COMPETITION AND THE PHARMACEUTICAL VALUE CHAIN

Competitive Issues in the Over-the Counter and Generic Drug Segments of the Canadian Pharmaceutical Industry.

Final Report
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EXECUTIVE SUMMARY

The purpose of this report is to examine the issues affecting the competitiveness and corporate strategy of companies manufacturing off-patent pharmaceuticals. In particular, we focus on two segments of the industry; the generic and over-the-counter (OTC) drug segments respectively. The conceptual platform for our analysis is the "Value Chain". Considering the rapid changes that are occurring in the industry, we have modified the traditional value chain to make it representative of the industry and firms in the 1990s.

The generic and OTC segments of the industry are receiving growing attention by the traditional brand-name manufacturers. These companies have embarked upon several strategies to respond to the changing environment that increasingly emphasizes managed care and the ultimate consumer. Consolidation and integration through acquisitions and collaboration, increased generic drug production by brand-name manufacturers, and Rx-to-OTC switches have all contributed to the growing complexity in the pharmaceutical industry. Greater attention is being placed on the latter stages of the value chain and generic and OTC drugs have become far more important for corporate profitability.

The report examines the corporate strategies and competitive issues that influence the structure of the conventional generic and OTC drug segments in Canada. In addition to discussing issues affecting the segments at the international level, the report focuses on some specific issues that are unique to the Canadian market—for example, the impact of the regulatory environment on the generic drug segment and the wide range of retail marketing practices that are used by companies in the OTC drug market. Significant changes are occurring both globally and nationally and it is the interrelationships of these changes at different geographical and jurisdictional scales that contribute to the evolving structure of the generic and OTC market segments in Canada.

TABLE OF CONTENTS

CHAPTER 1 INTRODUCTION

It is well known that the global pharmaceutical industry has been undergoing significant restructuring over the past ten years. Even within the past year the considerable acquisition and collaboration activity has heralded a new phase of competition in which pharmaceutical firms seek new opportunities to maintain profitability. The purpose of this report is to examine the issues affecting competitiveness and corporate strategy in the Canadian pharmaceutical industry. In particular, we focus on competitive issues the OTC and generic drug segments of the pharmaceutical industry.

There is a limited amount of data and information available on these two segments. This study is based on material we have collected from literature in business, health, and industry publications, and from a series of interviews and correspondence with company representatives and industry associations.

The conceptual platform for our report is the "value chain". In this chapter, we introduce the value chain and relate it to the manufacturing and delivery of products and services in the pharmaceutical industry. This serves as the basis for the chapters which follow.

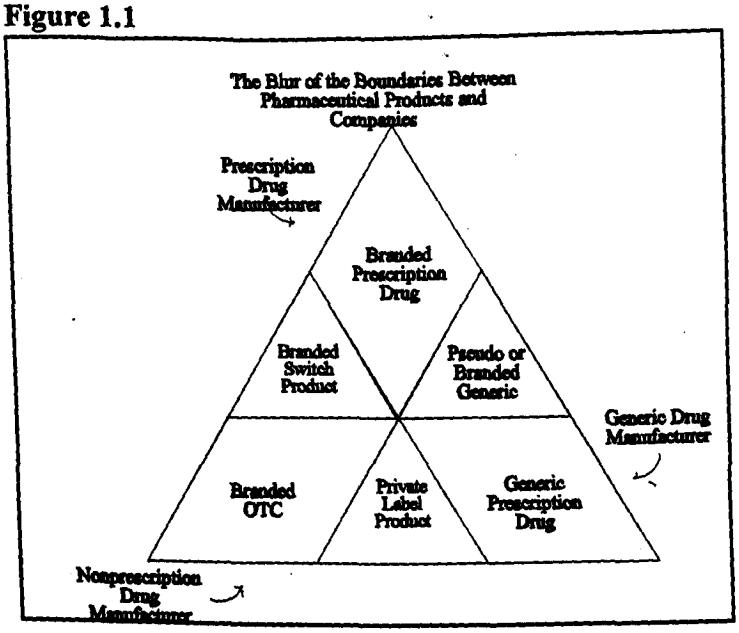
Definitions

One of the purposes of this study is to examine the strategic behaviour of companies that manufacture off-patent pharmaceuticals. A common use of the term "off-patent" is to refer to a drug for which the patent is expiring. The generic and OTC segments of the pharmaceutical market are clearly affected by drugs that come off patent. Discussing the corporate strategy and competitiveness in these two segments is, however, difficult since the segments overlap and companies no longer produce products solely for one of them.

To illustrate the uncertainty, figure 1.1 shows how producers traditionally associated with one form of production are now entering new product markets; this gives rise to new terminology. For example, traditional, independent generic drug manufacturers used to produce products that were in the lower right corner of the diagram. These products were generally prescription drugs that had come off patent, allowing the generic drug manufacturer to enter the market. The generic drug manufacturer of today is no longer limited to such products. Many generic drug companies produce products under voluntary licences from branded prescription drug manufacturers, creating a "pseudo-generic" product category. Also, generic drug manufacturers are producing more nonprescription drugs, many of which are packaged under "private label" (house-brand) names belonging to large retailers. Additionally, some companies that have been traditionally defined as generic drug manufacturers are beginning to conduct innovative research to find new drugs. This new role for these companies makes it increasingly difficult to discriminate between generic and branded pharmaceutical manufacturers.

Nonprescription drug manufacturers (in the lower left corner of figure 1.1) are also redefining themselves within today's pharmaceutical industry. In this segment of the industry, the dominant producers are the multinational, prescription drug manufacturers. Within these companies, the nonprescription and prescription divisions are becoming more closely integrated, and are launching products, that were once prescription only medicines, into the over-the-counter (OTC) market. These "switched" products are another example of the blurring boundaries between pharmaceutical products and companies.

Figure 1.1



For the purpose of this study, we use the traditional definitions of a generic drug manufacturer and a nonprescription drug manufacturer. Nonprescription drug manufacturers are those companies, or divisions of larger companies, whose *primary function* is the production of drugs that are available for sale without a prescription. We use the phrase OTC when referring to the nonprescription segment of the pharmaceutical industry. Generic drug manufacturers are companies whose *primary function* is the production of drugs that were previously discovered and produced by another firm (typically a research-based manufacturer of branded products). We have included a Glossary of Terms (Appendix A) to help identify the usage of many terms used to delineate pharmaceutical products and companies.

The Pharmaceutical Value Chain

The path that a product takes from inception through to delivery and consumption can be described as a "value chain." A value chain identifies the sequence of stages to deliver value to the ultimate consumers, who use the product for their own purposes. Each stage in the chain represents the creation of value under a given theme - production, marketing, and so on. Value is added at each stage by combining products and/or services (as in manufacturing) and by supplementing a product or service with other services, such as marketing or customer service.

The total value of a good is the sum of the incremental values added at each stage. Different agents such as manufacturers, distributors and retailers may be involved in the creation of value at various stages along the chain. There are very few industries, however, in which a single

organization controls the entire value chain. In most cases, a good is passed along the chain from intermediate suppliers to consumers. The producers of raw materials, for example, are intermediate suppliers of a good used by an intermediate consumer, the manufacturer, which is then an intermediate supplier to a wholesaler, and so on. Firms who control stages, or sections, of the value chain extract rents for their value added by selling the product to agents further along. The end consumer extracts utility from consuming the final good.

Figure 1.2a shows a value chain for a simple commodity good. The stages in the product's evolution are delineated into innovation, development, manufacturing, marketing, and distribution. The sequential order of the stages shown in Figure 1.2a is merely a simplification of the model. In the real world, some stages along the value chain may overlap. It is also possible that some stages of a value chain are interdependent in non-sequential ways; for example, marketing research may suggest problems that need to be re-worked.

A value chain in the pharmaceutical industry is different from standard commodity value chains. Science is of significant importance to the innovation, development, and manufacturing stages. The roles of other stakeholders - physicians, pharmacists, insurers and patients - influence heavily the distribution, marketing, and consumption. Behind the value chain and its stakeholders lurks the problem of the precise role of pharmaceuticals within the health care system - making it difficult to distinguish what the "end product" is, or should be.

Figure 1.2b shows an extended value chain for pharmaceutical products. It is comprised of the same stages as the simple commodity value chain, plus two additional stages: dispensing and treatment. The stages in the pharmaceutical value chain are segregated into three major themes: research intensive stages, sales stages, and service stages.

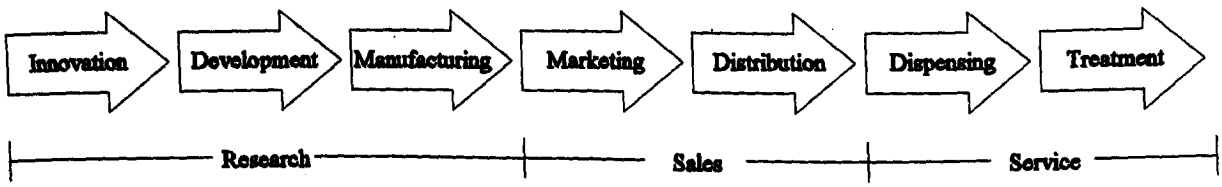
In the first three stages of the pharmaceutical value chain - innovation, development, and manufacturing- emphasis is placed on research. The pharmaceutical industry is well known for its investment in R&D. These expenditures include scientific research on diseases and their mechanisms, pharmacology, and engineering. Some of the research in these stages can occur simultaneously, while some research must be done sequentially. Process research, for example, may be done at the same time as product development, but it must follow the original innovative research and precede the regulatory research that determines the quality of the end product.

One of the unique features of the pharmaceutical industry is the importance of granting patents to innovating firms. A patent provides firms that are leaders in early research stages monopolies in the subsequent sales stages. These temporary monopolies are granted because, in the absence of intellectual property protection, it is difficult to extract rents in the research intensive stages. Thus, there is (in theory) a sub-optimal incentive for innovation. Having a monopoly over sales during the life of the patent allows a firm to extract extra-normal profits prior to the entry of competitors. Competitors who enter after patent expiry can compete on a cost basis because they need not invest as heavily in early research stages.

Figure 1.2

Figure 1.2a: A Simple Value Chain for a Commodity Good

Figure 1.2b: An Extended Value Chain for Pharmaceuticals



The next two stages in the pharmaceutical value chain - marketing and distribution - are sales oriented. It is during these stages that health professionals are targeted by pharmaceutical sales forces aimed at raising awareness of their drug. This targeting occurs because physicians, and increasingly pharmacists, make product choices on behalf of the ultimate consumer. Firms will deal with pharmacists and physicians differently depending on their product type. Generic drugs, for example, are marketed to physicians far less than their branded competitors, and consumer direct marketing is more heavily relied upon by branded OTC manufacturers than by prescription drug manufacturers.

Wholesaling and retailing also take place in the sales stages. This is the process by which the good is delivered from the factory to the consumer. The mechanisms for product delivery are becoming as sophisticated and critical to the profitability of a firm as product development. Value is added in these stages by delivering the product and associated services to the wholesalers, retailers and, eventually, consumers in a timely, efficient and convenient fashion.

The final two stages - dispensing and treatment - are service-oriented. These stages are unique to the pharmaceutical industry because of its role within the health care system and the risks associated with drugs. These last two stages may best be understood by viewing pharmaceuticals as part of a treatment regime involving physicians, pharmacists, other health care workers, insurers and patients. The net outcome of the treatment is a change in health status. In these service stages, physicians offer diagnostic, prescribing, and follow-up services; pharmacists offer information, pharmaceutical counselling, and retailing services; insurance companies offer coverage and health information; and patients are ultimately responsible for implementing drug therapies as they are intended.

The multiplicity of agents involved in the latter stages affects the dynamic of the whole value delivery process. Although it may be difficult to delineate how each agent appropriates her/his rent, the health outcome to the consumer is the ultimate goal of the process. The pharmaceutical industry is paying increased attention to the final consumer's role in the delivery of this outcome.

The transformation of the role of pharmaceuticals is just part of the broader restructuring occurring in the health care system. Canada's publicly funded health care system is being placed under increasing pressure to cut costs and improve the use of limited resources. Hospitals face bed reductions and closure, new funding mechanisms are being explored as alternatives to the traditional fee-for-service environment, and pharmacists and allied health professionals are assuming greater importance in the provision of services to consumers. There is a shift toward devolution and regionalization, community-based care, health promotion and illness prevention - all of which suggest a more informed role for the consumer.

The use of pharmaceuticals in this restructuring can be understood at two levels. First, concerns over cost containment clearly impact on the use of drug therapy. To some observers drug use provides a cost-efficient alternative to hospitalization. To others, however, drug costs are soaring and have reached a point where a publicly funded system can no longer afford to pay for drug therapy. At a second level it is argued by many that drug therapy truly enhances the quality of life for people requiring care. Other observers, however, point out that while this is so, drugs are misused and inappropriate in many cases. The population should be much better educated on the use of drugs.

Generic and OTC drug use can be seen as critical to improving the quality of care and to reducing health care costs. While generic products offer cost savings to provincial governments, private insurance groups and the individual, OTC products have the potential to provide consumers with greater control over their health care. Both market segments, therefore, are increasingly of interest to public policy makers.

CHAPTER 2 SELECTED CORPORATE ACTIVITY

Given the changes occurring in the health care environment and the increasing significance attached to the ultimate consumer, the generic and OTC segments of the industry have been receiving growing attention by the traditional "ethical drug product manufacturers". As the leading companies respond to the broader health care changes, and emphasize global management, production and markets, there is a marked process of consolidation and integration occurring in the industry. And as this unfolds, the traditional stereotypes of pharmaceutical companies are being replaced by new characterizations that are based upon companies attempting to increase, or sometimes just maintain, their profitability. This has led to greater attention being placed on the latter stages of the value chain.

This chapter outlines examples of relevant corporate activity in the drug industry which influence the changing balance between firms marketing patented and off-patent products. There is not, in fact, an easy separation of patented and non-patented products. As patents expire, many companies find themselves selling a mix of both. Brand-name companies, traditionally selling patented products originating in their own R&D laboratories, are increasingly entering the generic drug markets, and looking to expand further into the OTC market segment. Another factor contributing to the dynamism of the industry is the proliferation of acquisitions and alliances among drug companies. The nature and extent of inter-firm activity, makes it problematic to focus on "off patent" product markets only.

Acquisitions, mergers and alliances among drug companies have been a growing phenomenon, and take a variety of different forms. In what follows, we offer a series of case studies of recent activity in the industry. We do not necessarily suggest that the motivation we chose to highlight is the only one, or even the most important one. We do, however, hope to convey that the industry is characterised by continuous restructuring, and that the increasing attention being paid to non-patented products is just one element of this ongoing transformation.

Penetration of Brand-Name Firms Into Generic Markets

In May 1994, Roche Holding Ltd. of Switzerland announced the offer to purchase Syntex Corp. (based in Panama, with main public relations office in Palo Alto, California), for U.S.$5.3 billion, i.e. $24 a share. The takeover would create the fourth-largest pharmaceutical company in the world, and combine the strength of Syntex in Canada, the U.S., and Mexico with Roche's strength in Europe and Asia. Roche's cash offer represented a 54-per-cent premium above the closing price of Syntex shares. The announcement of the offer raised the share price of Syntex from $15.25 to $23.50 in a single day.

