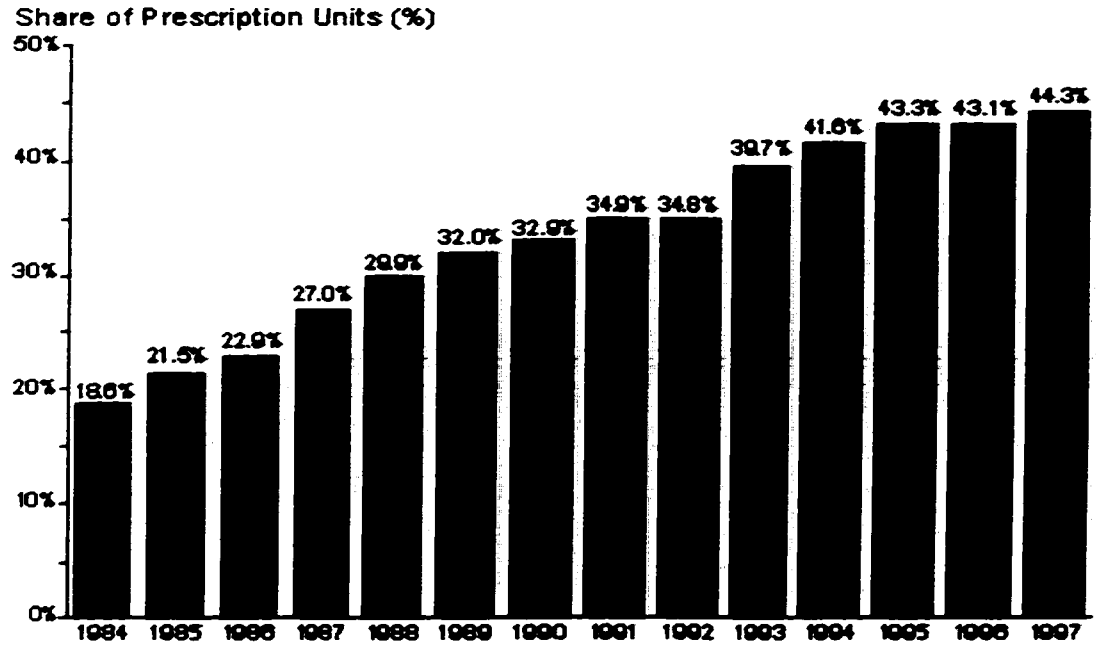
market from 18.6 percent at the end of 1984 to 44.3 percent in 1997 (PhRMA, 1998, see figure 5). The large number of innovator products losing patent protection over the next 10 years will foster robust growth in the generics industry (IMS Health, 1998).

Figure 4: New Pioneer Drugs Face Increasing Rapid Growth of Generic Competition



Source: PhRMA Industry Profile, 1998

Figure 5: Generics' Share of U.S. Prescription Drug Market, 1984-1997



Source: PhRMA Industry Profile, 1998

The retail generics markets are growing in the top 10 countries on average, at a rate almost double that of the total retail sector (IMS Health, 1998). This growth is driven primarily by five factors:

1. The future commercialization of generic versions of drugs with patents that (i) have already expired or (ii) will expire over the next several years. Through the year ending 2002, about 120 molecules including the "blockbusters" Omeprazole, Enalapril and Fluoxetine, with sales of US$15 billion in 1998, face patent expiration in many of their major markets (IMS Health, 1998);
2. Modification of certain state laws allowing and/or requesting pharmacists to substitute generics for brand-name drugs;

3. Increased acceptance of generic drugs by physicians, pharmacists, and consumers;
4. Pressure from government, managed care and third party payers to encourage health care providers and consumers to contain costs;
5. The enactment of abbreviated procedures for obtaining FDA approval to manufacture off-patent prescription drugs.

C) The New Frontiers of Biomedical Research

Despite a number of challenges to their business environment, the research-intensive pharmaceutical firms face a major opportunity. In fact, there are a number of emerging areas of technology – such as biotechnology - which offer valuable future opportunities for the technology-intensive pharmaceutical firms. Scientific progress in biochemistry, molecular biology, cell biology, immunology, genetics, and information technology is metamorphosing the process of drug discovery and development. Substantial interaction between modern biological science and modern information technology generated valuable information about the underlying causes of disease, the fashions in which drugs act, and how to originate new therapies (PhRMA, 1998).

The United States Congress Office of Technology Assessment (1991) defined biotechnology as "any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses". It should be noticed that drugs produced through this process are not really New Molecular Entities (NMEs) since they are generally identical, or very similar, to

substances that occur naturally in the body (Ballance et al, 1992). Among other uses, new genetic technology is being used to develop vaccines preventing or treating diseases that have escaped traditional vaccines, such as AIDS, malaria, tuberculosis, and cervical cancer (PhRMA, 1998).

Between 1973 and 1993 about 1500 companies have been founded worldwide (approximately 900 in the United States) to focus on biotechnology techniques and methods (Spinkler, 1994). The Food and Drug Administration (FDA) have approved more than 50 new marketed biological therapeutics and vaccines (PhRMA, 1998). These medicines produced through biotechnology have been already used by more than 60 million patients (PhRMA, 1998). Approximately, 350 biotechnology medicines created by 140 pharmaceutical and biotechnology companies are in human clinical trials or at the FDA for approval for diseases like AIDS, cancer, diabetes, multiple sclerosis, hepatitis, Parkinson's disease, heart attack and many other diseases (PhRMA, 1998).

Approximately all biotechnology firms were founded at an early stage of product development as joint ventures between academic centers, venture capital entrepreneurs and / or integrated pharmaceutical firms (Ballance et al, 1992). Biotechnology firms typically sustain operational losses at early stages of operation since their research expenditures exceed revenues earned from royalties. Once their distinctive product is approved in major markets, they become targets for acquisitions. As a result, an important number of biotechnology firms are increasing their integration with global-research driven firms in the pharmaceutical industry (Ballance et al, 1992).

Due to the difference in size between biotechnology and pharmaceutical companies, a metaphor utilized to contrast them is that of a large ocean going vessel and a small high-powered speedboat. Although the difference in size, power and resources are obvious, the smaller vessel can move ahead rapidly, change directions more easily, and is often more fun for those aboard (Spinkler, 1994).

In addition to advances in science, changes in government regulations are the two most substantial factors to influence the discovery and development of medicines since the Second World War (Spinkler, 1994). Many regulations have affected medicine development but two of the most important are the 1938, Food, Drug and Cosmetic act, which mandated that medicines must be safe, and the 1962 Kefauver-Harris amendments to the 1938 act. A description of the latter amendment and more precisely its multiple effect exerted on the industry's innovative and marketing activities and on the industry's structure follows.

Influence of regulations on medicine discovery and development

The 1962 Kefauver-Harris amendments raised the standards for approval of new medicines, particularly in terms of their efficacy. These amendments included primarily the following key features (Thomas, 1996):

1. *Proof of effectiveness*: new drugs had to demonstrate significant proof of effectiveness for indicated uses. Only safety had to be demonstrated before 1962.
2. *Clinical testing:* FDA authority was enlarged to cover pre-market testing in humans, no such requirements existed before 1962.
3. *Good manufacturing practice:* the FDA was authorized to establish and control minimum standards for the operation of pharmaceutical research and manufacturing facilities in the USA. No such standards existed before 1962.

As a result of these amendments, certain ineffective and partially effective drugs were removed from the market.

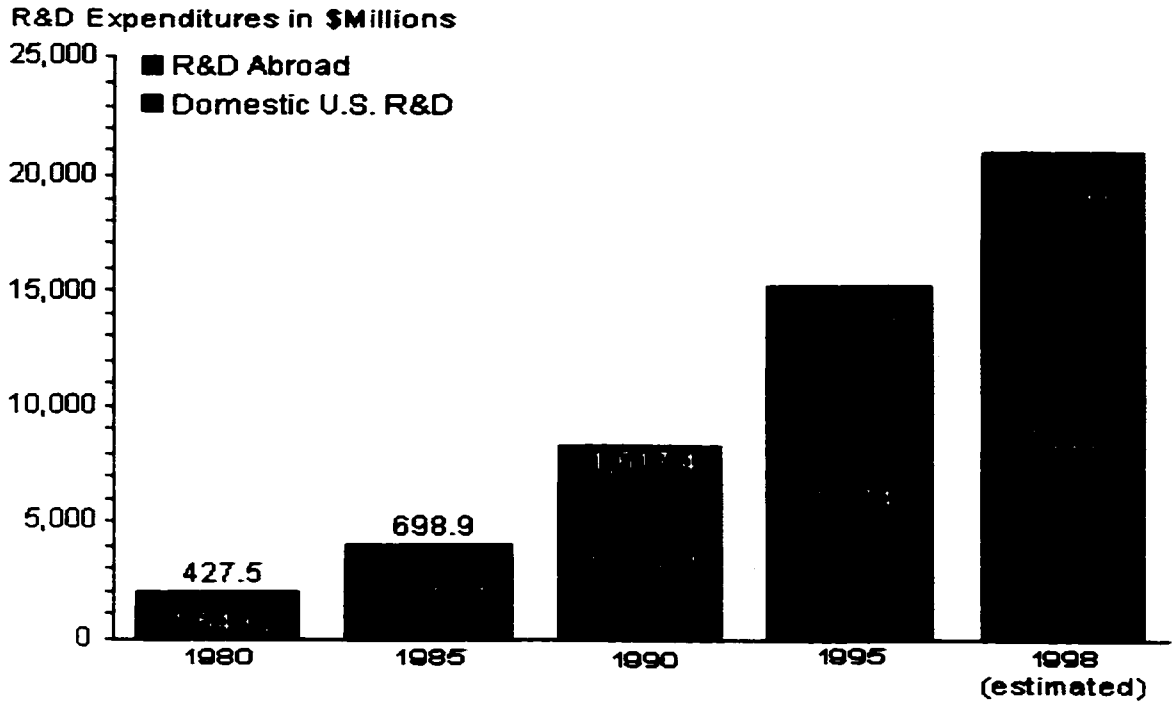
The effects of the 1962 Kefauver-Harris Amendment were both short and long term on the US pharmaceutical industry. The new regulation has produced a multiple effect on the industry's innovative and marketing activities and on the industry's structure.

A) Increased costs of innovation

Food and Drug Administration regulations have required many more pre-marketing tests to be conducted than previously (Spilker, 1989). Good Laboratory Practices and Good Manufacturing Practices regulations have also increased the costs of bringing a new medicine to market. A significant portion of the cost increase was directly connected to the expenses incurred in satisfying regulatory requirements and the long time incurred between submitting product information and release for product marketing.

In 1971, the members of the pharmaceutical manufacturers association spent about 360 million dollars on research and development (Henderson & Cockburn, 1996). In 1998 they will invest $21.1 billion in R&D, an increase of over 57000 percent (PhRMA, 1998). These expenditures consist of $17.2 billion spent within the United States by both U.S.-owned and foreign-owned companies, plus an additional $3.9 billion spent abroad by U.S.-owned firms. Since 1990, technology-intensive companies have increased their R&D expenditures by more than 100 percent (see figure 6). It should be stressed that pharmaceutical firms themselves finance a high proportion of these R&D expenditures.

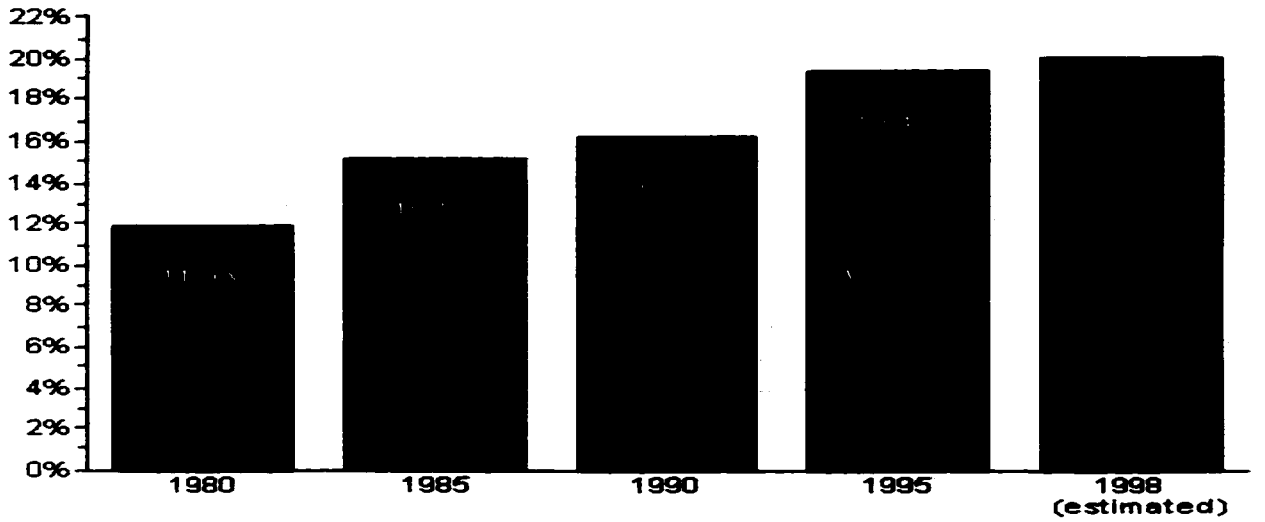
Figure 6: R&D Expenditures on Ethical Pharmaceuticals by Research-Based Pharmaceutical Firms, 1980-1998.



Source, PhRMA Industry Profile, 1998.

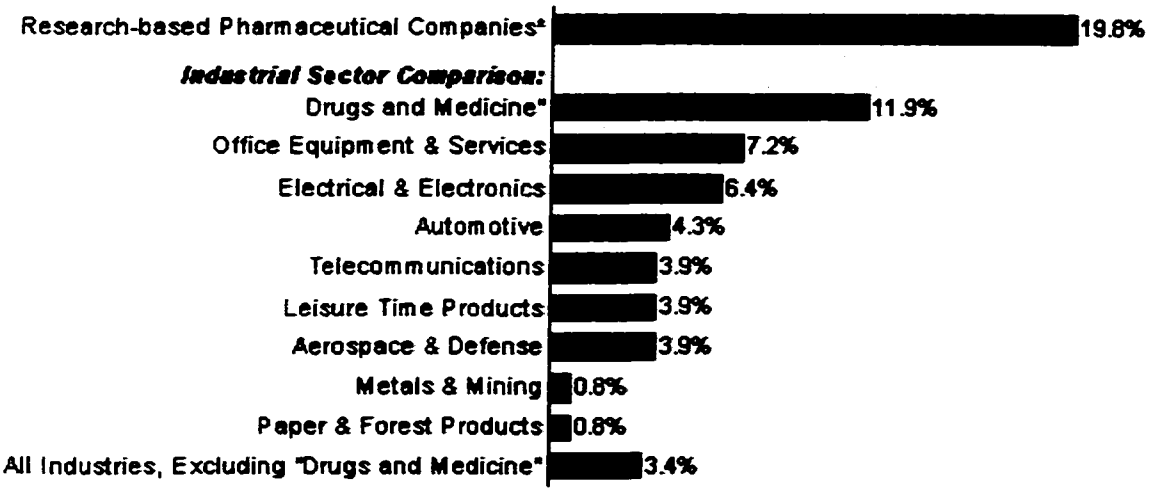
Over the past two decades, the percentage of sales spent in R&D has increased from 11.9 percent in 1980 to approximately 20 percent in 1998 (see figure 7). This level is almost six times greater than the 3.4 percent level for US industry as a whole (see figure 8). Based on corporate tax data collected by Standard & Poor's Compustat, pharmaceutical manufacturers invest a higher proportion of sales in R&D than virtually any other industry, including high-tech industries such as electronics, aerospace, office equipment (including computers), and automobiles.

Figure 7: R&D as a Percent of Sales, Research-Based Pharmaceutical Firms, 1980-1998.



Source: PhRMA Industry Profile, 1998.

Figure 8: R&D as a Percent of Sales for Research-Based Pharmaceutical companies and U.S. Industrial Sectors, 1996.



*"Research-based Pharmaceutical Companies" based on ethical pharmaceuticals sales and ethical pharmaceuticals sales and ethical pharmaceuticals R&D only as tabulated by PhRMA. "Drugs and category based on total R&D and sales for companies classified within the "Drugs and Medicine" sector as tabulated by Standard & Poor's Compustat, a division of McGraw-Hill.

