THE ROLE OF INTELLECTUAL PROPERTY IN THE COMPETITIVENESS OF THE PHARMACEUTICAL SECTOR : 1991 PHARMACEUTICAL REVIEW

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I EXECUTIVE SUMMARY

The purpose of this paper is to situate the role of intellectual property rights generally, and in particular patents, in terms of the competitiveness of the pharmaceutical sector. The specific impacts of compulsory licensing of pharmaceuticals are to be examined in another paper specifically addressing this issue.

To protect their inventions, pharmaceutical companies supplement patent protection with other forms of intellectual property rights such as trade secrets and trademarks. Patents provide the base or foundation on which IP strategies are engineered but the product life cycle, revenue streams, marketing strategies and nature of competition are affected by the cumulative effects of the entire array of IP rights. The effect of patents on competition in the pharmaceutical sector - especially the levels of price competition and product differentiation - is also affected by the unique characteristics of the pharmaceutical market including the drug regulatory approval system, government and privately financed drug plans and the relationship between consumers/pharmacists/physicians and the pharmaceutical manufacturers.

Patent rights are only one of several IP rights which affect the patentee's revenue stream for pharmaceutical firms. The financial returns for innovation are also dependent on policies affecting investments in IP (R&D and marketing), the level of IP protection for trade secrets and trade marks, as well as, the extent of exhaustion of IP rights. Any changes in patent rights must be considered within this context and it is necessary to determine how these changes will enhance or reduce the impact of the other factors affecting competitiveness in the Canadian pharmaceutical sector. The strategies employed by innovative pharmaceutical companies in adapting to differing standards and enforcement of intellectual property rights represent their attempts to optimise revenue streams and control over innovation within the entire spectrum of market forces.

The role of intellectual property protection in determining the location of pharmaceutical manufacturing and R&D is best characterized as an apparently necessary but not a sufficient condition. One of the key factors affecting locational decisions is a firm's strategic corporate policies. A wide array of local revenue/cost variables are also considered by pharmaceutical companies when locating manufacturing and R&D facilities. The decision to make direct capital investments in Canada is not based solely on those market conditions which the patent system directly affects but rather is based on a system of conditions beginning with the relative costs of producing an input at various locations. Given this scenario, an increase in

investment in Canada - R&D or manufacturing - will not necessarily follow automatically from changes in the level of prices and profitability in the small, open Canadian economy. Rather, as is the case in several other developed countries, the location of high technology investments may be contracted for in negotiations with the industry. Levels of investment and employment may be negotiated by Canada in return for concessions or incentives in any, some or all of the conditions affecting profitability in the Canadian market - including policies affecting patent protection and/or generic substitution of trademarked pharmaceuticals.

The important fact for all to realize is that a balanced approach must be adopted where, if a concession is made in one area, gains may be required in another. As well, where a change in one of the conditions has an impact on the market, it may cause one of the other players to adopt a strategy to nullify or reduce its impact.

II INTRODUCTION - TERMS OF REFERENCE

Competitiveness is a concept which does not have an agreed meaning in economics. However, many economists, from Porter to Ostry, are recognizing that the factors underlying competitive advantage are changing due to pervasive and continuous technological change, the globalization of industries and the internationalization of companies. Another central theme in creating a competitive advantage is the role of innovation at the firm level and in terms of public policy strategies.

The role of intellectual property in the competitiveness of the Canadian pharmaceutical sector is primarily that of a necessary, but not sufficient condition, for attracting investments in R&D, manufacturing and marketing/distribution. Domestic IP laws affect the abilities of MNE subsidiaries operating in Canada to attract capital funds and thereby the level of innovation, domestic rivalry and the nature of marketing strategies in Canada. Differences between Canadian and foreign IP laws, especially U.S. policies, affect the global competitiveness of Canadian innovative and generic pharmaceutical companies.

The main objective of this paper is to define Canadian competitiveness in the international pharmaceutical industry and determine the importance of intellectual property rights within this context. The purpose of this analysis is to situate IP laws in a comprehensive model of competition in the pharmaceutical sector and identify the important factors affecting a Canadian IP strategy that could be used to encourage Canadian competitiveness.

III INTERNATIONAL COMPETITIVENESS

Competitive Advantage of Firms in Global Industries

Michael Porter states that "firms create competitive advantage by perceiving or discovering new and better ways to compete in an industry and bringing them to market, which is ultimately an act of innovation." Innovation is defined broadly to include both improvements in technology and better methods or ways of doing things. Innovation is manifested in product changes, process changes, new approaches to marketing, and new forms of distribution. Innovation always involves investment in developing skills and knowledge and usually in physical assets and marketing effort. In international markets, innovations that yield competitive advantage anticipate both domestic and foreign needs (Porter, 1990). Thus, the importance of intellectual property to competitiveness in global industries results from the fact that IP protects innovation and that such protection is a critical factor for firms in creating a competitive advantage. Another important aspect in global competitiveness is that a minimum level of IP protection in both Canada and foreign markets is essential in knowledge intensive industries to ensure sufficient returns to both product development and global commercialization.

Innovations shift competitive advantage when rivals either fail to perceive the new way of competing or are unwilling or unable to respond. The possibilities for new ways of competing usually grow out of some discontinuity or change in industry structure. Every new structural change in an industry creates opportunities for new early movers. Moving early can allow a firm to translate an innovation into advantages such as economies of scale and to establish brand names and customer relationships. These early mover advantages may be another source of sustainable competitiveness complementing innovative activities based purely on new products. The most common causes of innovation that shift competitive advantage include the following:

(1) New Technologies
(2) New or Shifting Buyer Needs
(3) The Emergence of a New Industry Segment
(4) Shifting Input Costs or Availability
(5) Changes in Government Regulations (Porter, 1990)

Innovation has also been characterized as primarily resulting from a conscious, purposeful search for innovation opportunities, which are found only in a few situations. Purposeful, systematic innovation begins with the analysis of the sources of new opportunities. The following are some of the opportunities that exist within a company or industry:

(1) Unexpected Occurrences

(2) Incongruities
(3) Process Needs
(4) Industry and Market Changes (Drucker, 1985).

Sources for innovation opportunities also exist outside a company in its social and intellectual environment:

(5) Demographic Changes
(6) Changes in Perception
(7) New Knowledge (Drucker, 1985).

There are two concepts of innovation: the "ladder" and the product cycle. The most common perception of the relationship of innovation to production is the step-by-step reduction to practice of new scientific knowledge that then generates a radically new product. This process can be conceptualized as a "ladder" since breakthrough products or commercial processes are the result of cumulative scientific research. Another more important process of innovation is characterized by incremental improvements or cyclic developments which are governed by the product life cycle. Many products, after going through the ladder process, are absorbed in cyclic development (Gomory, 1989).

Sustaining competitive advantage depends on the source of the advantage, the number of distinct sources of advantage a firm possesses and constant improvement and upgrading. There is a hierarchy of sources of competitive advantage in terms of sustainability. Higher-order advantages such as proprietary process technology, product differentiation based on unique products or services, and brand reputation based on cumulative marketing efforts are more durable. Lower-order advantages, such as low labour costs or cheap raw materials are relatively easy to imitate and are difficult to sustain. Sustaining advantage requires that its sources be expanded and upgraded, by moving up the hierarchy to more sustainable types. Sustaining advantage necessitates that firms exploit, rather than ignore, industry trends (Porter, 1990).

Competitive advantage grows out of the way firms organize and perform discrete activities. The operations of any firm can be divided into a series of activities or value chain. To gain competitive advantage over its rivals, a firm must either perform activities more efficiently than its competitors (lower cost) or act in a unique way which commands a premium price (differentiation through new product development).

The ability to commercialize technology, to move a product from concept to market quickly and efficiently, is crucial in creating and maintaining a competitive advantage in the current business environment. The major trends increasing the importance of commercialization capability include:

(1) The increasing proliferation of new technologies which accelerate obsolescence and shrink the life cycles of many products.

(2) Knowledge of technological innovation is spreading more rapidly such that important technological breakthroughs are more difficult to maintain as proprietary.

(3) Markets are becoming more fragmented, thereby offering increasing opportunities for niche products (Nevens, 1990).

These competitive realities make the firm's capability to commercialize technology at least as important as traditional sources of advantage such as scale, skilled labour, possession of proprietary technology and access to technology. Commercialization capability or a firm's ability to commercialize and to compete can be analyzed using the following factors:

(1) Time to Market - When base technologies are widely available and product life cycles are short, getting to market quickly is essential especially in some industries, like prescription pharmaceuticals, where the market share rewards for being first are great.

(2) Range of Markets - The cost of developing technologies is high and rising so companies must spread costs across as many product and geographic markets as possible.

(3) Number of Products - Market fragmentation creates opportunities for companies that can easily adapt products to appeal to market niches.

(4) Breadth of Technologies - In many markets, products incorporate an increasing number of technologies, and companies must be able to master - or access and integrate - all of them to compete (Nevens, 1990).

A firm's home base is the nation in which the essential competitive advantages of the enterprise are created and sustained. It is where a firm's strategy is set and the core product and process technologies are developed and maintained. The home base will be the location of many of the most productive jobs, the core technologies, and the most advanced skills. The presence of the home base in a nation also stimulates the greatest positive influence on suppliers and other industries employing similar technology.

Competitive Advantage of Nations

An emerging trend influencing the government-corporate interface in global competitiveness is innovation policy; a policy set focused on the promotion and adoption of new technology. A wide range of public policies, both macro and micro, affect the generation and application of new technologies.

Two basic models of innovation policy strategies focus on the two goals of: (1)creating state-of-the-art technology at home; and (2)fostering rapid technological diffusion in the domestic market of technologies developed abroad. Innovation policy centres on the competitive advantages associated with technology externalities and first-mover rationale. Those technologies and industries that generate significant externalities or benefits across a wide spectrum of domestic industries are strategic. First-mover advantages enable a country or firm to preempt foreign rivals through consolidation and extension of competitive advantage.

As countries compete to foster domestic innovation there is system friction. There are simultaneous trends towards international convergence or harmonization in a range of regulatory and trade related policy areas while countries also pursue differing strategies to create a competitive advantage in strategic technologies or industries. Increasingly, countries must be concerned not only with other countries' trade and innovation policies but with the international impact of many of their domestic policies. Canadian public policy, including intellectual property rights, must compete with other countries to create an environment that encourages investment in innovation while ensuring that Canadians have access to both foreign technology and global markets and receive a fair share of the benefits of innovation in terms of Canadian value-added and employment.

National economies exhibit a number of stages of competitive development - factor-driven, investment-driven, innovation-driven and wealth-driven - reflecting the characteristic sources of advantage of a nation's firms in international competition and the nature and extent of internationally successful industries and clusters. In the innovation-driven economy, firms not only appropriate and improve technology and methods from other nations but create them. The sources or determinants of competitive advantage in an innovation-driven economy - factor conditions; demand conditions; related and supporting industries; and firm strategy, structure and rivalry - can be influenced by national innovation policy (Porter, 1990). In an innovation-driven economy the environment for local firms which promotes the creation of competitive advantage includes:

(1) Factor Conditions - advanced and specialized factors are created and upgraded
- selective factor disadvantages stimulate product and process innovation

(2) Demand Conditions - demand sophistication becomes an advantage
- domestic demand begins internationalizing through a nation's multinationals

(3) Related and Supporting Industries
- related and supporting industries are well-developed

(4) Firm Strategy, Structure and Rivalry
- firms develop global strategies

National competitiveness can be evaluated using the assets and liabilities of an economy in world competition. Competitiveness is described in terms of the attractiveness of an economy for investment and the aggressiveness of an economy in world markets. In 1991, Canada's quality of health care system ranked number one among developed countries as an asset contributing to global competitiveness. Canada's health care makes the country an attractive economy for investment across all sectors. The pharmaceutical sector is one component of the Canadian health care system and intellectual property is one policy instrument affecting the pharmaceutical sector. Thus, IP rights affect Canadian competitiveness through their impacts on the costs and quality of health care. It should also be noted that patents granted to residents and Canadians securing patents abroad are considered Canadian liabilities to international competitiveness (World Economic Forum, 1991).

The Pharmaceutical Industry

World production of and trade in pharmaceuticals are dominated by large multinationals with headquarters mainly in the United States, the United Kingdom, the Federal Republic of Germany, Switzerland and France. The world pharmaceutical industry is not dominated by an oligopoly of firms but rather an oligopoly of countries; the U.S. has 17 of the 30 largest drug companies (Tucker, 1984).

The pharmaceutical sector is characterized by a heterogenous, highly fragmented market where multinational firms are able to achieve dominant competitive positions for therapeutic classes.

The pharmaceutical market is comprised of a wide range of products which are suitable only for a few purposes (i.e., drugs can only treat a limited number of diseases) and the market is therefore divided into a number of therapeutic classes. In general, alternative drugs are available within each therapeutic class. Pharmaceutical markets can also be segmented based on availability restrictions: prescription markets versus over-the-counter (OTC) markets. Prescription drugs are marketed through pharmacies and paid for through drug insurance plans and direct consumer purchases. The pharmaceutical market can also be segmented into innovative patented brandname pharmaceuticals and generic drugs.

There are several features of the international pharmaceutical industry common across countries:

(1) Large promotional expenditures by branded pharmaceutical firms.
(2) Limited price competition.
(3) High accounting rates of return (a high ratio of accounting profits to book value of equity) for branded pharmaceutical firms.
(4) Division of markets between institutional purchasers (hospitals and governments) and individual consumers or patients with lower prices and less promotional efforts in institutional markets.
(5) Health insurance plans which may cover some proportion of drug costs.
(6) Branded pharmaceutical firms that are both multinational and vertically integrated into research, production, and marketing (Mathewson and Winter, 1984).