Analysts expressed surprise at the amount Roche was prepared to pay for Syntex, which was characterized as a firm that has "evolved into a generic company". It sells bulk products to generic drug companies, as well as through its own generic subsidiary, Hamilton Pharma. It was also

planning to bring out an over-the-counter version of Naprosyn (called Aleve) in a joint venture with Procter & Gamble Co. The merger was expected to generate product synergies, uniting Roche's strength in anti-infectives, AIDS, and hospital-based drugs with the traditional strength of Syntex in oral contraceptives, anti-inflammatory drugs, and pain killers. Syntex also had a number of drugs in the pipeline. They included: an oral drug for CMV (a virus that causes blindess in AIDS patients), and treatments for transplant rejection, angina, male sexual dysfunction, Lou Gehrig's disease, the nausea resulting from chemotherapy, and osteoporosis. Syntex was expected to benefit from Roche's marketing presence in South America, Japan, and the Middle East.

The president of the Canadian operations of Hoffmann-La Roche noted that the merger would give his company access to such product areas as antiarthritic drugs and oral contraceptives. At the same time, Roche would bring to Syntex large fine chemicals (such as vitamins for industrial use) and diagnostics business. As well, since Roche does not have manufacturing facilities in Canada, manufacturing possibilities could develop with Syntex. [Globe and Mail, May 4, 1994, p. B3].

Entry Into Managed Health Care

Eli Lilly and Co., based in Indianapolis, announced on July 11, 1994 that it would purchase the largest managed health care company in the United States, PCS Health Systems Inc. PCS is one of the "pharmacy benefits management companies", which represent one of the fastest-growing segments of the U.S. health care industry. Such firms are hired by corporate benefits departments and U.S. health maintenance organizations to process prescription claims, negotiate volume discounts with drug companies, and monitor physician prescribing.

In 1993, some 110 million Americans belonged to managed health care plans, and PCS alone managed various health care plans for about 50 million of them. In late 1993, Merck & Co. Inc. of Rahway, N.J. had bought another managed care company, Medco Containment Services Inc. Executives of both Merck and Lilly expressed the opinion that their benefit management businesses can be adapted to most markets outside the U.S. (presumably including Canada).

Some analysts criticized the acquisition as too expensive for Lilly, while others described it as an important step for Lilly toward a new corporate focus which emphasizes pharmaceutical production, sales and benefit management. The stock market reaction was not favourable: Lilly's share price dropped U.S.$7.25 on the New York Stock Exchange, closing at $50.12. McKesson shares, on the other hand, rose $24.50, closing at $97.75. [Globe and Mail, July 12, 1994, p. B1].

Merging Large, Multinational Firms

On January 23, 1995, Glaxo PLC offered £8.9 billion ($20.2 bill. Can.) for Wellcome PLC. Glaxo would pay £10.25 for each Wellcome share, or offer £722 in cash and issue 47 new Glaxo

shares for each 100-lot block of Wellcome shares or American depositary receipts. The bid represented a 49 per cent premium above Wellcome's pre-bid closing share price of £6.88. Wellcome shares rose £2.73, to close at £9.61, while Glaxo shares dropped 44.5 pence to £5.99. The merger between the two British multinationals would create the largest prescription drug company in the world, with about 3.5 per cent of the world prescription business.

While some of the recent drug company mergers involved companies offering complementary goods and services, Glaxo chose to buy another research-based company. In choosing to do so, it indicated the desire to "remain on top of the international pharmaceutical industry". The potential efficiency from the merger include economies of scale in production and marketing, and job reductions from merging of overlapping departments. Wellcome, with its strength in anti-viral medicines, would be able to take advantage of Glaxo's marketing network in emerging markets such as India, China, and South America. The research strength of Wellcome would also benefit from Glaxo's marketing expertise, which becomes increasingly important as government health care budgets shrink and the purchasing power of large drug users (such as Health Maintenance Organizations) increases.

On March 7, 1995, Wellcome announced it would give up its defence against the takeover and would recommend that its shareholders accept the Glaxo offer. Since both Glaxo and Wellcome have large U.S. subsidiaries, the merger has to be approved by the U.S. Federal Trade Commission, but as of March 1995 the approval progress has been described as "satisfactory". The FTC did, however, express concern that Glaxo-Wellcome could monopolize the migraine therapy market, because both companies were developing drugs in this area. Glaxo therefore announced that it would sell the development rights to the compound 311C under development by Wellcome, and would continue to work on its own compound, naratriptan. The antitrust authorities of the European Union also announced that they would clear the merger only on condition that Glaxo-Wellcome sell the right to one of the two migraine drugs [Globe and Mail, March 8, 1995, p. B21; March 17, 1995, p. B4].

The Glaxo takeover of Wellcome will not only create the world's largest drug company, it will also give the new company a dominant share in a number of therapeutic markets: 35 percent of the gastro-intestinal market; 25 percent of the antibiotics market; 25 percent of the respiratory market; and perhaps up to 70 percent of the anti-viral market, which includes drugs for herpes, AIDS, and hepatitis. Since about 90 percent of R&D activities of Glaxo and Wellcome currently overlap, the merged company is expected to rationalize R&D activities and product lines in several other therapeutic markets [The Economist, January 28, 1995, p. 58]. Glaxo-Wellcome will have combined workforce of 61,500 (Glaxo alone employs 44,000 people), but it was expected that at least 11,500 jobs would be cut as a part of the rationalization process.

Distribution Agreements

In December 1994, Novopharm Ltd. and Wyeth-Ayerst International Inc. (a division of American Home Products Corp. of Madison, N.J.) signed a distribution agreement. Wyeth-Ayerst already operates a European generic subsidiary called Pen-Efeka, and the new agreement gives it the right to distribute Novopharm's 200 generic drugs outside North America, with the help of its 7,000 sales people around the world. According to Novopharm, this arrangement has the potential to add anywhere from 5 to 20 percent, over a period of time, to its current $ 500 mill. in annual drug sales. It may require the hiring of additional 100 people to fill the extra orders, but the company officials note that the location of these jobs in Canada is questionable because of a provision of the 1993 modification of the Patent Act. This provision prevents Canadian generic companies from exporting a drug from Canada if it cannot be legally sold in Canada, i.e. if its Canadian patent protection is still in force. [Globe and Mail, December 13, 1994].

Joint pursuit of designated therapies

In the spring of 1993, the world's 15 largest drug companies reached an agreement to collaborate on clinical research for AIDS therapies. Based on this agreement, the Montreal-based BioChem Pharma Inc. and its British partner Glaxo Holdings PLC announced on March 23, 1994 that they would team up with Wellcome PLC of Britain to sell BioChem's 3TC drug to HIV-infected patients (the drug inhibits an enzyme that replicates HIV). BioChem and Glaxo will thus be able to take advantage of the extensive sales networks developed by Wellcome for its product AZT, without having to form a costly sales force of their own.

Glaxo holds 17 per cent of BioChem's stock. The two companies have been in partnership since 1990 when Glaxo agreed to pay the cost of developing and marketing BioChem's cancer and viral treatments around the world. Following the announcement of the new agreement, BioChem's stock price on the Toronto Stock Exchange rose 37 cents to $15.62.

As of March 1994, BioChem's drug 3TC was still being tested and had not been approved for sale. The strategy was to test 3TC in combination with other drugs, since some AIDS patients have developed a resistance to some single drugs, such as AZT. Under the agreement, BioChem retains exclusive rights to the drug in Canada, where the market for similar therapies is estimated at $17 million a year. Wellcome would have the option to develop and sell 3TC outside Canada, based on the results of the second and third stages of clinical trials, which were expected to be known by the end of 1994. While Wellcome would develop 3TC for HIV therapy, Glaxo would continue its development for the treatment of hepatitis B.

If Wellcome exercised the option, it would sell 3TC under a different name and would pay royalties to Glaxo, which, in turn, would pay royalties to BioChem. The original agreement between Glaxo and BioChem entitled BioChem to royalties of 15 per cent of sales revenues from 3TC. The new agreement would lower the royalty rate to 13 per cent. BioChem would, however, be

compensated by receiving lump-sum payments from Glaxo at certain stages of clinical testing, and by gaining exclusive access to the Canadian market. [Globe and Mail, March 24, 1994, p. B1].

Financing arrangements

The Canadian biotechnology company Cangene Corp. of Toronto has engaged a U.S. investment banker to help it find a bridge financing in the public or private capital market or arrange a merger or consolidation with a more strongly capitalized company. In the fiscal year 1993/94, Cangene lost $7 million on revenue of $2.2 million, compared with the previous year's loss of $5.2 million on revenue of $3.7 million. Cangene, started by two scientists from Connaught Laboratories Ltd., has been developing commercially viable products using antibodies and custom-designed proteins to diagnose and attack disease. For example, Akzo Pharma International BV of Holland is selling clinical tests that use Cangene's technology to test for the presence of HIV. [Globe and Mail, October 28, 1994].

Another medical innovation company, Quadra Logic Technologies Inc. of Vancouver, announced in March 1995 that it entered into a 10-year agreement with Ligand Pharmaceutical Inc. of San Diego, California. Under the agreement, Quadra will sell to Ligand the exclusive right to market and distribute in Canada its most promising drug, a light-activated cancer drug Photofrin. To date, the drug has been approved in Canada for treatment of superficial bladder cancer, and as of March 1995 it was under review for treatment of oesophageal cancer. Authorities in the Netherlands have already given regulatory approval for use of the drug against lung and esophageal cancers. In Japan, it has also received approval for treatment of those cancers, as well as gastric and cervical cancers. The drug uses photodynamic therapy, in which it is injected into cancerous cells and then activated by lasers.

Ligand has paid Quadra an initial (undisclosed) fee, and agreed to three "fixed performance-driven milestone payments" based on sales. In addition, the agreement provides for division of Photofrin revenues according to a formula specified in advance. Quadra Logic expected to receive more than 32.5 percent of the gross revenues [Globe and Mail, March 10, 1995, p. B17].

Another potentially important developing form of financing of pharmaceutical industry is the Canadian Medical Discoveries Fund. It was initiated in December 1994 by the Medical Research Council of Canada in partnership with MDS Health Ventures Inc., the Professional Institute of the Public Service of Canada (a union for scientists, doctors, lawyers, and other professionals employed by the government), Talvest Fund Management Inc., CIBC Wood Gundy Capital, and CIBC Wood Gundy.

The fund will invest in small, private Canadian companies in the health sciences sector, especially those in early stages of research and development. The promising research projects are first identified by the peer review process of the Medical Research Council and then evaluated by a blue-ribbon panel of experts. The commercial viability of the selected projects is assessed by MDS

Health Ventures. Because the fund is labour-sponsored, it offers special tax advantages to investors. They include a 20-percent federal tax credit, another 20 percent in an Ontario tax credit, and additional tax advantages if investment is included as part of an RRSP.

In 1995, the fund invested money into three-dimensional ultrasound research, conducted by Life Imaging Systems Inc., a commercial joint venture incorporated by University Hospital of London, Ontario. The fund also entered into a strategic alliance with Sandoz Canada Inc. of Dorval, Que., where Sandoz and other partners will be able to invest in projects the Fund has sponsored and identified [Globe and Mail, February 23, 1995].

Legal Cases

There has been substantial legal activity in the Canadian pharmaceutical industry related to patent infringements. This section provides a brief discussion of selected cases.

Cimetidine (Tagamet)

In May 1994, SmithKline Beecham PLC reached an out-of-court settlement of a trademark lawsuit against Novopharm Ltd. and Schein Pharmaceutical Inc. The patent on anti-ulcer drug cimetidine (sold by SmithKline Beecham under the brand name Tagamet) expired on May 17, 1994. Tagamet was the first of a new class of ulcer drugs, known as H2 blockers, which suppress stomach acid secretion. Novopharm U.S.A. was planning to manufacture a generic version, to be distributed by Schein. The Novopharm version of cimetidine tablets was scheduled to have light or pale green colour similar to Tagamet, and SmithKline Beecham alleged a trademark violation. Under the terms of the settlement, Novopharm agreed to change the colour of its tablets in the U.S. to a darker green. SmithKline also sued Mylan Laboratories of Pittsburgh, alleging Tagamet trademark violations. The 1993 worldwide sales of Tagamet were estimated at U.S.$1.01 billion.

Zidovudine (Retrovir)

In 1991, Apotex Inc. filed an application with the U.S. Food and Drug Administration asking for the right to sell a generic version of the AIDS drug AZT in the U.S. market. Novopharm Ltd. filed a similar application in 1992. In 1993, a U.S. court ruled against these applications, and that decision was upheld by the U.S. Court of Appeal in November 1994. It identified scientists of the Burroughs Wellcome Co. based in Research Triangle Park, N.C. as the inventors of AZT on five of the six disputed patents and gave Novopharm permission to present evidence on the sixth patent.

Burroughs Wellcome sells the drug (Zidovudine) under the brand name Retrovir. It originally sold for $10,000 a year per patient, but public outcry forced the company to reduce the price to about $2,500. The applicants' case was based on the contention that Burroughs has no legal ground for its patents because the original compound was invented long before it was discovered to be effective against AIDS. The U.S. law, however, allows manufacturers to patent an innovative

application of an existing medicine; the Burroughs patent on the anti-AIDS application of the drug expires in 2005.

In Canada, the courts have always ruled against the validity of this type of patent. As a result, cheaper generic versions of AZT have been available in Canada for several years. This interpretation is, however, expected to be tested in the near future. In turn, the president of Apotex indicated in November 1994 that the company might consider appealing the unfavourable ruling of the U.S. Court of Appeal to the U.S. Supreme Court. The AZT market in the U.S. is estimated at about U.S.$100 million, and the Canadian market at about C$10 million. [Globe and Mail, November 24, 1994].

Enalapril (Vasotec)

Merck Frosst Canada Inc. won a lengthy patent infringement case against Apotex Inc. On December 14, 1994, the Federal Court in Ottawa ruled that Apotex was violating Merck's patent on Vasotec by producing and selling its generic version Apo-Enalapril. The drug is used to treat high blood pressure and congestive heart failure. More than 250,000 people in Canada take it, and Merck derives up to $140 million of its total annual revenue of $400 million from the sale of Vasotec. Vasotec comes off patent in 2007.

The dispute began in February 1993, when the federal Health Department ruled that Apo-Enalapril met all the legal requirements and should be licensed for sale. However, before the licence was formally issued, the tightening of patent protection resulting from enactment of Bill C-91 came into force. The Supreme Court of Canada ruled on December 15, 1994 that Apotex should have been given government approval to sell its drug. This ruling is, however, merely a technical victory, since the Federal Court ruled the day before that Apo-Enalapril violated Merck's patent and ordered Apotex to withdraw the drug from the market. Apotex argued that it did not violate Merck's patent, because it began work on its version of the drug in 1987, three years before Merck's Canadian patent was issued. Apotex announced that it will take the patent infringement case to the Federal Court of Appeal. [Globe and Mail, December 15, 1994; December 16, 1994].

Mail-order Pharmacy Sales in Canada

In November 1994, the Quebec Court of Appeal issued an injunction against a mail-order pharmacy MediTrust Pharmacy Inc., with headquarters in Toronto. The injunction temporarily prevents the firm from selling, advertising, or delivering drugs in Quebec, on the grounds that the mail-order procedure eliminates personal communication between patients and the pharmacist, which could be risky if there were drug interactions. In December 1994, Quebec's Order of Pharmacists asked at least two Ontario-based firms (Canadian Tire Corp. Ltd. and Klockner Moeller Ltd.) to stop their Quebec employees from using the services of MediTrust.

MediTrust claims it can provide savings of 20 to 40 percent by charging a flat dispensing fee of $5, and providing a 90-day supply of drugs where possible. It has a policy of asking clients for a full record of medications they are using before dispensing a new prescription. It views the action by the professional association of pharmacists as an attempt to restrict competition. MediTrust was planning to appeal to the Supreme Court of Canada. [Globe and Mail, December 3, 1994].