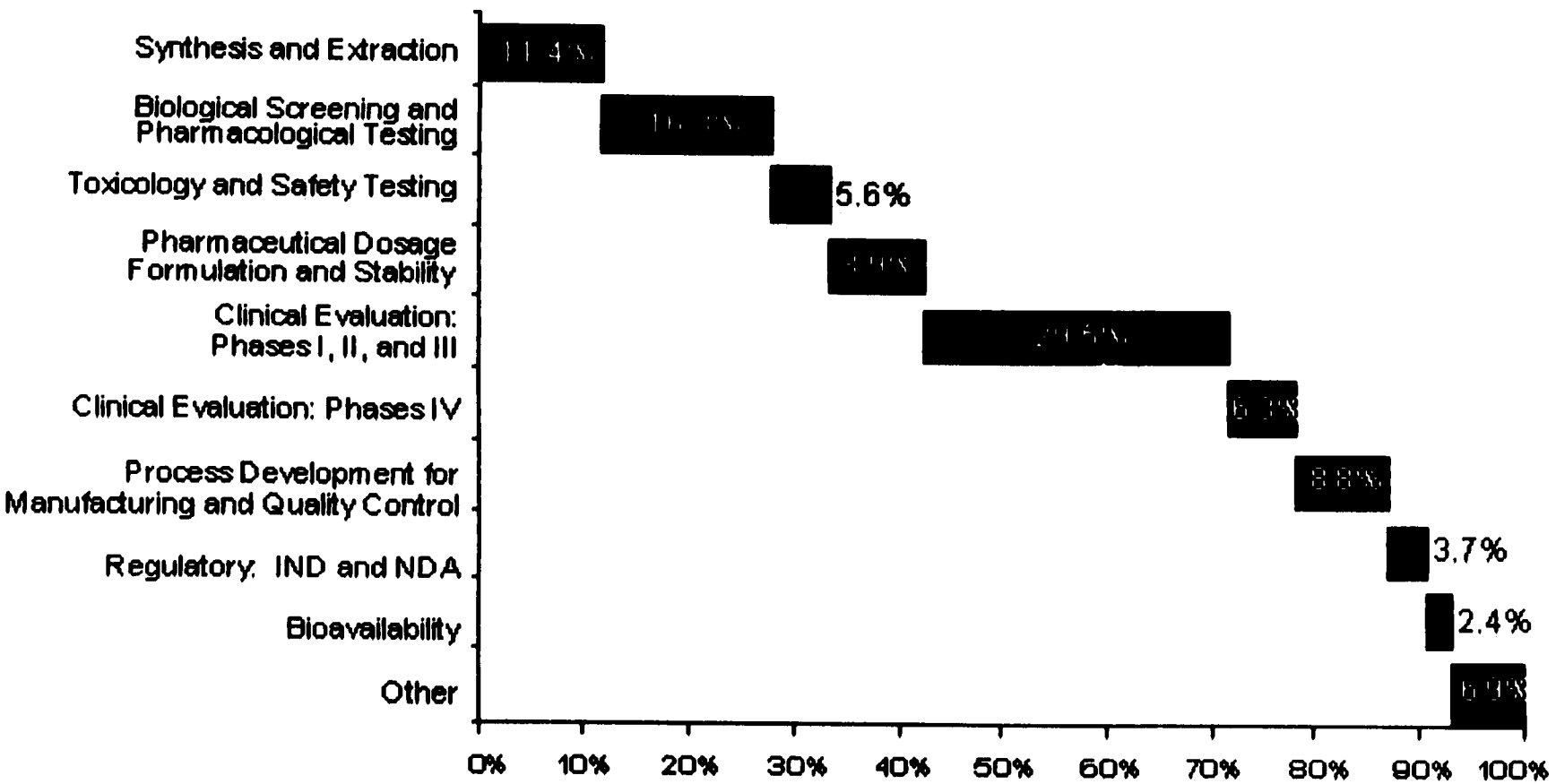
Schwartzman estimated the 1960 cost of developing a new chemical entity at $1.3 million (Schwartzman, 1976). Following the Kefauver-Harris Amendment, this cost increased to $69.8 million in 1979 and $126 million in early 1980s (James 1982; Henderson & Cockburn, 1996). The most recent estimate—by The Boston Consulting Group—shows that the pretax cost of developing a drug introduced in 1990 was $500 million, including the cost of research failures as well as interest costs over the entire period of the investment.

In 1996, more than one-third (US$ 6 billion) of R&D expenses in the United States was allocated to evaluation of promising drug compounds in human clinical trial (PhRMA, 1998, see figure 9). Phase I, II, and III trials, essential for drug approval, represented 30 percent (US$5 billion) of R&D expenses. An additional 6 percent (US$1 billion) of R&D was devoted to Phase IV clinical trials, which may occur after the product has been

approved by the FDA. In addition, strict manufacturing standards necessitated nearly 9 percent (US$ 1.6 billion) of R&D for process development and quality control functions (PhRMA, 1998). As a comparison, the cost of regulatory approval was 0.3-0.4 million in 1960 and 4-5 million in 1970. (Hughes & al, 1980).

Regulations, however, represent only one of many other factors that have generated the higher prices charged for drugs. Inflationary trends (increasing costs for laboratory equipment, clinical trials, and staff salaries) and technological complexity are also important factors (James 1984).

Figure 9: Allocation of Domestic U.S. R&D by Function, 1996



Note: Totals may not add exactly due to rounding. R&D functions are not exactly sequential in practice.

Source: PhRMA Industry Profile, 1998

B) Increased time to bring a new product to market

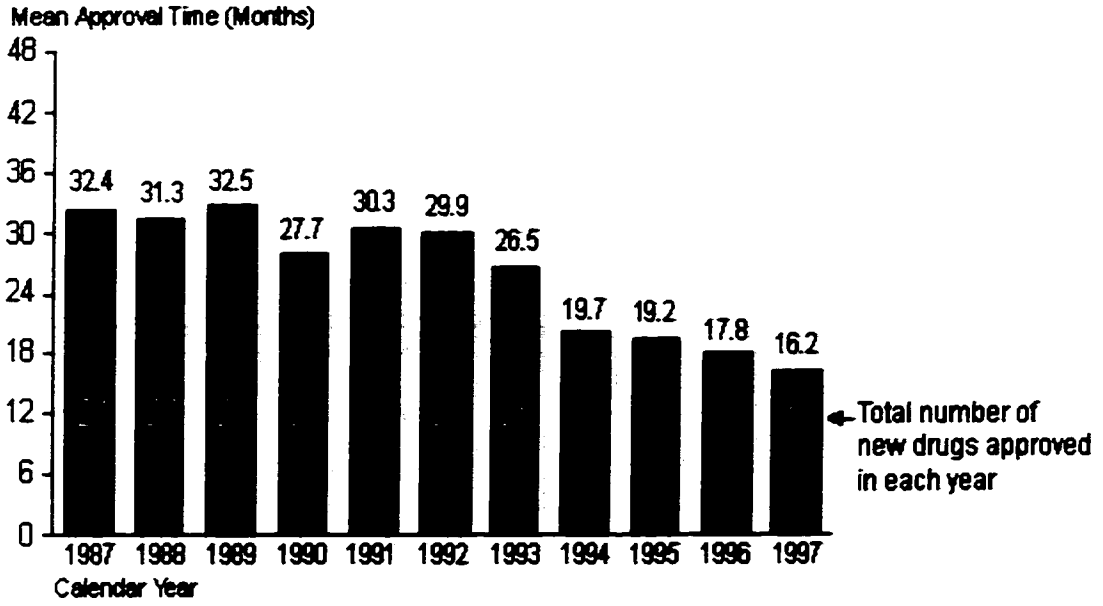
In addition to stringent regulations, the drug discovery and development process is lengthy, complex, and particularly uncertain. It is estimated that of the 5,000-10,000 chemically synthesized molecules screened only one gets the approval from the FDA. According to data gathered by the Tufts Center for the Study of Drug Development and published in PhRMA industry profile 1998, only 18.3 percent of the drugs that entered clinical trials during 1980-1984 are now marketed and a total of 23.5 percent are expected to be approved for marketing.

Clinical trials involve three phases. In Phase I, safety studies are performed on 20 to 100 healthy volunteers. Potential side effects are detected, and a dosage range is determined. Phase II trials are useful to determine the effectiveness of a drug. Generally 100 to 300 volunteers who have the targeted disease participate in these trials. Phase III involves 1,000 to 5,000 patients (in some cases many thousands more) in clinics and hospitals. They are particularly monitored to assess a drug's efficacy and safety (PhRMA, 1998).

If the data produced by these trials confirm safety and efficacy, a company submits a New Drug Application (NDA) to the FDA including all the scientific information the company has collected. One NDA typically includes more than 100,000 pages (PhRMA,1998).

The FDA has been progressing toward attaining the statutory six-month period for New Drug Application (NDA) review. The average review time for NDAs approved decreased substantially in the past five years (PhRMA,1998, see figure 10).

Figure 10: Mean Approval Times for New Drugs, 1987-1997.

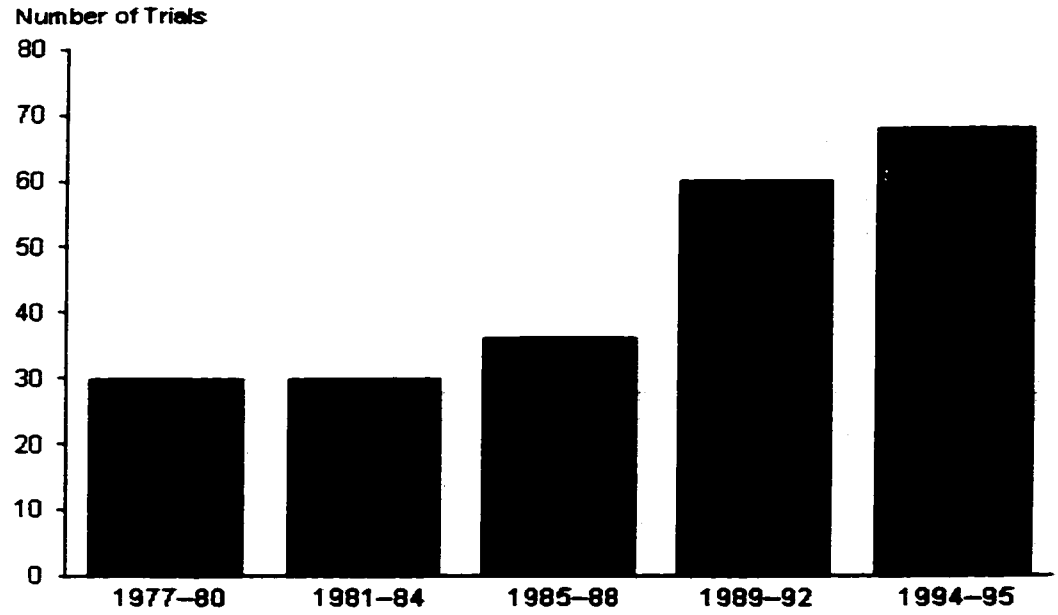


Source: PhRMA Industry Profile, 1998.

Average time required for development of a new drug was 8.1 years in the 1960s, 11.6 years in the 1970s, 14.2 years in the 1980s, and 14.9 years for drugs approved from 1990 through 1996 (PhRMA, 1998). According to the Tufts Center for Drug Development, a substantial proportion of this increase is related to longer clinical phase of drug development (PhRMA, 1998).

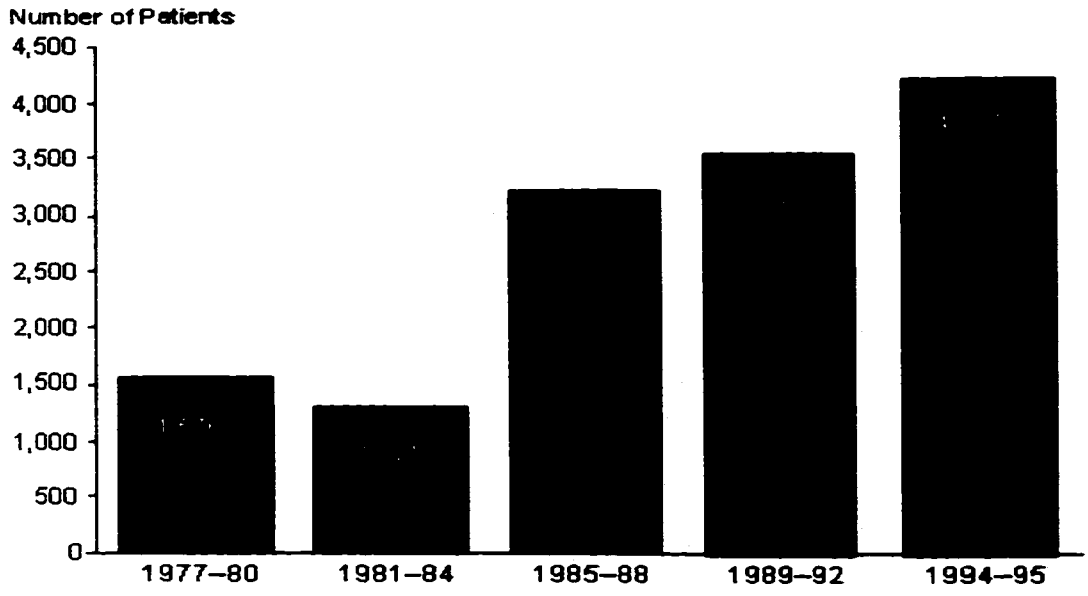
A meaningful measure of intensifying rigorous standards is the increase in the number of clinical trials per drug. Indeed, the average number of clinical trials conducted prior to filing a new drug application has increased significantly over the last decade (PhRMA, 1998, see figure 11). Similarly, the number of patients in clinical trials per NDA has increased substantially (PhRMA, 1998, see figure 12).

Figure 11: Average Number of Clinical Trials per New Drug Application



Source: Boston Consulting Group, 1993.

Figure 12: Each New Drug Application Requires More Patients



Source: Boston Consulting Group, 1993.

According to the Tufts Center for the Study of Drug Development other factors that have favored the increase in development times include:

- Pre-clinical and clinical studies are frequently designed to simultaneously satisfy standards in multiple countries. This practice may decrease global time to marketing approval, but it may also increase clinical development time.
- Increasing complexity of new products discovered is leading to longer development times.
- Increased importance of pharmacoeconomic and market-oriented analysis in the pre-registration phase is justified by the need to prove the cost-effectiveness of new drugs over existing therapies.

In 1997, the FDA Modernization Act extending the 1992 Prescription Drug User Fee Act was passed. Pharmaceutical firms agreed to pay $327 million during 1993-1997 to enable the FDA to hire 600 additional reviewers and ameliorate the drug approval process (PhRMA, 1998). Under the user-fee law, drug approval times decreased by 50 percent over the past five years. It is estimated that more than 11 million Americans were treated by a drug in 1997 that would not have been made available in that time frame without user fees (PhRMA, 1998).

Over the next five years, pharmaceutical firms will pay an estimated $550 million in user fees in order to reduce further approval times (PhRMA, 1998).

As a result of these stringent regulations, pharmaceutical firms spend more time performing research and development than any other industry, including high-tech industries such as electronics, aerospace, office equipment (including computers), and automobiles (Clarkson 1996, see table 2).

Table 2: Accumulation periods for basic research and for development by industry in 1993

Industry	Basic research accumulation	Development accumulation
Pharmaceuticals	11	8
Petroleum	8	5
Paper and allied products	7	4
Industrial/other chemicals	7	4
Rubber products	7	4
Ferrous metals	7	4
Aerospace	7	4
Food and kindred products	6	3
Engines	6	3
Office machines and computers	6	3
Electronic machinery	6	3
Motor vehicles	6	3
Computer software	6	3
Entertainment	5	2

Source: Clarckson, 1996

C) Reduced rate of new drug introduction

On the one hand, the cost of research & development in the pharmaceutical industry has increased dramatically as a result of 1962 amendments to Food, Drug, and Cosmetic act. On the other hand, the development time for new chemical entities has also augmented. Both effects have combined to reduce notably the output of new drugs. A comparison of the rate of introduction of New Molecular Entities (NMEs) since 1961 confirms the persisting decline (see table 3).

Table 3: Country of discovery of New Molecular Entities (NMEs) marketed worldwide, 1960-1990

Period	Total number of NMEs	US	W.Europe	Japan	E.Europe	Other countries
1961-1970	844	201	509	80	49	5
1971-1980	665	152	375	75	58	5
1981-1990	506	117	243	126	10	10
Total	2015	470	1127	281	117	20
Percentage	100	23.3	55.9	13.9	5.8	1

Source: Ballance & al (1992).

D) Reduced patent life

Effective worldwide patent protection is fundamental to stimulate pharmaceutical innovation. The US patent Law provides inventors with protection from unauthorized use of their patented inventions for a period of 17 years (James, 1982). There are three types

of patents applicable to pharmaceuticals: product, use and process. The most effective and familiar form of patenting is the product since this claims as invention the chemical formula of the drug (Spinkler, 1994). By protecting intellectual property, patents enable pharmaceutical firms a period of market exclusivity necessary to recuperate their huge investments and provide them with the cash flow necessary to develop the next generation of drugs. Without patent protection, it is highly unlikely that a company would be rewarded for its invention. This is confirmed by a survey based on a random sample of 100 U.S. firms in different industries (PhRMA, 1998). Drug firms argued that 65 percent of their medicines would not have been developed or commercially introduced without patent protection (PhRMA, 1998). This proportion is greater than any other industry (see table 4). In other industries, scientific advances are in certain cases difficult and costly to copy. In other cases, firms utilize trade secrets rather than patents to compete in an environment of accelerated technological change (PhRMA, 1998).

Unlike most other patented products, innovative drugs must demonstrate safety and effectiveness before they can be approved. In contrast, generic copiers of innovative drugs do not generate clinical data demonstrating the safety and effectiveness of their products. Generic producers have only to refer to the innovator's data and prove bioequivalence. The estimated cost of developing a new drug was $359 million in pretax 1990 dollars for drugs that first entered human testing in the period 1970-1982 (Office of Technology Assessment in 1993). This cost has increased to $500 million for drugs introduced in 1990 (Boston Consulting Group, 1993). In contrast, the cost of

demonstrating the bioequivalence of a generic drug is presently estimated at approximately $1 million (PhRMA, 1998).