World consumption of pharmaceuticals is dominated by the U.S., Japanese and European markets. Global competitiveness requires that firms commercialize products in the major international markets for pharmaceuticals so commercial access to these markets is critical. The leading markets in terms of pharmaceutical consumption in 1990 were:

Country	Consumption as a Percentage of World Market Share

Source: Scrip No. 1555, October 5, 1990.

There are key trends which are changing the structure and conduct of the global pharmaceutical industry. These market trends are sources of potential competitive advantage for firms and countries which adopt optimal strategies to innovate. The opportunites for establishing a competitive advantage are presented in a hybrid framework of Potter's and Drucker's sources of innovation:

(1) New technologies;
(2) New or Shifting Buyer Needs;
(3) The Emergence of a New Segment;
(4) Shifting Input Costs on Availability;
(5) Demographic Changes
(6) Industry and Market Change.

(1) New Technologies

(i) Biotechnology

The golden era of chemotherapy was around WWII and advances in such pharmaceuticals since the 1969's have been limited to incremental improvements on existing products and techniques with the occasional bona fide "breakthrough". Recent advances in chemotherapy pale in comparison to advances made in biotechnologies. The biopharmaceutical sector will revolutionize the pharmaceutical industry since monoclonal antibody technology will lead to new diagnostics and the availability of low cost mass produced, safer (purer substances) and more specific drugs. The scientific knowledge underlying the new biopharmaceuticals coupled with an increased understanding of basic life processes will shift medicine development towards prevention rather than the curing of illnesses. The biotechnology revolution will swing the pharmaceutical industry to prediction and prevention of disease from diagnosis and treatment by chemotherapy. The established pharmaceutical companies must now compete in the newly defined "drug" market with new, specialized companies in genetic enzyme and cell engineering (Tucker, 1984). Biotechnology will provide opportunities to establish Canadian innovative biopharmaceutical companies with a global presence.

(2) New or Shifting Buyer Needs

(i) Medical Care Cost Containment

Drug costs, particularly in areas such as government prescription drug purchasing, is becoming a major issue in developed countries faced with fiscal spending restraints.

(Scrip No. 1552, September 26, 1990).

(ii) Cost Effectiveness of Drugs

In the past, the regulatory emphasis has been on proving that medicines were effective and safe. As health care costs soar; insurance companies, hospitals and government drug plans are increasingly concerned about the cost effectiveness of medicines. The marketplace is demanding that pharmaceutical companies undertake outcomes research in which the economic and quality-of-life impact of new products are estimated (Business Week, August 26, 1991).

(Scrip No. 1547, September 7, 1990). The changing role of drugs in preventative medicine and the potential for savings in overall health care costs is changing the nature of product competition in the pharmaceutical sector and there will be opportunities for firms adapting quickly to these trends.

(3) The Emergence of a New Industry Segment

(i) Growth for World-Wide Generics

Products in almost every major therapeutic class are among more than 65 major branded pharmaceuticals in the U.S. facing patent or market exclusivity expiry by 1995.

(Scrip No. 1588, February 6, 1991).

(Scrip No. 1540, August 15, 1990).

(Scrip No. 1549, September 14, 1990). There will be significant opportunities for marketing generic drugs globally during the 1990s, however, access to process technologies will be a critical determinant of competitiveness.

(ii) RX To OTC Switches

Pharmaceutical companies are planning on switching some important prescription-only drugs to over-the-counter (OTC) status.

(Scrip No. 1523, June 15, 1990). Industrialized countries outside the U.S. appear to allow a large number of OTC drugs which are restricted to prescription use or are not available in the United States.

(Scrip No. 1523, June 15, 1990). Given the trends toward self-medication by consumers and the proximity of U.S. consumers, it would appear that a Canadian strategy of accelerated Rx to OTC switches could expand Canadian pharmaceutical sales through American cross-border shoppers.

(4) Shifting Input Costs or Availability

(i) Increasing R&D Costs

The increasing cost of pharmaceutical R&D - particularly development costs associated with obtaining regulatory approval will provide many opportunities to innovators in the drug industry. The process of developing marketable drugs from lead compounds resulting from basic R&D is generally long, convoluted and costly. New discovery technologies are likely to accelerate and improve the drug development process by weeding out useless compounds before substantial resources are allocated for development and focusing on the more promising lead compounds. Some of the emerging tools for discovery drugs include:

(1) Receptor screens have become fairly common in the pharmaceutical industry and have contributed to identifying useful families of therapeutics (Netzer, 1990).

(2) Artificial Intelligence (AI) techniques are currently being used to gain a better understanding of the drug development process and, eventually, to produce software to assist drug design (Netzer, 1990).

(3) With pharmaceutical companies experiencing increasing difficulties in developing drugs in a cost-effective manner, the need for systematic and creative approaches to decision making at every stage in the development of new drugs is well accepted. Decision analysis applications in pharmaceutical R&D include evaluating new compounds, prioritising projects, allocating resources, and choosing research strategies. Decision analysis techniques enable R&D managers to make more efficient use of limited resources, often increasing the benefits of research programs with no additional expenditure (Phillips, 1990).

(5) Demographic Changes

(i) Aging Population

The aging populations of developed countries are providing substantial opportunities for innovative pharmaceutical companies. It is estimated by the Pharmaceutical Manufacturers Association (PMA) that the annual economic impact in the U.S. of the most important diseases of aging are as follows : cancer ($104 billion), cardiovascular ($101.3 billion), Alzheimer's ($88 billion) and arthritis ($36 billion).

(Scrip No. 1635, July 19, 1991). The opportunities for developing innovative pharmaceuticals targetting the aging population are sizeable for firms given the total economic impact of these diseases on the economy and government expenditures.

(6) Industry and Market Changes

(i) Niche Markets

The trend towards very large firms and the focus on specific therapeutic areas in the pharmaceutical industry are resulting in opportunities for smaller companies. To be successful, niche products: (1)should be too small to attract the interest of major pharmaceutical companies; (2)should meet a clinical need; (3)should be responsive to promotion; and (4)should have some degree of IP protection. Niche marketers can compete through patenting improvements in drug formulations and delivery systems, developing branding and packaging strategies and patenting new pharmaceutical processes.

(Scrip No. 1630, July 3, 1991).

(ii) Increased Numbers of Blockbusters

Lehman Brothers has forecast that there will be more than 50 prescription pharmaceutical products across a wide range of therapeutic classes with sales of more than $500 million by the year 2000.

PART 1 - INTER-FIRM - COMPETITIVENESS

IV THE USE OF INTELLECTUAL PROPERTY AS A SOURCE OF COMPETITIVE ADVANTAGE

Effectiveness of Alternative Means of Protecting the Competitive Advantages of New and Improved Processes and Products

Multinational pharmaceutical companies rank, in order of importance, technological advantage, marketing skills, managerial skills, trademarks and scale economies as the most significant sources of competitive advantage. The pharmaceutical sector also ranks patents, know-how advantages and brand-name recognition as more important methods of protecting and/or securing technological advantage than secrecy, economies of scale and the costs of imitation for competitors (Wyatt, 1985).

For new processes, patents are generally rated the least effective of the mechanisms - secrecy, lead time, learning curve advantages, and sales or service efforts - of appropriating competitive advantages from improved processes. Generally, lead time, learning curves and sales and service efforts are regarded as substantially more effective than patents in protecting new products. However, obtaining both product and process patents is considered to be more effective in protecting the competitive advantages of innovation than all other factors (Levin, 1987).

Patents for products are typically considered more effective than those for processes and secrecy is considered less effective in protecting products than processes. The tendency to regard secrecy as more effective than process patents but less effective than product patents is indicative of the greater ease and desireability of maintaining secrecy about process technology. Firms may refrain from patenting processes to avoid disclosing either their existence or the details of an innovation (Levin, 1987). There is a greater incentive for undertaking product rather than process innovation in the pharmaceutical industry since firms are unwilling to invest large amounts toward reducing production costs where the effective life of individual products is short due to obsolescence (Comanor, 1964).

The gross profit margin (revenues minus cost of sales) which a pharmaceutical product can earn is directly related to the degree of protection it has from competition. A 95% gross profit margin for patented products can generally be achieved compared with the 20-25% gross profit which unbranded generics garner. Between the two ends of the profitability spectrum, products can command varying margins depending on the level of complexity of the product differentiation and/or level of IP protection. For example, patents on delivery systems (e.g., injectable formulation instead of a tablet) of generic drugs can double the gross profit margin on pharmaceutical products to 40%. Packaging

(trade dress, industrial design) and branding (trademarks) can also improve margins for generics. Improved formulations provide significant opportunities for patentees (Scrip No. 1630, July 3, 1991). Controlled substances subject to government quotas and registration also enjoy higher profit margins. As indicated earlier, process patents are less important than product patents, however, process patents still are one of the most important IP strategies for lessening domestic rivalry and can result in gross profit margins up to 75%.

The impact of patent protection depends on the strength of other appropriability mechanisms and varies widely among industries. In those industries such as pharmaceuticals in which patent protection is effective, other means of appropriation may be poor substitutes for strong patent protection (Levin, 1987).

The chemical and chemical products industries included among the top R&D performers in Canada use a range of intellectual property rights although patents and trademarks are the most important. The percentage of chemical firms that use the various intellectual property rights is: patents (85%), trademarks (82%), industrial designs (73%), copyrights (64%) and trade secrets (60%). The percentage of firms in the chemical and chemical products industries, included in a survey of high technology sectors, that use the various IP rights is: trademarks (69%), patents (66%), trade secrets (50%), copyrights (28%) and industrial designs (14%). (Price Waterhouse, 1989). The conclusion drawn from this survey data is that while patents are important in the pharmaceutical sector, other types of IP rights are also used to appropriate competitive advantages.

Trade Secrets

A trade secret is defined within the context of its use. Trade secrets must lend a competitive advantage, must be kept secret within an enterprise, and must not be generally known within an industry. There is a burden on the owner of a trade secret to use and maintain it in as much secrecy as is reasonable under the circumstances. There is a wide array of matter regularly used in business that may be entitled to trade secret protection (Milgrim, 1974). Some of the potential sources of trade secrets in the pharmaceutical sector include:

(1) Processes for manufacturing active chemical compounds or pharmaceutical compositions.

(2) Formulas for manufacturing medicines.

(3) Methods and techniques (know-how) for establishing operating and maintaining mass production lines and for making highly complex instruments and apparatus in which tolerances and specifications are not readily discernible.

(4) Products such as computer software used in pharmaceutical R&D and complex products such as genetically-engineered microorganisms that can not be readily reverse engineered.

(5) Business information such as customer lists, cost and pricing data, market research and management systems and methods.

Trade secrets may be used instead of patenting when:

(1) The inventor has a patentable invention of only modest economic value which will take as long or almost as long as the patent term for anyone else to reverse engineer or reinvent.

(2) The inventor has a patentable invention which will take much longer than the patent term for anyone else to invent.

(3) Firms have a non-patentable invention (i.e. obvious) that will yield a substantial return if it can be kept secret.

Trade secrecy supplements the patent system since inventors choose trade secret protection when they believe that patent protection is too costly relative to their invention or that patenting will give them a reward substantially less than the benefit of the invention. Unlike patents, trade secrets are not publicly disclosed and may result in an expenditure of resources by rivals to duplicate the invention (Friedman et al., 1991).

Trade secrets can be used in combination with patent strategies. Double protection of the product (patent) and process technology (trade secret) of pharmaceutical products creates an additional barrier to entry to both imitators attempting to reverse engineer the products and processes, as well as, generic manufacturers producing off-patent medicines. Strategically, pharmaceutical firms have an incentive to undertake both basic research and the primary manufacturing of active ingredients in the home country to maintain stricter controls over secrecy. The pharmaceutical sector is unique in that regulation results in transparent and accurate market signals in the form of strategic business information such as pricing and sales data being made available to competitors.

However, the advantage to competitors from the easy availability of market information is partially offset by the requirements for safety and efficacy data used for regulatory approval of medicines which may delay the marketing of imitation products.

Patents

To have the incentive to undertake R&D and commercialize an invention, a firm must be able to appropriate returns sufficient to make the investment worthwhile. The benefits consumers derive from innovation are increased if competitors can imitate and improve on the innovation to ensure its availability on favourable terms. A patent confers appropriability for a limited time in return for public disclosure that ensures widespread diffusion of benefits when the patent expires.

The advantages of the patent system are characterized as follows:

(1) A patent "prospect" increases the efficiency with which investment in innovation can be managed since the patentee is in a position to co-ordinate improvements on the technology.

(2) The patentee has an incentive to make investments in appropriable product development such as safety and efficacy data to maximize the value of the patent.

(3) The patent system lowers the cost for the owner of technological information of contracting with other firms possessing complimentary information and resources.

(4) Patents enable firms to signal each other, which reduces the amount of duplicative research in innovation and facilitates the creation of substitute technologies.

(5) Patents reduce the cost of maintaining control over technology as compared to using trade secrecy.

(6) The patent system, covering all useful arts, is more technology neutral thereby improving the structure of returns to innovation as compared to trade secrecy which creates greater incentives for process technologies than product innovations (Kitch, 1977).

The appropriability of returns for inventors is dependent on the scope and duration of patents. The breadth of patent claims granted influences the level of competition from close substitutes (innovative and imitation products) whereas the length of the patent term affects the level of competition from perfect substitutes (generic copies). The longer the patent term or the broader the scope of patent grant, the greater the potential to appropriate returns for a given patent. The impact on financial returns from a given effective patent term cannot be determined in isolation from the scope of the patent grant (Gilbert and Shapiro, 1990).