MediTrust applies interactive technology in a retail setting. The customer end of the system is centred around a kiosk called Pharmaphone, and uses Northern Telecom multimedia technology that can manage simultaneous transfer of data, voice, and images by telephone, computer and video. The kiosk itself was designed by a Toronto marketing and design company, Bulldog Group. When ordering a drug, the consumer is shown a video explaining how to place a prescription on the scanner, and is given the option of having any questions answered by a pharmacist. The technology is in its prototype stage and costs about $125,000. Northern Telecom estimates that when produced in large quantities, the costs may drop to between $30,000 to $50,000. [Globe and Mail, February 7, 1995].

Summary

The recent examples of corporate activity in the industry have been presented because changes in the broader industry context have an effect on the nature and extent of change in the generic and OTC market segments. At the same time, litigation surrounding Canadian generic drug companies' infringement of patents reflects the increasing pressure and threats which the traditional branded product manufacturers face despite the substantially strengthened patent protection resulting from the 1987 and 1993 amendments to the Patent Act. Similarly, price-conscious managed care organisations, mail order pharmacies, and changes in the way pharmaceutical products are distributed reflect the new competitive structure in which the branded manufacturers must operate.

CHAPTER 3 THE GENERIC SEGMENT

3.1 Introduction

Multinational pharmaceutical firms prospered in the 1980s. Many companies' product pipelines contained blockbuster drugs with many years of patent protected revenue potential. In Canada, multinationals had little "true" protection until the 1987 amendment to the Patent Act (Bill C-22). Demand for drugs grew steadily and so did the profits of multinational companies. Generic drug manufacturers competed in this market by selling, at substantially reduced prices, copies of drugs which had gone "off patent", or, as in the case of Canada, copies of drugs for which they took a compulsory licence. This pricing differential was possible since generic manufacturers did not have to invest in the early stages of research and development. Instead, these companies focused research efforts on process technology, dosage form, delivery systems and the development of expertise in the regulatory approval process.

The pharmaceutical climate of 1995 presents a stark contrast to the "glory" years of the 1980s. The global pharmaceutical industry is in a state of rapid change. Patents for many of the 1980s blockbuster drugs are now expiring and many multinational pharmaceutical companies have few promising new product pipelines. These companies are faced with declining revenues and market erosion at the hands of generic manufacturers. This is particularly significant for companies which relied heavily on a single blockbuster drug. Many companies are forced to launch a defensive strategy to counter the generic threat.

3.2 Global Context

A number of factors have contributed to the growth in the U.S. generic industry and its prospects in the future. The 1984 Waxman-Hatch Act extended patents for drugs by up to five years (from the baseline of seventeen years protection) provided that post-regulatory approval patent protection not exceed fourteen years. However, this act also provided substantial fast-tracking for generic manufacturers by permitting generic products approval on the basis of bioequivalence or bioavailability testing rather than by reproducing clinical trials. This provision of the act facilitated new generic entries into the U.S. market.

The late 1980s became known as the time of the generic drug scandal in the United States. A number of generic drug companies were charged with filing fraudulent applications for new drug approvals, bribing Food & Drug Administration officials and price fixing. The post-scandal changes at the FDA, and the Generic Drug Enforcement Act of 1992 imposed complex new requirements for manufacturing plants and new drug applications for companies competing in the industry. This stricter regulatory climate has contributed to a new legitimacy of generics and helped to fuel the growth in the post-scandal market. Cost containment and health care reform

are significant additional driving factors, as managed care and generic product substitution continue to grow.

The U.S. generic industry has also been helped by the large number of blockbuster drugs going off-patent. Faced with declining revenues and few new blockbuster drugs in the product pipeline, many innovative drug companies have been forced to develop new strategies to protect market share after patent expiry. The wave of merger activity described in Chapter 2 illustrates how intense this search for the right strategy is and how quickly the industry is being reshaped.

The U.S. generic industry is in a period of rapid growth following the generic drug scandal of the late 1980s. Industry analysts estimate that the next few years will see generic penetration represent between 50% and 80% of all new prescriptions dispensed. While these figures are obviously imprecise, the generic industry is seen as a significant area for new growth.

The outlook for generic pharmaceuticals in Europe is seen as promising due to fundamental changes occurring in the health care environment. For example, the market for generic pharmaceuticals is expected to grow to between 50 and 60% of all prescriptions dispensed in the U.K. by 1995. Increases in this market have been stimulated by government initiatives, particularly the 1985 introduction of the selected (limited) list scheme which was said to increase the market from 20% to 35% percent of all prescriptions. (Darbourne, 1993) It is important to note that most generics dispensed in the U.K. are manufactured by companies owned by the brand-name manufacturers.

There is also potential for growth in the generic drug sector in Japan, but the market is not yet as large as the U.S. or the U.K. It is estimated to reach approximately 15% of the total Japanese pharmaceuticals market by the end of the decade (Scrip, June 11, 1993, p.24). Generic sales in Japan are focused on specialized market segments such as gastro-urinary and dermatological products. The ultimate potential for the Japanese generic sector must be examined in light of the Japanese government's desire to promote an internationally competitive research-based pharmaceutical industry. It is unclear what this will mean for the generic industry.

The increased competition in the pharmaceutical industry will force an inevitable "shakeout" and rationalization of the global industry within the next few years. Ultimately, this will spill over into the generic side of the industry. Fully-integrated firms with strong distribution and manufacturing capabilities in the growing hospital and traditional dosage form market will have the advantage when this happens (Haddadd, 1992).

3.3 The Canadian Generic Drug Industry

The Canadian pharmaceutical industry is unique in many ways. Canada is one of the smallest markets for pharmaceuticals among developed countries, representing only 2% of the

total expenditure worldwide. None of the world's multinational pharmaceutical corporations are based in Canada. Instead, multinationals operate subsidiary (or branch) companies for marketing, testing, and final production (combining and packaging ingredients) within Canada. Those multinationals with branches in Canada invest a smaller fraction of total sales in Canadian research as compared to investment in other OECD countries. Of the pharmaceutical research done in Canada, only a small fraction is basic, innovative research (Gorecki, 1984). The remainder of research is for regulatory testing required by the Health Protection Branch within Health Canada.

The Canadian Regulatory Context

If one is to understand the evolution of the Canadian generic drug industry over the last twenty-five years, it is essential to understand the regulatory context. Canada's system of compulsory licensing contributed to the development and growth of the Canadian generic industry. Compulsory licensing for drug patents has existed in Canada since 1923. The compulsory licensing provision of the Canadian Patent Act permitted a firm to apply for a licence to manufacture and sell a patented drug subject to a fixed royalty fee paid to the patent holder. A compulsory license effectively negated market protection before the expiry of the Canadian patents. Innovating firms could not legally block these licences (hence, *compulsory*).

In its early stages this amendment to the Canadian Patent Act allowed the sale of patented drugs under compulsory licence provided that all manufacturing was done in Canada. The Commissioner of Patents at the time had hoped that multiple firms would compete for market shares of the same drug, thereby lowering prices. However, the manufacturing of pharmaceuticals' active ingredients was (and remains) extremely capital intensive. Without access to exports, returns to scale make the production of fine chemicals infeasible in markets as small as Canada's. Since few active chemical ingredients were produced in Canada, the early compulsory licensing program was not effective: only 22 compulsory licenses were granted between 1923 and 1969 (Lexchin, 1993, p.148).

During the early 1960's many people were concerned about the cost of patented medicines in Canada. Several reports found that, at that time, Canadian drug prices were among the highest in the world (see Gorecki and Henderson 1981). Some Canadian officials and commentators felt that foreign owned multinationals were earning excessive monopoly rents in Canada for innovation done in their home countries. This prompted the government to amend the compulsory licensing provision in 1969. By adding section 41(4) to the Patent Act, this new law permitted any firm to import patented drugs, including the active ingredients, for sale under compulsory license, subject to a 4 percent royalty fee. This amendment effectively provided price competition during the life of the patent while partially compensating the patentee with the royalty.

Initially it was felt that this law would not significantly affect the profits of the multinationals, because patent holders enjoyed an entry lag due to the regulatory testing required of the generic entrant. Entry lags in the early stages of this new version of compulsory licensing

were found to be significant barriers to entry in the Canadian pharmaceutical market (McRae and Talon, 1985). These delays were soon removed for generic drugs that could prove therapeutic equivalence to their brand name counterpart. Over the years to follow, in conjunction with the growth of provincial drug benefit programs, provincial governments passed various laws requiring pharmacists to dispense the cheapest substitutable drug within a therapeutic class. Together, these measures made compulsory licensing an undisputed success in terms of reducing the costs of Canadian pharmaceuticals.

In 1984 the federal government established the "Commission of Inquiry on the Pharmaceutical Industry," headed by commissioner Harry Eastman. Eastman found that the compulsory licensing provision had successfully reduced the costs of pharmaceuticals to varying degrees - depending on the province and drug class. In his report, Eastman recommended that the federal government maintain the compulsory licensing provision with only minor changes. Notably, Eastman recommended that the government consider implementing a waiting period of up to four years before allowing generic entry, and an increase in royalty fees from 4 to 14 percent.

Using the Eastman report to back its agenda, the government introduced Bill C-22 in 1987, which amended section 41(4) of the Canadian Patent Act. This amendment provided the patent holding firm a seven-year period of exclusive market protection before the entry of generic competition. The duration of market exclusivity could be extended to ten years if competitor's active ingredients were not made in Canada, or to the life of the patent if the inventing firm was a domestic corporation (PMPRB, 1991, p.6). Due to first mover advantages, and regulatory hangups, this amendment alone may have rendered the compulsory licensing provision totally ineffective.

One stipulation of Bill C-22 provided that, after December 1991, the Governor in Council could reduce or remove the period of exclusivity. This would be done to restore early competition under compulsory licence should the amendment cause unwanted price increases (PMPRB, 1989, p.2). However, in 1991 the government created even greater barriers to entry by introducing Bill C-91 that would extend the period of exclusivity and the total life of the patent.

Bill C-91, passed in 1993, brought Canadian pharmaceutical patent protection up to par with that of the United States and the United Kingdom. The 20-year protection of intellectual property is a part of both the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT). The compulsory licensing provision no longer shortens the effective life of patents held by multinationals. Indeed, this provision no longer truly exists.

Bill C-91 prohibits Canadian generic companies from exporting any licensed drugs before they can be legally sold in Canada, even if their patent in the importing country has already expired. In addition, Bill C-91 made the 20-year patent protection retroactive to December 1991, which is two years before the legislation came into effect, and before the NAFTA and GATT

provisions became binding. This affected several generic drugs which were already awaiting regulatory approval. Ultimately, CDMA believes that some form of compulsory licensing is possible, despite the provisions of NAFTA and GATT [Globe and Mail, April 26, 1994, p. B1; May 27, 1994].

Canadian Generic Drug Manufacturers

The Canadian generic drug industry is relatively small with sales around C$550 million. Most generic drug manufacturers are represented by the Canadian Drug Manufacturers' Association (CDMA). The 1994 members of the CDMA are shown in Table 3.1. This organization works to ensure that generic drugs are listed on provincial formularies and lobbies to encourage the provinces to implement mandatory substitution regulations so that the lower-priced generic is dispensed unless the prescribing physicians specifies "no substitution". At the federal level the CDMA is actively involved with lobbying the government to modify the current legislation (C-91) and to improve lags in the regulatory approval process. The generic divisions of the multinationals are not members of the CDMA since the mandate of the association is in conflict with the goals of their parent companies.

Table 3.1: Canadian Drug Manufacturers' Association Membership (1994)

Finished Dose Retailer/ Finished Dose Manufacturer	Active Ingredient Manufacturer/Industry Supplier	Industry Supplier
Apotex Inc. Weston, ON	ACIC (Canada) Inc. Brantford, ON	Atlantic Chemicals North York, ON
Confab Laboratories Inc. St. Hubert, PQ	Chorney Chemical Co. Ltd. Toronto, ON	PDI-Pharma Distribution Inc. Richmond Hill, ON
David Bull Laboratories Vaudreuil, PQ	Torcan Chemical Ltd. Aurora, ON	
Genpharm Inc. Etobicoke, ON		
Laboratoires Pro-Doc Ltee Laval, PQ		
Novopharm Limited Scarborough, ON		
Nu-pharm Inc. Richmond Hill, ON		
Pharmascience Inc. Ville St.Laurent, PQ		

Finished Dose Retailer/ Finished Dose Manufacturer	Active Ingredient Manufacturer/Industry Supplier	Industry Supplier
Rogier Inc./Desbergers Ltee Montreal, PQ		
Stanley Pharmaceuticals Vancouver, BC		
Taro Pharmaceuticals Inc. Bramalea, ON		
Technilab Inc. Mirabel, PQ		

The industry is dominated by two private firms, Apotex and Novopharm, who together account for 85% of the Canadian generic market (The Financial Post, January 25, 1995, p. 17). These companies have a full line of generic pharmaceutical products and their size and the brand recognition associated with their names have led them to be called "full line branded generic manufacturers".

The remaining portion of the market is comprised of small "niche" companies with sales of less than C$20 million (e.g., Genpharm, Pharmascience, etc.), and the so-called "pseudogenerics" operated by multinational pharmaceutical companies.

Genpharm Inc. is well positioned to move from being a niche player in the industry to a full line generic drug manufacturer. It was established in Canada in 1982 to develop and manufacture generic products. In 1994, E. Merck purchased 51% of Genpharm. The company received marketing approval for 16 products in Canada and has more than 65 products at various stages of the regulatory process.

The Value Chain in the Canadian Generic Drug Industry

The value chain described in chapter one can be used to provide the context to understand how Canadian generic drug manufacturers compete. Traditionally, the generic drug manufacturers focused attention on the stages from development through to marketing and some distribution. While this continues to be the focus for many firms, some companies are strategically moving backward into innovative research and forward into distribution and treatment.

Research and Development

Generic drug manufacturers have traditionally focused research and development efforts on finding innovative, low cost ways of producing existing drug products no longer under patent.

This focus included research into the best methods and practices for obtaining regulatory approval (through applications for new drug approvals, clinical trials, etc.) from government agencies, dosage form, delivery systems, and process technologies.

The CDMA reports that on average, generic drug companies in Canada spent 13% of their sales revenue on R & D in 1993. This industry average has risen from 7% in 1988. Apotex (25th) and Novopharm (50th) were listed in the top 50 spenders on R & D in Canada according to a 1994 survey published in the Globe and Mail Report on Business. The CDMA also reports that the majority of R & D conducted by its member companies is carried out in Canada. These figures have not been categorized by the type of research they represent but they are said to include synthetic chemistry, analytical chemistry, pharmaceutical formulation development and clinical testing on bioavailability and clinical efficacy (Drug News and Views, p. 5).

The drug approval process has always been an important research focus for generic drug manufacturers. Since the original drug has already been established as a safe and effective product by the original brand manufacturer, the generic drug companies concentrate on meeting federal standards for safety, efficacy and quality by conducting comparative bioavailability studies. These studies demonstrate that the copied drug is shown to release the medicinal ingredient(s) in the same manner as the original drug.

In Canada it takes approximately four years from the time initial studies are done by the generic drug company until the company receives its final approval or Notice of Compliance (NOC) from the federal government. In the U.S., the review process for both generic and brand-name drugs takes about two years. The U.K. has an independent drug approval agency, which approves almost 89 per cent of generic drugs in 60 days or less. The executive director of Health Canada's Drug Directorate stated that the median review time for brand-name drugs approved in 1994 was 700 days, which is comparable to the U.S. He argued that many of the delays were caused by the companies themselves, rather than by the agency. [Globe and Mail, January 18, 1995].

Many generic drug companies have expressed frustration with these long delays in obtaining this approval. The approval process is further complicated by the rules and regulations of the ten provinces regarding new drug approvals. One company likened this process to having to obtain approval in 11 different jurisdictions.