Table 4: Influence of patent protection on innovation

Industry	Percent of products that would not have been introduced	Percent of products that would not have been developed
Pharmaceuticals	65	60
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Fabricated Metal Products	12	12
Primary Metals	8	1
Electrical Equipment	4	11
Instruments	1	1
Office Equipment	0	0
Motor Vehicles	0	0
Rubber	0	0
Textiles	0	0

Source: PhRMA Industry Profile, 1998.

Since the patent life varies from compound to compound in relation to the time within the development cycle that the patent was granted, the average patent life fluctuate.

The average effective drug patent life was almost the full 17 years in 1950 (James, 1982). By 1963, the patent life was still around 16 years (James, 1982). The decline in patent life for drugs accelerated from 1963 and was estimated to be at 9.6 years in 1977 (James, 1982). The average period of effective patent life for new drugs introduced in the 1990s has been 11-12 years (PhRMA, 1998). In other industries, innovators typically secure 18.5 years of effective patent protection (PhRMA, 1998). The increase in the average period of effective patent life between 1970s and 1990s is attributable to the Patent Term Restoration Act of 1984.

The Drug Price Competition and Patent Term Restoration Act passed in October 1984 substantially modified the U.S. pharmaceutical market. Under the law, innovator drugs have been allowed market exclusivity for restricted periods of time. In addition, they received restoration of some of their patent periods lost as a result of FDA review. At the same time, generic drugs were granted accelerated approval by being authorized, after a certain period, to use the safety and efficacy data developed by the originator.

The Drug Price Competition and Patent Term Restoration Act instituted the Abbreviated New Drug Application (ANDA), under which a generic is required to prove that it is "bioequivalent" to the innovative drug. A bioequivalent generic drug will then be approved after expiration of the innovator's patent and market exclusivity. A generic applicant is required to justify one of the following conditions in its Abbreviated New Drug Application ANDA (PhRMA, 1998):

- Patent information on the drug has not been filed,
- The original patent has expired,
- The patent will expire on a specific date, or
- The patent is invalid or will not be violated by the manufacture, use, or sale of the new medicine for which the application is submitted.

The Drug Price Competition and Patent Term Restoration Act also established the current five-year provision of data exclusivity for innovator drugs. This period is ten years in many European countries like the U.K. and Germany (PhRMA, 1998). Consequently, generic producers are allowed to submit an application to the FDA only five years after a pioneer drug has been approved. For new indications for existing drugs, the data exclusivity period is reduced to three years and a generic application may be approved only after expiration of the exclusivity period. Many other governments adopted similar measures to extend the advantages allowed to patent holders (PhRMA, 1998).

Although a generic version of an innovative drug may not be labeled with the new therapeutic indication during the three-year period, physicians and pharmacists may be able to dispense the generic for the new indication. This significantly reduces the efficiency of the three-year data exclusivity (PhRMA, 1998).

Certain countries, particularly Argentina, India, Egypt, and South Africa freely copy (pirate) innovative drugs that are protected by a patent in the United States and other countries without remunerating patent holders. It is estimates that U.S. firms lose $1 to piracy for every $3 worth of products shipped overseas (The Congressional Research Service, 1993).

In 1995, the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) has approved and harmonized internationally patent rights. In particular, TRIPs adjusted the patent term to 20 years from the filing of the patent application (PhRMA, 1998).

Why should we expect existence of strategic groups in the pharmaceutical industry?

The existence of mobility barriers that deter movement between strategic groups because of substantial cost, significant lapses of time, or uncertainty about the outcome is fundamental in strategic groups analysis. Accordingly, the selection of the industry to be studied should be thoroughly guided by the existence of these mobility barriers. The pharmaceutical industry emerges as an appropriate environment for this analysis for three principal reasons. First, changes in government regulations significantly influenced the pharmaceutical industry's innovative and marketing activities by increasing the minimum effective size necessary to maintain a solid presence over time in the research oriented side of the industry (see table 5). It is argued that this increase in minimum effective size erected major mobility barriers in the pharmaceutical industry. Second, various forms of strategic interactions among strategic group members are detected in the pharmaceutical industry. These strategic interactions constitute a necessary condition for the validity of strategic groups (Dranove, Peteraf & Shanley, 1998). Finally, several dynamic longitudinal studies have identified distinct strategic groups in the pharmaceutical industry (Cool & Schendel, 1987; Fiegenbaum, Sudharsan & Thomas, 1987, 1990; Cool & Schendel, 1988; Cool & Dierickx, 1993; Veliath & Ferris, 1997). Given, the new competitive trends in the pharmaceutical industry developed above, particularly the

emergence of generic and biotechnology firms, it is unlikely that these groups have merged into a single group during the period studied (1995-1997).

Table 5: General comparison of multinational pharmaceutical companies in the 1950s and 1960s versus the 1990s.

	1950s to early 1960	1990s
Number of pharmaceutical firms	Many	Fewer and larger
Number of biotechnology firms	None	Many
Costs of pre-clinical research	Modest	Much higher
Competition	Modest	More intense
Regulatory requirements	Modest	More sophisticated
Time to develop medicines	Two or three years	Eight to twelve years

Source: Spinkler (1994)

A) Increase in the minimum effective size

As a result of the 1962 Kefauver-Harris Amendments, entry into the research oriented side of the industry, became more difficult due to the high cost of R&D and marketing, both in terms of time and investment. In fact, the number of pharmaceutical firms engaged in innovation declined and innovative activity became more concentrated. The number of companies participating in innovation decreased from 108 immediately prior to the 1962 amendments to 33 in 1972 (James, 1982). It is clear that this number has

decreased since 1972 because of the high number of mergers that occurred in the pharmaceutical industry.

This innovative concentration may be explained by the increase in the minimum effective size, which reduced the number of firms that the research oriented side of the industry could sustain (Bogner & Thomas, 1996).

Bogner & Thomas (1996) suggested that the costs and risks related to gaining economies of scope and scale in R&D and promotion influence the number of research oriented companies in the pharmaceutical industry. As developed in the previous sections, the major factor influencing both costs and risk of discovering a new drug is the long procedure. As a result, research driven pharmaceutical firms react through balancing their research portfolios (Bogner & Thomas, 1996). A broader R&D scope not only yields more research projects within a particular therapeutic class, but also stimulates research diversity across therapeutic classes.

By attempting to reduce market risk through pursuing a broader R&D scope, pharmaceutical firms face a major constraint. In fact, these firms aspiring to increase the likelihood of launching successful new drugs with some degree of regularity will need quite large sums to finance their R&D. Consequently, a large firm having the same R&D to sales ratio as a smaller firm can seek a greater number of potential products. This gives a scope advantage for the large firm in risk-return analysis (Bogner & Thomas, 1996). The more diversified a research scope, the greater the probability of a new successful

drug appearing with regularity. This new 'blockbuster' will in turn pursue funding the research function. The risk of a catastrophic lag in the pipeline of new drugs is, thus extremely attenuated, even if regulatory process remain long (Bogner & Thomas, 1996). This is confirmed by the recent wave of mergers in the pharmaceutical industry. A frequently advanced reason for merger is the limited breadth of the research scope of one or both of the merger partners (Bogner & Thomas, 1996).

Prior to the 1962 Amendment, studies suggested that the largest pharmaceutical companies did not market a larger proportion of drug innovations nor did they spend more on R&D in relation to their sales than did the smaller firms (James, 1982). Following the 1962 amendment, Vernon & Gusen (1974) concluded that the larger firms surpassed, in terms of new product innovations, the smaller firms between 1965-1970. Similarly, Schwartzman's (1976) study of the 1965-1970 period reached the same results. The 1962 amendments granted an advantage to the larger companies who were better able to finance the costs related to increased R&D complexity, inflation and regulatory activity (Schnee, 1979). An examination of data from twenty-six international firms for the years 1987 through 1989 revealed also that firm size is an important determinant of R&D productivity (Alexander, 1996).

Alexander (1996) suggested that larger companies are more diversified in the R&D process and, hence, profit more from the specialization of R&D personnel in several different therapeutic classes. He added that R&D personnel in larger companies attain higher levels of productivity because they have access to more resources.

A similar scope economy impacting minimum effective firm size also affects marketing and promotion of products (Bogner & Thomas, 1996). Like R&D, a given spending ratio allows larger companies to more effectively configure their sales force and ameliorate the company's image than smaller firms (Bogner & Thomas, 1996).

Improving a pharmaceutical company's image is important both internally and externally because (Spilker, 1994):

- Many physicians prescribe certain drugs based (at least in part) on the reputation and image of the company that market them.
- The firm's symbol may project a positive image and promote positive values (e.g., promoting health).
- The firm's history and tradition of emphasizing basic research or developing important orphan medicines treating rare diseases may attract the most valuable workers.
- Regulatory authorities may have positive opinions on a firm based on its willingness to elaborate a portfolio of medically important but commercially unattractive drugs.

The economies of scope in R&D and marketing make minimum effective size important. In the short term, a firm entering the pharmaceutical industry with a single product protected by a patent may earn important returns. However, without the large scope in research and marketing of the larger companies, this position is fragile (Bogner & Thomas, 1996). The low probability of discovering a new successful drug, the threats of competitive new drugs from other research companies, and the effect of powerful competitive marketing all associated make the narrowly based companies susceptible to

failure. Therefore, Bogner & Thomas (1996) define minimum effective size as the size necessary to maintain a solid presence over time as early patents expire or competitive substitutes enter the market.

Minimum effective size has therefore become larger than entry size (the size necessary to generate a single product or group of products). According to Bogner & Thomas (1996) these two levels of minimum size are better illustrated in the case of biotechnology firms. Biotechnology firms are facing serious problems sustaining their research programs. Bogner & Thomas (1996) argued that these firms pass the first obstacle, often without a viable product, but not the second. As an example, Genentech, which introduced a successful product (tPA) shortly after entry, was not able to sustain its stated goal of independence (Bogner & Thomas, 1996). This example illustrate clearly that the increase in size necessary to maintain a solid presence over time in the research intensive side of the pharmaceutical industry erected a major mobility barrier justifying the presence of distinct strategic groups in the industry.

B) Strategic interaction among strategic group members

Dranove, Peteraf & Shanley (1998) propose a definition of strategic group existence. They state that "a strategic group exists if the performance of a firm in the group is a function of group characteristics, controlling for firm and industry characteristics". They suggest that if true group-level effect described as the effect of strategic interaction among group members exists, then groups are more than an analytical convenience. Strategic interactions include all sorts of firm behaviors in which there is some form of

cooperation or coordination among group members. Strategic interactions can range from explicit collusion typically at issue in antitrust cases, to non-cooperative interactions, to mutual R&D or other cooperative ventures that enhance efficiency, to various types of group level effects on differentiation (Dranove, Peteraf & Shanley, 1998). In the pharmaceutical industry, examples of strategic interactions within strategic groups are abundant. Brand name drug companies are exerting great efforts to extend their pharmaceutical monopolies using essentially three techniques:

- ***Special legislation:*** Over the last few years, brand name drug firms have used their considerable resources to push for special legislation to increase the life of their patents. For instance, in May 1997, an amendment to the Supplemental Appropriations and Rescissions Act of 1997 would have granted a 14-month patent extension for Toradol, a pain reduction drug (NAPM, 1998). In 1996, Wyeth-Ayerst lobbied for a two-year patent extension for Lodine, an anti-inflammatory pain-killer (NAPM, 1998). The provision was added to several bills, including the Department of Defense Authorization bill, without requisite notice to members of Congress to favor full debate after appropriate public hearings (NAPM, 1998). The Congressional Budget Office (CBO) estimated that the extension would cost the Federal Government and the taxpayers $10 million (NAPM, 1998).

  In the fall of 1997, brand name drug firms adopted a different technique in order to increase the life of their patents. They proposed to pay the National Institutes of Health a 3% royalty payment in exchange for an additional ten years of market

exclusivity (NAPM, 1998). The U.S. Congress judged this proposal as anti-competitive and thus rejected it.

- ***Citizen petitions:*** Independent from the abbreviated new drug application (ANDA) approval process, companies and individuals can submit citizen petitions to FDA to exercise their right to petition the government. Brand name firms have applied the citizen petition process to attempt to block or delay FDA approval of Abbreviated New Drug Application (ANDAs) (NAPM, 1998).
- ***State substitution laws and narrow therapeutic index drugs:*** Under the Drug Price Competition and Patent Term Restoration Act of 1984, a generic drug can be marketed only after being certified by the FDA that the generic drug product is bioequivalent and therapeutically equivalent to the brand name product.

  State formulary boards elaborate lists of generic products that pharmacists may substitute for brand name products when filling prescriptions. While most state boards accept FDA s therapeutic equivalence determinations, some state boards are requesting the submission of data already reviewed and found acceptable by FDA (NAPM, 1998). By challenging FDA s therapeutic equivalency decisions on generic drugs, brand name drug companies are trying to obstruct the substitution of generic products at the state formulary boards, on a drug-by-drug basis (NAPM, 1998). Frequently, such challenges concern drugs that the brand name drug producers identify as narrow therapeutic index (NTI) drugs. The FDA dismissed brand name drug manufacturers challenges to FDA determinations of therapeutic equivalence in a January 28, 1998 in a letter to health care providers (NAPM, 1998). FDA confirmed that there is no scientific basis for an independent judgement of therapeutic

equivalence by state pharmacy boards once the FDA approves a generic drug product (NAPM, 1998).

Another form of strategic interaction adopted by brand name drug producers involves cooperative agreements among this group of firms to develop new technologies, pool production and promote new products. Dranove, Peteraf & Shanley (1998) describe this type of strategic interaction as "efficiency" interaction. Strategic alliances between brand name drug producers is an attempt to improve quality of their assets and acquire missing skills through long-term relationships with partners who, in turn, have their own resource bases (Bogner & Thomas, 1996). For both partners, the alliance decreases the time and risk involved in building some skills internally. In addition, the product or service that the alliance introduce into the market is imbued with distinctive advantages from the asset bases of both companies, thereby improving their competitive posture beyond that which could have been achieved by either firm acting individually (Bogner & Thomas, 1996). In Research & Development, this trend is principally true between large pharmaceutical and biotechnology firms. Most of the largest pharmaceutical companies worldwide are more and more engaging in biotechnology programs (Spinkler, 1994). Whittaker & Bower (1991) conducted a four-country study of 20 firms representing over 30 percent of the global pharmaceutical market. They found that 24.3 percent of the drugs in their pipelines were part of R&D joint venture, while their existing major products were only 6.4 percent collaborative. In addition to R&D alliances, brand name drug producers engage in co-marketing and copromotion agreements. Some examples of co-marketing agreements include: (1) Nifedipine was licensed by Bayer to Pfizer, (2) Inderal was

licensed by ICI to American Home Products and (3) Lisinorpil was licensed by Merck to ICI (Spinkler, 1994). Merck & Co, which formed a new company with Dupont called Dupont-Merck represents a good illustration of increasing trend of alliances between research-intensive firms. The new company was granted many Merck's products to promote and sell while it developed other new medicines to add to its portfolio. Moreover, Merck formed a major joint venture with a leading pharmaceutical company: Astra. Finally, Merck formed an alliance with Johnson & Johnson to sell OTC medicines (Spinkler, 1994).

On the other side, generic producers are joining their forces to confront brand name drug companies activity in the field of lobbying. For example, the International Generic Pharmaceutical Alliance, IGPA was formed in April 1997 and consists of the European Generic Medicines Association (EGA), Canadian Drug Manufacturers Association (CDMA), National Association of Pharmaceutical Manufacturers (NAPM), National Pharmaceutical Alliance (NPA) and Generic Pharmaceutical Industry Association (GPIA). The overall objective of IGPA is to promote generic medicines throughout the world. Similarly, the National Association of Pharmaceutical Manufacturers (NAPM) along with the Generic Pharmaceutical Industry Association (GPIA) and the National Pharmaceutical Alliance (NPA) are joining their resources to develop consumer access to generic drugs with the creation of the Coalition for Affordable Pharmaceuticals (CAP) (NAPM, 1998). The Coalition is realizing a public awareness campaign to inform consumers and policy makers that FDA-approved generic drugs are therapeutically equivalent to their brand counterparts (NAPM, 1998). The objective of the coalition is

primarily to publicize the different tactics brand-name firms adopt to extend their market monopolies beyond allowable patent extensions and exclusivities (NAPM, 1998). Additionally, the Coalition is promoting federal legislation to assist consumers obtain generic drugs more easily. The coalition (CAP) has been dynamic in lobbying for additional funding for the FDA, Office of Generic Drugs (OGD) (NAPM, 1998). Furthermore, generic pharmaceutical industry associations organize seminars and conferences, distribute draft guidelines and legislation to their members, advise members on various regulatory issues, and maintain relations with the pharmaceutical press (NAPM, 1998). The main objective of these activities is to promote the profile of the generic medicines sector and address the issues of concern to their members.

Description of various forms of strategic interaction existing in the pharmaceutical industry clearly suggests the existence of two groups of firms (Brand name and generic) facing different threats and opportunities. At the same time, firms within each group are facing similar threats and opportunities. This picture corresponds exactly to the definition of strategic groups introduced by Hunt (1972). Indeed, Hunt defines strategic groups as a set of firms facing similar threats and opportunities that are different from the threats and opportunities facing other firms in an industry. In addition, firms within each group are interacting to promote their products and to increase their performance.