The internationalization and importance of patents in the chemical/pharmaceutical sectors is indicated in that several multinational drug companies are represented among the top 20 patenting companies in the United States. In 1984, Bayer (10,647), Ciba Geigy (6,971), Dow Chemicals (6,488) and Hoechst (6,471) ranked 2,13,14 and 15 in U.S. patents granted, respectively. Of the 35 firms with the largest number of pharmaceutical patents granted by the U.S. Patent and Trademark Office (USPTO), there were 20 American firms and the number of drug companies from other countries included United Kingdom (5), Japan (4), Germany (3), Switzerland (2) and France (1). The sources of U.S. pharmaceutical patenting (drugs and bio-affecting agents) in the United States between 1969 and 1986 was dominated by large firms (65.6%), with smaller firms having a significant share (32.3%) and government agencies having a negligible patenting presence (2.0%). (Patel and Pavitt, 1990).

International patent strategies may be aimed at achieving exclusive protection, defensive purposes, licensing for income and licensing with know-how. Exclusive protection enables companies to maintain exclusive lines of products and is most effective when the product utilizes one or more basic patentable inventions which provide very substantial advantages over alternative products. Defensive patenting strategies are employed to enable the company to freely use its technology without infringing anothers patents and for negotiating licences with other patent owners. Establishing a patent portfolio can be useful for licensing the technology to other companies in countries where the patentee is not active. Firms primarily engaged in R&D can use their patents to sell know-how to licensees manufacturing and marketing the invention (Shipman, 1967).

The reasons given for patent strategies cited by pharmaceutical MNEs, from most important to least important, include:

(1) upon brief examination, drug firms patent most things which have a chance of technical success (32.0%);

(2) drug firms patent most things which are patentable (16.0%);

(3) drug firms patent in order to have a patent portfolio with which to negotiate licensing agreements with other companies (16.0%);

(4) drug firms, after critical scrutiny, patent only those discoveries that have a strong chance of technical success (12.0%);

(5) drug firms patent only those discoveries that have a clear application to the company's products or processes (12.0%); and

(6) drug companies patent only the occasional discovery of quite exceptional importance (8.0%) (Wyatt, 1985).

The foreign patenting policy of pharmaceutical firms reflects the nature of global production and distribution of pharmaceuticals. Foreign patents are obtained primarily in export markets (30.8%), in countries where production facilities are located (25.6%), strategically to block competitors' entry into a market (17.9%) and in countries where firms have licensing agreements with other organizations operating within that foreign country (15.4%) (Wyatt, 1985).

The ability of competitors to invent around both process and product patents is considered by businesses to be the greatest limitation to the effectiveness of patents. Other important limitations to patent protection include the lack of patentability, lack of enforcement, patent documents disclose too much information and patents are unlikely to be valid if challenged. Compulsory licensing is rarely judged as a significant limit on the effectiveness of patents, however, some industries, such as the pharmaceutical sector, that are subject to these specific restrictions consider compulsory licenses to be a significant limitation (Levin, 1987).

Trademarks

Historically, enabling consumers to distinguish one product from another, thereby preventing fraud, was the basic theoretical raison d'être underlying trademark law. The primary consumer benefit of trademarks is the lowering of consumers' marketplace search costs. Trademark law was later expanded to encompass the concept of company goodwill. Protecting the firm's goodwill is presumed to motivate the company to invest in maintaining and improving the quality of its products. Trademarks also protect

businesses from lost sales and reduced product reputation through unauthorized use of their marks (Cohen, 1991). Additionally, the trademark provides a recognizable and legally protected basis on which advertising may be based with a view to creating and maintaining a demand for the brandname product, rather than for the generic item. The growing importance of promotion and advertising to invest in trademarks is reflected by recent amendments in U.S. trademark law, the Lanham Act, to include provisions which prohibit advertisements which are explicitly false or have a tendency to mislead. Additionally, false claims on labels and packages are covered under the Lanham Act. U.S. trademark law has been the centre of the ongoing "aspirin wars" in which American Home Products, maker of Anacin and Advil, has been embroiled in disputes over advertising claims with Johnson & Johnson, maker of Tylenol (Cohen, 1991).

There are two competing theories of the economic/legal rationale of trade marks law: the source theory and the guarantee theory. Under the former regime the mark indicates the production source whereas the latter theory trademarks are guarantees of quality. Guarantee marks are, functionally, the same as certification marks. A phenomenon of modern society is that trademarks can become commodities in their own right, valued independently of their role as indicators of source or guarantors of quality (Adams, 1990).

Drug Formularies as Certification Marks

Drug Formularies were originally created in an attempt to standardize and improve the quality of prescription drugs. Patent [secret] medicines or nostrums posed problems in terms of safety and efficacy since there was a problem with the adultering of active ingredients with inert fillers and false claims were made. Patent medicines were characterized by products with secret formulas (trade secrets), a reliance on brand strategies (trade marks) and unsubstantiated and/or questionable product claims. Because prescription drugs had to meet the standards for composition of pharmaceutical formularies they played an important role in the specification of drug standards (Wardell and Lasagna, 1975).

Drug formularies have evolved into a system of setting standards or certifying bioavailability of pharmaceuticals or the amount of active drug made available to the body from a given dosage and the way in which it is released. Formulary sanctioning by governments and prescription monitoring by private insurance companies are parallel mechanisms being currently utilized to facilitate generic substitution and price competition to restrain the cost of drug therapies (Bezold, 1983). Drug formularies amount to an intellectual property right in that the government certifies the interchangeability of

pharmaceutical products (i.e., generic drugs for off-patent brandname pharmaceuticals) and enabling pharmacists, to distuinguish between drug therapies and to substitute the chemical formula equivalents (generics) for the trade-marked medicines.

The use of formularies to facilitate the use of generic pharmaceuticals was driven by the fact that pharmaceutical firms were usually successful in maintaining the market position of innovative drugs long after their patents expire. Trademark law plays a major role in maintaining the dominant market position created during the period of market exclusivity (approximately ten years) associated with patent protection. Some pharmaceutical industry analysts conclude that product differentiation strategies provide the primary barrier to entry into some therapeutic markets and the associated high costs of R&D and promotion keep small generic firms from entering some markets (Statman, 1983).

The Lowy Commission report on prescription drugs in Ontario recommended that the concept of best available price - usually set by the generic manufacturer - should be maintained and strengthened in respect to reimbursement price to pharmacists for multi-source drugs. When one generic drug is on the market, unit price as a percentage of the highest brandname price is in the range of 75-88%. The Lowy Commission found that the Ontario Drug Benefit Plan can make large savings once two or more generics are competing with a brandname innovative pharmaceutical; generics are listed on the 1990 Ontario formulary at approximately 45-53% of the price of the brandname product (Scrip No. 1563). It is apparent from the Lowy Commission's findings that generic substitution facilitated by formulary listings shifts domestic rivalry in the pharmaceutical industry from product to price competition.

V THE COMMERICALIZATION OF INNOVATIVE PHARMACEUTICALS

The concept of the product life cycle is useful to analyze the role of intellectual property throughout the different stages in marketing innovative pharmaceuticals products. Several characteristics of the commercialization of innovative pharmaceutical products result in a unique drug product life cycle which affects business strategy, the nature of competition and the attainment of social welfare objectives. Intellectual property protection provides the incentive system to encourage the commercialization of new pharmaceutical products through the granting of market exclusivity and consequently represents a key component in influencing inter-firm competition and financial returns in the pharmaceutical industry.

The Product Life Cycle

Products and services can be defined in terms of the market dimensions affecting price - form, time and space. Product form, defined in terms of patent claims or the scope of the invention, can be described in both a temporal (i.e., the effective patent term) and a spatial context (i.e., exhaustion of IP rights and grey market goods). Commercially successful products pass through several stages during their life cycle: (1) market development; (2) market growth; (3) market maturity; and (4) market decline.

(1) Development Stage - Bringing a new product to market is fraught with the risk and uncertainties associated with product and market development. The marketing focus is on getting consumers to try the product. A gradual rise in a product's sales curve occurs during the market development stage.

(2) Growth Stage - As sales increase, some competitors enter the market with copies of the originator's product while others make functional and design improvements. Product and brand differention competition develops and the marketing focus shifts to getting consumers to prefer a particular brand.

(3) Maturity Stage - Market saturation occurs when most households are using the product and future sales grow based on demographic changes. Competitive attempts to achieve and hold brand preference now involve making finer and finer differentiations in the product, in customer services, and in the promotional practices and claims made for the product. The market maturity stage results in producers concentrating distribution outlets, as well as, attempts to secure even more intensive distribution. The originator is increasing forced to appeal to the consumer on the basis of price and marginal product differences.

(4) Decline Stage - As demand declines, overcapacity becomes endēmic and sales are depressed (Levitt, 1986).

Innovator Strategies

The original marketer of an innovative product bears most of the costs and risks of developing the product and the market. Innovators begin to lose market share during the market development stage and prices begin to decline resulting in a profit squeeze.

There are several strategies which can be used to increase sales and extend the product life:

(1) Promoting more frequent usage of the product among current users.

(2) Developing more varied usage of the product among current users.

(3) Creating new uses for the product by expanding the market.

(4) Finding new uses (Levitt, 1986).

Product life extension strategies reguire an active rather than a reactive product policy since they necessitate the planning of a company's long-term marketing and product development in advance. Intellectual property protection is a key component of both product development (trade secrets/patents and industrial design) and market development (trademarks). A pharmaceutical product embodies several types of IP protection known as a product's IP portfolio. The impact on the originator firm from adopting multiple strategies to expand sales and extend the product's life cycle is dependent on the standards of IP protection (e.g., length and breadth of patent protection), as well as, the cumulative strength of the barriers to market entry (trade marks, brand loyalty etc.).

Pharmaceutical Product Life Cycle

The pharmaceutical product life cycle is characterized by an extended period of product development due to the safety and efficacy requirements of health regulatory approval regimes. The product life cycle is altered in that significant expenditures are incurred during the product development stage and the stages of product growth and maturity are characterised by a shortened effective patent term. The industry's dependence on patent protection arises from the ease and speed of imitation of drugs

and from the higher incidence of failure of new drugs during product development and pre-clinical and clinical trials (Redwood, 1990).

Innovative pharmaceutical firms are able to accelerate the development of "me-too" products for the market while promising patented medicines of rivals are undergoing clinical trials. The ease in which competitors can reverse engineer and market imitation products is dependent on the breadth of the patent grant. The effective patent term determines the length of product life cycle stages and the timing of generic competition.

It is estimated that only 1 in 6.5 compounds subjected to clinical trials reached the market during the period between the mid-1960s and mid-1980s. Of these, only 1-in-23 achieved annual sales in excess of $100 million (1980-dollars) in the early-1980s. Thus, only 1-in-150 compounds that were deemed to merit serious development (i.e., costly clinical trials) produced a significant financial return (Redwood, 1990).

(Scrip No. 1509). Preclinical costs for each NCE were US $156 million with clinical costs representing US $75 million. Additionally, of the total number of products that entered into Phase I trials, 75% progressed to Phase II, 36% moved into Phase III and only 23% were finally approved by the US Food and Drug Administration (FDA). The product development costs of chemicals which do not receive regulatory approval must be recouped through the revenues of pharmaceutical products which reach the market.

(i) Regulatory Approval

The effective patent life of pharmaceutical products is much shorter than the nominal patent term. The effective patent life has been progressively eroded by increased requirements for clinical research to prove the safety and efficacy of drugs. The innovative drug development period increased by about 8 years since 1960 due to new regulatory regimes which had the effect of reducing the effective patent life substantially.

Regulatory approval has resulted in increased costs and delays in commercializing new products, as well as, indirect effects on competition that arise from the asymmetrical distribution of the regulatory impact among different sizes and groups of firms. The deteriorating competitive positions of smaller innovative drug firms in the U.S. after 1962 has been partially attributed to FDA regulation. This certainly also had an impact on the smaller North American innovative firms of the day and contributed to the acquisition of those companies by

larger foreign-based MNEs. The impact on Canadian firms may even have been greater than in the U.S. because of the smaller market from which Canadian companies were able to draw the revenues needed to finance additional expenses of expanded regulatory requirements. In contrast to the U.K., many of the U.S. firms on the innovative fringe of the industry completely ceased innovation after 1962 with a resulting sharp drop in total approvals of new chemical entities (NCEs). However, any declines in NCE introduction rates after 1962 were more than offset by sharp increases in the sales and profitability of each NCE. Thus, the costs and delays of the regulatory regimes have increased the profitability of new patented medicines by creating an effective market entry barrier to both patented "me-too" products and generics and eliminating small competitors lacking the financial resources to market drugs on their own (Thomas, 1990).

The pure productivity effects of drug regulation are becoming more significant due to the increasing costs and delays in obtaining regulatory approval and the rising opportunity cost of pharmaceutical company funds associated with high levels of profitability. The recorded increases in regulatory approval delays would, in and of themselves, more than double the present value of innovation costs, even with no productivity effect at all. R&D expenditures must compete with other investment opportunities of pharmaceutical companies and with a discount rate of 37.4% (average return on equity in the Canadian pharmaceutical sector), firms may find it more profitable to invest in marketing existing trademarked products, engaging in acquisitions of other pharmaceutical firms or stockmarket repurchases of their own shares. Regulatory delays, therefore, place R&D at a significant financial disadvantage relative to downstream market opportunities with shorter payback periods.

Longer U.S. and Canadian regulatory delays may also be placing North American pharmaceutical firms at a competitive disadvantage against foreign firms (i.e., market barrier). In a globalized ethical pharmaceutical industry the benefits from the domestic advantage provided by regulation to large U.S. firms may have been offset by the international disadvantage of the slower approval of U.S. pharmaceutical products. This factor will be even more significant to the competitiveness of a non-affiliated Canadian firms due to the small size of the immediately available market.