The CDMA lobbied to speed up the regulatory process for approval of new drugs. The most recent proposal, presented in January 1995, argues for the establishment of a quasi-independent drug approval agency, which would be run like a business, and would be partly financed by the industry. The CDMA was joined in this effort by the Pharmaceutical Manufacturers Association of Canada (PMAC) which represents the brand-name companies.

The generic companies interviewed expressed optimism that approval times would improve if the government goes to a system of cost recovery. This would mean that companies would pay a fee to submit an application for new drug approval (ANDA). This fee would then establish a "customer/service provider" type relationship between the company and the government which should give the companies the power to push for faster approvals. One company felt that the turn around time for approvals could be reduced to 18 months once cost recovery is implemented.

Some Canadian generic companies are entering new areas of innovative research. Biotechnology, including fermentation, blood fractionation and recombinant DNA, represents such an area for some generic drug companies. Novopharm, for example, has two biotechnology divisions — Novopharm Biotech in Winnipeg and Hygeia Holdings Inc. in San Diego — dedicated to innovative cancer research. Apotex has a fermentation facility in Winnipeg and has an active New Chemical Entity (NCE) and innovative drug research program. Apotex is currently working on seven products in its Innovative Drug Development Program. These include new molecular entities developed by Apotex and licensed in products that range from early preclinical studies through Phase I and II all the way up to Phase III clinical trials. The products under development cover a wide therapeutic range, and include drugs with potential utility in the treatment of asthma, spinal cord injury, transplantation, stroke, peptic ulcer disease, cancer, AIDS, wound healing and burn therapy, as well as the inherited blood disorder, thalassaemia (Apotext, Winter 1995).

Many generic drug manufacturers fund research activities at outside organizations such as contract research organizations and universities. This funding may take the form of research grants, contracts and fellowships for scientists. Both Apotex and Novopharm have endowed academic chairs at Canadian universities. This type of research activity can be expected to continue as generic drug manufacturers move into more innovative research.

The shift to more innovative research has contributed to the "blur" of boundaries in the pharmaceutical market. The distinctions between generic and brand name manufacturers are becoming less clear. Some generic companies refer to themselves as "pharmaceutical companies" with emphasis on multi-source markets. It is important to note that no manufacturer - generic or branded - is developing products specifically for the Canadian market since this market comprises only 2% of the global pharmaceutical market.

Fine Chemicals Industry

The CDMA reports that its member firms use Canadian-made fine chemicals wherever possible. This has contributed to the growth of the Canadian-made fine chemicals industry. The chemical companies have achieved sufficient expertise to be considered highly efficient and competitive with fine chemicals divisions within the multinational companies. In a move to be more competitive, the multinationals are shedding internal divisions and contracting out the fine chemicals business.

The presence of a Canadian fine chemicals sector has contributed to, and legitimized, the generic companies' move into innovative research. ACIC (Canada) Inc., for example, has developed process and purification technology that makes it an expert in the field. The firm provides customer driven research for generic and brand name pharmaceutical manufacturers as well as other industries. As multinational drug companies become increasingly cost conscious, fine chemicals manufacturers like ACIC are in a good competitive position because of their least cost methods of development and state of the art multi-purpose production technology.

Manufacturing

Traditionally, generic drug manufacturers have had a competitive edge over their "pseudo-generic" rivals in the area of low cost production. Because of the commodity nature of the generic drug market, manufacturers have developed expertise in low cost manufacturing through innovations in process technology. Increasingly, branded manufacturers are viewing generic manufacturers as the "benchmark" of best practices for low cost production. In some cases, branded manufacturers have licensed the production of some drugs to generic drug manufacturers because they can make them more cost-effectively.

Marketing and Distribution

In Canada, generic drug manufacturers market directly to the pharmacy more than to physicians or wholesalers. Companies compete by adding value at the pharmacy level because of the commodity nature of the products. It is advantageous both to the pharmacy owner and the supplier to have one generic company serve most of their needs. Generic companies endeavour to carry as broad a line as possible to entice the pharmacy to carry all their products. One generic drug company executive said that "in Canada we market 95% of our products to pharmacists while in the U.S.A. 95% of products are marketed to wholesalers."

The Canadian Generic Industry Post Bill C-91

The representatives of the Canadian generic drug industry have argued for some time that the C-91 legislation has a number of negative features which, in their view, can/should be modified without violating Canada's international treaty obligations. Each of these features are discussed briefly in terms of its impact on the generic drug industry and possible legislative remedies.

Restrictive Impact on Exports

The legislation prohibits exports of drugs which are still protected by Canadian patent, even though the patent on the product in question in the importing country may have already expired. Anecdotal evidence suggests that, in order to supply the export markets, some Canadian generic drug manufacturers have moved their production facilities out of Canada.

Novopharm Ltd., for example, announced in October 1994 that it decided to spend more than $60 million to expand manufacturing and sales capacity at its Wilson, N.C. facilities. At the same time, it announced spending to expand a variety of functions at four southern Ontario locations amounted to only $12.5 million. The company officials blame Bill C-91 for "diverting the majority of investment dollars out of the country".

Novopharm's Canadian investments will increase its manufacturing capacity from the current 4 billion tablets to 6 billion over the next 12 to 18 months and add between 100 and 125 new jobs to the company's current 1,200 employees. Novopharm reports about $ 250 million in sales from its Canadian operations and the same amount from its U.S. and Hungarian subsidiaries. Most of the additional production will be exported, mainly to the U.S. [Globe and Mail, October 12, 1994].

Fine chemical manufacturers based in Canada depend heavily on exports to survive and are placed at a disadvantage in world markets due to the export restrictions in Bill C-91. ACIC, a producer of fine chemicals, has formed a joint venture in Mexico. The CDMA attributes this move, in part, to the legislative provisions which make it impossible to export generic drugs from Canada. The exporters, therefore, have to establish their manufacturing operations abroad [CDMA, 1994d, p.8].

The CDMA commissioned a legal analysis of the relevant provisions of the Patent Act, and of two international agreements: (I)The North American Free Trade Agreement (NAFTA), and (ii) the proposed Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which is a part of the General Agreement on Tariffs and Trade (GATT), 1994. It concludes that Canada is not obliged to prohibit a non-patent holder from producing for export a product protected by a Canadian patent [CDMA, 1994d, Appendix B].

Different Patent Expiry Dates

The problem of the prohibition on exports of drugs patented in Canada is aggravated by the fact that patents in the importing country sometimes expire much earlier than in Canada. This may occur for a number of reasons, including regulatory delays in new product approval, and whether the patent term is deemed to commence at the date of filing of patent application or at the date of patent grant.

The following examples illustrate the problem of different patent expiry dates Canadian generic exporters face in the U.S. market:

Drug	Canadian Expiry	U.S. Expiry
Lisinopril	2007	2001
Astemizole	2000	1997
Sufentanyl	1997	1993

Source: CDMA, 1994d, p. 9.

A study commissioned by the CDMA examined the patent expiry dates for a sample of drugs on the 1993 new product list published by the Patented Medicine Prices Review Board. Patents equivalent to the Canadian ones were found in Italy, France, Japan, the U.K., the U.S., and Germany. On average, patents in Italy expired 17.5 months earlier than equivalent Canadian patents, patents in Japan 14 months earlier, in the U.K. 10.6 months earlier, in the U.S. 19 months earlier, and in Germany 21.9 months earlier [CDMA, 1994d, Appendix A, p. 11].

This poses special competitive problems in the marketing of generic drugs, where "speed to market" is a key to success. The date of patent expiration was not that important in Canada prior to C-91. Before then most products were, in effect, off-patent for firms willing to pay the royalties. Now, the date is an important one, with companies competing to gain approval to market drugs as soon after patent expiry as possible.

Pseudo-generics are also cutting into the rewards of first entry by licensing their own products just before the "true" generics can enter. The race to be first on the market at expiry day is so intense that a matter of days can make or break a generic launch. The financial payoff in the U.S. is so much larger than in Canada (due to size of purchasers such as retail chains) that the patent expiry date in the U.S. is a key strategic focus. Each generic manufacturer interviewed claimed that it focused on being first on the market whenever possible. In other words, "if one is not on the market at the time of patent expiry, there is little point in coming onto the market at all".

Legal Challenges by Patent Holders

Bill C-91 came into force on March 12, 1993. Its provisions prevent Health Canada from issuing a Notice of Compliance to a generic drug manufacturer if there is any challenge over the patent rights to the product. Any such challenge can delay the market entry of a generic competitor for up to 30 months or until a settlement is reached in the courts. As of September 1994, there were about 55 challenges issued. The generic drug manufacturers argue that the right to challenge is "systematically abused" by patentees in the following ways: First, the patentees sometimes list non-qualifying patents in their challenge. For example, they may hold only

a process, but not a product patent. While in the past the Courts have dismissed such challenges, the marketing of a new generic product has been delayed. Second, some patent holders have challenged licences not terminated by Bill C-91; again this delays the marketing of the generic product [CDMA, 1994b, pp. 6-9].

Retroactive Application of the Legislation

Although Bill C-91 was not implemented until 1993, compulsory licensing was abolished retroactively to December 20, 1991. This affected a number of generic drugs which were already awaiting regulatory approval. For example, over 90 % of the products under challenge discussed previously had new drug submissions filed prior to Bill C-91 coming into force. The legal challenge thus results from retroactive application of the law. In the view of CDMA, "retroactivity is particularly unfair and is repugnant to Canadian parliamentary tradition" [CDMA, 1994b, p.1].

According to CDMA estimates, the two-year loss of competition from generic drugs due to retroactive application of the legislation alone cost the provincial governments and consumers as much as $2 billion in higher drug prices. [Globe and Mail, April 26, 1994, p. B1, May 27, 1994].

The introduction of Bill C-91 has forced Canadian generic drug manufacturers to find new ways to compete in the pharmaceutical industry. This legislation, combined with the rapid changes in the global pharmaceutical industry, has contributed to the emerging corporate strategies discussed below.

Me-Too Innovations

As product lives shorten and price competition increases generic drug manufacturers can be expected to increase the competitive pressure on branded drug manufacturers firms by introducing "me-too" drug innovations on the existing molecule. Me-too drugs are "discovered" by testing the pharmacological properties of minor variations of the original molecule then patenting the "new chemical entity". This form of research is an effective way of getting around existing patents, while marketing the drug based on the (minor) differences in pharmacological profiles.

Licensing Products from Branded Manufacturers

Some generic drug manufacturers are forming strategic alliances with branded manufacturers by licensing their products. Branded manufacturers in the U.S. have a need for large volumes of generic products to meet the demand from the managed care market. They are looking for alliances with manufacturers capable of low cost production of high quality products.

This presents an interesting dilemma for the generic drug manufacturers. The alliances provide opportunities to enter new markets but the generic drug firms may actually cut into their own markets. Apotex will not license products from branded manufacturers - it equates this practice with "sleeping with the enemy". Novopharm has licensing agreements with Merck Frosst Canada, Marion Merrell Dow Inc., and Fisons.

Litigation

Chapter 2 reported some of the current legal cases regarding patent infringements by generic drug manufacturers. This appears to be a growing trend. Generic drug manufacturers submit applications for new drug approvals (ANDA) and the branded manufacturers retaliate by suing the generic manufacturer for alleged patent infringements. There is a 30 month approval delay for alleged infringements. This stops or halts the competition allowing the branded drug manufacturer time to regroup and plan a counter strategy such as a me-too drug or a pseudo-generic product. One generic drug executive suggested that generic firms may begin challenging these lawsuits which would mean that they would have to publicly disclose products in their pipelines. This may give competitors an opportunity to launch the drug before the first company can.

The enormous legal costs lead one to question why the companies would bother filing ANDAs that might violate the patent. The potential revenue for the first on the market is so attractive that many companies feel it is worth the risk.

Manufacture Abroad

Bill C-91 has forced some generic drug manufacturers to suspend growth in Canada and to concentrate instead on establishing manufacturing facilities in the United States. This trend can be expected to continue particularly if the legislation is not amended.

Marketing

Entering new markets can pose a significant challenge to a Canadian generic manufacturer. Most companies acknowledge, however, that export markets are an essential focus in the post C-91 era. Relationships play an integral role in establishing the linkages necessary to penetrate a foreign market. One strategy for foreign market penetration is to align with another firm skilled in distribution in external markets. This is what Novopharm did when it entered into an agreement with Wyeth-Ayerst (a division of American Home Products). This agreement gives Wyeth-Ayerst the right to distribute Novopharm's 200 generic products outside North America. Wyeth-Ayerst gets a greater range of top quality generic products and Novopharm gets access to a worldwide sales network of over 7000 people (Globe and Mail, August 23rd, 1994). Apotex

plans its global penetration by building more relationships with foreign companies. Apotex buys 51% of a company to whom they will licence products. All manufacturing is done in Canada, and the packaging, marketing and distribution is done by the foreign "partner".

Rx-to-OTC Switches

Some generic drug manufacturers are developing strategies to take advantage of a number of Rx-to-OTC switches anticipated in the future. The switch category is appealing to generic manufacturers since it offers a company the opportunity to provide value to its customers (pharmacies) by providing a full line of pharmaceutical products while extending the product life cycle of a particular product.

Managed Care

The managed care market in the United States is one of the major factors contributing to the growth in the U.S. generic drug industry and the increased competition in the industry in general. Canadian firms are positioning themselves to participate in this market by establishing manufacturing facilities in the U.S., licensing products from branded manufacturers and by developing alliances with U.S. companies skilled in distribution in this market.

The Canadian generic drug industry is changing. The globalization of the pharmaceutical industry combined with the legislative restrictions imposed by Bill C-91 has made it necessary for companies to find new ways to compete to survive. The distinctions between generic and branded drug manufacturers are becoming less clear. The trend is towards developing capability as a "fully integrated pharmaceutical company" with a strong product pipeline and competence throughout the different stages of the pharmaceutical value chain.

CHAPTER 4 THE OTC MARKET SEGMENT

4.1 Introduction

There is growing support for self-medication in health care. With self-medication, there are potentially fewer demands on the medical profession, greater individual control over health care and an opportunity to fully utilize the expertise of pharmacists. Moreover, as the industrialized countries restructure their health care systems and look to a number of measures to reduce the burden on limited health care budgets, self-medication has become increasingly attractive to governments. With the shift towards greater levels of self-medication by consumers there exists enormous potential for drug manufacturers to enhance their profitability by focusing on the later stages of the value chain.

As drugs move off patent, the brand-name manufacturers may choose to patent new prescription dosage formulations, develop generic versions and/or switch their prescription products to OTC status in a bid to retain some profitability (pre-tax profits on OTC drugs average 15% compared with a 25% average for Rx products and a 5% average for generic drugs) (New York Times,27th Sept, 1994). As prescription drugs move off-patent, price competition from generic products in the prescription market makes the OTC environment more attractive for extending the life cycle of the drugs. This is particularly the case for highly profitable branded products such as Zantac, Zovirax, Pepcid, and Tagamet, all of which are potential switch candidates.

There are a wide range of OTC products that are sold to consumers without prescription. In Canada, consumers can self-select, or be advised to purchase, branded-switch, generic-switch, private label (house brands), branded GP (general public) and generic GP products. Products are assigned by the Bureau of OTC Drugs either a DIN label (drug identification number for sale only in a pharmacy) or a GP label (available in all retail outlets). Products vary in therapeutic value, ranging from recently switched prescription drugs (Rx-to-OTC) through to more consumer-oriented proprietary drug products that are available in any retail outlet (e.g. cosmetic products, mouthwashes, sleeping aids and sun care goods).