C) Strategic groups in the pharmaceutical industry

Several dynamic longitudinal studies have identified distinct strategic groups in the pharmaceutical industry (Cool & Schendel, 1987 ; Fiegenbaum, Sudharsan & Thomas,

1987, 1990; Cool & Schendel, 1988; Cool & Dierickx, 1993; Veliath & Ferris, 1997).

Using strategic variables reflecting scope and resource deployment dimensions, Cool & Schendel (1987, 1988) identified six strategic groups in the U.S. pharmaceutical industry during the period 1963-1982. The first group is composed by large, R&D-intensive ethical drug firms active in many market segments with a broad range of products. The second group consists of large firms differing from the first group on three key dimensions: (1) they are advertising-intensive and not R&D intensive; (2) they compete in the OTC as well as the prescription market segments; and finally (3) they serve fewer market segments in the prescription drug market and offer a less comprehensive product range. The third group includes medium-sized firms pursuing principally a "me-too" strategy. The fourth group also consists of medium sized firms without real competence in R&D. The fifth group is composed by small prescription drug firms with a narrow product range and a selective participation in market segments. Finally, the sixth group includes only one member, a very small firm, with a very focused product line and a narrow scope.

Cool & Schendel (1987) suggested that the six strategic groups experienced important changes from 1963 to 1982. The 1960s displayed an explicit strategic group structure characterised by high asymmetry. In the early 70's, firms attempted new strategies motivated by environmental change and their poor performance. In the late 1970s, a consolidation took place, which was in turn broken apart in the early 1980s as new groups formed. Using similar strategic variables reflecting scope and resource deployment dimensions, Fiegenbaum, Sudharsan & Thomas (1987, 1990) identified four

distinct strategic groups for the years 1974-1975 and three groups for the period 1976-1981. More recently, Veliath & Ferris (1997) identified nine strategic groups in the U.S pharmaceutical industry during the period 1986-1989 based on strategic dimensions such as scope, resource deployments, differentiation, efficiency and size.

As developed earlier, the last decade showed the emergence of new competitive forces competing in a distinct way for the same customers in the pharmaceutical industry. These new competitive forces include generic producers and biotechnology firms that have become major players in the world pharmaceutical industry. The fundamental differences in strategy between major research-intensive firms, biotechnology firms and generic producers described above suggest that distinct strategic groups still exist in the pharmaceutical industry. More specifically, it is expected there are three or four groups including: (1) major R&D intensive firms, (2) generic producers, (3) biotechnology companies and perhaps a group composed by firms widely diversified in activities other than pharmaceuticals.

Mobility barriers in the pharmaceutical industry

The current market structure of the pharmaceutical industry suggests the presence of at least two strategic groups of firms: technology-intensive pharmaceutical companies seeking product differentiation and generic producers looking for cost advantage. Firms within each group resemble one another and perceive their mutual dependence most sensitively (Caves & Porter 1977). As suggested by Caves & Porter (1977), barriers to entry then become specific to the group rather than protecting all firms in the industry

equally. Entry seems to be easy into the generic producers group and difficult into the technology-intensive group.

In the pharmaceutical industry there are signals showing that entry into the basic chemical-processing field – generic drugs- is not considerably sensitive to scale effects (Bogner & Thomas, 1996). The absence of significant scale economies in this segment leads to presence of a large number of companies and a very competitive market.

On the contrary, entry into the research-oriented side of the pharmaceutical industry, is more complex due to the huge costs of R&D and marketing, both in terms of time and investment. As these two costs increase, entry barriers emerge keeping out potential new firms and more importantly increase the minimum effective size (Bogner & Thomas, 1996). Thus, minimum effective size has become larger than entry size necessary to surmount entry barriers. This minimum effective size has increased as a result of 1962-act.

Because within each group firms are active in different activities, their operative cost curves are not the same, creating scale-economy barriers among the two groups (Caves & Porter, 1977). In addition, firms' preference functions differ in risk aversion between the two groups, generic producers being risk averse and technology-intensive pharmaceutical companies risk taking. This difference in risk aversion created risky entry investment barriers (Caves & Porter 1977).

Caves & Porter (1977) suggested that if groups differ in their levels of product differentiation, the group with lower product differentiation will be retained to a degree

from entering the high differentiation group just as a firm with zero differentiation (a new firm) would be. All the standard sources of entry barriers thus translate into mobility barriers. Consequently, technology-specific entry barriers not only give to pharmaceutical technology-intensive firms differential protection against new firms entering the industry. They also protect the members of technology-intensive group against entry by a member of the generic producers group (inter-group mobility).

The group-specific particularity of entry barriers has then important implications for the entry of companies from outside the industry. Entry is no longer a simple "yes-no choice" (Caves & Porter 1977). Rather, entry must be targeted to a particular group. Therefore, potential new pharmaceutical firms are discouraged from entering the technology-intensive group by an increase in that group's investments in entry barriers (R&D and marketing investments). These investment barriers are steadily increased by changing regulations in the pharmaceutical industry.

As a result, entry into groups whose capital needed for entry are huge and risky as the technology-intensive group is likely to occur along a circuitous path. Caves & Porter (1977) argued that it makes sense to go for bite-sized pieces when considerable capital and skills capabilities generate major barrier to entry. Caves & Porter (1977) added that expenditures for production facilities and other tangible assets are overall reversible costs, while expenditures for product differentiation and other intangibles are fully irreversible (most risky). Therefore, it seems to be more judicious to enter a group characterized by tangible asset outlays (generic producers) first and move to the group necessitating more risky intangible asset expenditures only after a strong base in the industry is attained. The lower-risk barriers are surmounted earlier (Caves & Porter

1977). It should be emphasized however, that costs of product differentiation and other intangible assets are tremendously huge in the pharmaceutical industry making mobility barriers quasi-insurmountable.

An illustration of these rigid barriers is presented by (Thomas III, 1996). For companies that want to develop innovative new drugs after 1962, the amendments required a large and increasing interaction with physicians and pharmacologists who would perform the clinical trials for safety and efficacy needed for regulatory approval. The reputation of the 'superexperts" conducting these tests is considerably important for the ultimate marketing of new drugs to US physicians. However, the accessibility to this class of scientists varies significantly among drug companies, despite the importance of this access (Thomas III, 1996). For the large companies possessing substantial R&D facilities and employing the most valuable industrial research scientists, attracting the attention of these "superexperts" is relatively simple. In contrast, this task is considerably much more difficult for smaller firms with less extensive R&D efforts aiming for imitative products (Thomas III, 1996).

The threat of generic company entry has increased as the overall barriers to market entry have declined. This threat has been amplified by the above normal profits generated by the pharmaceutical industry. The pharmaceutical industry had an average annual rate of return on assets between 1980-1993 of 12.07 percent, 5.8 percent above the average annual rate of return of all US. industries (Clarkson 1996, see Table 6). Since standard accounting practices do not include investments in intangible capital- specifically investment in R&D and promotion- in measurements of profitability, accounting rates of

return among industries have systematic biases (Clarkson, 1996). When corrections are made the pharmaceutical industry's still have an above average rate of return of 9.86 percent, compared to an overall average of 6.30 percent.

Table 6: Average accounting and corrected rates of return on assets by industry, 1980-1993

Industry	Accounting ROA	Corrected ROA
Computer software	12,56	16,70
Pharmaceuticals	12,07	9,86
Petroleum	9,00	8,08
Foods	8,17	7,69
Electrical machines	6,36	6,01
Chemicals	5,52	4,90
Rubber products	5,26	4,24
Aerospace	4,99	5,18
Engines	4,95	4,85
Entertainment	4,14	4,11
Paper	4,12	4,32
Office machines	3,37	4,99
Motor vehicles	0,73	1,45
Ferrous metal	-0,73	-0,40
Average	**6.27**	**6.30**

Source: Clarkson (Calculated using 1993 constant dollars).

Five barriers to entry are often cited in the Structure-Conduct-Performance and strategy literature (Porter 1980). These barriers are (1) economies of scale, (2) product differentiation, (3) cost advantages independent of scale, (4) contrived deterrence, and (5) government regulation to entry. An evaluation of the ability of these barriers to deter entry to the *generic market* is presented in the following paragraph.

1. ***Economies of scale***: frequently deter entry by forcing new firms to either concede a cost disadvantage or enter on a large scale in terms of production, marketing, distribution, research, finance and service (James, 1982).

   Economies of scale do not appear to be an effective barrier to market entry of generic drugs. Cost advantages of the pioneer drug related to the scale of operations and to the positive effects of the experience curve do not appear sufficient deterrents to market entry of generic drugs (James, 1982). While generic companies are prepared to charge lower prices and obtain lower margins, the brand name drug companies frequently opt to maintain prices of their patent-expired products. Generally, innovative firms maintain the same margin over their patent expired products. In contrast, generic firms charge lower prices and obtain lower margins. This situation creates an incentive for the generic company to enter the marketplace. In addition, research costs for generic firms are considerably low due to the FDA's policy of accepting Abbreviated New Drug Application (ANDA).

   Capital requirement is frequently an entry barrier to new competitors particularly if the expenditures are non-recoverable. The reasonable cost of generic promotion and

the relaxed regulations to generic product approval has reduced the overall capital requirement for generic market entry.

2. ***Product differentiation:*** consists of creating a barrier around a product through branding. Product differentiation forces potential new market entrants to invest heavily in marketing and promotion to overcome brand loyalty.

   The FDA's policy of accepting Abbreviated New Drug Application (ANDA) and the repeal or amendment of anti-substitution laws reduced significantly the efficiency of product differentiation by forcing segments of the market to accept price as the criteria for use rather than a particular branded drug (James 1982). Branded generics reflect an attempt to differentiate generic products and create brand loyalty among physicians and pharmacists.

3. ***Cost advantages independent of size*** may produce barriers to market entry if these advantages are not available to new entrants. Porter (1980) suggests that proprietary technology, access to raw materials, and favorable locations can be powerful cost advantages.

   - *Proprietary product technology* is eliminated as an effective barrier to entry on the lapse of patent protection. In addition, the freedom of information act (introduced in page 63) provides access to proprietary technology under certain circumstances.
   - *Raw materials,* except under rare conditions, are freely available. The continuous growth of generic drug volume created growth opportunities for firms specializing

in the supply of raw materials to the larger pharmaceutical firms (Bogner & Thomas, 1996). Competition increased in the three principal supply sources for the pharmaceutical companies: specialty chemical manufacturers, pharmaceutical chemical manufacturers and pharmaceutical firms themselves who found a new outlet for excess productive capacity and older products (Bogner & Thomas, 1996).

- *Favorable geographical locations:* does not seem to produce any cost advantages given the cost structure of the pharmaceutical industry (James, 1982).

Contrived deterrence: reaction from already established firms in the industry influences significantly market entry. However, the desire of the innovative producers to maintain margins of their patent-lapsed drugs when faced with generic competition neutralized this barrier and has precipitated market-share erosion of pioneer drugs (James, 1982).

Government policy: can limit or open a market to new entrants. As developed previously, the Drug Price Competition and Patent Term Restoration Act reduced significantly the barriers to market entry into the generic segment (James, 1982).

In addition to creating mobility barriers between research oriented and generic sides of the pharmaceutical industry, increase in minimum effective size has encouraged the use of mergers and acquisitions between pharmaceutical firms. The development of novel technologies by many small biotechnology companies has also favored acquisitions of such companies by large pharmaceutical firms. Therefore, factors influencing this trend are presented in the following paragraph.

Factors promoting mergers and acquisitions in the pharmaceutical industry

Reasons encouraging mergers in the pharmaceutical industry can be classified into two main categories: general industry concepts and company specific reasons (Spinkler, 1994).

A) General industry concepts that promote mergers

Spinkler (1994) advances two general industry concepts independent of the specific company characteristics that promote mergers in the pharmaceutical industry. These concepts include essentially:

1. The bigger is better concept: this concept is principally justified by the notion of economies of scale.
2. Only large firms can survive in a rapidly changing and hostile environment. (regulatory authorities, legislators, other companies, and consumer advocates).

B) Specific company factors that promote mergers and acquisitions

The most frequently company-specific factors cited as reason for mergers in the pharmaceutical industry includes (Spinkler, 1994):

- Increase the cash flow necessary to fund the R&D machine. On the other side, the

cash-rich firm may improve its productivity in research, development and marketing.

- Improve the rapidity of product development.
- Gain management and R&D expertise currently not available in the firm.
- Improve the quality of the firm's portfolio of drugs.
- Share the risk and increase the probability of developing a new successful product.
- Acquire an access to a considerable new technology (medicine delivery system, sustained-release formulation).
- Achieve a competitive advantage in a particular field.
- Increase the number of development and marketing staff.
- Join resources to attain a larger critical mass in an important area.

The analysis of the competitive environment of the pharmaceutical industry revealed two important entry/mobility barriers. These barriers consist of product differentiation based on R&D; and the associated capital requirement for successful product differentiation. Therefore, product differentiation reflected in new product development and advertising strategy combined with the ability to invest resources necessary to develop a market presence and achieve differentiation -reflected in firm size- constitute major mobility barriers in the pharmaceutical industry. Consequently, business strategic variables used to form strategic groups should reflect primary product differentiation and firm scope.

CHAPTER III: RESEARCH METHODOLOGY

Methodological approach

Thomas & Venkatraman (1988) proposed a classificatory scheme for organizing the empirical research on strategic groups using two dimensions:

1. The operationalization of strategy
2. The approach adopted for the development of groups.

Thomas & Venkatraman (1988) distinguished between studies that have operationalized strategy in narrow terms (focusing on one functional area or a single dimension) versus studies that viewed strategy in relatively broader terms (focusing on multiple functional areas or dimensions). However, it is clear that the development of strategic groups using a narrow conceptualization of strategy is unlikely to cover the complexity of the strategy construct, consequently restraining the usefulness of strategic groups for both descriptive and predictive purposes (Ketchen & Shook 1996).

The other dimension of the scheme focuses on the researcher's approach to the development of groups. Some researchers embrace a deductive approach to strategic group development meaning that the number and suitability of clustering variables, as well as the expected number and nature of groups in a cluster solution, are strongly tied to theory. In this case researchers specify the characteristics of groups a priori, based on actual theoretical rationale, and subsequently apply data-analytic techniques to confirm or validate their theoretical groupings. In the context of pharmaceutical industry for example, a priori examination suggests existence of three groups including (1) generic

producers, (2) biotechnology firms and (3) global pharmaceutical firms. On the other hand, others researchers determine the grouping structure a posteriori based on empirical results on a specific data set. (Data-driven perspective).

The approach to selecting variables should match a study's purpose (Ketchen & Shook 1996). Consequently, since the study proposed attempts to test the nature and extent of links between key constructs (Performance and group membership) a deductive approach should be adopted.

The methodological approach adopted in this study involves essentially five phases.

Phase I: Strategic variable selection

The analysis of an industry's structure through strategic groups analysis involves first finding measures of strategic similarity between firms. This is accomplished by developing measures that capture essential aspects of the firm's strategies. These measures will then be used to develop clusters of similar firms- the strategic groups. Fiegenbaum, Sudharsan & Thomas (1990) proposed a model illustrating the process of strategic groups formulation involving three steps. This model is as follows:

Step 1: The characteristics of the competitive environment (strategic space) should be identified. Three dimensions: (a) the levels of organizational strategy (corporate, business and functional), (b) the components of strategic decisions (scope and resource

deployment) and (c) the time period (in this case 1995-1997) define the broad characteristics of the strategic space.

Step 2: The researcher should identify whether corporate, business or functional level strategies should be taken into account and assess which dimensions (components) best describe those strategies. In almost all previous studies dealing with the pharmaceutical industry (Cool & Schendel (1988); Lawless Bergh & Wilsted (1989) and Cool & Schendel (1987), the strategic groups of firms reflected business level strategic competition and have scope and resource development as the dimensions that best describes the strategies. Hofer & Schendel (1978) and Cool (1987) argued that the key strategic dimensions discriminating between firms and, therefore, forming the basis of strategic groups are those associated with scope and resource commitment decision. Indeed, Cool (1987) defined a strategic group as ' a set of firms competing within an industry on the basis of similar combinations of scope and resource commitments'.

Step 3: Involves identifying the variables that best apprehend the firm's scope and resource deployment decisions. This requires a clear and thorough knowledge of industry economics and the range of competitive strategies adopted by competing firms. The specification of particular strategy variables depends on the industry selected, in this case upon the pharmaceutical industry during the period 1995-1997.

In previous studies (Cool & Schendel, 1988; Lawless Bergh & Wilsted, 1989; Cool & Schendel, 1987; Cool, 1987 and Fiegengaum, 1990), the selection of strategic variables in the pharmaceutical industry has been a union of strategic variables that covered the strategic behavior in the strategic management literature and those identified by industry analyst and industry researchers. These strategic variables reflected the specific investment strategies of firms, especially their scope and resource commitments.

In order to avoid the choice of inappropriate strategic variables, the selection of strategy variables was performed in two stages. In the first stage, extensive analysis of the drug industry was undertaken. This analysis involved careful examination of academic literature related to the drug industry, industry surveys (such as those published by IMS and PhRMA), published interviews of industry and drug experts and 10-K reports.