(ii) Generic Substitution

The profitability of a patented pharmaceutical is also affected by the rate of generic substitution of brandname off-patent drugs. The relationship between the prescription drug manufacturers and consumers (patients) is distorted by the doctors who do not pay for the drugs (and therefore cost

considerations are downplayed) which they prescribe to patients. Additionally, information contained on labels of over-the-counter (OTC) drugs such as price, active ingredients, formulation etc. is not as readily available from either physicians or pharmacists to patients filling prescriptions. Information on drugs from vertically-integrated firms is targetted at physicians and pharmacists with little patient access to scientific efficacy and safety data and analysis. The conclusion of some industry analysts is that pharmaceutical patenting strategies coupled with the prescription practices of physicians has led to higher prices (Mathewson and Winter, 1984).

The nature of competition in the pharmaceutical market has led to various methods being used by governments to encourage generic substitution. Provincial formularies and their use in provincial drug cost reimbursement schemes can have a significant impact on the returns from brandname off-patent and compulsory licensed pharmaceuticals in Canada. The key ways in which the provincial programs differ include the eligibility of drug plan recipients, the level of benefits, the determination of formulary prices, determination of interchangeable products, product selection criteria, product selection liability, and restrictions on competition.

The two criteria having the greatest impact on the level of generic substitution are the product selection criteria and product selection liability. In some provinces product selection is permitted unless the physician specifies "no substitution". The requirements for product selection by pharmacists may have a significant effect on the level of generic substitution when coupled with complimentary reimbursement schemes and product selection liability conditions. In some provinces such as Quebec, Alberta and British Columbia, pharmacists are liable for substituting generics for a brandname product. Risk averse pharmacists in these provinces have little incentive to substitute cheaper generic drugs. In other provinces such as Ontario, Manitoba and Saskatchewan, generic substitution is encouraged by the provincial government protecting the pharmacist and prescriber from liability.

(iii) Rx/OTC Switches

Many prescription drugs are scheduled to switch to over-the-counter (OTC) status. Two examples of planned switches are Zantac (ranitidine) and Tagamet (rimetidine), two of the most heavily prescribed products in the United States. American Home Products was highly successful in managing the switch of Advil (ibuprofen) from the prescription to the retail market.

(Scrip No. 1523, June 15, 1990).

The IP Life Cycle

The product life cycle of patented medicines is characterized by a corresponding IP life cycle. The IP portfolio for an innovative pharmaceutical consists of trade secrets (processes, microorganisms), patents (products, processes and uses) and trademarks (house mark, brand name and trade dress). The use of several types of IP to commercialize an innovative drug affects both the nature of competition and the effective level of barrier to new market entrants.

(i) Patent Strategies

The two predominant patent strategies in the pharmaceutical industry are designed to: (1) obtain broad patents to limit competition from "me-too" products during the patent term; and (2) to sequentially over several years, to patent the processes and product improvements which will extend the life cycle of the key patented invention. The innovative firm may be able to sustain a first mover advantage through a stream of improved products, more efficient production processes and new clinical uses for pharmaceuticals. The patent claims on the successful patented pharmaceutical product often include several compounds, several compositions or formulations, several delivery mechanisms (capsule, injection etc.) and the processes necessary to manufacture the chemical. Pharmaceutical firms attempt to patent broad claims to chemical analogues of the pharmaceutical product with similar structural or functional properties. Pharmacetuical product per se patent claims may protect thousands of chemical entities similar in structure or functional properties from use by rivals.

(ii) Trade Secrets

Another patent strategy is to draft patent applications such that the invention is not fully disclosed and competitors will have to undertake R&D in the form of reverse engineering to manufacture the pharmaceutical product. Trade secrecy is a complimentary strategy to the patent system since process technologies can be effectively protected through tightly-controlled and centralized manufacturing operations.

— (Scrip No. 1546, September 5, 1990).

(iii) Product Differentiation

It has been suggested that intellectual property law - patents, trade-marks and industrial designs - is an instrument to facilitate product differentiation. In this regard, patents can contribute to significant product innovation by encouraging investments in R&D. However, patents can also be used to protect inventions of limited therapeutic value (combinations and imitations) and patent licensing may also lead to brand proliferation. There are two differing viewpoints on innovation in the pharmaceutical industry - the focus on product differentiation strategies versus innovation of significant social and therapeutic value.

The National Pharmaceutical Council has concluded that:

(1) Pharmaceutical R&D is an evolutionary process characterized by incremental advances - The accumulation of small successive improvements to older drugs is more important than high profile "breakthrough" therapies in the vast majority of clinically important medicines.

(2) Incremental changes result in better products and cost competitive care - Important new drug uses are often discovered as a result of clinical experience after initial marketing and multiple agents in a class enable physicians to optimize therapy and provide the best treatment for patents.

(3) Savings to society exceed the cost of R&D - Incremental innovations result in substantial cost savings to public and private health insurers and consumers through reduced hospital and nursing home stays, physician visits and surgery.

(4) Public policy should encourage incremental innovation - The evolutionary process of pharmaceutical R&D is best appreciated from a long term developmental perspective whereas a static analysis may lead to the mistaken appearance that incremental innovations are duplicative, profit-driven imitations of successful drugs already in the market. Public policies such as therapeutic substitution or formularies which restrict the use of incremental innovation reduce the incentives to develop such products and should be used to penalize progress through incremental innovation in pharmaceuticals (Levy, 1990).

The pharmaceutical industry perspective of the social benefits of incremental improvements contrasts sharply with findings of the United States Senate Special Committee on Aging. The findings pertaining to the value of new prescription drug products include:

(1) The bulk of R&D by prescription drug manufacturers produces insignificant new compounds that add little or nothing to drug therapies already marketed. Evidence to support this finding consisted of the following:

- The top 25 pharmaceutical companies introduced just 12 important new drugs to the market between 1981 and 1988.

- Eighty-four percent of the 348 new drugs brought to market by the 25 largest U.S. drug manufacturers between 1981 and 1988 were "C"-rated by the Food and Drug Administration (FDA) meaning that they had little or no therapeutic gain.

- For every "important" or "A"-rated new drug marketed by the 25 largest drug manufacturers, 24 "C"-rated drugs with little therapeutic value were brought to market (i.e., the drug duplicates the medical importance and therapeutic usage of drugs already on the market).

(2) Prescription drug manufacturers charge the public high prices for new drugs that duplicate existing and generally less expensive drug therapies. This finding is supported by the following information:

- FDA classifications of new drugs include an implicit consideration of the potential for a large cost reduction; therefore, the FDA "C"-rating on most new drugs means these drugs did not provide significant economic advantages to the patient compared to existing drugs used for the same ailment.

- Prices for new "C"-rated anti-ulcer drugs during the 1980s were higher than the therapeutically equivalent innovative product; an example given is Glaxo's anti-ulcer drug Zantac which was marketed at a cost 46% higher than the innovative brand Tagamet made by SmithKline Beckman Corp., even though Zantac was FDA "C"-rated and offered little or no therapeutic gain.

- Based upon the industry's published figures for R&D costs for a "new drug" between 1981 and 1988, the top 25 U.S. drug makers spent, and passed on to consumers, about $37 billion for R&D to produce 292 new drugs with little or no potential for therapeutic gain over existing drug therapies.

(3) Present governmental incentives to spur true innovation by pharmaceutical manufacturers appear to have failed (Pryor, 1989).

The total product concept is a useful framework through which to gain insight into the issue of product differentiation of pharmaceuticals. The total product consists of a generic product, an expected product, an augmented product and a potential product. The generic product is the rudimentary substantive undifferentiated commodity necessary to participate in the market. House brands of off-patent pharmaceuticals are probably the closest to generic products on the Canadian market. The expected product represents the customer's minimal expectations which may include such items as payment terms, technical support, minimum quantities etc. The generic product can be augmented by offering the customer more than what he has become accustomed to expect. Free trips and drug samples to physicians are examples of a means of differentiation of brandname drugs through an augmented product. The potential product consists of everything - tangible and intangible - which can be used in differentiating a product to attract and hold customers. The premise is that the "differentiation of anything" enables firms to most effectively maximize sales (Levitt, 1980).

A pharmaceutical firm has widely differing techniques for differentiating its products from other products that it manufacturers itself or from the products of other firms. Differentiation may assume various forms - geographical division of markets, segmentation of markets into different consumer strata, differentiation of products over time and altering product attributes. The potential for product differentiation is greater where the consumer has reduced opportunities to determine the objective usefulness of a good and/or service and the more likely the product is to meet subjective needs. Pharmaceuticals are especially liable to subjective and/or unessential product differentiation. This is reflected in the number of pharmaceutical products which are combinations of preparations or very specific product features and in the fact that there is high prescriber preference for a definite product (small differences in therapeutic effects may lead to large price differentials between substitute therapies). Because there is little scope for substitution, there is a derived demand based on prescriber decision-making which fails to induce flexible pricing and

drugs are par-excellence products which cannot be easily checked for quality by the prescribing physician. The conclusion is that pharmaceuticals are a product that can be easily differentiated (Stuyck, 1983).

The individual trade-mark is, by its nature, an instrument of differentiation - even if that product differentiation is artificial. A trade-mark enables a manufacturer to advertise a pharmaceutical product in the abstract (i.e., separate from any sales negotiations). Trade-marks and industrial designs can also be used to differentiate innovative pharmaceutical products from generic drugs since the appearance of the medicine may be important in consumer preference. Additionally, intellectual property rights are important to the innovative pharmaceutical sector in segmenting national markets. Product differentiation can have a variety of functions including creating value in a product image, enabling price discrimination among consumers, evasion or avoidance of price regulations on existing products, allowing segmentation and price discrimination between geographic markets, and creating barriers to entry (i.e., large promotional expenses).

(1) Differentiation by Product Name

Virtually all patented drugs have brand or trade-mark names. The naming of a product only has a differentiating character if the name is not generic. Differentiation in regard to a generic pharmaceutical product distinguishes the company's own products and is accomplished with the use of both house marks (company trade-mark) and/or product marks (branded trade-mark). The generic name is also used to identify pharmaceutical products.

Pure brand differentiation consists of a pharmaceutical firm marketing, in a single geographical market, a single product under different brand names without any product differences between the brands. This practice is increasing in the case where innovative pharmaceutical manufacturers are marketing both trademarked innovative products and cheaper generic versions under different house marks and brandnames.

Physicians have a strong preference for prescribing a relatively small number of trademarks, (i.e., brandname drugs) which is probably a rational response to the proliferation of trademarked drugs in the pharmaceutical industry as a whole. Brands that are the first innovative product in a therapeutic class on the market will maintain an advantage over late-entering brands of equivalent therapeutic value. Indications are that no amount of promotion for the second brand can achieve a sales volume equal to that attainable by the first brand. There is also a spill-over effect on sales of follow-up brands marketed by the first firm offering an innovative product; the incentive is for the innovative firm to market several product formulations of

the patented medicine using a portfolio of trademark names prior to competitors entering the market with therapeutic substitutes. However, physicians will prescribe late-entering brands that offer a therapeutic advantage to a subset of patients (Bond and Lean, 1977).

The effect of physician's preferences for brandname pharmaceuticals is to cause companies to increase promotional expenditures as a proportion of sales for late entering firms and minimize the incentives for price-cutting on large selling brands. The Federal Trade Commission (FTC) conclusions in a study of pharmaceutical product differentiation are that: 1) preferences for the first brands in therapeutic classes appear to insulate firms from competition even more effectively than patents; and 2) through product differentiation innovating firms receive substantially greater financial rewards then they would from the patent system alone (Bond and Lean, 1977).

The expiry of patents enables competitors to imitate the product and market it under a different brandname or the generic name. Excessive brand advertising reduces the chances for successful generic market entry. During the patent term the innovative firm can utilize promotional activities to strengthen the brandname. Promotion in the absence of competition from substitute drugs is effective in strengthening post-patent market shares and prices.

Patent licences are important in the pharmaceutical sector. The market for a patented medicine may be increased by extensive licensing of the patents with the resulting effect that there is brand proliferation by means of patent licences. Strong patent portfolios are often necessary in obtaining a patent licence. This situation may lead to cross-licensing of patents between a limited number of companies which form an oligopoly in a given therapeutic class and may result in small innovative and generic firms competing at a significant disadvantage. Patent licence agreements not only reduce market transparency but in some cases the product-differentiating effect of advertising is made possible only by the grant of a licence; a patent licence can fulfill the function of brand differentiation (Stuyck, 1977).

(ii) Differentiation in Product Properties

Product differentiation activities are based on both real and artificial distinctions created by pharmaceutical manufacturers. In the pharmaceutical industry, firms are known to differentiate some of their pharmaceuticals geographically by means of colour, quantity, and size of pack. These product differences may be legitimately responding to differing national

(v) Geographical Differentiation

Differences in pack size, prescribing practices, and methods of reimbursement are means of differentiating drug products geographically. Changing the colour of tablets and capsules may also be used to differentiate identical pharmaceutical products sold in different markets. Geographical differentiation can also be created by using different trade-marks in different countries such that parallel imports of drugs would represent an unfamiliar brand to consumers.

Post-Patent Barriers to Entry

While the effective period for market exclusivity of an innovative pharmaceutical is shortened due to regulatory delays, a firm's competitive position may also be increased due to the advantages inherent in being a patent-holding, pioneering brand. The most important barrier to entry which may extend beyond the life of the patent is product differentiation. Investments in the trademark of a patented medicine are made during a period of market exclusivity which may be exploited after patent expiry through the continued promotion of brandnames. Patent and trademark protection may produce a combined entry barrier which extends indefinitely into the future (McRae and Tapon, 1985).