Given the heterogeneity of the products and the range of manufacturers, there does not exist a stereotypical "OTC Company". Many of the major drug manufacturers, in fact, operate "consumer products divisions" to run their OTC product lines. But the OTC market is not the sole domain of the traditional, ethical drug manufacturers as independent drug firms, retail outlets, contract manufacturers and generic drug producers all compete with one another to gain profits from the segment. Thus a range of manufacturers produce drugs for the OTC segment which contributes to the increasingly blurred profile of the two segments of the pharmaceutical industry.

The OTC segment is quite different from the Rx world. The focus is the consumer and the retailer (in contrast to physicians), margins per unit sold are smaller but volume is more important, and the central point of sale (i.e. the retailer) is quickly becoming itself a competitor through house brands (these house brands are mainly produced by independent private label manufacturers). Advertising and promotion are far different than in the Rx world, and considerable regional variations exist in retail practices, consumer behaviour and product preference.

Markets within the OTC segment are highly variegated. A good example of this is the OTC market for analgesics. In Canada, for example, Internal Analgesics represent 88% of the Analgesic market. Submarkets of Internal Analgesics are Ibuprofen (8%), Codeine (21%), ASAs (24%), and Acetaminophen (47%). Within the Acetaminophen market there is Tylenol, 222AF, Anacin-3 and Midol. Similarly, the Ibuprofen market is dominated by Whitehall/AHP's Advil (60%), Sterling's Actiprofen (8%) and Upjohn's Motrin IB (10%) (UPDATE U.S.A.,12,94:389). In the cough and colds market, with "colds" there are solid, powder and liquid-based products. Within solids alone there are about 10 major products and numerous smaller brands from a number of different companies, and the emergence of private label products.

Although the U.S. and Canadian markets may seem relatively similar when compared to Europe and Asia, there are still some structural differences. One example of this is the 1/8th codeine in the Internal Analgesics market. In the U.S. it simply does not exist as an OTC product, whereas it does in Canada. As a result, although rising, Ibuprofen has only 8% of the market in Canada compared to 24% in the U.S. There are also differences between the Canadian and U.S. markets for cough and cold remedies. Americans are more interested in tablets/pills while Canadians prefer liquid and powder formulations. Powdered products account for 20-24% of the market in Canada, but just 4% in the U.S. There is also the obvious market distinction of a francophone culture (i.e. Quebec).

There are three key features characterizing the OTC segment of the pharmaceutical industry. They are:

- Rx-to-OTC switches
- Private label/house brands
- Changing inter-firm relationships.

This chapter examines these and other competitive issues as they relate to firms in the OTC segment of the Canadian pharmaceutical industry. We first provide the global context for OTC products because the Canadian OTC market, like the Rx environment, is dominated by the foreign "global" pharmaceutical corporations. Although there are some Canadian-specific issues impacting on the OTC segment, the corporate strategies of the Canadian operations are intricately connected to the broader organizational transformations of the parent companies. We identify the nature and extent of the global market for OTC products, and follow this with a discussion of the

key competitive issues and strategies that firms are currently facing. This sets the scene for a closer examination of the Canadian OTC market. It should be emphasized that the segment, like the industry more generally, is dynamic as firms constantly realign themselves to be in stronger competitive positions.

4.2 The Global Context

Global demand for OTC products grew at an average of 7.3% annually between 1982 and 1992, with consumption growing to U.S.$46 billion in 1992 (Pharmaceuticals '94, 07,03,94). The recent report from IMS, OTC Insight 1994-1998, indicates that the major OTC markets are the United States, Europe and Japan (Table 4.1).

As Table 4.1 shows, OTC sales worldwide are expected to increase to U.S.$57.1 billion in 1998. This is due to growing markets in developing countries and a continuation of cost containment measures and aging populations in the industrialized countries. Table 4.2 shows the leading OTC product categories, with the top six product categories representing almost 75% of the total OTC market. These segments are expected to remain as the leading categories for the remainder of the 1990s.

Table 4.1: Global OTC Market by Region

	1993		1998	
Region	U.S.$ Billion	% Share	U.S.$ Billion	% Share
United States	11.3	28.9	15.0	26.2
Europe	9.2	23.7	14.2	24.9
Japan	8.8	22.7	11.4	19.9
Others	9.6	24.7	16.5	29.0
Total	38.9	100.0	57.1	100.0

Table 4.2: Leading OTC Product Categories

Product Category	1993 (%)	1998 (%)
Cough/cold preparations	16.3	19.4
Pain remedies	14.6	15.0
Digestive Medicines	12.4	12.1
Skin preparations	11.1	10.0
Tonics	10.3	10.2
Vitamins/ minerals/supplements	9.8	10.9
Total of these 6 markets	74.5%	77.6%

Table 4.3 shows the leading companies in terms of sales for the global market, Canada, United States and Europe. Clearly, the OTC market is dominated by American firms, with Johnson and Johnson (J&J) and American Home Products (AHP) each achieving close to U.S.$2 billion in sales in 1993. In both cases, a high proportion of their sales came from the domestic U.S. market. Within Europe there is a fragmented market presence depending on the company and country that is being examined. This heterogeneity, however, will likely be reduced as harmonization in the European Community is further developed. The top ten companies in the U.S. hold about 50% of the American market, as do the top ten in Canada.

One of the dominant trends at the international level has been the increasing level of consolidation by European and American firms through acquisitions and inter-firm collaboration. Both U.S. and European firms are attempting to gain critical mass in their specific product categories and increase their market presence in the other industrialized countries. In 1992, for example, AHP bought the Italian firm Seronno's OTC business and expanded operations in Spain. Similarly, BMS expanded into Europe by acquiring 33.5% of the French firm Upsa, and J&J purchased Woelm Pharma (Germany) in 1991 and in 1993 acquired Laboratories JP Martin (France). P&G has been expanding in Europe since the early 1980s through a series of takeovers (i.e. Norwich Eaton,1982; Richardson Vicks and Searle OTC brands,1985; Blendax,1987; Noxell,1989). As a result, P&G now has a solid presence in Europe with about 23% of its total sales being European. At the same time, European firms such as Bayer, SKB, Ciba, Sandoz and Hoffmann La Roche have undertaken to increase their presence in the North American market.

Many analysts question whether the leading companies have reached their limits for expansion in the OTC markets. Some companies may consider markets in eastern Europe, Asia and Latin America but these are still relatively uncertain environments, despite the advantages which will be gained by first-movers. More likely is the prospect that companies will choose to

remain in the established markets in light of the broader social changes taking place as governments look for ways of reducing the growth of health care budgets.

Table 4.3: Leading OTC Companies

Rank	World (1993 sales U.S.$ million)	Canada	United States	Europe
1.	AHP (1,929)	J&J	J&J (1,477)	Sterling/Sanofi
2.	J&J (a) (1,780)	AHP	AHP (1,245)	RPR
3.	SKB/ Sterling (b) (1,619)	WW	WW (836)	Bayer
4.	Proctor & Gamble (1,383)	P&G	P&G (669)	Roche Nicholas
5.	WW (c) (1,357)	BMS	Bayer/ Sterling (620)	P&G
6.	Bayer/Sterling (d) (1,260)	Schering	SKB (544)	Boehringer I.
7.	Taisho (1,240)	MMD	BMS (484)	SKB
8.	BMS & Upsa (801)	SKB	Schering (471)	Boots
9.	Schering (574)	Ciba	Sandoz (250)	AHP
10	Roche (572)	Bayer	Pfizer (193)	WW

KEY:
(a) includes J&J and Merck
(b) Sterling (Europe and "third world")
(c) with Halls and Rolaids
(d) Sterling (U.S. and Canada)

AHP: American Home Products
J&J: Johnson and Johnson
SKB: SmithKline Beecham
WW: Warner-Lambert/ Warner Wellcome
BMS: Bristol Myers Squibb
MMD: Marion Merrell Dow
RPR: Rhone-Poulenc Rorer
P&G: Proctor and Gamble

Note: In 1994 Bayer A.G. bought back the North American trademark it had lost in 1918 from SKB which purchased Sterling's OTC line. With the exception of Canada, rankings for Europe are prior to the Sterling restructuring. Canadian rankings are estimates based on interviews.
Source: UPDATE U.S.A.,01,94:18; UPDATE U.S.A.,12,94:379.

4.3 Key Issues and Strategies

Rx-to-OTC Switches

The majority of OTC products are for the relief of minor ailments such as colds and headaches. These products do not require medical supervision unless the problem persists. Increasingly, however, products are becoming available to the consumer that were once available only through prescription. Some products, such as vaginal antifungals, for example, may still require an initial visit to the physician, but once the sufferer is familiar with the condition repeat visits to the physician may not be necessary. Theoretically this should increase the role and responsibility of the pharmacist at the point of sale. But the extent to which this occurs will be a function of the retail environment in which the product is sold.

Rx to OTC switching is a key competitive strategy for pharmaceutical firms that is expected to increase in significance in the 1990s. There are several reasons for the switching strategy. First, there is already a loyal consumer base established from the ethical heritage of the Rx world and the products will be familiar to a number of potential patients/consumers. Second, the switched products will likely have the support of health professionals who already know their therapeutic value. Third, the ethical background and branded recognition of the product will confer a sense of product superiority (real and perceived) over existing OTC brands. Finally, the switched products with proven efficacy and safety may be considered as more realistic alternatives by governments to costly physician consultations.

When an Rx product moves off-patent it can lose up to 30% of its market share to price-competitive generic products within six months (Dudley,1993). The life cycle of the prescription product, however, can be extended through the OTC switch. There will be a high entry cost and considerable promotional costs incurred over the initial phase of the switch, which means a relatively low level of return on investment. But there is an expectation that long-term profitability will justify the initial low rate of return. This is particularly the case when firms achieve first-mover advantage in a product category. Firms may choose to differentiate their products through dual branding if the OTC indications and dosage differ from those of the Rx product, or elect to keep the same name if the indications are similar.

The extent of profitability will also depend on the specific market segment which the switched product is entering. There may, for example, be situations where more than one switched product is entering the same market or other recently switched products already exist. In such cases, the perceived product cycle will be truncated (this truncation has been cited in the market for seasonal allergies in the U.K. where data have indicated over 50% of seasonal allergy sufferers are likely to try a new brand) (Dudley,1993).

Profitability will also depend on the ability of firms to shift their marketing and promotion emphasis from a physician focus to one oriented to the consumer. The strongest competitive position will be gained by those companies that have both Rx and OTC divisions, assuming that they operate in similar product categories and have developed integrated strategic plans. If the internal synergies do not exist within a company then it will look to establish collaborative relationships with other firms. The key competitive factor is to have a new product pipeline and the ability to market products to consumers. The Warner Lambert ventures with Glaxo and Wellcome—now run by the newly formed Warner Wellcome group, are classic examples of one firm's product lines being complementary to another's expertise in marketing and distribution of consumer products. Warner Wellcome have explicitly stated that the Rx-to-OTC switch is central to their OTC growth strategy.

Although switch candidates typically have a strong, proven safety record as an Rx drug, some governments and consumer groups can be reluctant to regulate certain products to the OTC category. One example is Warner Wellcome's Zovirax (acyclovir), a treatment for genital herpes, and one of the biggest selling Rx products. Concern has been expressed regarding its OTC role with regard to the potential for incorrect self-diagnosis: a consumer may increase the level of damage incurred because of the delay in correct diagnosis
as the condition may be a disease with similar symptoms; the level of counselling and education available to a consumer will be an issue, the drug may be inappropriately used to treat other diseases; and, for some consumers, the product may become inaccessible (financially) if it is subsequently removed from drug benefit plans which seldom cover OTC products.

According to the FIND/SVP market research firm, if most of the current U.S. switch applications are approved, it could add an additional $3.6 billion to U.S. self-medication market (Skinner, 1993). In the U.K. and Scandinavia, where switching is more prevalent, several blockbuster Rx products have now been given OTC status. In January, 1995, for example, Zantac 75 was launched in the UK and will compete in the OTC market with its former Rx competition Tagamet (SKB) and Pepcid (J&J/Merck).

Yet despite the enormous potential, 40% of companies in Europe are somewhat reluctant to make the Rx to OTC switch because of the increased likelihood that the product would then be taken off reimbursement lists. The European OTC pharmaceutical manufacturers association (AESGP) meanwhile, has signed formal agreements with the European pharmacy association to ensure that the appropriate switch environments can be in place. At the same time, it must be emphasized that the switch environment is different in Canada than in Europe where it appears more switches are occurring.

Some companies may also have difficulty adjusting to the consumer-oriented marketing and sales environment but this can be addressed through the formation of collaborative relationships with firms like Schering which is well known for its expertise with switching. A key strength of Schering has been the ability to extend their product's life cycles (as of 1992 Schering

had eight successful OTC switches to its name). Schering was screening its Rx line for potential switching years before other companies and promoted a close working relationship between the Rx and OTC product personnel (in contrast to other firms). Schering speaks of the interrelationship as the "consumerization" of the Rx lines and the "pharmaceuticalization" of the OTC lines. Schering, like many other firms in the 1990s, believes the future of the OTC market lies in the switching strategy.

Private Labels

Competitive pressures are being felt by the increasing intrusion of private labels across a wide range of product lines. Private label manufacturers supply retailers with generic products that are then marketed under a retailer's name, or a name that is exclusive to that particular retailer. These private labels are also known as house brands or store brands (examples include Shoppers Drug Mart's "Life Brand", and Wal-Mart's "Equate" or "Sam's Choice").

Private label products have become fast growing alternatives to brand-name products. According to the trade journal UPDATE U.S.A. (01,94:1), they have progressed from being "cheaply produced generic alternatives ..... into high quality equivalents to market leading [branded] products". They are competitively priced products that represent a considerable threat to the profitability of branded manufacturers in the OTC market. Private label manufacturers produce store brand drugs. The primary advantage of house brands are improved value for money for the consumer, reduced overheads for manufacturers (since many advertising and promotion costs are borne by the retailer), and increased profit margins for the retailer.

The leading manufacturer of private labels in the U.S. is Perrigo. Perrigo has over 900 OTC and personal care products for almost every national and regional retail grocery, drug and mass merchandising store in the U.S. In 1993 Perrigo had OTC sales of U.S.$365 million. Perrigo has generic equivalents of major OTC products (e.g. McNeil/J&J's Imodium and Ortho/J&J's Monistat-7), and places a strong emphasis on high quality manufacturing. It also has a commitment to new product development—in particular because of the opportunities seen in the Rx-to-OTC switches. The strategy is based on internal growth (to position itself as a strong developer of switch products) and the expansion of externalized relationships (forming collaborative product development relationships with generic drug manufacturers).

In part, some industry analysts say the growth of private labels has been due to the increasing use of discounting and couponing strategies by brand-name OTC producers, which has encouraged consumers to look for more price competitive products. Given such competitive threats brand-name manufacturers of OTC products are re-focusing on the brand-name price, image and reputation. Some manufacturers have sought to extend their product lines to maintain consumer interest in the branded items.

Some manufacturers have lowered their prices in a bid to curtail the growth of private label products, hoping that brand equity developed over years of advertising will serve to maintain consumer loyalty (Wotch, 1994). If prices are maintained at a competitively low level compared to the house brands, the difference can still be attributed to the perceived higher quality, safety and efficacy of the product. It is argued by some industry analysts that consumers are more likely to make compromises on price rather than quality (UPDATE U.S.A., 01,94:1). Nevertheless, the growing share of markets being taken by private label products suggests that consumers are in fact recognizing that quality exists in these products.