The second stage dealt with the actual selection of the specific variables chosen to represent strategic scope and resource commitments. The use of investigator-defined strategy variables for strategic groups analysis raises the question of whether the end result is a reflection of competitive reality or merely an artifact created by the investigator's unique perception and biases. To reduce the potential for investigator bias when compared to single investigator-defined strategy variable studies, multiple measures and factor analysis are used. A total of twelve strategic variables which reflect strategic dimensions that capture the bases of competition and competitive advantage described by researchers in the pharmaceutical industry were selected. Almost all firms

studied, in their 10-K and other reports, perceived these variables as very crucial in competitive rivalry in the pharmaceutical industry.

The twelve strategy variables were operationalized using patent and financial data that attempt to portray the absolute and relative investment emphasis firms place on different functional areas.

Scope commitment variables

Scope commitment in the drug industry can be described along the following dimensions:

Overall size:

The size of the firm influences the ability to allocate different amounts of resources to different functional areas. To account for the influence of minimum effective size on resource allocation to functional strategies, firm size was included as a variable. In this study, the size aspect is described in terms of net sales per year, number of employees, total assets, R&D expenditures and Marketing expenditures.

Total number of employees was used, in addition to total sales, to proxy firm physical size to avoid the problem of fluctuations in the demand for a firm's products in a given year. In addition, differences in demand conditions faced by firms in different markets might affect sales even though physical size of the firm did not change.

The pharmaceutical industry places a unique demand on the role of marketing. Indeed, the nature of the product requires that firms interact with many heterogeneous publics, including highly educated professionals faced with important tasks (Harrell, 1978). Given the non-availability of advertising expenditures for the time period studied, ranking of selling and administrative expenditures was used as estimation for advertising expenditure. The forty-two firms were ranked according to their selling and administrative expenditures. The firm reporting the largest selling and administrative expenditures was ranked number one while the firm reporting the lowest selling and administrative expenditures was ranked forty-two.

Geographic reach of product-market strategy:

The spatial or geographic reach of market activity was determined by the proportion of sales generated from operations in foreign countries to total firm sales.

The range of market segments:

Substitution across therapeutic classes is not possible with pharmaceuticals. Therefore, a broadly balanced product line gives a firm a form of diversification against a breakthrough drug of a competitor. A measure of how balanced and broad a firm's product line was obtained by establishing to what extent a firm competes in a smaller or larger number of the therapeutic classes. A classification including twelve therapeutic areas applied by IMS Health was used (see table 7). Since each firm may be active in up to twelve therapeutic classes, the range of market segments variable contains values from

one to twelve. If for example, ABC Corporation is active in three therapeutic areas, it will carry a value of three.

Table 7: Classification of therapeutic areas

Therapeutic areas
(A) Alimentary Tract & Metabolism
(B) Blood & Blood Forming Organs
(C) Cardiovascular System
(D) Dermatologicals
(G) GU.System & Sex Hormones
(H) Systemic Hormonal Preparations (excl. Sex Hormones)
(J) Systemic Anti-Infectives
(M) Musculoskeletal System
(N) Central Nervous System (CNS)
(P) Parasitology
(R) Respiratory System
(S) Sensory Organs

Source: IMS Health / http://www.ims-global.com/resources/resources.htm

The product/industry scope

During the 1970s many pharmaceutical companies diversified into various other businesses. Some of these businesses were unrelated to pharmaceuticals. During the late

1980s and 1990s it was apparent that many companies were divesting some or all of these other non-pharmaceutical businesses and had decided to focus primarily or solely on discovering, developing and marketing medicines (Spinkler, 1994). Being highly focused or highly diversified for a specific company depends primarily on its history, financial status, pipeline of new products, and management philosophy. The degree of risk taking that the senior managers are comfortable with will undoubtedly influence which specific businesses to enter (Spinkler, 1994).

Two variable reflecting whether a company is extensively diversified into other businesses (e.g., chemicals or agricultural products) or whether it is 100% focused on discovering, developing, and marketing ethical pharmaceuticals were used.

Product/industry diversification: this variable was defined as the firm's sales within the pharmaceutical industry divided by the firm's total sales. Firms operating only in the pharmaceutical industry will record a value of 100, whereas firms operating in additional industries will record values lower than 100. This measure reflects product/industry diversification that has been shown to be a key determinant of firm profitability (Varadajan, 1986).

Segmentation: this variable indicates how many industry segments (for a total of ten segments) collected by Standard & Poor's Compustat are available for each firm. Since each company may have up to ten industry segments per year, segmentation variable contains values from 1 to 10.

Resource Commitments Variables

Resource commitments consists of business-level deployments of resources to functional areas that are key to gaining and maintaining competitive advantage in target product-market segments. The primary functional area from which competitive advantage is likely to come in the pharmaceutical industry is R&D.

R&D resource commitment

Two strategic variables were often utilized to measure the important dimension of the firm's R&D resource commitment. The R&D to sales ratio (R&D intensity), which measures the intensity of current R&D spending for each firm, constituted the first variable.

The second variable measures the cumulative number of innovative drugs approved by the Food and Drug Administration. This measure reflects the R&D capital stock resulting from past commitments to R&D. This variable was developed using the government database of the U.S. Food and Drug Administration (FDA) and avoids problems in measuring the R&D focus of large companies where non-pharmaceutical research may distort or obscure the real size of pharmaceutical efforts. In other words, patent data permits focusing precisely on pharmaceutical products, separating them from other products and businesses in the corporate portfolio more efficiently than through financial

data. The ability of a firm to regularly develop new patentable substances is captured better by the patent counts (Bogner, Thomas & McGee 1996).

Data on new product and patent activities allows reliable measurement across firms of different national origin due to the uniform registration requirements of the U.S Patent Office and the Food and Drug Administration (FDA). The use of patent counts appeared to be reliable, even for the non-U.S. firms. There is an incentive for all companies to patent all their drugs in the U.S.A and, therefore, protect the firm in the world largest market (Bogner, Thomas & McGee 1996). Listing of drug therapies approved by the Food and Drug Administration (FDA) for years 1995-1997 was given by CenterWatch. Previous studies (Cool 1987) have utilized ratios of NDAs (New Drug Application) and NCE (New Chemical Entities- the wholly new compounds on which significant new drugs are based). Using all New Drug Application (NDAs) allows both a better profile of the company's entire product line and a reliable method of comparing research firms without references to NCEs or patents (neither of which generic firms have) (Bogner, Thomas & McGee, 1996).

In addition to R&D skills, economies of scales were determined to be quite a significant source of competitive advantage within the pharmaceutical industry. Degree of capital intensity was judged to be an adequate proxy variable to reflect firms' strategy and ability to exploit these economies of scale.

The twelve variables outlined above formed the basis of the grouping procedures (See table 8). The means and standard deviation of strategic variables are provided in table 9).

Table 8: Strategic Variables and Measures

Variable	Abbreviation	Measurement & Definition
A) Scope		
Total Asset	AT	Total of current assets, net property, plant and equipment and other non-current assets.
Total Employees	TEMP	Number of employees reported by the company at fiscal year-end.
Total net Sales	SALE	Net sales or revenues during the accounting period
R&D Expenditures	XRD	All direct costs related to creation and development of new processes, techniques, applications and products.
Marketing Expenditures	RMKG	Rank of each firm based on selling & administrative expenditures.
Spatial Reach	TFSALEP	Proportion of sales generated from operations in foreign countries to total firm sales.
Range of market segments	THCLASS	Number of therapeutic classes in which the corporation is active
Product/industry diversification	DIVERS	Sales generated from operations within the pharmaceutical industry divided by firm total sales.
Segmentation	SEGM	Indicates how many industry segments are available for each firm.
B)Resource-Commitment		
R&D intensity	RDINT	R&D expenditures over sales
R&D Orientation	RDOR	Number of new drugs approved by the FDA in each year.
Capital intensity	CAPINT	Capital expenditures over sales

Table 9: Means and standard deviation of strategic variables

Strategic variable	Mean	Standard Deviation
Total Asset	8433	10719
Capital Intensity	0.076	0.030
Product/Industry diversification	80.743	21.341
Total Employees	27,061	33,247
R&D Orientation	2.031	1.833
R&D Intensity	0.149	0.115
Total Net Sales	6468	8025
Segmentation	1.929	1.113
Spatial Reach	0.415	0.296
Range of Market Segments	4.786	2.798
Marketing Expenditures (Rank)	21.500	12.268
R&D Expenditures	728	769

Phase II: Assessing data characteristics

Fiegenbaum, Sudharsan & Thomas (1990) suggested that analysis of strategically similar groups become more significant only after identifying time periods of homogeneity with regard to competitive strategic behavior (stable strategic time periods: SSTP).

According to Cool & Schendel (1988) a SSTP can be identified as a period in which the variance-covariance matrix formed from the strategic variables within the considered time period is notably more stable than that which exists across periods. Fiegenbaum, Sudharsan & Thomas (1990) added another criteria, which is that the mean behavior of

firms in terms of the strategic variables should remain relatively unchanged over the time period studied.

In the literature (Cool & Schendel 1988 and Cool & Schendel 1987), Bartlett's test have been used for comparing one year's variance-covariance matrix with that of the next year. A significant difference detected using this test for any adjacent years indicates a new period. Similarly, Hotelling's test has been used to investigate shifts in the means between two adjacent years.

While the utility of identifying stable strategic time periods could not be easily challenged, the statistical procedure that has been used to detect these periods is seriously questionable. Indeed, Bartlett's test which has been used for comparing one year's variance-covariance matrix with that of the next year assumes that these two variance-covariance matrices are independent from year to year. Obviously, this assumption is not justified since it is the same sample of firms that is used each year. Thus, it is reasonable to think that variance-covariance matrices are not independent from year to year and that the use of Bartlett's test is not appropriate. Given these serious doubts about the statistical test applied and the relative shortness of the period studied, stable strategic time periods will not be identified.

High correlation among clustering variables can be problematic because it may overweight one or more underlying constructs. Thus, we may want to correct multicollinearity, especially if it is desirable that constructs be equally weighted.

Multicollinearity was addressed through subjecting variables to factor analysis (specifically, principal components analysis with orthogonal rotation) and using the resultant uncorrelated factor scores for each observation as the basis for clustering.

Phase III: Identifying strategic groups using cluster analysis

Once multicollinearity has been addressed, firms can then be clustered into strategic groups using cluster algorithms available in SPSS.

Cluster analysis takes a sample of elements (firms) and groups them such that the statistical variance among elements grouped together is minimized while between-group variance is maximized.

While cluster analysis is the most frequent statistical technique used to combining groups, it suffers from two major problems (Ketchen & Shook, 1996):

- Cluster analysis does not propose a test statistic (such as an F-statistic) that provides an indisputable answer concerning the support or lack of support of a set of results for a hypothesis of interest.
- Cluster analysis' sorting endowment is powerful enough that not only can it offer distorted depictions of the groupings in a sample but can also impose groupings where none exist. This negative effect is decreased in this study, since it adopts a deductive approach (theory driven).

Ketchen & Shook (1996) proposed the use of a two-stage procedure when identifying clusters. A hierarchical algorithm will be used to define the number of clusters and clusters centroids. The number of clusters is determined by visually examining

dendrograms. A dendrograms is a graph showing the order that observations join clusters and the similarity of observations joined. These results then will serve as the starting point for following nonhierarchical clustering. Ketchen & Shook (1996) suggested that this two-stage procedure increases the validity of the solutions.

Phase IV: Operationalizing firm sustainable growth capability

After identifying strategic groups, a firm's sustainable growth capability was evaluated using financial measures. The important role of a sustained cash flow to fund ongoing research clearly emerges from the preceding discussions. Cash flow funds the R&D machine. As the cost of research increases, the attention to cash flow also increases.

A firm's sustainable growth capabilities are thought to be a very important variable as a result of persisting increase in the minimum effective size of pharmaceutical firms. Sustainable growth is defined by Higgins (1977) as the increase in sales that is consistent with the firm's established financial policies. In other words, a firm's sustainable growth capability is the individual firm's potential to create resources to attain a certain sustainable growth. Even, larger firms are becoming dependent on a few major products for the majority of their cash flow needs (Bogner & Thomas, 1996). The individual firms' sustainable growth indicators that have been used in this study are the following: (Higgins, 1977, and Bettis & Mahajan, 1985)

1. Debt to Equity defined as long term debt over common equity
2. Cash flow to sales, which represents annual cash flow from operations as a percent of net sales.
3. Fixed to total assets defined as fixed assets over total assets.

4. Fixed asset turnover defined as net total sales over fixed assets.
5. Net margin, which represents annual net income as a percent of net sales.

Phase V: Testing performance-growth capability correlation

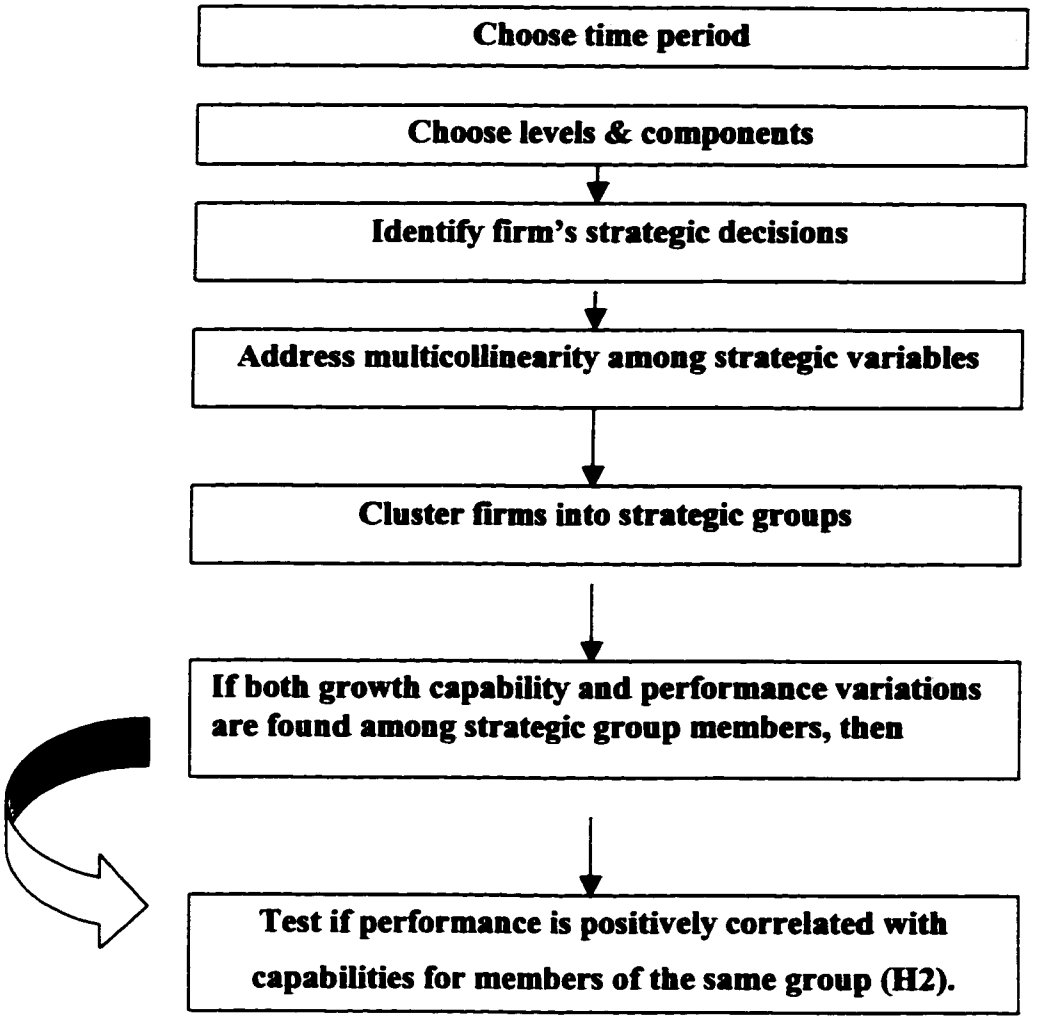
After identifying strategic groups in the pharmaceutical industry, it is essential to determine if there is substantial and continuous within-group variation in sustainable growth capability and performance. If both growth capability and performance variations are found among strategic group members, it can be tested whether there is a relationship between the two.

Hypothesis two proposes that performance differences within groups are positively correlated with sustainable growth capability differences within groups. Hypothesis two will be tested for each strategic group using a multiple regression model with Return on Assets as the dependent variable and firm sustainable growth capabilities as independent variables. Return on assets was chosen as a return measure. ROA was chosen because it reflects a return more directly under the control of management and is widely employed by managers, analysts and researchers (Bettis & Mahajan, 1985).

The correlation coefficient between ROA and the capability variables as well as p-value will be computed in order to interpret the existing relationship. High and positive correlation coefficient combined with significant results at the .05 level will lead to conclude that performance is positively correlated with capability. All the analysis was carried out using the SPSS Windows 7.5 package.

As a conclusion, the methodology adopted in this study can be summarized as follows

Figure 13: Methodological Approach



Sample selection

The pharmaceutical industry is more and more multinational in scope. Most major research-based firms sell their drugs throughout the world. Historically, the centers of global research have been in developed nations that encourage free markets and thus innovation. U.S firms are the leaders with a 43 % market share of the global pharmaceutical industry, and Japanese firms are second with a 20 percent share of the global sales (Thomas III, 1996). World sales by Japanese companies are almost totally located in an immense home market that is protected by important non-tariff trade barriers (Thomas III, 1996). The market share of 20 percent therefore, reflects Japanese protectionism far more than it does the superior competitive performance of Japanese pharmaceutical firms (Thomas III, 1996). Thomas (1996) has analyzed the way that various countries' industrial policies have affected competitive performance in international markets. Reviewing several measures of competitive performance, he found two different groups of performers among the nine major producing nations. The US leads Switzerland, Great Britain and Germany, the group that he calls "strong competitive performers". Weak competitive performers include France, Italy, Sweden, the Netherlands, and Japan. These two groups are described by (Ballance & al. 1992) as countries with a sophisticated pharmaceutical industry and a significant research base.