The strength of post-patent barriers to entry in the Canadian pharmaceutical sector varies significantly between provinces. The market advantage of first entrants is not significantly eroded in Quebec in the post-patent period since the prescribing habits of Quebec doctors is relatively unchanged. In contrast, market power or the ability of innovative drug manufacturers to maintain simultaneously higher prices and higher market shares than lower priced generics declined for the majority of drugs in Saskatchewan. A provincial guarantee of bioequivalence coupled with protection from liability, and a system of tendering the entire province's drug needs has effectively reduced the market power initially possessed by many innovative drugs marketed in Saskatchewan. The generic substitution program in Ontario is also effective in eroding the post-patent brandname innovative product advantages (McRae and Tapon, 1985).

It is apparent that two aspects of provincial drug reimbursement schemes, the guarantee of bioequivalence with authority to substitute and price information on each brand listed, are necessary conditions for limiting the effectiveness of the product differentiation strategies of patent holders. McRae and Tapon conclude that compulsory licensing is a necessary but not sufficient condition to reduce post-patent barriers to entry, however, together - compulsory licensing and generic

substitution policies - represent the crucial necessary and sufficient conditions (McRae and Tapon, 1986).

Government Strategies

Governments in many developed countries have adopted differing mixes of policies designed to encourage investment and competition in the pharmaceutical industry to better achieve health and social objectives. The measures adopted seek to:

(1) Counter the negative impact of regulatory delays on the innovative pharmaceutical sector.

(2) Encourage price competition and generic substitution to reduce the cost to drug plans.

(3) Reduce incentives for new drugs with little or no potential therapeutic gain over existing therapies.

(4) Limit the use of product differentiation strategies and investments in brandnames.

(1) Regulatory Delays

The two strategies being employed to counter the negative impact of regulatory delays on the effective patent life of pharmaceuticals include stream-lining regulatory approval processes and extending the patent term to compensate for delays in market introduction.

To address the issue of regulatory approval delaying the commercialization of patented medicines Supplemenaty Patent Certificates (SPCs) are being introduced in European countries and patent term extensions are being granted in the United States.

(Scrip No. 1631, July 5, 1991).

(2) Price Competition

In most developed countries, the majority of pharmaceutical expenditures are on prescription products and the costs are largely borne by the state or by state-run health insurance schemes. Governments have conflicting objectives on the issue of pharmaceutical pricing since there are pressures to curb rising

drug costs to national health services by ensuring low-priced medicines while also enabling domestic companies to expand investment, research and exports through adequate price and profit levels. Prices in the European Community (EC) vary due to the following differences between countries:

(1) price control schemes;
(2) drug reimbursement control plans;
(3) consumer price levels;
(4) drug consumption volumes;
(5) exchange rate variations;
(6) manufacturing costs;
(7) transfer price controls;
(8) patent protection;
(9) wholesalers' and pharmacists' margins;
(10) value-added tax rates; and
(11) pack sizes (ie bulk dispensing).

Policies intended to control pharmaceutical expenditures by controlling prices and/or reimbursement are found in all EC countries. Negotiations between governments and pharmaceutical companies are often prolonged and national objectives are promoted in many countries by favouring local research activity, increased manufacturing and investment, and higher employment. Four basic control mechanisms used in the EC to control prices include:

(1) Cost-plus - prices are based, product-by-product, on the cost of production plus a profit margin (eg. Greece).

(2) Internal reference - the prices are based, product-by-product, on the price of comparable products already on the market with a premium added for therapeutic advantages (eg. France).

(3) International comparison - prices are based, product-by-product, on price levels in other countries (eg. Spain).

(4) Profit control - prices on individual products are established in the market while overall profitability is controlled (eg. United Kingdom).

Even in EC countries with relatively free markets for setting drug prices such as West Germany, moral suasion and drug reimbursement systems are used to control drug costs. Failure to achieve reimbursement status will usually severely limit a drug product's commercial prospects; in some countries such as Italy reimbursement pricing is an integral part of the process of obtaining market authorization. Some of the reimbursement controls used in the EC include:

(1) Establishing criteria for entry to the reimbursement list;

(2) Using negative lists of products or product categories that do not qualify for reimbursement;

(3) Levying a patient co-payment prescription charge;

(4) Changing products from reimbursable to non-reimbursable status (i.e., prescription to OTC status);

(5) Delaying the listing of products on reimbursement list; and

(6) Reimbursing the reference price irrespective of the market price (Macauthur, 1989).

(3) Efficacy and Cost/Benefit of New Pharmaceuticals

The French Social Affairs Ministry issued a decree on rationalizing reimbursement, especially for expensive medicines. The measures include a requirement that the inclusion of a new drug on the reimbursement list is conditional upon greater efficacy than equivalent products already on the market, and/or a lower cost with equivalent efficacy.

~ 65(a)

(Scrip No. 1561, October 26, 1991).

The French Transparency Commission examines new pharmaceutical products for their eligibility for reimbursement particularly in relation to their advantages over currently available products in the same therapeutic class. Factors considered include improved efficacy and tolerance, ease of administration, dosage, length of treatment and packaging. The Transparency Commission gives its findings to the Pricing Committee for use in negotiations over a final reimbursement price.

~ 65(a)

(Scrip No. 1459, October 27, 1989).

The French Ministry of Health, in an effort to curb costs, has limited reimbursement for some pharmaceutical preparations. A product qualifies for reimbursement if its pharmaceutical formulation appears on the list or all of the ingredients in a combination appear on the list.

(Scrip No. 1435, August 4, 1991).

(4) Product Differentiation

The measures adopted to limit the use of product differentiation strategies consist of various controls over promotional expenditures which are a primary source of investment in the trademarked brand.

France has created a Commission on the "Control of Promotion and Information on the Proper Use of Medicines". Company representatives marketing products to doctors are required to provide a data sheet which includes the scientific product information, as well as, all information required under the pricing legislation. (Scrip No. 1591, February 15, 1991).

France first introduced a pharmaceutical promotional tax in 1983. Recent amendments increased the tax from 5% to 7% and extended the tax to expenditures on company representatives, meetings and the promotion of drugs to hospitals. The French government justifies the tax on pharmaceutical promotions since excessive marketing expenses (17% of sales) are thought to lead to the over consumption of drugs.

(Scrip No. 1588, February 6, 1991).

The U.S. FDA is also taking strong enforcement action against pharmaceutical companies which have promoted unapproved uses of their drug products and engaged in promotional activities disguised as scientific exchange.

(Scrip No. 1628, June 26, 1991).

In the United States, 58% of U.S. hospitals have a formulary with almost no duplication of generic equivalents and minimal duplication of therapeutically equivalent drug products.

Additionally, 62% of the 188 largest health management organizations (HMOs) in the U.S. employ formularies to control costs and improve prescribing and another 11% are in the process of adopting formularies.

(Scrip No. 1558, October 17, 1990).

The U.S. Office of the Inspector General (OIG) is making efforts to curb illegal and inappropriate promotional practices in the pharmaceutical industry. The OIG has concluded that promotional practices involving items of value do appear to affect physician's prescribing decisions. OIG research is focused on the promotion of prescription drugs through payments and gifts and the truthfulness and educational value of prescription drug advertising in medical journals. A couple of the promotional plans being investigated by OIG include:

(Scrip No. 1652, September 18, 1991).

In the United Kingdom, a voluntary limitation on journal advertising of pharmaceutical advertising has been supported by the majority of UK ABPI member countries.

(Scrip No. 1356, October 28, 1988).

(5) Demand Side Measures

The French Director General for Health has proposed reducing healthcare spending in France by limiting the number of prescribing doctors.

(Scrip No. 1654, September 25, 1991).

The French Social Affairs Minster has launched a campaign aimed at the public, doctors and pharmacists to promote the correct use of drugs. The objective is to improve public awareness of the dangers of overconsumption as part of its plan to reduce prescribing costs and rationalize prescribing. Overconsumption of drugs is a public health concern because irrational use of drugs multiplies their health risks, as well

as, straining drug reimbursement budgets.

(Scrip No. 1606, April 10, 1991)

The French Medical Committee has published prescribing guidelines for doctors to help curb the rising consumption of medicines and healthcare spending.

(Scrip No. 1531, July 13, 1990).

PART 2 - INTRA FIRM COMPETITION

VI CANADIAN SUBSIDIARIES AND FOREIGN DIRECT INVESTMENT

Multinational Enterprises (MNEs) and Subsidiaries

The multinational enterprise (MNE) is a corporation which owns (in whole or part), controls and manages income-generating assets in more than one country. The MNE engages in international production, namely production across national boundaries financed by foreign direct investment. The MNEs are integrated business systems in which the linked subsidiaries are planned and operated together to achieve established objectives and it is only in this context that MNE behaviour can be analyzed. The parent MNE is the company which operates out of the home nation and exercises ultimate control, while the subsidiaries are located in the host countries. The range of MNE management systems varies from tight central or parent MNE control over strategy to allowing considerable autonomy in subsidiaries both in finance and product development.

The affiliates within multinational enterprises have differing abilities to tap sources of funds to finance local operations. These sources include:

(1) The parent firm's home country - financing may come from the parent itself in the form of equity or loans or alternatively from other financial sources.

(2) Undistributed profits and depreciation provisions - profitable subsidiaries can finance expansion from profits not remitted to the parent company and from cash flow associated with depreciation expenses.

(3) The host country or third countries - a wide range of other sources of funds exist for subsidiaries including raising equity capital, borrowing from financial institutions or other subsidiaries and government assistance.

The sources of funds for a sample of majority-owned foreign affiliates of U.S. companies (1966-1972) consisted of external funds (45.5%), internal funds (49.5%) and other sources (5%). The key sources of external funds were foreign debt (28.4%) and the U.S. parent (12.5%) whereas, funds sourced internally were primarily through depreciation (34.1%) and undistributed profits (15.4%) (Hood and Young, 1979).

The Determinants of Foreign Direct Investment

The study of foreign direct investment has traditionally focused on a number of MNE ownership advantages: (1) technological advantages; (2) industrial organization; (3) managerial and entrepreneurial capacity; (4) financial and monetary factors; and (5) access to raw materials. These factors are important in explaining the choice of foreign direct investment over other alternatives such as exporting or licensing. The sources of advantage can also be distinguished between ownership- and location-specific factors. The location-specific characteristics of a country - resources, capital, management, government policies - will influence the operations of all firms operating in the host country. Companies also possess internal knowledge which is not available to other firms and these ownership-specific factors are capable of being combined with other resources in the home or foreign country. It is the interrelationship of ownership- and locational-specific factors which determines both the nature of competitive advantage over rivals and where that advantage will be exploited.

(1) Technological Advantage

Technical advantage, variously described as technology information, knowledge, intangible capital and know-how, is recognized as playing a cental role in MNE competitiveness. Technology does not merely include the discovery of new products and production processes but includes assets such as management, organizational and marketing skills. New products and processes are the most tangible components and can be more easily protected by IP rights (i.e., patents). Within the MNE, internal knowledge may have the characteristics of a public good to the firm whereby market analysis, access to cheaper inputs etc., can be utilized by a subsidiary without any additional costs to the parent company.

(2) Industrial Organization

Another source of advantage to multinational enterprises derives from the oligopolistic market structure and behaviour which economic literature closely links to discussions on technological advantage. Firm size is important given the increasingly high costs and economies of scale of R&D. Barriers to market entry are, in some instances, a necessary condition to exploiting technology and large firms receive more protection from the patent system because they are more able to defend patents internationally.

(3) Managerial and Entrepreneurial Capacity

Management skills and organizational ability are a source of competitive advantage of MNEs. Entry into foreign markets or increased scale of foreign operations can result in an increased utilization of the internationally mobile resource of management.

(4) Financial and Monetary

A diverse range of factors associated with capital markets impact on foreign direct investment. Strategies designed to react to currency fluctuations, access cheaper capital and ensure portfolio diversification may affect FDI. In general, while financial and monetary factors may provide MNEs with some exploitable ownership specific advantages, they do not seem to be sufficiently important to be other than permissive factors in foreign investment.

(5) Access to Raw Materials

A requirement for particular raw materials may be a country-specific factor influencing the location of MNE activities. If a MNE has privileged access to raw materials, then this becomes a firm-specific advantage.

The Theory of Foreign Direct Investment

National and international market imperfections lead to MNEs internalizing activities across borders. The incentive to internalize depends on the relationship between four groups of factors:

(1) industry-specific factors (e.g., nature of the product, economies of scale);

(2) region-specific factors (e.g., geographic distance and cultural differences);

(3) nation-specific factors (e.g., political and fiscal factors); and

(4) firm-specific factors (e.g., management expertise).

The main emphasis is on industry-specific factors, and within this group the knowledge factor is considered to be the most important. Knowledge is key in that it provides a monopoly advantage and flows of knowledge are useful for transfer pricing. The MNEs advantage in appropriating the returns to its investments in the production of new technology is also cited as a key factor in MNE theory.

The trend is towards greater North American economic and corporate integration. The limited size of the Canadian market deters many companies from making investments in R&D and process technologies unless there is access to foreign markets, especially the United States. U.S. non-tariff barriers dissuade U.S., offshore and domestically-owned firms from including Canadian operations in their global competitiveness strategies. Additionally, American governments (federal, state and municipal) are providing subsidies to U.S. firms, using innovative policy and regional development programs, to relocate their manufacturing and R&D operations in the United States. Without secure and enhanced access to the U.S. market, there will be little incentive for MNEs to locate advanced manufacturing technology in Canada to enhance the international competitiveness of Canadian manufacturers (Litvak and Warner, 1987).

The internalization/appropriability model provides a partial basis for explaining MNE preferences for FDI over other alternatives (e.g., licensing) since firms with a competitive advantage deriving from marketing skills, production co-ordination or secret technology are likely to favour direct foreign investment. A number of locational factors relating to the host country are pertinent in explaining the preference of FDI over exporting. Nation-specific factors affecting foreign direct investment include:

(1) Labour costs - differences in real wage costs may affect the location of foreign direct investment.