Changing inter-firm relationships

As in the Rx environment, mergers, acquisitions and collaboration have characterized this segment of the industry. Firms decide whether to internalize or externalize various elements of the conventional business value chain. In the OTC segment the decision as to internalizing or externalizing usually revolves around accessing new products or gaining access to new markets through expanded distribution, marketing and sales networks. A critical mass for maintaining a competitive position in specific OTC market segments is achieved by some firms through mergers, although a fair degree of control is lost with such actions. More commonly, the larger, globally mobile companies embark on a series of acquisitions to build the critical mass.

A more flexible and increasingly popular inter-firm relationship has been collaboration. Alliance formation, whether it is referred to as strategic alliances, joint ventures, co-marketing and so on, combines firm-specific expertise and resources to effect stronger market positions. Many companies form relatively flexible collaborative relationships with other firms whereby the partners pool complementary resources (e.g. capital, products, technology, labour force). In theory, both partners benefit from these collaborative relationships.

The emerging picture of the segment is one in which corporate boundaries are blurred as firms take on ethical, generic and OTC drug production, either for themselves through acquisition, or in association with other companies through collaborative linkages. One example of the blurring of company boundaries is the recent acquisition of Copley, the generic drug manufacturer by Hoechst. Copley had 16 OTC products on the market when Hoechst acquired it in 1993. The acquisition give Hoechst access to generic product lines, opened up new competitive opportunities in OTC markets and helped to build a stronger presence in the North American market. Despite the range of firms competing in the OTC market the overwhelming consensus of industry representatives with whom we spoke was that there will be increasing levels of consolidation both globally and nationally as the larger brand-name manufacturers maintain their market share and other firms are squeezed out through the growing strength of private label products.

The predominant corporate structure for the major OTC players is a distinct consumer products division that is separate from the Rx operations of the firm. Some companies have a

number of smaller operating units within the OTC market, while others channel all OTC operations through one unit. The key corporate strategic issues affecting OTC operations are acquisitions and collaboration. A synopsis of the various structures and strategies employed by the dominant global corporations in the OTC market is provided in Appendix B.

Acquisitions

The developments in 1994 illustrate some of the acquisition activity that has characterized the OTC segment of the pharmaceutical industry. AHP bought American Cyanamid and its Lederle OTC division for U.S.$9.7 billion, which pushed AHP ahead of J&J in terms of leading company sales, and enabled it to have presence in just about every OTC category. SKB acquired the Sterling OTC business for U.S.$2.9 billion a few months later and sold the U.S. and Canadian OTC business to Bayer for U.S.$1 billion. Meanwhile, Ciba acquired the U.S. and Canadian rights to Rhone-Poulenc Rorer's (RPR) OTC products which, according to Ciba, provided them with the critical mass required to be a major player in the U.S. OTC market. Ciba had previously purchased the U.S. OTC division of Fisons in 1992. RPR will instead focus its OTC operations on Europe.

The OTC segment is characterized by constant corporate restructuring. Changes in the 1980s included AHP's acquisition of AH Robins in the U.S. in 1986, which provided AHP with what it felt was necessary critical mass. In the same year the Bristol-Myers and Squibb merger created the sixth largest OTC manufacturer in the U.S. overnight. Other companies such as Sandoz, Ciba and Hoffman-La Roche have all endeavoured to expand their operations in the United States through acquisitions. Roche, for example, tried to take-over Sterling in 1988 (and did acquire Nicholas in Europe in 1991 - where it still has 80% of its total OTC sales). Sandoz has also expanded in the U.S. but primarily through the acquisition of specific products (e.g. Triaminic and Ex-Lax).

Smaller players have also been active in expanding into the OTC business. Roberts Pharmaceutical—well known for its acquisition activity, recently acquired a line of 5 OTC and Rx products from Glaxo Canada and plans to acquire another 13 products. Roberts has also purchased marketing rights to 10 BMS OTC products as part of its plans to pursue late-stage development products and small Rx and OTC brands. In 1993 alone, Roberts doubled its number of OTC brands by acquiring products from Glaxo Canada, Searle Canada and BMS. Roberts is supported by its financial partner - Yamanouchi (Japan), which is seeking to become a major global player (Yamanouchi holds 29% interest in Roberts). Through the distribution channels provided by the acquired products Roberts plans to bring more products into Canada that are currently only available in the U.S. (UPDATE U.S.A.,06,93:212: UPDATE U.S.A.,09, 94: 279).

Collaboration

Collaborative relationships are being established by both market leaders and the smaller players in the industry and are explicitly referred to as central to corporate growth strategies. J&J, for example, even though it was the leader in the global OTC market, established a joint venture with Merck in 1989. The huge investment by Merck in this venture is based on its product Pepcid being a potential switch candidate. J&J/Merck have also started to use Mylanta as an flagship brand like McNeil has used Tylenol. Indeed, much of J&J's new competitive strength is based on its venture with Merck, which, along with its own Rx portfolio, provides one of the strongest group of switch candidates in the industry (UPDATE U.S.A.,06,93:182).

In 1993 J&J/McNeil formed an alliance with Upjohn. Upjohn received the marketing rights to the Ibuprofen-based products developed by J&J/McNeil, but which had never gone to the market. McNeil agreed to help expand Upjohn's retail distribution and in-store promotion of Motrin. In exchange, Upjohn paid cash and gave McNeil access to future Upjohn technology. McNeil had a failed Ibuprofen entry (Medipren) which it had pulled from the market, and wanted to focus on its Tylenol. Upjohn saw this as an opportunity to build an "umbrella brand" of Ibuprofen (UPDATE U.S.A.,07,93:245).

Warner-Lambert's (WL) OTC operations - now Warner Wellcome Consumer Health Products - is well placed for further expansion through the collaborative agreements it made with Wellcome and Glaxo in 1993 to take care of the switching of Zovirax and Zantac. Through the deal with Wellcome, the Warner Wellcome venture will market the OTC Zovirax as well as most of the OTC products owned by the two companies. In addition to Zovirax and Zantac, Beconase (a nasal steroid) is another potential switch candidate in the U.S. Warner-Lambert's president of Consumer Products, John Walsh, stated in 1994 that the switches accessed through the collaborative ventures with Wellcome and Glaxo "will be the engine that drives our double digit growth in consumer health products". WL sees these products as integral to the company's goal of being the leading company in the OTC consumer products sector within the next five years. Warner Wellcome also has a number of other collaborative marketing agreements with companies internationally.

The recent legal battle over patent rights with Glaxo and Canadian companies Novopharm and Genpharm will be of interest to the newly-merged consumer operations of Warner Lambert. If Glaxo's Zantac remains patent protected to the year 2000 then there is plenty of time to put the switch in place. But if Zantac moves off-patent there is increased pressure for an early switch application. In the meantime an OTC version of SKB's competitor, Tagamet, is also going through the FDA so Glaxo and its partners may be anxious to accelerate moves to get Zantac onto the self-medication market.

With considerable switching experience Schering is well placed to work with other companies on their switching strategies. The president of Schering has stated that the company will pursue strategic alliances with other firms. It has, for example, a long standing agreement with Marion Merrell Dow (MMD) to develop and market an OTC version of the off-patent ulcer treatment, Carafate (sucralfate). At the same time MMD has also pooled its OTC resources with SKB, which has its own switch in the same category (Tagamet).

Other Trends

There are other trends occurring in the OTC market which could impact on the Canadian market. Information technology, for example, may play a greater role in the sales and marketing of OTCs, although its widespread use may be a long way off. Given that 88% of American homes already shop with catalogues, interactive shopping through television, computer, and/or telephone is seen as the next logical step (UPDATE U.S.A., 10,94:315).

In early 1995, in Orlando, Florida, residents subscribing to cable TV were able to shop from their home on the Drugstore Channel of Shoppervision, which has contracted with Eckerd drug stores. Viewers could see the products as they would if they were in the store and could read the ingredients on the screen. Remote controls could be used to place orders and payment made by credit card or through the cable TV provider. Viewers shop for the products at their own free will in their own time.

Online computer OTC sales are also in place and offer discounts, coupons and so on. Some OTC manufacturers are looking into computer services that teach consumers how to better self-medicate. Insurance groups and OTC manufacturers have also expressed interest in the information service potential. Plans are underway to have these services in emergency departments and clinics in the hope that they can resolve the less serious health problems. Interactive telephone calls are being considered as a marketing tool—some manufacturers, for example, provide hotline services for consumers to call and ask for information relating to their products. Another potential development is the use of vending-type machines that could dispense products based on the consumer inserting a smart card with his or her health information. This would completely sidestep pharmacist interaction but has some broader implications regarding privacy.

Consumers, however, may still prefer to have the product in hand and desire the personal consultation that a pharmacist may provide on a range of products. The developments are most advanced in the U.S. but it may be some time before they become widespread in Canada.

Although managed care has not encompassed the Canadian health care environment as it has in the U.S., it has created incentives for the key players in Canada to modify their North American operations. Managed care organizations see a role for OTC products since they can be

used instead of Rx drugs when appropriate, can help reduce the use of medical facilities and, through educating the general public, may contribute to providing preventive care which can avoid more serious and costly illnesses.

Profits, traditionally the domain of the larger ethical pharmaceutical companies, are now being eroded by generic drug producers, pharmacy benefit management companies (PBMs) and other managed care organizations. Self-medication, however, provides competitive opportunities for pharmaceutical manufacturers to maintain or increase profitability. Given these pressures, the massive costs of research and development for new chemical entities, the re-configuration of the industry and the blurring of company focus, it seems only logical that more attention will be directed to the expanding OTC segment.

Corporate strategy is moving away from a "nationally-based" geographical focus to one which endeavours to integrate the various components of the value chain at the global scale. Consolidation of the OTC segment of the industry is an outcome of a broader global rationalization process within the pharmaceutical industry, the realignment of corporate strategy and core competencies and the continual integration of different firms complementary expertise.

An integral part of this restructuring is a transformation of the roles various stakeholders play in the profitability of the pharmaceutical industry. The combination of cost containment pressures, consumer empowerment, diminishing product pipelines, acceptance and growing use of generic drugs, together with pressures from managed care organizations and retail outlets has seen the traditional branded pharmaceutical company becoming more a price-taker than a price-setter. The increasing importance being placed on the OTC segment is indicative of the strategic reorientation of the branded manufacturers as they seek to retain some control over the pharmaceutical care given to consumers. Thus in the OTC segment control is moving towards the retailers, distributors and pharmacists, and reflects a shift in focus towards the end user - the consumer.

4.4 The Canadian Market

The OTC market in Canada grew at an average annual rate of 10% between 1985 and 1990, when total sales reached just over $1.2 billion (Skinner, 1993). The total OTC drug sales in Canada for 1994 were almost $1.5 billion. The largest segments of the OTC market are cough and cold, and headache and upset stomach remedies. Consumer health-related products such as deodorants represent up to 20% of the market. Table 4.4 shows the market shares for each of the main categories, each of which includes both DIN (Drug Identification Number, for sale in pharmacy only) and GP(General Public) products. The total Canadian market is forecast to grow to $2.7 billion by the year 2000 (as a measure of comparison, the global operations of a single U.S. firm, American Home Products, has close to U.S.$2 billion in annual sales while the entire Canadian OTC market is C$1.5 billion—approximately 3.9% of the global market).

Approximately 85% of OTC products are sold in drug stores and the remainder of sales is accounted for by outlets. At present, Canada's mass merchandisers have made little inroads into the sales of OTC medication (only about 5% of sales). This is in contrast with the U.S., but food stores in Canada are adding pharmacies at an increasing rate with the lure of "one-stop"shopping, and it is expected that their role will increase in the future.

Some analysts believe that Canadian OTC manufacturing and marketing has declined over the past few years. In part this is due to the Free Trade Agreement (FTA) which has encouraged increased levels of U.S. manufacturing and subsequent exporting to Canada. Tariffs on many products have been reduced by 50%, and all Canadian pharmaceutical tariffs will be gone by 1998. On the positive side, however, there has been an increase in the volume of exports to the U.S., which may reflect the growing level of North American rationalization by a number of companies.

The following table lists the ten major firms, accounting for over 50% of all sales in the Canadian OTC market. The industry is dominated by U.S. owned brand-name manufacturers. These firms also dominate product groups such as internal analgesics, cough & cold and allergy medications, and digestive products.

Table 4.4: Sales of OTC Medication in Canada by Product Group, 1994

Product Group	Volume, 1994 ($ millions)	Percent	Media expenditure ($ millions)
Acne Remedies	32,371	2.2	na
Analgesic Rubs	29,024	2.0	2,175
Antidiarrheals	24,452	1.7	.536
Antihistamines	76,198	5.2	11,327
Cold remedies	138,418	9.4	11,457
Contact lens preps	83,423	5.7	na
Cough Syrups	91,431	6.2	6,819
Dentrifice	112,460	7.6	8,560
Deodorants	140,863	9.5	10,399
Eye drops/lotions	19,748	1.3	na
Headache remedies	219,491	14.9	10,684
Haemorrhoidal remedies	12,905	0.9	.714
Laxatives	64,969	4.4	.829
Medicated shampoo	39,346	2.7	2,780
Multiple vitamins	63,006	4.3	1,408
Oral Antiseptics	59,749	4.0	5,370
Sleeping AIDS	10,629	0.7	.627
Sun care products	49,701	3.4	1,479
Topical wound care	39,736	2.7	.023
Upset stomach remedies	91,147	6.2	7,343
Vitamin B	18,519	1.3	na
Vitamin C	33,144	2.2	na
Vitamin E	23,743	1.6	na
Total	1,474,473	100.0*	

Note: may not add up to 100 due to rounding. Media expenditure is the amount of money spent television, radio and major newspapers/magazines. Information provided by the Nonprescription Drug Manufacturers Association of Canada, (1995).

Table 4.5: Major Players in the Canadian OTC Medication Market

Rank	Company	Main Product Lines
1.	Johnson & Johnson (McNeil, Janssen and Ortho-McNeil)	internal analgesics, allergy relief, cold medications, and home diagnostic test kits
2.	American Home Products (Whitehall Laboratories and A.H. Robins)	infant formulas, cold medications and internal analgesics
3.	Warner Wellcome Consumer Health Products	cough and colds, allergy remedies, antacids and stomach remedies, and mouthwashes.
4.	Procter & Gamble	mouthwashes, laxatives, lozenges, acne AIDS, antacids and upset stomach remedies, and cough syrups
5.	Bristol Myers Squibb (Mead Johnson Canada and BMS Consumer Products Group)	prepared infant formulas and internal analgesics
6.	Schering	allergy relief, suncare, cold medications, and foot care products
7.	Marion Merrell Dow	allergy relief and cough syrups
8.	SmithKline Beecham	antacids and upset stomach remedies, cold medications, lozenges and acne AIDS
9.	Ciba (also recently acquired Rhone-Poulenc Rorer Consumer)	contact lens solutions and nasal decongestants
10.	Miles (now Bayer - as of April 3, 1995)	vitamins and mineral supplements, home diagnostic test kits, and antacids and stomach remedies.

Source: Interviews with industry representatives.

The largest item in the cost structure of a typical manufacturers of OTC products is marketing expenses. These include advertising, promotional activities, and sales, distribution and marketing departments. Advertising of OTC medication is heavily focused on television (86%), followed by magazines (7.4%), outdoor (e.g. billboards) (2.9%), newspapers (2.0%) and, increasingly, radio at (1.8%). (NDMAC, 1995)

Corporate Governance

The level of autonomy of the Canadian subsidiary can be attributed to the nature of the global management of the OTC operations of the parent company and the success of the subsidiary; if the subsidiary is doing well, there is more likelihood it will have greater control of its destiny. The Canadian operations are judged on their performance in the specific product markets over time and in comparison with other operating units of the parent company. Industry representatives acknowledge, however, that Canadian management must be cognizant of the parent company's strategies, understand how the Canadian context fits and then try and balance the two. At the same time the parent companies need to recognize the differences between the Canadian and other markets.