Several criteria guided selection of the firms to be included. Firms were required to have significant commitments to the ethical drug industry. Therefore, only firms that have 2834 as primary SIC were selected for this study. In total 42 (one-third European and two-thirds US) firms accounting approximately for 65 per cent of the worldwide

pharmaceutical sales were sampled (IMS Health, 1998). These firms represent the largest firms in the world operating in the pharmaceutical industry. Large firms that were excluded were primarily Japanese firms. These firms were principally excluded because their market share represents Japanese protectionism far more than it does their superior competitive performance. In addition, patent data was not available.

In addition to global leader firms in the pharmaceutical industry, generic manufacturers and biopharmaceutical firms were added to the sample. Despite the fact that generic companies do not perform research for new drugs, they are considered to be an important force in the competitive market. Generic producers are considered to be competing in a distinct way for the same customers- a difference in competitive posture that reflects precisely the intra-industry distinction that strategic groupings were intended to capture. Therefore, 12 U.S generic firms were added. Similarly, 8 global biopharmaceutical firms were sampled.

Data sources

The database of Disclosure Worldscope constituted the major source of information on strategic, capability and performance variables. Other data bases included Standard & Poor's Compustat, PhRMA, annual reports, U.S Security commission 10 K forms (e.g., for business segment information). Additional sources included the "orange book" published by the FDA entitled "Approved Drug Products with Therapeutic Equivalence Evaluation", Physician's Desk Reference, IMS Health, and CenterWatch: a clinical trials listing service.

A 3-year time period was chosen for this study. First data was obtained and calculated for each of the years (1995-1997) and then averaged across the years.

Strategic group research has frequently limited its analysis to stable time periods. Indeed, Fiegenbaum, Sudharsan & Thomas (1990) suggested that analysis of strategically similar groups is significant only in stable strategic time periods.

As developed in chapter two, the pharmaceutical industry evolves in a dynamic and highly competitive environment characterized by demanding regulations and frequent innovation. In particular, the three-year time period 1995-1997 appears to be more likely unstable. The significant number of new innovative products and technologies as well as the numerous mergers and alliances that have occurred during this period suggest that the period studied is not stable. This supposed instability is not considered as restrictive to the study. Indeed, Petraf & Shanley (1997) suggest that groups are more likely to be important for firm performance during periods of industry instability that can stem from lack of legitimacy, innovation, new entry, or deregulation. In dynamic and highly competitive environments, the executives of corporations may find it less profitable to act alone, but instead engage in collective strategies with other group members (Bresser & Harl, 1986). In addition, Bresser, Dunbar & Jithendranathan (1994) found evidence of strategic groups during a period of deregulation in the U.S. thrift industry.

The study analyzes a static view. Results at this level are a first step to more complex studies. The next level of complexity would incorporate a dynamic view where changes

in strategy position, sustainable growth capability and performance over time would be studied.

As with all studies of this type, data availability placed some constraints on the chosen set of variables. Wherever possible, 3-year averages were used, although due to data availability, point estimates were necessary in some instances (for marketing expenditures).

CHAPTER IV: RESULTS

Strategic group identification

High correlation among clustering variables can be problematic because it may overweight one or more underlying constructs. In order to correct for multicollinearity, the first step in our study was to conduct a factor analysis (specifically, principal components analysis with orthogonal rotation) and then, using the resultant uncorrelated factor scores for each observation, as the basis for clustering. The factor analyses employed Quartimax rotated principal-components analysis to reduce the number of factors (eigenvalues over 1 determined the appropriate number of factors).

The Kaiser-Meyer-Olkin measure of sampling adequacy is an index for comparing the magnitudes of the observed correlation coefficients to the magnitudes of the partial correlation coefficients. This measure of factor correlation showed a value 0.85 suggesting that the model was appropriate for our purposes.

For each variable, the communality - the proportion of the variance of that variable that can be explained by the common factors are reported in table 10. In this example, three components were extracted, and therefore, the estimates of the communalities report the proportion of the variance explained by these three factors. All communalities are significant. Table 11 indicates that almost seventy nine percent of the total variance is explained by the three principal components, which is an excellent result.

Table 10: Communalities

Strategic variables	Initial	Extraction
Total Asset	1.000	.896
Capital intensity	1.000	.735
Product/industry diversification	1.000	.782
Total Employees	1.000	.933
R&D Orientation	1.000	.609
R&D intensity	1.000	.638
Total net Sales	1.000	.931
Segmentation	1.000	.814
Spatial Reach	1.000	.545
Range of market segments	1.000	.734
Marketing Expenditures	1.000	.853
R&D Expenditures	1.000	.967

Extraction Method: Principal Component Analysis.

Table 11: Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	7.055	58.792	58.792	7.055	58.792	58.792
2	1.301	10.843	69.635	1.301	10.843	69.635
3	1.080	8.999	78.634	1.080	8.999	78.634
4	.742	6.185	84.819			
5	.713	5.945	90.764			
6	.416	3.467	94.231			
7	.299	2.489	96.721			
8	.202	1.687	98.408			
9	.096	.804	99.212			
10	.054	.453	99.665			
11	.026	.223	99.888			
12	.013	.112	100			

Extraction Method: Principal Component Analysis.

The objective of rotation is to make larger loadings larger and smaller loadings smaller than their unrotated values. The rotated component matrix obtained by quartimax rotation suggests three factors:

1. Sales, number of employees, total assets, R&D expenditures, Marketing expenditures, Spatial reach, Range of market segments and R&D Orientation are highly correlated with the first component representing size.
2. Product/industry diversification and segmentation are highly correlated with the second component representing product-industry scope. The larger the proportion of the firm's sales generated from operations within the pharmaceutical industry, the smaller the number of segments on which the firm is active, which explains the negative correlation between product/industry diversification and segmentation.
3. R&D intensity and capital intensity are highly correlated with the third component representing resource commitments. (See table 12, figure 14).

The fact that R&D orientation which is measured by the cumulative number of innovative drugs approved by the Food and Drug Administration for each firms is highly correlated with the first component representing size and not the third reflecting resources commitments should be stressed. This is essentially due to the long and uncertain procedure of developing a successful new drug. In fact, firms aspiring to increase the likelihood of launching successful new drugs with some degree of regularity will need quite large sums to finance their R&D. Consequently, a large firm having the same R&D to sales ratio as a smaller firm can seek a greater number of potential products.

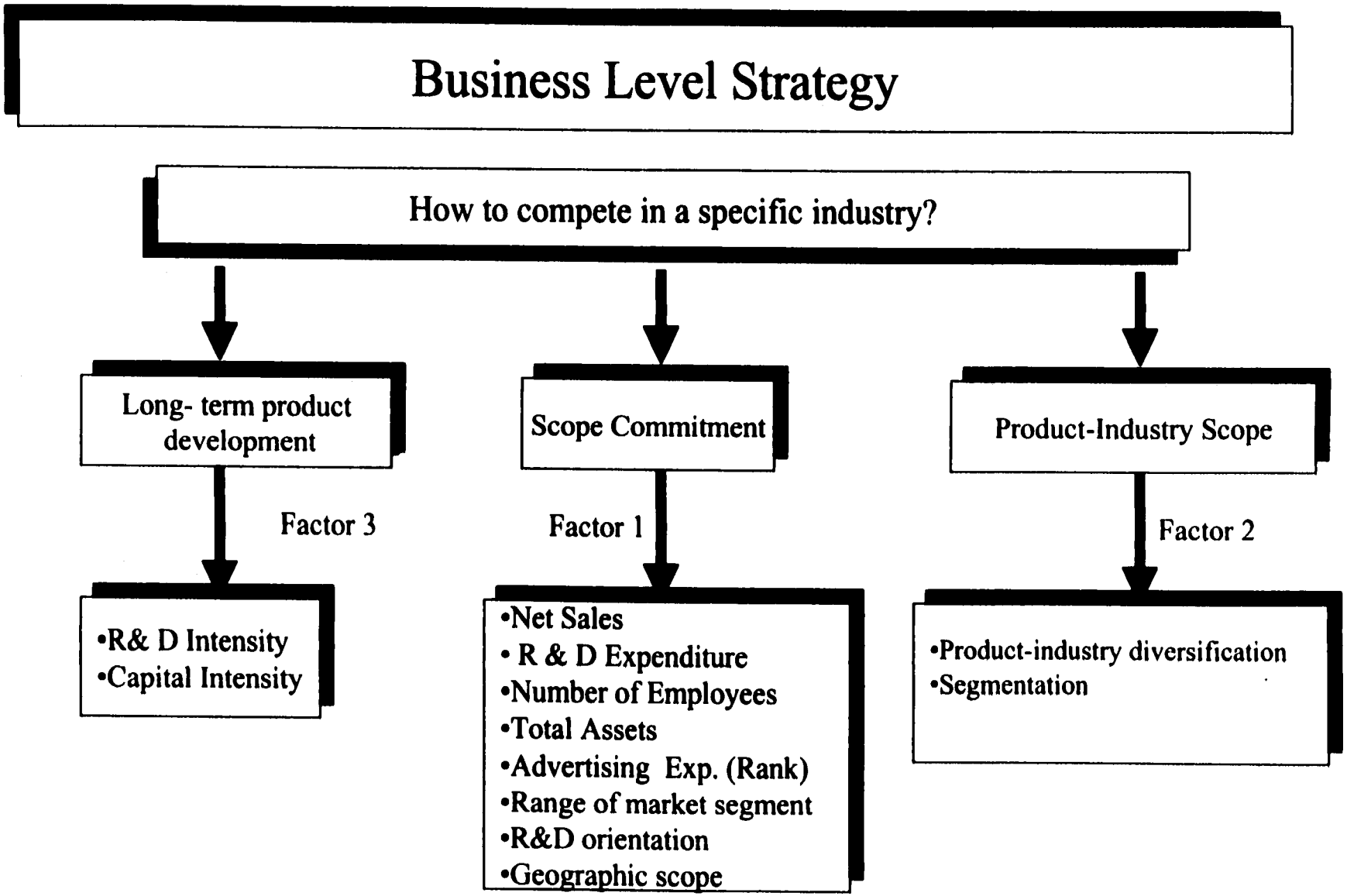
Table 12: Rotated Component Matrix

	Descriptive title of strategy component		
Strategic variables	**1- Size/Scope**	**2- product-industry scope**	**3- Resource commitments**
❑ R&D Expenditures	.982		
❑ Total Employees	.960		
❑ Total net Sales	.959		
❑ Total Asset	.946		
❑ Marketing Expenditures	-.916		
❑ Range of market segments	.819		
❑ R&D Orientation	.773		
❑ Spatial Reach	.578		
❑ Segmentation		.755	
❑ Product/industry diversification		-.727	
❑ Capital intensity			.820
❑ R&D intensity			.636

Extraction Method: Principal Component Analysis. Only loadings greater than 0.5 are displayed.

Rotation Method: Quartimax with Kaiser Normalization.

Figure 14: Descriptive Title of Strategy Component



After correcting for multicollinearity using factor analysis, the next step is to use factor scores to perform cluster analysis. As noted above, a two-stage procedure, where a hierarchical algorithm is used to define the number of clusters and cluster centroids is utilized. These results then serve as the starting points for subsequent nonhierarchical algorithm.

The historical analysis of the pharmaceutical industry undertaken prior to the clustering of groups improves the study primarily in two ways.

First, by forming expectations about breaks in clustering *ex ante* confirmation and validation of groupings that emanate from the statistical techniques can be attained. Second, the knowledge of firm and industry histories ameliorates the interpretation of the statistical output by providing an understanding of the facts behind the output.

Ward's minimum variance technique was employed as the hierarchical algorithm to define the number of clusters. Ward's algorithm has been used in other strategic group studies (Fiegenbaum 1987, Cool 1985,). It does, however, carry some biases. First, Ward's method has a bias for outliers. However, box-plots, QQ-plots and plots of component scores revealed that there are no extreme cases.

The second bias of Ward's method is to balance groups equally. However, equal size is not consistent throughout demonstrating that the bias did not stop the formation of large groups when the data indicated such.

Inspection of dendogram, a graph of the order that observations join clusters and the similarity of observations joined, revealed that four clusters solution predominate suggesting that hypothesis one is supported. (See figure 15).

Figure 15: Dendrogram Using Ward Method

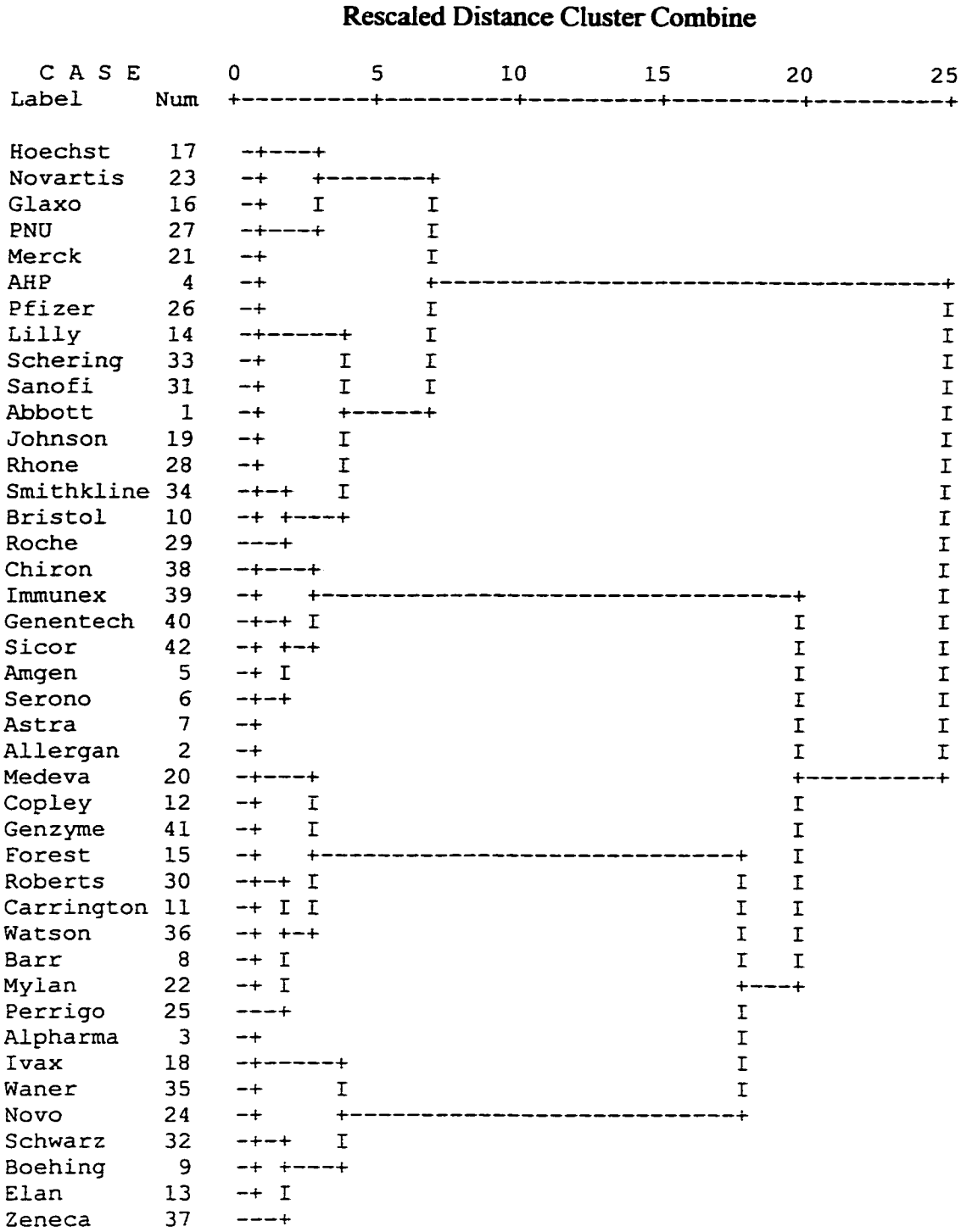


Table 13 reports the means of the strategic factors for each cluster resulting from non-hierarchical (also referred to as K-means) algorithms. The means for each cluster define the cluster center. This table reveals that the average size for cluster one is 1.21 standard deviation above the mean of all firms suggesting that this cluster groups the major drug producers. On the other hand, average product-industry scope for cluster two is 1.43 standard deviation above the mean of all firms indicating a cluster assembling diversified firms. Cluster three is composed by focused-biotechnology firms (average product-industry scope is 0.72 standard deviation below the overall mean). These biotechnology firms have an average resource commitments (R&D intensity & Capital intensity) 1.37 standard deviation above the mean of all firms indicating that these firms are research driven. Finally, the average size for cluster four is 0.76 standard deviation below the mean of all firms. In addition, cluster four indicates an average resource commitments (R&D intensity & Capital intensity) 0.84 standard deviation below the overall mean suggesting a prevalence of generic drug producers in this cluster. Strategic group comparisons based on strategic variables are provided in table 14.