(2) Marketing factors - characteristics of host countries such as market size, market growth, stage of development and the presence of local competition will influence decisions on direct investment.

(3) Trade barriers - transportation costs and the existence of tariff and non-tariff barriers will also affect the level of foreign direct investment vis-à-vis exports.

(4) Government policy - the general political, social and economic environment (the investment climate) and specific government policies affecting mergers and acquisitions, technology transfer restrictions, IP protection etc. influence the location of manufacturing and R&D facilities.

The relative importance of location-specific characteristics of host countries will change as the product itself moves through its life cycle. The locational decisions made by firms can be equated with the progressive stages in the product life cycle. The emphasis for market competition is initially placed on product innovation whereas over time there is a shift to increased competition based on process technologies and price.

Subsidiaries and World Product Mandates

The globalization of markets has resulted in new competitive pressures on MNE parents and subsidiaries. Three factors are likely to influence the role of Canadian subsidiaries in the future:

(1) the competitive conditions in the industry in which the firm is competing;

(2) the parent company strategy toward international markets as a whole; and

(3) the level of management initiative taken by subsidiaries to position themselves effectively within the MNE (Crookell and Morrison, 1990).

Traditionally, subsidiaries have produced multiple products in small-scale facilities for their own protected domestic markets. The reduction of trade barriers has resulted in the requirement that subsidiaries become globally competitive by specializing in those aspects for which it can maintain a competitive advantage. Specialization can occur through "rationalization" where the subsidiary manufactures a parent company product or component in sufficient scale to serve an international market but continues to be dependent on the parent for non-operational strategic management. Rationalization changes the location of manufacturing but product design and marketing continues to be carried out by headquarters. In this case, specialization means changing from "technological dependence and strategic autonomy" to "technological and strategic dependence" (Crookell and Morrison, 1987).

Assigning a "world product mandate" to a subsidiary is another form of specialization. A world product mandate refers to the corporate strategy of allocating to the local subsidiary of a foreign-owned corporation, the global responsibility of research and development, production, market research and promotion of a particular product. With a "world product mandate" the subsidiary gains both exports and R&D activities. A subsidiary granted a world product mandate moves from a position of technological and strategic dependence to "technological and strategic autonomy" (Crookell and Morrison, 1987).

As a general rule, rationalization agreements are negotiated while world product mandates are earned. World product mandates are earned most readily when the original product innovation is developed in the subsidiary and involves growth products which have never been made anywhere else in the MNE. The subsidiary with a world product mandate becomes an autonomous division and profit centre as compared to the branch plant mentality of an integrated factory and cost centre (Crookell and Morrison, 1987).

Globalization is likely to transfer the role of Canadian subsidiaries. The potential gains for subsidiaries include an influence on parent strategies, a global vision, specialist depth and in-house R&D. Losses in strategic independence, local autonomy, generalist scope and imported technology may result from the internationalization of markets. The most effective subsidiary strategy is to minimize the losses and maximize the gains.

There are a number of things that subsidiary managers can do to influence both the strategic direction and competitiveness of Canadian operations. Managing the transition to a global environment requires that subsidiaries consider the following:

(1) Examine the parent's strategy. To map out an appropriate role for the Canadian, subsidiary industry trends (i.e., rationalization) and the parent's strengths and weaknesses (i.e., R&D in different drug therapeutic classes).

(2) Examine the subsidiary's strengths and weaknesses. Canadian subsidiaries must compete with sister subsidiaries and the parent divisions for major projects. Therefore, subsidiaries need to evaluate their own strengths and weaknesses relative to intra-firm competitors.

(3) Determine Canada's strengths. To generalize, Canada's strengths appear to be in product design, flexibility and low-volume production, however, Canadian subsidiaries also have some impediments such as a higher cost of capital.

(4) Manage the integrating mechanisms effectively. The importance of integrating R&D and marketing functions throughout the MNE is crucial in determining the level of interdependence/dependence of the Canadian subsidiary.

(5) Develop unique products in subsidiaries. Canadian subsidiaries can utilize their accumulated R&D capacity to extend the parent's product line or new products which it can develop a distinct competence. These areas of distinct competence are often the basis for obtaining or earning world product mandates for the MNE. Another source of distinctive competence for subsidiaries is through the acquisition or licensing of technology (Crookell and Morrison, 1990).

The benefit to the Canadian economy of obtaining world product mandates in high technology sectors includes:

(1) greater operational efficiency, reduced costs of production and lower final selling prices due to longer production runs and economies of scale;

(2) increased employment in higher skill occupations involved in R&D activities;

(3) the generation of high value added at the local level through production activities and sourcing through local suppliers;

(4) reduced distortions associated with transfer pricing on imports between the parent and subsidiary; and

(5) an improved balance of trade position (Donner and Mogil, 1986).

From the perspective of the parent MNE, the decision to grant a world product mandate has been inhibited for the following reasons:

(1) Loss of control to the subsidiary - Government policy designed to encourage world product mandates (WPMs) has to overcome corporate philosophy that R&D, product development and marketing are strategic decisions which should be controlled by the parent organization.

(2) Reallocation of MNE profits and resources - the granting of a WPM to a foreign subsidiary causes changes in the allocation of revenues, profit, labour and capital within the corporate structure and between countries.

(3) Reduction in the flexibility of the multinational - WPMs reduce the flexibility of MNEs to shift production between countries to the least cost location and to use transfer pricing in order to maintain profitability for the parent corporation rather than the corporate family (Donner and Mogil, 1986).

The correct parent MNE corporate culture seems to be a necessary but not sufficient condition to bring about the award of a world product mandate to a Canadian subsidiary. Targeted government policies, combined with cost competitiveness in Canada, can often influence the parent MNE in allocating Canadian WPMs. However, government efforts which provide incentives in the absence of the required parent corporate culture would likely represent wasted effort. Therefore, universal incentive policies are a non-optimal approach. Influencing MNEs to establish WPMs in Canadian subsidiaries include government incentives of which the following are recommended as appropriate policy levers:

(1) targeted preferential procurement policies in the purchase of goods and services in Canada;

(2) R&D grants and loans for the development of new and innovative product lines;

(3) selective tax incentives to encourage additional investment in high technology R&D and capital investment;

(4) financial assistance for local manufacturers who supply foreign subsidiaries to improve their products; and

(5) joint private-public sector ventures as a means of spreading the risks in the development of new products (Donner and Mogil, 1986).

Location of Pharmaceutical R&D, Product and Marketing Activities

(i) Interrelationships between R&D, Production and Marketing Activities

The strategic nature of technology in corporate growth and profitability, necessitates that the corporate technology strategy be a "core" management function exercised at the level of corporate headquarters. The technological profile of the parent company is the key determinant of plant technology. Branch plants in the pharmaceutical industry are, therefore, dependent on corporate contacts and linkages for both resources and information. The location of R&D facilities is, in part, dependent on the location of production facilities. Several studies have concluded that intercountry shifts in R&D activity follow capital investments in science-based industries. In the past, the relationship between R&D and production activities has been explained by the fact that overseas laboratories are frequently oriented to the needs of foreign markets and, therefore, the percentage of R&D expenditures spent overseas should directly correspond to foreign sales (Mansfield, 1979). In contrast to R&D and manufacturing investments, pharmaceutical marketing is almost always a geographically localized function due to differing health care systems, disease patterns and product preferences among nations. Accordingly, there is an incentive for decentralization of marketing activities independent of the location of the company's production and R&D facilities (Bustall et al, 1981).

(ii) Factors Affecting the Location of Production Activities

The location of manufacturing of final dosage forms and active chemical ingredients is affected by differing cost structures and government regulations. The manufacturer of active ingredients is normally centralized due to economies of scale in production and low transportation costs. It is usually located in developed countries, especially in the multinational's home country or in countries with generous tax concessions. Local formulation and packaging is a common practice, however, in the absence of significant restrictions on the imports of

finished pharmaceuticals (i.e., tariffs), such production would typically be found only in large markets (Burstall et al, 1981).

R&D is conducted in the MNE's home country to foster closer linkages with overall corporate policies or because of its orientation on basic or applied research which is not directly related to individual product lines. Surveys of pharmaceutical companies indicate that the main factors influencing the location of R&D within a country include:
(1) proximity to the company's headquarters; (2) proximity to the main pharmaceutical production unit; and (3) attractiveness of the premises and site (Howells, 1983). This study illustrates that the most important factors determining the location of R&D are related to internal characteristics of the firm.

Usually, the original function of an affiliate R&D facility is adaptive research such as the design of dosage forms, supply of analytical methods and standards, and technical support to manufacturing facilities. The functional progression from adaptive research to creation a new pharmaceutical product is predetermined by the scope of the research activity in the home country. The past profitability of research conducted by affiliates and a demonstrated ability to undertake research by its self-financing capabilities are crucial in accessing corporate funds for basic and applied research.

Clinical research is the R&D function most widely distributed internationally. The location of this R&D is determined by such factors as relative costs, regulatory approval regimes and legal requirements in certain countries that tests be conducted locally (Pazderka, 1985).

In 1987, Canada strengthened intellectual property protection for pharmaceutical products by introducing limitations on the use of compulsory licences. Nevertheless, competing economies (U.S., France, Italy and Japan) have implemented or are actively considering the implementation of legislation to provide increased periods of market exclusivity for drug products in response to concerns about the erosion of effective patent protection due to lengthy R&D and regulatory approval periods.

In Canada, the pharmaceutical industry is provided with set periods of market exclusivity of 7 to 10 years while among other industrialized nations, the patent protection standard for these products is evolving towards a period of market exclusivity of about 14 years. Furthermore, countries such as Mexico have, and Argentina and Brazil are proposing to, strengthen intellectual property protection for pharmaceuticals.

Among other objectives, compulsory licences are used in Canada to regulate prices of patented medicines. While most other countries have some form of price regulation mechanism for pharmaceutical products, pricing controls are usually separate from the patent regime. Compulsory licensing provisions and their linkage to a price control mechanism are at issue in the GATT but not the principle of price control itself.

Canada has a number of positive features to attract investments in the pharmaceutical sector but it must be emphasized that these features are not all unique or superior to what is offered in other countries. With many factors being similar, the issue of intellectual property protection may be an over-riding consideration working against Canadian subsidiaries in location decisions and resource allocations by international pharmaceutical firms. Compulsory licensing provisions can limit the return on investments made in Canada, but more importantly in the international context, the industry perceives these provisions as hostile.

(iii) Canadian Competitive Position for Pharmaceutical Investments

In the emerging global business environment, Canadian subsidiaries will need to complete successfully with affiliated subsidiaries in other locations for mandates to carry out specific R&D and manufacturing activities with a large regional market. Location decisions by multinational corporations are not made solely on the basis of short-term cost minimization, but other strategic considerations are also important.

Canadian subsidiaries realize they must pursue growth strategies based on the concepts of specialization (e.g., by therapeutic class or drug formulation technology) and by competitively bidding against other subsidiaries located in the U.S. and Europe.

Important investments will be needed to bring Canadian operations up to a more integrated and competitive level. The fact that Canada's intellectual property protection legislation is not internationally competitive with that of other important economies is claimed to be a major obstacle to attracting these investments.

The MNE's choice of a location for intermediate production is based on the relative costs, including taxes, of producing that input in various locations. The decision is usually to produce in the least-cost location and sell the product in the most profitable markets or differentiate prices among national markets based on demand conditions.

The location of high-technology investment may be contracted for in negotiations with the industry in return for increased patent terms and for reduced generic substitution of trademarked pharmaceuticals. The increase in investment in Canada - R&D or manufacturing - will not necessarily follow automatically from increased prices and profitability in a small, open economy. Thus, competitive patent protection is a necessary but not sufficient condition for foreign direct investment in the pharmaceutical sector. There are also alternative means of contracting for greater pharmaceutical investment in Canada such as improving investment conditions (Mathewson and Winter, 1984).

(iv) Corporate R&D Decision-Making in Canada

The general R&D budget of innovative pharmaceutical companies is generally allocated as a relatively constant portion of sales. There is considerable variation in the strategic position of R&D among firms, however, generalizations can be made about some underlying principles and patterns of R&D expenditures. Expenditures on R&D are fairly rigid because it is not practical to undertake rapid downsizing or expansion of R&D programs. The long-term trend in the R&D/sales ratio can fluctuate in response to changing corporate policies based on a firm's product pipeline and competition from rival firms (Brogan, 1990).

Companies specialize in specific therapeutic classes in which they have global scientific and marketing expertise. The decision to target new therapeutic classes depends on the global market potential, the firm's scientific and marketing capabilities and the product development costs. The traditional therapeutic class orientation is now competing with a basic R&D approach focusing on human systems (i.e., auto-immune diseases) which may lead to products in several therapeutic classes (i.e., arthritis and asthma) (Brogan, 1990).

The amount spent annually on basic research is rigid because it is only practical to do most R&D in-house. Because decisions to close research units are taken only after several years of poor productivity and managerially it is not feasible to rapidly expand new research facilities, spending on basic research is relatively rigid. Increasing world-wide requirements for safety and efficacy tests limit the resources available for basic R&D and, therefore, the rate of pharmaceutical innovation (Brogan, 1990). Expenditures on clinical research varies more than basic research because clinical research can be contracted with private facilities to respond quickly to successful discoveries of new compounds from basic research. Countries with a high level of scientific expertise and affiliate profitability tend to draw more research (Brogan, 1990).