Several industry representatives observed that their companies were moving toward a North American supply strategy. Parent companies are asking their subsidiaries to be more efficient — a move toward "efficiency alignment". The North American continental production model is beneficial to Canadian operations when exchange rates are favourable, but when the Canadian dollar is high, pressure to compete with similar operations in the U.S. and elsewhere increases.

One American-owned OTC operation we interviewed is part of a "global management" approach where teams of personnel work together irrespective of location. Considerable time is spent on learning what is working in other operational units and then applying the successful practices to the Canadian operations. Similarly, other operating units learn from the Canadian experience. There is a continual movement of managers globally as the company emphasises the need to exchange ideas. At the same time, the company is continuing to rationalize its operations with fewer and fewer manufacturing sites.

Other firms commented that their Canadian operations are very much part of broader plant rationalizations occurring at their parent companies' global scale. Rationalization is even more apparent when considering just North America. For some firms there is a move towards the "harmonization" of production in such aspects as product formulation and sizes. Harmonization cannot, or course, be applied across all national markets; while it can lead to efficiencies, it also creates possible tensions, since ultimately every operating unit must give up something in the process. Companies have stated that it is usually the capital intensive products such as gel caps and the key ingredients in the medication that get sourced from the U.S..

Free trade agreements play an important role in determining the nature and extent of OTC manufacturing in Canada. As a result of the U.S.-Canada Free Trade Agreement, some OTC manufacturing has moved to the U.S. and has been replaced by greater levels of exportation into Canada. Even though Canadian government regulations may require a unique Canadian production run, this can be made in U.S. manufacturing plants. There is also concern that the

Canadian manufacturers will face increased competition from Mexican producers as a result of NAFTA (UPDATE U.S.A.,04,94:109).

In some markets, like vitamins for example, free trade is not a major issue because of the variation between U.S. and Canadian regulations. In these cases (e.g. labelling and packaging requirements), there is still a separate Canadian production run, which may or may not be located in Canada. As with other manufacturing, the value of the Canadian dollar is an important consideration—the lower the exchange rate, the lower the production costs for the Canadian operations of the parent company, expressed in U.S. currency.

Collaboration on the global scale forces the Canadian operations to reconstitute their competitive position in the Canadian market vis-a-vis new partnerships. An example of this is the recent formation of Warner Wellcome, which is an evolutionary product of Warner's globally based restructuring initiatives. One of the manifestations of the global rationalization of multinational companies is the restructuring of their organizational charts. The modifications performed at Warner Lambert are typical of many other drug companies (Clouston, 1994).

Warner Lambert's corporate reorganization.

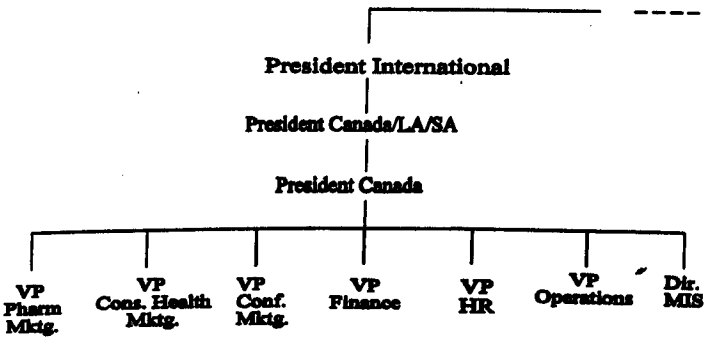
In 1992, Warner Lambert reorganized its corporate structure away from the "geographic" principle, where each local subsidiary was responsible for managing a whole range of corporate functions. It was replaced by a more centralized system, where the corporate headquarters coordinates activities more tightly among the various subsidiaries.

As shown in Figure 4.1, the traditional multinational corporate structure (in effect at Warner-Lambert until 1992) can best be described as a set of "miniature replicas" of the company's U.S. operations distributed around the world. Within this structure, the company found it difficult to develop a cohesive worldwide strategic focus and capture synergies between the U.S. operations and the affiliates. Plants in different locations were producing the same product lines, sometimes with excess capacity. Other problems included lack of consistency in product formulation, packaging, and positioning, and little opportunity for global management development.

The organizational structure put in place in 1992 is illustrated in Figures 4.2 and 4.3. The company was "globalized" along product lines, one of them being Consumer Products and the other Pharmaceutical Products. A structure of centrally managed interdependencies among the various world regions was created, with matrix reporting relationships. The new arrangement made it possible to harmonize the product, packaging, pricing and positioning across the regions, while leveraging local strength, capturing economies of scale and improving capacity utilization.

Figure 4.1

Warner-Lambert Canada Inc. Organization Prior to 1992



- President Canada responsible for all three lines of business plus support functions.

Figure 4.2

Warner-Lambert Organization Since 1992

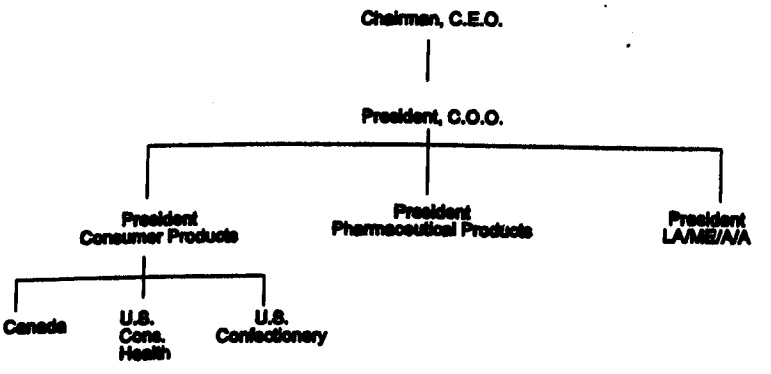
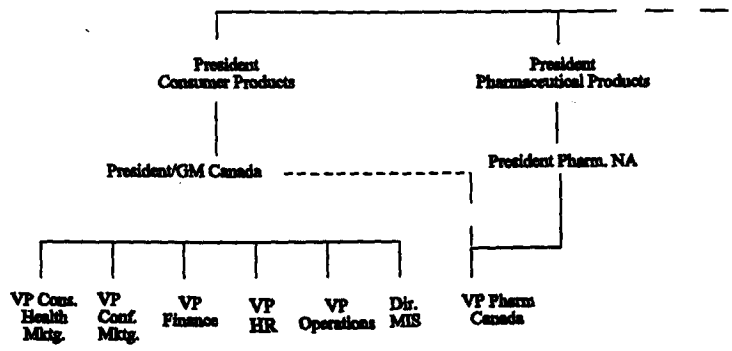


Figure 4.3

Warner-Lambert Canada Inc. Since 1992



- President/GM Canada now responsible for consumer products marketing and all support functions including pharmaceutical manufacturing. Pharmaceutical marketing has "dotted line" reporting relationship with President/GM.

Company priorities are now managed centrally. The assignment of product mandates to the various affiliates provides an illustration of the change. In the pre-1992 system, world product mandates have been assigned to the local subsidiaries largely on the principle "you seem to have a good idea, so carry on". This was consistent with the traditional geographically-run company. But the system was too "entrepreneurial", and perhaps wasteful, since the various subsidiaries may have duplicated each other's efforts.

The new approach is consistent with the formation of regional trading blocks (such as NAFTA), where the "national markets" are less well defined. In addition, the recent wave of mergers and acquisitions is putting pressure on cost containment. Thus, cost-increasing duplication of effort must be avoided.

While in some ways the autonomy of a subsidiary has decreased, in other ways it has increased in the new structure: Within the scope of his/her authority, the local manager now has more autonomy to respond to local conditions and be creative in the way in which the company manages the local market (sales force, marketing practices, etc.). It can also influence the R&D priorities of corporate headquarters; one manager described this as "taking advantage of the size of Warner Lambert as a whole".

Since the reorganisation, the Warner Wellcome venture has been established, with its global strategy based on three objectives: increasing consumer interest in existing brands by improving the products and their use; improving retail distribution and merchandising; and

capitalizing on brand potential. As the CEO commented, "Only brand equity can win in a parity game dominated by pricing issues. Our goal is to continue to make brands our focus, to put resources into developing a single dominant brand, rather than squander the company name and identification" (U.S.A. UPDATE,06,94:171).

One trend that some companies mentioned in our interviews is the move towards closer relationships between the Rx and OTC segments of their operations. Generally, about half of the branded OTC manufacturers report to the parent OTC operations (usually in the U.S.), while the other half report directly to the Canadian operations which also oversee the Rx market. Although some parent companies could move the OTC manufacturing out of Canada because of short production runs and idle capacity, politically it could be very unpopular and the backlash could harm the sales of the manufacturer. This, in part, may explain why some Canadian operations are expanding production by undertaking contract manufacturing for other firms.

Industry representatives felt that a critical mass is usually possible with sales volume between $35-40 million in sales (critical mass is said to exist when a firm is able to have its own sales force, investment potential in new products and new line extensions). Some of the medium-to-smaller sized Canadian operations (i.e. with sales up to $30 million) are considered to be prime candidates for takeovers. Knowing that this is a possibility and given the continual prospect of broader corporate rationalization, some firms endeavour to use their excess capacity by undertaking contract production for other brand-name manufacturers to ensure that their current scale of operations is not further reduced.

There are very few Canadian-owned operations in the OTC business. The most successful example of is W.K. Buckley, a small family-owned firm that has been making cough formula for the past 75 years. What is particularly interesting about Buckley has been its ability to remain competitive in a market that is dominated by large multinational concerns. In 1985, for example, with just 22 employees, Buckley had $2.5 million in sales. In 1995, with the same number of employees, its sales have climbed to $8 million.

Buckley can perhaps serve as an example to other small companies. It has remained competitive by embracing the advantages of new process and information technology, it has internalized what it does best (i.e. making the formula), and has developed external relationships to provide more cost-effective means of distribution and sales. Buckley attributes its success to four main elements: It manufactures 90% of its Canadian production in-house and now exports directly to its distributors overseas. It has a distribution linkage with NADISCORP which maintains a warehousing network across the country, and it also uses independent sales brokers instead of maintaining its own sales force. Finally, much of its recent success can be attributed to its advertising campaign which has embraced the perception of the product as "bad tasting" with a personal approach in which the owner, Frank Buckley, recommends the product. Although it has faced increased competition, W.K. Buckley Ltd. has responded effectively and still remains a significant player in its specific market niche.

Regulation

The regulatory environment is seen as one of the key issues impacting on the operational effectiveness of companies in the Canadian OTC market. The national group given the task of recommending uniform prescription and nonprescription schedules across the provinces and territories is the Canadian Drug Advisory Committee (CDAC). Even though the CDAC has proposed a national system to harmonize regulations, the present situation has been described by one industry official as a "marketing mosaic that's almost impossible to navigate". The issue is compounded at the present time by the upcoming elections in a number of provinces, and these will likely prevent any legislative changes in the near future. There does not yet exist a system of mutual recognition between Canada and the United States like there is in Europe, although both government and industry are looking closely at the idea.

One of the more important regulatory functions that impacts on the OTC market is the determination of whether a product should be shifted from Rx to OTC status. Within Health Canada the section charged with evaluating switch candidates is the Bureau of Nonprescription Drugs. The Bureau has a clinical division which evaluates the safety and efficacy of switch candidates, a pharmaceutical-chemistry review area and a product regulation division where consumer labelling for a proposed drug is reviewed. A switch application must provide data that show the risks and benefits of a change in status. Much to the frustration of the manufacturers, this can be a long process of at least 2-3 years, and sometimes longer.

Even when a product does come off prescription this does not ensure that it will be equally accessible to all consumers. Some molecules within a therapeutic class must remain behind-the-counter (BTC) while competing products within the same class have the advantage of being placed in the front shop. Ibuprofen, for example, was classed as a BTC product while its competitors acetaminophen and ASA were available in the front shop. Even then, the provinces each approach new products differently. With Motrin, Quebec has had it front shop for about two years, while Ontario has only just recently placed it at the front. Meanwhile, other provinces keep it BTC.

The distinction between front shop and BTC is critical to the sales of OTC products. This has been the case in the non-sedating antihistamine market where Hismanal (Janssen/J&J) and Seldane (MMD), both of which were switched products in the 1980s, were recently placed BTC due to concerns regarding their potential side affects. Claritin (Schering), the other major competitor in the market, remains in the front of the shop and has gained a large portion of the market as a result. Schering now controls about 50% of all sales in the allergy market. To enhance its competitive position, in 1993 Schering also introduced two line extensions of Claritin: Claritin syrup for children and Claritin Extra (a non-sedating antihistamine with pseudoephedrine). Schering also markets Chlor-Tripolon in the allergy market.

The market for allergy products, however, will be significantly altered when Pfizer's prescription non-sedating antihistamine Reactine is switched. This could likely occur in the near future as Reactine has had a very strong safety record which is at least comparable to existing non-sedating antihistamine OTC products.

The logic of the BTC location is that the pharmacist will intervene and counsel the consumer on the appropriate medication for a given condition. But questions are often raised regarding the extent to which this occurs, and some analysts feel that BTC regulation is unnecessary. The BTC classification, however, implies a greater level of responsibility placed on the pharmacist; whether this translates into counselling is another matter. The issue is confounded as provincial regulations differ on where certain products are placed within the retail outlet.

Other provincial regulations which affect the OTC market are the provincial drug plans, which, increasingly, are delisting OTC products. Similar delisting can occur with private plans but in cases this may lead to some consumers asking for prescription medication because they will be reimbursed whereas they would not be reimbursed for purchasing the OTC product. Whether this is a significant aspect of the industry is uncertain.

Rx-To-OTC Switches in Canada

Canada was once seen as a leader in switch products but recently has adopted a more conservative approach to the regulation of switches. Instead, it has been more content to watch products in other countries be switched first, to the point that now Denmark and the United Kingdom are considered to be leading the world in the commitment to switching to self-medication.

One explanation for the conservative approach given by industry representatives is that pharmacists may fear the loss of leadership with switches as they lose dispensing fees and are taken out of the health advisory loop as consumers potentially no longer need their assistance. While dispensing fees may be lost, the extent to which the advisory role diminishes will be a function of regulations governing the placement of the new product (i.e. BTC or front shop), and the commitment by the pharmacist to engage in an advisory capacity (independent pharmacists, for example, may behave quite differently compared to pharmacists of chain stores).

The timing of a switch is critical. In the U.S., for example, with Advil and Nuprin in the Ibuprofen market, there was just a few weeks between the switch of one over the other but the first-mover advantage proved critical to the longer-term market share. There are, however, some fundamental distinctions of the Canadian markets that need to be considered. These include the limited or restricted access of some products in some parts of the country as provinces have differing opinions on where in the store the product should be sold (e.g. front shop, BTC or

availability in any retail outlet), limited use of comparative advertising (although that is now changing) and more restrictive provincial regulations on advertising.

Successful switches depend on: being able to meet a large, unmet consumer need (in the case of OTC antihistamines there was a need for non-sedating products); the location in the store where the product is to be sold (being in the front-shop is critical as evidenced by the fall in sales of Seldane and Hismanal when they were placed BTC); and being recommended by health professionals (a study in the U.S. indicates that over 50% of switched brand users consulted a health professional). Canada's antifungal market is currently undergoing restructuring at present with the switching of clotrimazole and miconazole.

Production

Some brand-name manufacturers enlist the services of contract manufacturers (e.g. Custom Pharmaceutical, Contract Pharmaceutical, WestCan, CCL and the packaging firm Twinpak). This occurs when economies of scale are more conducive to smaller firms production runs, when the exchange rate makes it cheaper for production to remain in Canada, or when a company, having just extended its product line, requires additional capacity over the short term while it is running at full capacity itself. As in other industries, these types of relationships are increasingly seen as long-term in nature with a high level of cooperation. At times, for example, the contract manufacturer will receive the required process technology from the branded manufacturer.