Table 13: Final Cluster Centers

	Cluster			
Strategic factor	1	2	3	4
Size	**1.21071**	.19200	-.54138	**-.76534**
product-industry scope	-.42177	**1.43121**	**-.72137**	-.17646
Resource commitments	-.29998	.45557	**1.37768**	**-.84441**

Interpreting the analytically-based groupings

It is clearly important to ask whether the analytically based groups make sense strategically. Table 15 provides a summary of characteristics of the four strategic groups that were identified in the pharmaceutical industry during the period 1995-1997. Group one is composed by large multinationals investing huge sums in R&D and marketing. These firms appear to focus upon drugs as their dominant product. In contrast, group two is dominated by medium size European firms that are widely diversified. Group three includes non-diversified biotechnology firms characterized by a small size, a narrow research focus and most importantly considerable R&D and Capital intensity. In contrast, group four is dominated by small, focused generic firms characterized by insignificant R&D and Capital intensity.

Group one

Size

The first group contains eleven large research-driven pharmaceutical companies that, through their divisions and subsidiaries discover, develop, manufacture and market a broad range of human and animal health products. Certain firms also manufacture pharmaceutical chemicals and intermediates for use in their own products and for sale to others. The worldwide top eight pharmaceutical firms by sales in 1996 are found in this cluster (IMS Health, 1998). These firms are Novartis, Glaxo Wellcome, Merck, Hoechst Marion Roussel, Bristol Meyers Squib, Johnson & Johnson, American Home Products and Pfizer. Eli Lilly, Abbott and Pharmacia UpJohn were ranked respectively 13th, 15th and 17th. The eleven firms accounted for 34% of worldwide market share in 1996 (IMS Health, 1998). These firms commercialize their products in more than 150 countries.

Table: 15 Characteristics of strategic groups in the pharmaceutical industry

	Group 1	Group 2	Group 3	Group 4
Size / Scope	❑ Large Multinationals ❑ Huge R&D and Marketing expenditures. ❑ Broad focus research firms.	❑ Medium Multinationals ❑ Substantial R&D and Marketing expenditures. ❑ Quite broad focus research firms. ❑ Substantial foreign sales ❑ Dominated by European firms.	❑ Small biotechnology firms (except Astra and Schwarz Pharma). ❑ Narrow focus research firms.	❑ Small generic firms ❑ Small specialty drugs producers. ❑ Limited Research
Diversification	❑ Limited, related diversifiers around a core drug focus.	❑ Widely diversified firms, but large ethical content.	❑ Firms active exclusively in pharmaceutical activities.	❑ Very limited diversification
Resource commitments	❑ Medium R&D and Capital intensity explained by R&D scope and scale economies	❑ Medium R&D and Capital intensity explained by scope and scale R&D economies	❑ Important R&D and Capital intensity justified by small size of firms.	❑ Insignificant R&D and Capital intensity.
Composition	❑ Novartis ❑ Glaxo Wellcome ❑ Merck &Co ❑ Hoechst Marion Roussel ❑ Bristol Meyers Squibb ❑ Johnson & Johnson ❑ American Home Products ❑ Pfizer ❑ Eli Lilly ❑ Abbott ❑ Pharmacia UpJohn	❑ Boehinger Ingelheim, ❑ Elan, ❑ Ivax, ❑ Novo Nordisk, ❑ Rhone Poulenc, ❑ Roche, ❑ Smithkline Beecham, ❑ Warner Lambert ❑ Zeneca	❑ Amgen, ❑ Ares Serono, ❑ Gensia, ❑ Chiron, ❑ Immunex, ❑ Genentech ❑ Astra ❑ Schwarz Pharma	❑ Mylan, Barr, Watson, Alpharma, Medeva, Perrigo, Copley, Roberts and Forest. ❑ Schering Plough ❑ Sanofi ❑ Allergan ❑ Carringthon ❑ Genzyme General

The eleven firms belonging to group one are growing using different operations primary:

1. Mergers: Novartis, the world leader in life science products was created by the $27 billion merger of Ciba-Geigy and Sandoz.
2. Acquisitions of complementary businesses: rather than seeking mergers with other major health care companies, the firm Johnson & Johnson prefers to grow by forging partnerships with small firms capable of developing innovative new products. This decentralized approach encourages entrepreneurialism, leading to the creation of more new products
3. Drug-licensing agreements.

Research scope

Global leaders in pharmaceuticals invest heavily in research and development, which managers believe is critical to long-term competitiveness in the pharmaceutical industry. The growth in research and development expenditures and personnel over the past several years demonstrates both their continued commitment and the increasing costs and complexity of bringing new products to the market.

Firms belonging to this group attempt to reduce market risk through pursuing a broader R&D scope which increase the likelihood of launching successful new drugs with some degree of regularity. Consequently, these firms are active in a wide range of therapeutic classes like immunology, inflammatory diseases, central nervous system disorders, cardiovascular problems, endocrine and metabolic diseases, cancer, dermatology, and asthma. These areas are notably the most rapidly growing therapeutic classes. This result is consistent with large R&D expenditures and effort invested by these firms.

In addition to the research carried on in their own laboratories, these firms sponsor and underwrite the cost of research and development by independent organizations, including educational institutions and research-based human health care companies, and contracts with others for the performance of research in their facilities. They utilize the services of physicians, hospitals, medical schools, and other research organizations in the United States and many other countries to establish through clinical evidence the safety and effectiveness of new products. In addition, These companies actively seek out opportunities to invest in external research and technologies that hold the promise to complement and strengthen their own research efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements, and outright acquisitions.

Resource commitment

The medium R&D and capital intensity distinguishing firms belonging to the first group is primarily explained by significant R&D scope and scale economies present in the research driven side of the pharmaceutical industry. Indeed, firm size is an important determinant of R&D productivity in the pharmaceutical industry. This explains the fact that large firms spend less on R&D in relation to their sales than do smaller firms.

Product-industry scope

The eleven firms forming the first group are not widely diversified and appear to focus upon drugs as their dominant product. Indeed, approximately 75 percent of sales

generated by these firms are related to pharmaceutical activity. The remaining 25 percent are concentrated primary in three business segments:

- Health Care, which essentially includes brand name prescription pharmaceuticals. However, some firms that produce patented pharmaceuticals have entered the generic market; in some cases offering generic versions of their own brand-name products
- Animal Health, which includes antiparasitics, anti-infectives, anti-inflammatory medicines and vaccines for livestock, poultry and pets; and
- Consumer Health Care, which includes a variety of over-the-counter medications and personal care products.

Managers are convinced that these businesses derive synergies in certain research and regulatory matters.

Competition

Competition for firms belonging to cluster number one is very strong. These firms compete with worldwide research-based drug companies, many smaller research companies with more limited therapeutic focus, and generic drug manufacturers in highly competitive markets located in the United States and abroad.

Group two

Size

Group two appears to contain nine mid-size firms – Boehinger Ingelheim, Elan, Ivax, Novo Nordisk, Rhone Poulenc, Roche, Smithkline Beecham, Warner Lambert and

Zeneca- that are widely diversified. These firms are engaged in the discovery, development, manufacturing and marketing of a broad line of pharmaceutical products for human use.

Firms belonging to this group (dominated by European firms) are characterized by high percentage of foreign sales (an average of 65%). Some of these firms market their products in more than 130 countries through affiliates and distributors. Frequently, products of a local nature and variations of product lines are manufactured and marketed to customers outside the original country in order to meet local regulatory requirements and marketing preferences. This high level of international operations imply certain additional risks inherent in conducting business outside the original country including price and currency exchange controls, changes in currency exchange rates, limitations on foreign participation in local enterprises, expropriation, nationalization, and other governmental action. Other economic factors involve rate of inflation and interest rates.

Research scope

Firms belonging to the second group invest quite large sums in research and development. They also attempt to reduce market risk through pursuing a broader R&D scope, which increase the likelihood of launching successful new drugs with some degree of regularity. Accordingly, these corporations are active in a quite wide range of therapeutic markets. In addition, they actively seek out opportunities to invest in external research and technologies that hold the promise to complement and strengthen their own research efforts. These investments can take many forms, including licensing arrangements, co-development and co-marketing agreements.

Resource commitment

R&D and capital intensity of firms forming the second group are slightly higher than firms belonging to the first group. This might be explained by the difference in size and thus the difference in R&D productivity.

Product-industry scope

Companies forming the second group are widely diversified. Indeed, approximately 42 percent of sales generated by these firms are from activities other than pharmaceutical segment. In addition to the human pharmaceuticals business segment, these firms are engaged in various activities like:

1. Fine chemical: this segment includes detergent, food ingredients, paper production, environmental chemicals, capsules, plastics, cigarette filter tow, textile and denim products, synthetic polymers and fibers, leather coatings, resins, biocides, and many various other products.
2. Medical systems: includes intravenous products like intravenous solutions, irrigation solutions, intravenous administration sets, infusion pumps and other infusion supplies and equipment, primarily to hospitals and alternate site health care locations in the United States and, through independent distributors, in various foreign markets. This segment includes also drug-monitoring and medical diagnostic systems, clinical laboratory testing (body fluid and tissue sample diagnostic tests) and pharmaceutical management services.

3. Agrochemical and veterinary products, including herbicides, crop protection products; insecticides, veterinary anesthetics and pet care products.
4. Confectionery products like chewing gums, breath mints and cough tablets.
5. Consumer health care products including cosmetics lines, fragrances, flavors and Shaving products.

Competition

Most markets in which these firms are engaged are highly competitive and characterized by substantial expenditures in the advertising and promotion of new and existing products. In addition, there is an intense competition in research and development in all segments particularly in human pharmaceuticals segment.

Competitive factors are the same as group one and include (i) pricing pressures, both in the United States and abroad, primarily from managed care groups and government agencies, (ii) the development of new products by competitors having lower prices or superior performance or that are otherwise competitive with firms' current products, (iii) generic competition as products go off patent, (iv) technological advances and patents obtained by competitors and (v) problems with licensors, suppliers and distributors.

Group three

Size

The third group consists of eight firms: six small biotechnology and biopharmaceutical firms (Amgen, Ares Serono, Gensia, Chiron, Immunex, and Genentech), and two mid-sized pharmaceutical firm (Astra and Schwarz Pharma).

The six biotechnology and biopharmaceutical companies discover, develop, manufacture and market human therapeutics based on advanced cellular and molecular biology. These firms have committed their resources to the research and development of pharmaceuticals using recombinant DNA technology and other innovations in biology and chemistry. By contrast most of the drugs marketed by other firms employ chemotherapy, i.e., the ingestion of organic chemical compounds (Bogner & Thomas, 1996). Biotechnology firms are primarily known to possess specific expertise in computer assisted, structure based drug and drug design.

Firms belonging to the third group are characterized by a small/medium size as well as low percentage of foreign sales (an average of 31%).

Research scope

The R&D programs of biopharmaceutical firms constituting this group provide the driving force to support and sustain their growth. All of them have a strong commitment to research as the essential component of their product development effort.

At the same time, an important part of the research and development effort is undertaken in collaboration with third parties (usually major pharmaceutical firms) who are able to contribute significant enabling technologies and other resources to the development and commercialization of the product. These resources include in some cases marketing and sales expertise of 'major firms' having established positions and distribution networks in applicable market segments.

Biotechnology firms forming this third group are characterised by a narrow research focus. Biotechnology firms are generally founded in order to exploit a single or a small number of patents for the development of a unique drug, which explains their narrow research focus (Ballance et al., 1992). In addition, managers believe that strategic focus on a limited number of therapeutic classes could lead to expertise that can be applied to reduce development times, create innovative and cost-saving research techniques, optimize product quality, and discover new products and applications.

The clinical development and regulatory strategy for therapeutic products under development is often to pursue initial approval for a narrowly defined indication. The company then seeks to expand the indication for which the products may be marketed by conducting additional clinical trials and providing health economic data in support of the product's utility.

Factors affecting the firms' R&D expenses include, but are not limited to: the outcome of clinical trials being conducted, the number of products entering into development from late-stage research, in-licensing activities and future levels of revenues expected.

Product-industry scope

The third group includes firms active quasi exclusively in pharmaceutical activities. Indeed, approximately 99 percent of sales generated by these firms are related to pharmaceutical operations. This fact may be explained in part by their relatively limited financial resources. In addition, most of these firms become targets for acquisition once

their particular product is established in major markets. As a result, many are becoming more closely integrated with large pharmaceutical firms, which limits their diversification (Ballance et al., 1992).

Resource commitment

Firms forming the third group consists of small and medium sized companies engaged in research intensive activities requiring heavy investments. The combined effects of small size and considerable research expenditures needed to discover a new drug explain the high R&D intensity distinguishing this group. Typically, such firms incur operational losses at early stages of operation since their research expenditures exceed revenues earned from royalties (Ballance et al., 1992).

Competition

Biopharmaceutical firms operate in a highly competitive environment, and the competition is expected to increase as commercial applications for biotechnology products increase. Competitors include large pharmaceutical (firms belonging to strategic groups 1 & 2), chemical and diagnostics companies, as well as similar biotechnology companies belonging to the same strategic group that are researching, developing and marketing products, based on related or competing technologies.

In addition, a number of companies have recently entered the biological products field, some through acquisition or merger, and more may be expected to do so in the future.

Managers also believe that significant competition will come from established major pharmaceutical companies that have greater capital resources, manufacturing and

marketing experience, research and development staffs, sales forces and production facilities than mid-sized biopharmaceutical firms. These major pharmaceutical companies may develop products more rapidly or may be able to complete the regulatory approval process sooner, and therefore market their products earlier than biopharmaceutical firms.

In addition, certain specialized biotechnology firms have entered into cooperative arrangements with major companies for development and commercialization of products, creating an additional source of competition.

The technologies applied by biopharmaceutical firms are rapidly evolving, and new developments frequently result in price competition and product obsolescence. Substantial consolidation is underway in the global healthcare industry, and is expected to produce greater efficiencies and even more intense competition.

Important biotechnology research is performed in universities and nonprofit research organizations. These entities are becoming more active in seeking patent protection and licensing revenues for their discoveries. The competition among large pharmaceutical companies and smaller biotechnology companies to acquire technologies from these entities also is intensifying. These institutions also compete with each other to recruit scientific personnel and to establish proprietary positions in technology.

Over the longer term, the firms' ability to successfully market current products, expand their usage and bring new products to the marketplace will depend on many common factors, including but not limited to the effectiveness and safety of the products, FDA and

foreign regulatory agencies' approvals for new indications, the degree of patent protection afforded to particular products, and the effect of managed care as an important purchaser of pharmaceutical products.

In addition to biotechnology firms, the third group includes two other mid-sized pharmaceutical firms (Astra and Schwarz) characterised by high R&D intensity.
In the case of Astra, the significant R&D intensity might be explained by two factors:

1. CEO Hakan Mogren dismisses the pharmaceutical industry's trend to merge, instead investing in R&D efforts to facilitate growth.
2. Astra commercializes peptic ulcer remedy Losec which is the world's best-selling prescription drug and which accounts for about half of its sales. As the US patent for Losec moves toward its expiration in 2001, Astra is counting on its active R&D pipeline to produce replacements for its top performer.

Similarly, Schwarz's managers are convinced that, despite worldwide concentration processes affecting the pharmaceutical industry, mid-sized companies like Schwarz still have a good chance of success. They believe that pharmaceutical giants will not take over smaller companies but fast, innovative companies will take over slower ones.
Schwarz's managers intend to seize the opportunities presented by the extraordinary progress in medical research to establish an innovative and competitive position. Their R&D strategy consists in a close interaction with creative biotechnology and other

technology companies (belonging to the same group) in order to secure the supply of new and innovative projects for the company's development pipeline.

Group four

Size

The fourth group comprises fourteen small/mid-sized firms:

1. Nine small firms that develop, manufacture and sell both branded and generic forms of ethical drug products which require a physician's prescription, as well as non-prescription pharmaceutical products sold over-the-counter. These firms are Mylan, Barr, Watson, Alpharma, Medeva, Perrigo, Copley, Roberts and Forest;
2. Two mid-sized firms engaged in the discovery, development, manufacturing and marketing of specialty pharmaceutical and health care products worldwide. These firms are Schering Plough and Sanofi;
3. Allergan, a leading provider of eye care and specialty pharmaceutical products throughout the world with products in the eye care pharmaceutical, ophthalmic surgical device, over-the-counter contact lens care, movement disorder, and dermatological markets;
4. Carringthon, a small research-based pharmaceutical and medical device company engaged in isolating and developing naturally occurring complex carbohydrates and,
5. Genzyme General which develops and markets therapeutic and surgical products and diagnostic services and products.

Generic manufacturers' business strategy has mainly three core components:

Development and Marketing of Selected Generic (Off-Patent) Pharmaceuticals.

Generic manufacturers belonging to the fourth group have invested significantly in off-patent product development and are developing a wide variety of therapeutic products. Generally, each product is chosen based on the patent expiration date, market size and potential anticipated competition, availability of active ingredients and other considerations. These companies seek to be among the first companies to offer such products. Accordingly, such firms often pursues the development and marketing of generic pharmaceuticals that have one or more barriers to entry as difficulty in sourcing raw materials; difficulty in formulation or establishing bioequivalence; manufacturing that requires unique facilities, processes or expertise. Managers believe that products with such barriers will face limited competition and therefore provide longer product life-cycles and/or higher profitability than commodity generic products.

Challenging Patents Protecting Certain Brand Pharmaceuticals.