Where the MNE basic research facility has been established in the home country or in another developed country with a large domestic market (i.e., West Germany, United States, United Kingdom), the opportunities of relocating to or duplicating these operations in Canada are limited. Given that the minimum scale necessary for basic research facilities is approximately 200 researchers, significant resources must be committed in establishing and operating a basic research unit in Canada. Recently, some MNEs have decentralized their basic research facilities and established major facilities in countries with local scientific expertise. Additionally, pharmaceutical firms contract with universities and private laboratories that have specialized expertise to supplement in-house corporate basic research capabilities. Where firms have basic research facilities in Canada, the location decision was primarily based on the availability of Canadian researchers (Brogan, 1990).

MNEs may locate clinical research internationally based on either competitive bidding among subsidiaries or based on collegial decision making and the research capabilities of the subsidiary. The key factors cited by Canadian pharmaceutical industry managers as determinants affecting the location of clinical research among countries includes: (1) R&D costs; (2) subsidiary reputation; (3) availability of human resources; (4) domestic market size; and (5) political climate. The factors affecting location decisions vary depending on the type of clinical research. Early stage clinical R&D tends to be located with the basic research unit or units that have earned a reputation for demonstrated expertise due to the challenging nature and strategic importance of this research. There may be some opportunities for Canadian researchers to play a larger role in early clinical stage research in the future. Cost factors are more important in more routinized later stage clinical testing since many countries have the technical capabilities to conduct such research.

PART 3 - INTERNATIONAL COMPETITION BETWEEN COUNTRIES

VII THE COMPETITIVENESS OF NATIONS FOR FOREIGN DIRECT INVESTMENT

The International Trend Towards Innovation Policy

The international economic environment in the coming decades will be shaped by the interaction of governments and MNEs. There is a blurring of the boundaries between international and domestic policies in trade related areas such as intellectual property, services and investment. The process whereby business interacts with government in the formulation and implementation of trade policy differs markedly among countries; the process of policy making affects the substance of policy. Trade policy making among competing countries differs in the interaction of business with the government bureaucracy and the political system and these differences are impacting on trade and investment flows. An important trend in trade policy is the growing importance of policy directed to high-technology industries (Ostry, 1990).

Within OECD there has been an emergence of innovation policy - a policy set focused on the promotion and adoption of new technology. Two basic models of innovation policy strategies seek to develop state-of-the-art technologies and to foster the adoption of the best available technology through the diffusion of technology. Although the policy mix and government-corporate interface vary from country to country, the emphasis on policy making is shifting to competitiveness and high-technology sectors (Ostry, 1990).

The increasing importance of trade to economic growth and improved living standards and increased competition from newly industrialized economies has resulted in this preoccupation among developed countries with technological change and competitiveness. In some countries such as Japan, it is accepted that a country's economic performance is a result of a created comparative advantage and innovation policy is central to achieving these objectives. The role of government seems to be shifting and it is recognized that governments can take action in a variety of ways on behalf of its own firms by affecting the behaviour of foreign firms or governments. Countries must be concerned not only with other countries' trade policies but with the international impact of many of their domestic policies. A policy move in one country or regional trading bloc may evoke a countermove in other countries (Ostry, 1990).

There are pressures for policy convergence among countries due to the increasing interdependence of the international economy and the information and communication technology revolution. There is also competition between different

regulatory systems as governments compete for internationally mobile resources such as capital and entrepreneurship. This process of competition will produce convergence (harmonization) at the level of government intervention reflecting the preferences of the managers of mobile resources (Ostry, 1990).

At the heart of the innovation policy debate is the idea of government competition. Competition among innovation policy paradigms will optimize factor mobility and competition among governments for foreign direct investment in strategic sectors or technologies. Governments are using differing policy mixes to achieve economic and social policy objectives, however, there are emerging trends in the range and type of dominant regulatory policies being utilized. Policy mixes which are out of synchronization with global trends result in system friction. On the other hand, it is apparent that some countries are better than others in developing public policy strategies to achieve both innovation policy and domestic social policy objectives.

Many firms are driven more by the desire to appropriate the maximum value from their technologies than by concerns about the international competitiveness of their countries. In as much as private and public interests are not necessarily synchronized, public polices might be designed to promote and protect international competitive advantages of a country. Systematic market barriers or other restrictions on technology transfer have been utilized effectively by Japan to "acquire" competitive advantages in high technology industries (Shan and Hamilton, 1991).

Public Policy on Foreign Direct Investment

Two general principles have been espoused for providing the basis for evaluating policies towards foreign direct investment - national treatment of foreign firms in the home market and neutrality between trade and investment as alternative mechanisms as supply in the home market. The exceptions to the general rules on policy towards FDI include:

(1) Non-economic concerns such as national security and culture;

(2) Strategic behaviour by foreign firms or their governments;

(3) Employment creation, technology transfer and local content rules negotiated as a quid pro quo for investment subsidies; and

(4) Reciprocal access to foreign markets can be a condition of neutrality vis-à-vis foreign direct investment (Julius, 1990).

It is generally recognized that the choice of sites of MNEs will be dominated by local considerations that are different from the factors used by domestic firms. There is some evidence that the investment location decisions of MNEs strengthen the agglomeration tendencies prevailing in the spatial organization of market economies. Many MNEs have a preference for existing areas of heavy industrial concentration as part of a locational strategy for loss minimization in the event of commercial failure (Dunning, 1984).

It is also true that the locational strategies of foreign owned firms diminish the effectiveness of government regional development policies. However, MNEs can be influenced by regional polices incentives when selecting locations within a foreign country (Dunning, 1984).

MNEs and Regional Incentives

The factors affecting the level of regional policy incentives necessary to be effective in encouraging MNE capital investments to locate in Canada can be classified into two groups: product-related and enterprise-related factors. The type of regional policy incentives available will have quite different effects on the individual firms according to their structure and business strategies. The key product-related variables affecting economic development policy include:

(1) The skill and/or capital intensity of the production process affects subsidies in that:

- the higher the capital intensity of the foreign investment, the greater will be the size of the capital subsidy.
- as the skill intensity of the production process increases, the focus of investment shifts to labour-based policy oriented towards break-even subsidies.

(2) Economies of scale at the plant level are important since firms have a tendency to respond to regional incentives where the economies of scale at the plant level are small in relation to the size of market surrounding the firm's operations.

(3) Freight costs affect whether a plant will be located near either the source of its materials or its markets. If the freight costs are a low proportion of total costs, investments at locations in regional development areas will become more attractive at a lower level of break-even subsidy.

(1) MNEs have tended to undertake FDI which has shifted the production of lower skill jobs from the parent to the subsidiary. The differential in wages in affiliates using a high ratio of unskilled to skilled employees tends to be small between assisted and non-assisted areas so the required regional subsidy will tend to be small.

(2) The capital intensity of affiliates of MNEs is higher than that of indigenous firms. Therefore, MNEs are more responsive to capital subsidies.

(3) FDI is a substitute for exports so MNEs concentrate more than domestic firms in light manufacturing and science-based industries where there is a high ratio of value of products to transport costs.

(4) Manufacturing affiliates of MNEs usually produce standardized commodities.

(5) Both the multidivisional nature and vertically integrated structure of MNEs allows for more flexibility in location decisions (Dunning, 1985).

Several structural characteristics of MNEs tend to diminish the responsiveness to regional incentives:

(1) The locational requirements of certain MNE functions - R&D and marketing - are less flexible thereby reducing the impact of regional incentives on the location of non-manufacturing facilities and the production of new products.

(2) Scale economies are more important for MNEs, however, proprietary knowledge can be used in combination with other factors in many different locations rather than the initial source of R&D.

(3) Strategic considerations may be different in the choice of MNE subsidiary location rather than rate of return considerations (Dunning, 1981).

It is also suggested that MNEs influence location choices and, therefore, affect the level of responsiveness to regional incentives:

(1) MNEs have no particular commitments to specific regions of a country (or continent) so the locational efficiency of MNEs seems to be superior to indigenous firms.

(2) The alien status of MNE subsidiaries may make them more sensitive to reducing the political risks of investing in another country by responding to national priorities concerning a country's economic development.

(3) MNEs have more freedom in shifting tax burden forward or backwards within a country and between countries through its financing and transfer pricing policies. This additional ability reduces MNE uncertainty surrounding future changes in regional policies during the life of the investment since the tax burden can be shifted and transfer pricing used.

(4) Affiliates of MNEs may be controlled in their behaviour by the policies of host governments and the parent company. The location decision is often a sequential process in which the parent firm chooses the broad geographical area for new FDI and the subsidiary has freedom over the specific location in the national economy (Dunning, 1981).

Canada's Ability to Compete for Pharmaceutical Investments

(i) R&D Spend

Pharmaceutical R&D in Canada as a percentage of ethical drug sales, approximately 10%, compares unfavourably with other developed countries.

Note: Figures unavailable for Switzerland, however, R&D spend as a percentage of sales probably ranks the highest of all countries.

Source: Scrip No. 1546, September 5, 1990.

The EC countries with the highest R&D spend as a percentage of domestic sales - the U.K., Denmark, West Germany and the Netherlands - have the highest pharmaceutical prices. Among the countries with low price policies - France and to a lesser extent Belgium - have been best able to attract R&D investment. Among the countries with pharmaceutical prices above the EC average,

the United Kingdom has been the most successful in competing for R&D investment. A comparison of price indices and R&D levels illustrates both the relationship between prices and R&D and the varying competitiveness of EC countries for R&D investment.

Country	Price Index 1989	R&D Spend as a % of Sales

Sources: Scrip No. 1555, October 5, 1990.
Scrip No. 1559, October 19, 1990.

(ii) Strength of Scientific Base

The importance of a country's scientific base and its strength as a determinant of the location of R&D activity, especially basic research and early clinical trials, is well established. The two key determinants of the national capacity for pharmaceutical research are the national research intensity and the size and quality of the national scientific community (Pazderka, 1985).

Canada spends approximately 1.4% of Gross Domestic Product on R&D. Total Canadian R&D spending lags behind other developed countries, however, it is comparable to levels of spending as a percentage of GDP in the U.S. and other G7 countries in terms of non-defense R&D. In 1989, Canada's total expenditure on R&D was $8.3 billion of which the private sector accounted for $4.6 billion or 55% of all R&D activity. The federal government accounted for over $2.5 billion or one-third of all R&D and twelve per cent of all private sector R&D activity was financed by government agencies (Consulmed and Consultech, 1985).

The regional breakdown of R&D spending is heavily weighted in favour of Central Canada with more than 54% of all expenditures in Ontario and 23% in Quebec. Of the remaining R&D expenditures, most is spent in Western Canada (Consulmed and Consultech, 1985).

In Canada, the total number of R&D personnel per 10,000 of the labour force is .80 which compares favourably with the United States (.67), but lags behind Germany (1.43), Japan (1.32), France (1.15) and the U.K. (1.00). Approximately half of all R&D personnel are employed by the private sector, 34% are located in universities and 14% are employed by the federal government (Consulmed and Consultech, 1985).

Although Canada has a well developed medical and clinical research infrastructure, there are some difficulties in finding qualified researchers in the biosciences. A recent Conference Board of Canada survey revealed that Canadian firms are experiencing shortages of chemists, bioscience specialists and pharmacists. The shortage of qualified researchers has resulted in the cost of R&D in Canada rising significantly (Brogan, 1990). The Canadian pharmaceutical industry has also reported a shortage of clinical pharmacologists and toxicologists, however, increased international requirements for safety and efficacy data have created global shortages (Pazderka, 1985).

Strength in a number of scientific disciplines is important in attracting pharmaceuticals R&D - clinical pharmacology, medical chemistry, toxicology, pharmakinetics, physical pharmacy and pharmaceutics, as well as, basic science, medicine, biochemistry and microbiology. Data from the Science Citation Index 1980 indicates that the Canadian percentages of the world total citations were most significant for biology (8.25%), biomedical research (4.00%), clinical medicine - pharmacology (3.94%) and chemistry (3.27%), whereas, Canadians were represented less in clinical medicine - pharmacy (1.36%). It would seem that there are many strong departments of pharmacology and medicine at universities across Canada, however, there may be some potential areas of technical weaknesses (e.g., physical pharmacy) and a lack of a culture of collaborative research and interaction between industry/university/government in pharmacological research in Canada (Pazderka, 1985).

(iii) International Competitiveness of Canadian Tax Treatment

(1) Corporate Taxation

The Canadian corporate taxation system is internationally competitive, providing specific advantages for companies with manufacturing or R&D activities in Canada. The combined federal/provincial tax ranges from a low of 32.00% in Quebec to a high of 42.84% in Newfoundland and Manitoba. The combined corporate tax rate in most provinces is approximately 40-41 per cent which is competitive with many U.S. states such as California (40.1%), New York (39.6%), and Pennsylvania (39.6%) (Deloitte & Touche, 1990).

(2) R&D Tax Credits

Canadian tax legislation is much more flexible and generous with respect to R&D tax credits than the tax legislation of most industrialized countries. Canada provides firms with the flexibility of immediate write-offs for R&D expenditures or the option of deferring for claim in a future year. The competitiveness of the federal R&D tax credit system is complemented by further tax credit incentives that exist in some

Canadian provinces, especially Quebec, Ontario and Nova Scotia. This favourable tax treatment makes Canada a particularly attractive location for MNEs to leverage R&D investments (Consulmed and CCL Consultech Canada, 1990).

Relative to other industrialized countries, Canada offers one of the most favourable and stable treatment of R&D tax incentives. The after-tax cost of $1 R&D expenditure in Quebec ($.447) and Ontario ($.461) is very competitive with other locations including California ($.582), Japan ($.494) and the United Kingdom ($.650) (Warden, 1990). The Quebec government estimates that the Quebec tax system is very competitive with Ontario, Massachusetts and New York for company R&D expenditures conducted in-house and it is even more advantageous to undertake basic research in Quebec universities.