In some cases (Barr Laboratories), pursues development and marketing of branded pharmaceuticals protected by patents where the company believes that such patents are either invalid or not infringed by the company's product. This strategy is an extension of the company's generic strategy, in that, issued patents, even invalid patents, present barriers to entry to companies that do not have the capabilities to assess and challenge the validity of such patents. Barr Laboratories managers believes that the successful

development of pharmaceuticals that were perceived by competitors to be patent protected may offer longer product life-cycles and/or higher profitability.

Development and Introduction of Proprietary Pharmaceuticals.

Generic manufacturers are also pursuing the development of proprietary pharmaceuticals that may have some period of exclusivity, typically from three to seven years. These firms are convinced that such products will produce higher and more consistent profitability than the typical generic product. In other cases, these firms have organized their drug development, acquisition and marketing activities to focus on late-stage development drugs in Phase II or Phase III clinical trials and currently marketed prescription pharmaceutical products which:

1. Do not meet the strategic objectives or profit thresholds of larger pharmaceutical companies. Indeed, the marketplace economics that impact the much larger, multi-national pharmaceutical companies may limit their willingness to provide orphan drug products or therapies where the patient population is too small to provide a sufficient return on investment. Managers believe that these areas could provide an opportunity for limited competition for proprietary products, or
2. Are made available by government agencies and research institutions.

Therefore, the business strategy of generic manufacturers consists of a balanced strategy of developing off-patent and proprietary products. Over the next few years, patents on a relatively large number of branded drugs will expire, thereby providing additional off-patent product opportunities.

Research scope

In view of the substantial funds which are generally required to develop new chemical drug entities, firms belonging to this group do not attempt primary to undertaking such activities.

Resource commitment

The low R&D and capital intensity distinguishing firms belonging to the fourth group is primary explained by the fact that these firms do not develop new chemical drug entities.

Product-industry scope

Firms forming the fourth group are not widely diversified and appear to focus upon drugs as their dominant product. Indeed, approximately 90 percent of sales generated by these firms are related to pharmaceutical activity.

Competition

Due to the non-exclusive nature of generic products, the generic industry is comprised of numerous competitors engaged in researching, developing, marketing and selling products intended to treat the same conditions and diseases as the products currently sold by companies belonging to the first group. These firms are essentially the following:

1. Similar off-patent drug manufacturers;
2. Brand-name pharmaceutical companies that manufacture or market off-patent drugs;
3. The original manufacturers of brand-name drugs that continue to produce such drugs after patent expirations or introduce generic versions of their branded products, and

4. Manufacturers of new drugs that may compete with the Company's off-patent drugs.

This diversity provides significant price competition within the generic pharmaceutical industry, which generally results in decreasing prices of generic products over time as the number of off-patent manufacturers, which produce a particular product increases. In addition brand-name manufacturers frequently take actions to prevent or discourage the use of generic equivalents through marketing and regulatory activities and litigation. During 1997, some branded pharmaceutical companies appeared to increase their efforts to utilize state and federal legislative and regulatory forums to delay generic competition and limit the branded product market erosion that occurs once patent protection is lost for a branded product.

The consolidation of customers through mergers and acquisitions along with the emergence of large buying groups representing independent pharmacies and health maintenance organizations has also contributed to the severe price deterioration for the generic products.

In addition to price, principal competitive factors in the off-patent pharmaceutical market includes the ability to promptly introduce products after the expiration of market exclusivity, quality, methods of distribution, reputation, customer service (including maintenance of inventories for timely delivery) and breadth of product line. Approvals for new products may have a synergistic effect on a company's entire product line since

orders for new products are frequently accompanied by, or bring about, orders for other products available from such company.

Among the fourth group, two mid-sized firms (Schering Plough and Sanofi) engaged in the discovery, development, manufacturing and marketing of specialty pharmaceutical and health care products worldwide are present. This could be explained by the fact that these firms appear to have no clear strategy. In fact, they seem to be "stuck in the middle" since they are mid-large, moderately diversified and have low R&D and capital intensity. Similarly, membership of Allergan, Carringthon and Genzyme in group four is essentially attributable to their small size and low diversification level.

Testing performance-growth capability correlation

After identifying strategic groups in the pharmaceutical industry, it is essential to determine if there is substantial and continuous within-group variation in sustainable growth capability and performance. If both growth capability and performance variations are found among strategic group members, then we can test if performance is positively correlated with capabilities for members of the same group.

To investigate within-group variation in sustainable growth capability and performance two sets of variables have been used: central tendency and dispersion.

1. The mean and median are called measures of central tendency because they describe the center, middle, or most typical value in a sample. The median is the middle

observation when the data values are ordered from smallest to largest. When the sample size is even, the median is the average of the two middle values. For a symmetric distribution the mean and median coincide.

2. The minimum, the maximum, the range, the standard deviation and the standard deviation / mean are commonly used as measures of dispersion or variation. Large values of these measures suggest a substantial within-group variation in sustainable growth capability and performance.

If all companies in the same strategic group have identical or similar growth capabilities, then measures of dispersion within a strategic group in growth capability will be equal to zero or small. If firms in the same strategic group substantially differ in growth capabilities, then the dispersion measures (range, standard deviation and standard deviation / mean) will be large. The same reasoning is adopted to investigate within-group variation in performance.

Tables 16-17-18 and 19 clearly suggest that firms belonging to the same strategic group differ in both growth capabilities and performance. Indeed, we observe relatively large values of dispersion measures (range, standard deviation and standard deviation / mean) for each group, which indicate that growth capability and performance values differ considerably from their respective group mean. For example, the standard deviation for the ratio debt/equity in group one is approximately 184 percent, which is 2.15 times the group mean.

Table 16: Central tendency and dispersion of growth capability and performance measures - first strategic group.

	Central Tendency		Dispersion				
	Median	*Mean*	*Range*	*Minimum*	*Maximum*	*St. Deviation*	*SD/Mean*
Cash/Sales	21.20	20.64	20.2	9.47	29.67	5.93	0.28
Debt/Equity	16.00	85.58	624.77	10.68	635.45	184.43	2.15
F.Assets/T. Assets	49.96	52.60	47.77	30.25	78.02	15.81	0.30
Margin	13.56	13.30	16.35	3.33	19.69	5.34	0.40
Sales/F. Assets	140.33	167.69	128.67	108	236.67	51.95	0.31
ROA	15.80	12.93	16.46	4.16	20.62	6.54	0.50

All values are expressed in percentages.

Table 17: Central tendency and dispersion of growth capability and performance measures - second strategic group.

	Central Tendency		Dispersion				
	Median	*Mean*	*Range*	*Minimum*	*Maximum*	*St. Deviation*	*SD/Mean*
Cash/Sales	14.72	17.41	24.81	7.91	32.72	8.12	0.46
Debt/Equity	48.62	50.98	122.78	1.87	124.65	39.54	0.77
F.Assets/T. Assets	52.50	53.00	55.39	21.99	77.38	17.08	0.32
Margin	10.67	7.20	15.54	-1.48	14.05	5.90	0.82
Sales/F. Assets	150.33	152.62	140.66	88.67	229.33	52.01	0.34
ROA	6.63	8.15	13.40	1.38	14.78	4.86	0.59

All values are expressed in percentages.

Table 18: Central tendency and dispersion of growth capability and performance measures - third strategic group.

	Central Tendency		Dispersion				
	Median	*Mean*	*Range*	*Minimum*	*Maximum*	*St. Deviation*	*SD/Mean*
Cash/Sales	14.56	11.08	56.97	-21.55	35.42	19.71	1.77
Debt/Equity	21.73	28.37	67.02	3.11	70.13	24.38	0.86
F.Assets/T. Assets	44.40	44.73	8.94	40.42	49.37	3.67	0.08
Margin	6.82	0.46	74.60	-46.30	28.30	24.70	53.46
Sales/F. Assets	141	159.50	198.33	102.33	300.66	63.14	0.39
ROA	5.72	1.09	68.49	-42.16	26.32	22.53	20.66

All values are expressed in percentages.

Table 19: Central tendency and dispersion of growth capability and performance measures - fourth strategic group.

	Central Tendency		Dispersion				
	Median	*Mean*	*Range*	*Minimum*	*Maximum*	*St. Deviation*	*SD/Mean*
Cash/Sales	12.03	15.12	43.42	-4.38	39.04	10.91	0.72
Debt/Equity	6.63	21.00	108.84	0	108.84	32.47	1.54
F.Assets/T. Assets	46.49	44.23	61.02	6.05	67.07	19.15	0.43
Margin	6.39	7.59	50.21	-18.30	31.91	13.00	1.71
Sales/F. Assets	194.67	226.37	427.44	115.89	543.33	114.16	0.50
ROA	8.015	8.62	35.74	-8.74	27	10.06	1.16

All values are expressed in percentages.

Analysis of Variance has been used to test if any differences exist among the means (Return On Assets) for the four strategic groups. The F statistic for testing if a difference exists between one or more means is 1.507 with a p value of 0.228 (see Table 20). This result clearly indicates that strategic groups do not significantly differ in performance.

Table 20: ANOVA – Between groups differences in performance

		Sum of Squares	Df	Mean Square	F	P value
ROA	Between Groups	653.095	3	217.698	1.507	0.228
	Within Groups	5489.477	38	144.460		
	Total	6142.572	41			

Hypothesis two declares that performance differences within strategic groups are positively correlated with growth capability differences within groups. Hypothesis two is tested for each group utilizing a multiple regression model with Return on Assets as the dependent variable and company's sustainable growth indicators as independent variables. Results are found in table 21

The squared correlation coefficient (R^2) between Return on Assets and the growth capability variables are 0.987 for group one, 0.982 for group two, 0.999 for group three and 0.973 for group four. The F statistic is highly significant indicating that the simultaneous test that each coefficient is 0 is rejected. Results were significant at the 0.05 level for all four groups. However, the fact that the associated probability (Sig.) is so

small (< 0.01) does not imply that each of the independent variables makes a meaningful contribution to the fit of the model.

Thus, growth capability and performance differences are positively correlated among companies within the same strategic group. Considering these findings, we conclude that hypothesis two is also supported.

Table 21: Capabilities and Return on Assets - Regression results (3 factors solution ---- N = 42)

Capabilities	Group 1 n=11		Group 2 n=9		Group 3 n=8		Group 4 n=14	
	Beta	**p**	**Beta**	**p**	**Beta**	**p**	**Beta**	**p**
Cash/Sales	**0.155**	**0.113**	**0.202**	**0.343**	**-0.069**	**0.421**	**0.38**	**0.009**
Debt/Equity	**-0.023**	**0.724**	**0.195**	**0.206**	**-0.002**	**0.945**	**0.044**	**0.487**
F.Assets/T.A	**0.573**	**0.001**	**0.619**	**0.081**	**0.070**	**0.143**	**0.548**	**0.002**
Margin	**0.676**	**0.001**	**0.708**	**0.009**	**1.001**	**0.005**	**0.823**	**0.000**
Sales/F.Assets	**0.537**	**0.003**	**0.679**	**0.017**	**0.165**	**0.024**	**0.551**	**0.003**
R^2	**0.987**		**0.982**		**0.999**		**0.973**	
F	**78.151**		**32.902**		**338.578**		**57.581**	
P	**0.000**		**0.008**		**0.003**		**0.000**	

CHAPTER V: DISCUSSION & CONCLUSION

The brief overview of the relatively rich literature on strategic group concept reveals that the relationship between strategic group membership and firm profitability has been a central and controversial theme. The theoretical foundation for a direct link between strategic group membership and firm profitability has been the notion of mobility barriers. Mobility barriers preserve profitability differentials for two principal reasons. First, they inhibit imitation from competitors outside the group, which maintains the imperfectly competitive conditions needed for strategic groups to affect prices and profits. Second, mobility barriers delineate the boundaries of the group and increase the stability of the group over time. However, the empirical evidence for a direct link between strategic group membership and performance is inconsistent and conflicting. Consequently, this study proposes that individual firm sustainable growth capabilities, which reflect individual firm's potential to create resources to attain a certain sustainable growth, may moderate the effect of member's shared strategy characteristics on performance in the pharmaceutical industry.

The explanatory power of the strategic group concept is fundamentally dependent on the strength of the approach adopted to operationalize strategy. The mixed evidence for a direct link between strategic group membership and performance has been often associated to the large number of approaches used, which have generally not captured adequately the differences in the strategies adopted by firms in competitive environments. Consequently, particular care has been taken to ensure an adequate operationalization of

strategy when forming strategic groups. A thorough analysis of the key bases of competition in the pharmaceutical marketplace has been undertaken. This analysis identified key success factors that form the basis for effective strategy development. These key success factors has been confirmed by a panel of industry experts.

The analysis of the competitive environment of the pharmaceutical industry revealed two important entry/mobility barriers. These barriers consist of product differentiation based on R&D and marketing; and the associated capital requirement for successful product differentiation.

The first distinctive characteristic of this study is related to introduction of product/industry diversification as strategic variable. Product/Industry diversification has been absent in previous studies investigating strategic groups in the pharmaceutical industry, which implicitly assumed those pharmaceutical firms are equally diversified across industries. Therefore, three strategic factors (scope, diversification and resource deployment) representing a union of those typically used to capture strategic behavior in the strategic management literature and those identified by industry experts as key elements of competitive strategy in the pharmaceutical industry have been used in this study.

Another major particularity of this study involves the enlargement of the sample frame across national borders. Indeed, almost all previous studies dealing with strategic groups have been limited to examining the strategic groups within a particular national boundaries (usually, U.S.). This may be convenient if the competition is limited to national boundaries, but given the increasing trend towards globalisation of markets

(particularly in the pharmaceutical market) a rich study of strategic groups imply necessarily the presence of multinational and global participants.

The pharmaceutical industry had received considerable strategic management research. In particular, several dynamic longitudinal studies have identified distinct strategic groups in the pharmaceutical industry. Longitudinal analysis of strategic groups provides a valuable tool for studying the pharmaceutical industry since it allows meaningful perception of the stability and sustainability of competitive advantage and performance in an industry. Using similar strategic dimensions as those used in this study, Cool & Schendel (1987, 1988) identified six strategic groups in the U.S. pharmaceutical industry during the period 1963-1982. The first group is composed by large, R&D intensive prescription drugs firms active in many market segments with a broad range of products. It is clear that strategic characteristics of this group correspond exactly to the first group identified in this study. An equivalent strategic group was also identified by Fiegenbaum, Sudharsan & Thomas (1987, 1990).

The second group identified by Cool & Schendel (1987, 1988) consists of large firms differing from the first group on three key dimensions: (1) they are advertising-intensive and not R&D intensive; (2) they compete in the non-prescription as well as the prescription market segments; (3) and finally they serve fewer market segments in the prescription drug market and offer a less comprehensive product range. The third group includes medium-sized firms pursuing principally a "me too" strategy.

It seems that these two groups have merged into one group comparable to the second group identified in this study. Indeed, several common characteristics can be identified such as size (mid-sized), scope (less comprehensive product range), and market segments. It appears that these firms did not succeed in keeping pace with the innovative output of the R&D leaders.

The fourth group identified by Cool & Schendel (1987, 1988) consists of medium sized firms without real competence in R&D. This group shares its two principal characteristics with the fourth group found in this study and dominated by generic producers. It should be stressed however, that this group including generic firms represents nowadays a much more powerful competitive force in the pharmaceutical marketplace than during the 1970s and 1980s.

Small prescription drug firms with a narrow product range and a selective participation in market segments compose the fifth group detected by Cool & Schendel (1987, 1988). While some common characteristics do exist between this group and the third group identified in this study (composed by biotechnology firms), other important differences exist. Indeed, strategic group composed by small biotechnology firms is characterised by a narrow product range and a selective participation in market segments. However, These biotechnology firms have a strong commitment to research as the essential component of their product development effort which is clearly not the case for the strategic group identified by Cool & Schendel (1987, 1988). Finally, the sixth group identified by Cool

& Schendel (1987, 1988) including only one very small firm with a very focused product line and a narrow scope does not coincide with any group identified in our study.

As a conclusion, it seems that the six strategic groups identified by Cool & Schendel (1987, 1988) in the U.S. pharmaceutical industry during the period 1963-1982 have experienced important changes from 1963-1982 to 1995-1997. While the group composed by large, R&D intensive prescription drugs firms active in many market segments with a broad range of products persists over time, it seems that two other groups have merged to form a single widely diversified group of firms. Finally, the emergence of new competitive forces represented by generic producers and biotechnology firms has been confirmed by the identification of distinct strategic groups including these firms competing in a distinct way for the same customers.

It should be stressed that this study analyses a static view. Results at this level are a first step to more complex studies. The next level of complexity would incorporate a dynamic view where changes in strategy position, sustainable growth capability and performance over time would be studied.

In addition to studying the stability and sustainability of competitive advantage in the pharmaceutical industry, this study examines the hypothesis that individual firm sustainable growth capabilities may moderate the effects of member's shared strategy characteristics on performance in the pharmaceutical industry. Results indicate that measures of sustainable growth capability and performance are significantly different and correlated among firms in the four groups defined on strategy dimensions. Therefore, it is

suggested that the conventional model involving a direct link between strategic group membership and firm profitability should be ameliorated by including different forms of individual firm characteristics supported by the resource-based view. Future studies should investigate the effects of other core resources such physical, human, technological and organisational capabilities, although critical questions remain for future research about the most effective way to operationalize these variables.

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