The tax advantages to pharmaceutical companies operating in Puerto Rico under section 936 of the U.S. Internal Revenue Code are substantial.

(Scrip No. 1546, September 5, 1990).

(iv) Intellectual Property

The competitiveness of Canadian intellectual property strategies must be evaluated in the context of impacts on commercializing innovative pharmaceutical products, system friction, system competition and access to markets.

(1) The Rate of Innovation

Canadian IP laws affecting the level of profits in the Canadian markets contribute only marginally to the revenue stream necessary to finance product development and global commercialization of patented medicines. The level of Canadian IP protection in itself has minimal impacts on pharmaceutical innovation internationally. Perhaps the most significant effects of Canadian patent policies such as the C-22 compulsory licensing provisions on international revenues is its role as a "model law" and the potential adoption of its principles by many other countries without a significant domestic innovative pharmaceutical sector.

Canadian IP laws also must provide the incentives for the commercialization of innovative drugs in the Canadian market. IP protection is necessary to provide compensation for the costs incurred in, obtaining regulatory approval and marketing/promotional activities in Canada. Intellectual

property protection has also been used in some instances to target the commercialization of inventions with limited markets. The U.S. Orphan Drug Act provides broad IP protection and seven-years of market exclusivity for pharmaceutical products having a limited number of patients and sales (e.g., EPO as a substitute for kidney analysis). The pesticide data registration system in Canada has mechanisms which provide additional incentives for firms to undertake safety and efficacy studies to obtain regulatory approval for pesticides with limited use in Canada (e.g. horticultural crops with small acreage). Canadian IP laws do not specifically target innovation of pharmaceuticals with potential limited sales in Canada or dovetail with policies complementary to U.S. IP laws such as the Orphan Drug Act.

(2) System Friction

Canada has undertaken several initiatives to harmonize its patent laws with the evolving international standards such as first-to-file systems and the Patent Co-operation Treaty. It is the United States which is out of step with the rest of the world with its continued policy of first-to-invent and reduction-to-practice requirements. Given the importance of the U.S. market to Canadian firms, the incongruent U.S. patent policies are a problem. System friction affects pharmaceutical companies directly by increasing the administrative and marketing costs of implementing global IP marketing strategies. International pharmaceutical firms adapt their strategies in the Canadian market to the various mix of government policies, of which IP protection is only one aspect affecting the revenue stream. Thus, although Canadian effective patent terms for pharmaceutical are shorter than in some developed countries, the bottom line is that profitability in Canada is highly competitive with other markets. However, there is system friction in that the strategies which MNES must pursue in the Canadian market place may differ from other countries because of the lower level of IP protection.

The issue of system friction is highlighted with compulsory licensing. Countries such as the United States continue to use compulsory licensing of patents to encourage competition in the domestic market through a variety of mechanisms. The U.S. system, however, tends to rely on the court system rather than an administrative system for "compulsory licensing" patents. Additionally, limited compulsory licensing regimes have been used in legislation which strengthens IP rights such as the Orphan Drug Act and the Drug Price Competition and Patent Term Restoration Act.

Although the U.S. government has often asserted that, as a matter of policy it opposes compulsory licensing of intellectual property rights, there are at least 16 U.S. laws and programs

which allow for the compulsory licensing of patents. The U.S. programs dealing with compulsory licensing of patents include:

(1) compelled licensing for use by the government, or on its behalf;
(2) compelled licensing of patents critical to government interests;
(3) compelled licensing as a remedy for infringement, violations of antitrust laws, or misappropriation of trade secrets; and
(4) in exceptional circumstances, where transfer of technology is deemed more important than the protection of intellectual property rights.

Under the U.S. Patent Act, two provisions may be applied to issue a de facto compulsory licence. Courts are authorized to enjoin patent infringement on such terms as they deem reasonable and failure of the courts to grant an injunction in the face of an infringement is tantamount to issuing a compulsory license. Courts have been particularly willing to issue such a compulsory license:

(1) where the patentee is unable to satisfy U.S. demand for the product;
(2) where public interest in health, welfare or national defense outweighs the interest in the patent holder's property right; and
(3) where necessary to ensure that the patented technology or invention is exploited or worked in country (Weil, Gotshal & Manges, 1990).

Compulsory licensing has been specifically been used to serve U.S. government interests in the pharmaceutical sector. Under the Orphan Drug Act, a second firm may be authorized to sell the drug, notwithstanding any existing patents, which previously was subject of exclusive marketing rights if consumer demand is not being met. The Drug Price Competition and Patent Term Restoration Act allows infringement of pharmaceutical patents to the extent necessary to carry out testing of a drug product for marketing after the patent expires, thereby expediting development of "generic" drugs.

(3) System Competition

Parallel to international initiatives encouraging harmonization and minimum standards and enforcement of IP rights, countries are engaged in system competition especially for foreign direct investment. In this context IP is one element of strategic industrial policy and has been used to lever commitments from the pharmaceutical industry for higher levels of domestic R & D and manufacturing investments. The tendency is that the countries which are the home countries for the major pharmaceutical MNES - U.S., Switzerland, Germany, Japan - have

the stronger IP protection and highest levels of profitability and drug prices. These countries also benefit the most from investment, employment and tax revenues. Without agreements on the maximum level of IP protection, competition between countries for FDI encourages a ratcheting up of the competitive level of IP protection independent of the level of profitability of the industry. Thus, competitiveness between countries for FDI shifts the focus from providing incentives to encourage innovation to providing direct investment subsidies. Unlike R & D tax credits, competitive IP laws do not provide incentives targeting Canadian investments.

The Pharmaceutical Manufacturers Association of Canada (PMAC) has argued that the effective patent life in Canada is not competitive with protection in the EC and U.S. PMAC has suggested that to be internationally competitive, Canada should abolish compulsory licences and adopt a system of patent term restoration to create an effective patent life of 16 years, competitive with that available in the U.S., Europe and other countries and retroactive to January 1, 1984.

The primary PMAC concern is the granting of compulsory licensing of pharmaceuticals. In Canada, compulsory licences are granted to:

(1) manufacture a patented medicine in Canada for the purpose of selling the medicine for consumption in Canada seven years from the date of issue of the first notice of compliance (NOC); and

(2) import a patented medicine for the purposes of selling the medicine for consumption in Canada ten years after the date of issue of the first notice of compliance.

PMAC has also recommended that the Patent Act be modified to eliminate discriminatory aspects related to:

(1) products developed in Canada; and

(2) compulsory licences for export.

PMAC is also concerned that the current activity of market exclusivity under the Patent Act only apply to the original and distinct equivalent of the medicine or the first patent granted in Canada in respect of that medicine. Second generation drugs, improved processes and new uses for old drugs do not receive a period of market exclusivity but rather are dependent on protection under the original patent granted in Canada (PMAC, 1990).

(4) Access to Markets

Another factor essential in assessing the competitiveness of Canadian IP strategies is the level of access to the Canadian and foreign markets. Due to national regulatory approval regimes there is little cross-border competition in the pharmaceutical sector. Therefore, unlike most other sectors in which patents are important to strategic firm behaviour, pharmaceutical MNEs can price discriminate among national markets. Therefore, access to products on foreign markets is restricted. Similarly, Canadian access to foreign markets, especially the U.S. generic market, is limited by discriminatory IP policies and both regulatory and market barriers to entry. Negotiations on IP rights must be considered in this context and in terms of what levers Canada has to negotiate improved access to foreign pharmaceutical markets.

Future Trends and Opportunities

Canadian competitiveness for pharmaceutical R&D facilities and manufacturing operations will depend on the opportunities for future investment resulting from international trends as well as the relative advantages of locating in Canada.

Most companies are in a phase of increasing R&D in response to new market opportunities and greater competition as patent terms on major products expire. Restructuring of the pharmaceutical industry internationally is also leading to increased competition between governments for foreign direct investment using incentives such as tax credits and IP protection.

International competition for basic research facilities, employing 220+ researchers, will be intense and there are only a few MNEs that would be willing to consider financing a company-owned basic research facility in Canada. More companies seem prepared to finance smaller facilities which specialize in basic research projects that fit into the corporate plan.

Corporate research may offer the greatest potential for growth in pharmaceutical investment in the short run. Attracting early stage clinical research is an evolutionary process since the capacity to undertake more difficult research must be established over time. Strengthening of university-industry collaboration and the establishment of more private research companies are two institutional arrangements which may encourage additional MNE research expenditures in Canada.

Although the current business environment is positive, policies ~~t~~hat make the Canadian economy more efficient and competitive will have a positive influence on the location of R&D. It is apparent that other countries have developed industrial strategies targetting strategic technologies and industrial sectors and are structuring their domestic policy environment to create a long term competitive advantage. Additionally, public policies affecting inter-firm competition also affect the nature of domestic rivalry and innovation in the home market. Patent policy affects both domestic inter-firm competition and the ability of Canadian subsidiaries to compete for foreign direct investment.

VIII Summary and Public Policy Implications

The scope and length of intellectual property protection affects Canadian competitiveness in the pharmaceutical sector by changing the nature of intra-firm competition in the global market. This, in turn, appears to be important to Canada's ability to compete for foreign direct investment in R&D and manufacturing facilities. Foreign governments competing with Canada for the location of pharmaceutical investments are adopting agressive competitiveness strategies which seek to achieve the same public policy objectives using a different mix of institutions and regulatory programmes. Canada on the other hand, by maintaining the status quo, is increasingly faced with trade irritants caused by system friction. The primary conclusion of this research is that Canada needs to adapt quickly to the changing global economic realities by developing a comprehensive mix of industrial and healthcare programmes, which although they are made-in-Canada, are consistent with trends in the pharmaceutical industry and compatible with policies in other G-7 countries.

An important stategy for encouraging Canadian competitiveness in the international pharmaceutical industry is to adopt policies which encourage the creation of a competitive advantage for undertaking basic and clinical R&D in Canada. Intellectual property protection provides an incentive system to encourage innovation. However, successful innovation results from the interaction of many market variables including: factor conditions, demand conditions, related and supporting industries and firm strategy, structure and rivalry. Government policies that encourage competition in Canada - new products of significant therapeutic value or products of equivalent therapeutic value at lower prices - will provide the proper incentives for domestic pharmaceutical innovation. The intellectual property system in Canada and many other countries enables firms to link the barriers to entry associated with the market exclusivity granted under the Patent Act to product differentiation strategies based on trademark use. Inter-firm rivalry too often consists of seeking regulatory approval for "Me-too" products marketed at high prices with limited improvements in therapeutic value over the innovative product and inter-firm competition based on product differentiation stategies utilizing significant promotional expenditures.

To compete for foreign direct investment with other developed countries, Canada must have the necessary factor conditions and supporting industries. For the most part Canada appears to be competitive in terms of its human resources and public research institutions. However, there seems to be a lack of targetting of national efforts on a limited number of therapeutic areas and there are some weaknesses in the scientific base. It is not clear that the Canadian advantages in terms of innovative capacity are sufficiently superior to competing foreign countries to offset some negatives in industry- and firm-specific location factors. Additionally, it appears that the Canadian pharmaceutical innovation capacity must address shortages of qualified researchers in clinical pharmacology and toxicology if Canada is going to compete effectively for foreign direct investment.

Canada can influence the demand conditions for pharmaceuticals through drug reimbursement plans, generic substitution, regulation of promotional activities etc. These policies can be constructed such that the incentive system in the marketplace rewards activities that contribute to enhanced global competitiveness for both Canadian-owned firms and subsidiaries of MNEs.

Canada can also influence the demand conditions for drugs invented and manufactured domestically by gaining improved access to large markets such as the United States. Negotiating improved access to the U.S. market through the reduction of regulatory barriers to trade and the elimination of discriminatory provisions in American IP laws (reduction-to-practice, first-to-invent, S.301, S.337 etc.) must be done using bargaining leverage of which the level of patent protection is one element.

Influencing firm strategy, structure and rivalry in a regulated market is primarily achieved through influencing the demand and factor conditions. However, it is important for policies affecting the domestic competitive strategies to be consistent with the emerging global market opportunities and trends. Government policies need to not only encourage domestic firms to compete globally but should focus on areas of major structural change such as biotechnology, medical care cost containment, cost effectiveness of drugs, growth of the generic market, Rx to OTC switches, increasing R&D costs, aging populations, niche markets, increased mergers and acquisitions, increased numbers of blockbusters, etc. Obviously, it is not

possible for Canadian policies to target all of these market opportunities but encouraging firm strategies and domestic rivalry to focus on Canadian leadership in some areas would seem to be a competitive strategy complementary to improving IP protection.

To ensure that Canada benefits, the location and nature of pharmaceutical investment and pricing considerations must be contracted for in negotiations with the industry in return for increased patent terms and/or profitability in the Canadian market. Increased investment in Canada will not necessarily follow automatically from increased patent protection, prices, and profitability in a small, open economy such as Canada's. Thus, competitive patent protection is a necessary but not a sufficient condition for foreign direct investment in the pharmaceutical sector. Theoretically, the increased profitability of Canadian subsidiaries would lead to increased investments in Canada in cases where companies have a strategic policy of rewarding countries with more favourable business climates, however, firms weighing locational factors differently may have no incentive to locate investment in Canada. The world product mandate model of intra-firm competition for foreign direct investment must be treated within the context of other countries also competing for foreign direct investment through informal agreements or social contracts with national pharmaceutical trade associations; a commitment for a certain level of MNE investment in Canada would strengthen a Canadian subsidiary's position in negotiating for a world product mandate.

The ability of different provinces to compete for foreign direct investment in the pharmaceutical sector varies widely across Canada. Both Ontario and Quebec are most successful at attracting investment. Atlantic Canada is the least successful. Some of this provincial advantage is due to more favourable tax incentives, however, market size and the availability of innovative capacity are key determinants of location decisions within Canada.

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