Some branded manufacturers also use their excess capacity to produce products for private label production and for other companies' branded products. In a sense, there is a blurring of the traditional role of the "contract" manufacturer (as in other national markets, these same brand-name firms are also going to other brand-name manufacturers and offering their production facilities for making generic products).

The move of some brand name manufacturers to produce private label drugs is a logical step when they are feeling the competitive squeeze from existing private label products and leading brand-name manufacturers. For a company which is seeing its margins reduced as private labels gain increasing market share, it makes sense to take advantage of its excess capacity and produce private label products itself. The message, again, is clear. In order to maintain profitability, the OTC brand-name manufacturer must respond to the changing market if it wants to be in that market in the future. Private label production, regardless of how it is viewed by some industry representatives, provides an opportunity for some companies to remain in the pharmaceutical industry.

Some commentators and industry representatives, however, refer to this type of arrangement as "sleeping with the enemy". By facilitating increased distribution of private labels through "branderic" production, branded OTC companies may be doing more long- term harm than good.

Distribution

Further along the pharmaceutical value chain profits are being gained from traditionally small stakeholders in the drug market. Manufacturers are witnessing an erosion of influence as distributors and retailers take greater control of the OTC business. There are recognized cost advantages with shipping direct to a central point, but manufacturers are now faced with the prospect of minimized time and dealings with the retailer, who ultimately determines the product presentation and location in the retail outlets. Shoppers Drug Mart (SDM), which accounts for almost one third of OTC sales, is centralizing its distribution method. At present, stores in the chain purchase their products independently and this provides considerable flexibility for the franchise owners. But under the new system, called Vision '97, stores will be linked by computer to three regional warehouses that SDM will establish to do the purchasing for every store—similar to what now occurs in the U.S.

The system will not be fully operational until 1997, although changes are already occurring. For manufacturers this will mean they will require less staff to take orders, but prices will fall as SDM will expect discounts. Sceptics question how effective this will be given that the franchise owners have been accustomed to a high level of autonomy for a number of years and will have firm ideas on what and how products should be purchased. But as one executive commented, ultimately the "Suits" (i.e. business executives) will have the final say over the "professionals" (i.e. pharmacists).

For some of the medium to smaller-sized companies the vast geographical area to cover is not conducive to having a full sales force, and so brokers are employed. And as the likes of SDM invest in central distribution points, the role of the sales force will also change from one which does "selling" to one which meets with key account personnel and sells merchandising strategy. Indeed, the centralization of power that goes along with centralized distribution in stores such as Shoppers, Safeway, London Drugs, Big V, Jean Coutu and Pharmaplus will require new skill sets for manufacturers' sales staff and a likely reduction in the number of sale staff. The new management structure that will deal with the manufacturers will have much greater control over accounts than the independent stores, and thus less strategic room to manoeuvre for the manufacturers.

Marketing and Promotion

Increasingly in Canada, as in the other developed economies, there is a sense that the market is becoming more consumer driven. Products and associated services are becoming more customized as the consumer becomes better informed. A key theme in the Canadian marketing environment for OTC products is understanding what the consumer wants. Pharmaceutical companies are investing increasing resources into database marketing, toll-free lines, direct mailing and so on. They are also linking up with companies like Compusearch in an effort to understand the socio-demographic profiles of different regions—thereby linking products and pyschographic profiles with geographically defined (census and postal code data) markets. There are certainly costs to this approach but it is considered by many as more efficient in today's competitive markets.

The placement of OTC products in the distribution system is increasingly important in the fast changing markets. Given that the early stages of a products life are the most profitable, it is important that the young product be sold through high-end retailers (i.e. retail pharmacy only). These products will be priced high and demanded by consumers when marketed appropriately. Offering such product lines to the top retailers gives them high margins and should bring in more business.

Product life-cycles may be segregated into four phases. In the first phase, sometimes called the "child" phase, the product is new to consumers. Manufacturers launch major advertising campaigns to heighten awareness of the product. Once consumers become aware of a new product, the product enters the second stage of its life cycle, the "star" phase. Star products sell in large volume, while commanding premium prices due to their novel therapeutic advantage over older products. As the product continues to age, producers can no longer demand large premiums, and the product enters the "cash cow" phase. This phase is marked by sizable but declining volume and premiums, usually due to the entry of competition. Finally, a product for which mark-ups have fallen along with sales volume enters the "dog" phase of its life cycle. Profitability comes from extending the duration of the earliest phases of a product's life cycle.

To survive in the competitive OTC industry, manufacturers must prolong the most profitable phases of their product life cycles. One strategy for doing so is to carefully manage the distribution of a product, with new products being available only to high-end pharmacy customers. When a manufacture distributes a product to "warehouse-club" type retailers, they precipitate the cash cow and dog phases of the product. Although these are stages that must be entered into eventually, manufactures must consider the timing of entering them.

Manufacturers may also attempt to keep their product lines profitable by developing new products. Adding new dosage forms, combined ingredients, and other line extensions is one way to keep the average age of a product line younger and, thus, more profitable. Companies in other industries, such as Nike of the shoe industry, have successfully managed the introduction of

entirely new product lines on a yearly basis. These companies sell new products through exclusive retailers, leaving older products to department stores and discount outlets. In the pharmaceutical industry, similar introduction and management of line extensions may be important to maintaining profitability.

Manufacturers may continue to invest heavily in developing modified dosage forms of their OTCs. Introducing "new and improved" line extensions is the most effective way of keeping the product "young". There is an inherent health risk in such line extensions, however, as there is an assumption that consumers are highly educated in their self-medication selection. But are consumers really that knowledgable, especially given the combination of ingredients that may be put into line extension products? There may not be many cases of serious adverse health effects at this point, but if line extensions continue and switched products are increasingly placed on the shelves, consumers may not be fully aware of the differences in products and their intended and perceived effects.

There is a growing realization that line extensions do not confer expected market share, do not add enough therapeutic value, and contribute to increased levels of confusion by consumers. As the recent NDMAC publication observes, line extensions "continue to disappoint many of the firms that have launched them. There is a sense in the marketplace that they just don't add enough to existing product". (WOTCH,1994). Moreover, the publication notes, consumers turn to private label products to avoid having to sort through the tangled web of product indications, and pharmacists grow weary of line extensions because they compete for valuable shelf space.

When products are in a restricted access area (e.g. BTC) it is difficult to market the new product to consumers. Moreover, with a product being BTC, this brings pharmacists and other dispensers into the process, and as several industry representatives commented, the dispensing staff will more than likely recommend generic alternatives. The branded manufacturer may counteract by pointing out to the dispensing staff that the profit margins on a generic product will be smaller than those on the brand-name drug, but there is little else the manufacturer can do.

The primary focus of OTC marketing and advertising is the consumer. Professional endorsement from physicians still wields considerable influence on the self-medication patterns of consumers. Rx detailers will provide OTC samples to physicians in some cases, but the branded manufacturers can also use the Physician Hotline, which is based in Montreal. Physicians are sent a catalogue of product samples which they can then call the Hotline to order. The Hotline receives a "cut" for every sample sent out plus it charges to have the product listed in the catalogue. To the manufacturers this is still a cost effective approach when compared to canvassing physicians directly.

Professional endorsement from pharmacists is also critical to the OTC manufacturer. Pharmacists also play a dominant role as they recommend certain brands over others and make

key decisions regarding the shelf and promotional space given to different brands. These two elements, however, are changing as more and more chain stores control the retail environment in which OTC products are sold.

Regulatory requirements mean that the in-store location of products is variable across the country. Also, advertising is a key element of the OTC environment but requires specialized promotions which recognize brand-by-brand distinctions and regional differences. With aspirin, for example, promotions are done on television in Quebec, but in western Canada the attention is focused on partnership programs with retailers. Virtually every province requires a separate promotional campaign. In Quebec, for example, manufacturers can not do co-op advertising on DIN products, or couponing. There are also regional variations even in the extent of self-medication across the provinces. British Columbia, for example, has a higher rate of analgesics consumption. In Quebec, the cold powders market is underdeveloped compared to the rest of the country while the syrup market is overdeveloped.

Comparative advertising is another trend that is likely to increase in Canada. For a long time comparative advertising was discouraged. Just recently it has been officially allowed by the Health Protection Branch (HPB) so long as there is documentation to support the claims of one product being superior over another. But as one manufacturer admitted, in many cases there is not a lot of difference in some products and that is why brand loyalty is so important in this market.

There are a number of other differences among retail environments across Canada. In Quebec, for example, marketing and promotion is based on the knowledge that the population in general use more Rx drugs and less OTCs than in other parts of Canada.

In western Canada the large food chains such as Westfairs and Safeway have made huge inroads against the small independent drug stores and this is altering the selling environment. There is, according to drug company representatives, more bureaucracy when dealing with larger organizations than with independent pharmacies. The product managers of the larger stores are less flexible and the drug manufacturers are at the point where they are trying to determine just what the larger stores are actually interested in. Moreover, if a drug manufacturer offers one program to one chain and not the others, it faces considerable trouble. If the drug firm offers couponing to one chain, for example, it may face retaliation by the others as they deduct the value of the coupon of the invoice they get for the product. Group promotions are done by one drug company. The company sets standards for merchandising in retail outlets but at the end of the day, it is the retailer's store and they can do what they choose.

A number of marketing campaigns are in place in different regions and product classes across the country (e.g. television, couponing, household mailing, contests, refund offers and so on). The predominant trend has been to do less of these campaigns on the national scale and more on a regional basis which accommodates inherent regulatory differences and consumer behaviour

across the provinces. Couponing is illegal on DIN products in Quebec, for example, while price promotions are more important in the eastern provinces than in Alberta. In Quebec, where Jean Coutu controls half the market, there is a far greater focus on consumer promotions and contests.

Private Labels

Private labels are present in most segments of the OTC market but hold more significant shares of the following segments: allergy relief products, cough and cold medications, antacids and upset stomach remedies, laxatives, internal analgesics, vitamins and mineral supplements, and mouthwashes. House brands are linked to the very large chains (e.g. Shoppers Drug Mart, which has approximately 700 outlets and sells the Life brand), and can cost about 25% less than brand names with at least equal quality (UPDATE U.S.A.,11,93:368). In Canada, British Columbia has the highest private label penetration of all the provinces, while the lowest is in Quebec.

Private Labels such as Life Brand are taking the market share away from those competitors that may be 3rd or 4th in terms of sales in given therapeutic lines. The number one and two manufacturers may be able to maintain their competitive edge, but as shelf space becomes more crowded it is likely that the 3rd and 4th placed firms will be squeezed out by the house brands. What is more problematic for these manufacturers is the prospect that their distributor, i.e. the retailer, is also the competitor.

The branded manufacturer may choose to compete with the house brand in a number of ways. Apart from trying to emphasize brand loyalty, one option is to focus more on program selling rather than just the product—that is, provide education material, information, contact numbers and so on, in a bid to differentiate the product in such a way that it is unlikely to be followed by the house brand producer. Another option is to incorporate new technologies which will be too expensive to develop by the house brand producers. Coated technologies, gel caps or novel activities, for example, have been cited by industry representatives as technologies that could be promoted to distinguish the branded product from the house brands. The branded manufacturer may also try to promote an "ethical halo" around its product in a further bid to differentiate it from what might be perceived as an inferior house brand product.

Another option cited by one industry representative is to move sales and marketing focus towards the mail order environment (as of 1993, mail order pharmacy sold about 6% of all prescriptions). OTC products do not command a large market in mail order but with increasing fears of house brands the mail order business may prove to be a fruitful channel for some of the smaller OTC manufacturers.

Mail order, however, survives on servicing price-sensitive consumers who place a fair degree of faith in the pharmacists with whom they place orders. Since they are price shoppers who

"trust" the mail order company, they may actually be a target market for private label switching.

In Canada the production of private label products are not the sole domain of independent contract manufacturers as production is also being undertaken by generic drug producers and the foreign-owned branded manufacturers. Several industry representatives expressed frustration that some branded manufacturers are already producing private label products for the major stores. But given the competitive squeeze that some manufacturers are faced with (i.e. leading market brands and lower priced quality house brands), the most appropriate alternative for some branded manufacturers has been to manufacture house brands to at least maintain some level of existence in the market. Some firms, however, may speculate that this translates into ultimately "shooting themselves in the foot". The strategy chosen may, in any case, be decided upon by the parent company.

One competitive option for these branded drug manufacturers already producing private label products is to negotiate with the store to gain greater shelf space for other products in exchange for the production of the private label product. Small, Canadian-owned generic drug firms, branded foreign-owned subsidiaries and larger generic drug manufacturers have all embarked on producing private label products. Again, it is clear that there is not a "typical" firm in the pharmaceutical industry producing a "typical" product. Distinctions are becoming blurred as many firms manufacture a variety of different products for different customers. The only constant in all of this is the consumer, who is more educated and who will likely be receiving high quality, but cheaper, pharmaceutical products.

In a sense, as one manager explained, the branded manufacturers are "victims of [their] own success", in that they have actively encouraged consumers to be more educated in their self-medication. Indeed, there is a correlation between private label consumption and education.

4.5 The Future of the Canadian OTC Market

It is anticipated that companies that make between $20-30 million in sales will be acquired by the larger, pre-dominantely American-owned corporations. These larger firms are capable of competing with house brands, have access internally or through collaborative agreements to Rx pipelines for switch products, and have the critical sales mass already in place to maintain a presence in the Canadian retail environment. Moreover, these firms also can benefit from the broader global OTC strategies that have been put in place by the parent company.

There will likely be more manufacturing linkages which connect generic drug manufacturers and contract manufacturers with the branded OTC subsidiaries, while in the retail environment we may see the disappearance of the smaller independent stores, less influence by

the branded manufacturers and greater control of the distribution channels and shelf space by the chain stores.

If companies continue to develop line extensions this will place additional pressure on shelf space and potentially squeeze firms will smaller market shares out of the market. Indeed, there will be increased importance placed on the role of the retailer. Given the emergence of retailer-owned house brands the retailer is becoming both final distributor and competitor for the brand-name manufacturers. Increasingly the brand-name manufacturers are becoming price-takers as opposed to price-setters.

These trends are already occurring. Finally, the Canadian industry still remains a very small piece of the global OTC market. There will always be a Canadian OTC market which recognizes the regional differences in consumer preferences and provincial regulations, but given the anticipated increase in private labels and North American manufacturing rationalization, the outlook for growth for all firms in the industry remains uncertain at the very least. As is the case in the pharmaceutical industry more generally, the current wave of acquisitions, mergers and collaborations will leave the OTC market with fewer players at the global scale and nationally in Canada.

CHAPTER 5 SUMMARY

The way value is added in the pharmaceutical industry has changed during the past decade. Indeed, commentators have remarked that more change has occurred in the past three years than in the previous thirty. In the Canadian setting, the composition of manufacturers has evolved to a point where the distinction between generic, nonprescription and branded firms is beginning to blur. Internationally, globalization and rationalisation of the industry have created huge multinational corporations, many of whom are in the midst of restructuring to increase organisational efficiency in response to cost pressures. Evolution of the pharmaceutical industry has not been limited to manufacturing but is occurring throughout the value chain. Drug marketing, distribution, and delivery have also undergone significant change. Retailers have grown in size while the pharmacy profession has matured, extending new services to customers. Insurance benefits have grown to cover large portions of the population in developed countries. At the same time, the development of new drugs and delivery systems continues to increase the overall reliance on pharmacotherapy in health care. These changes have heightened the awareness of the role of pharmaceuticals in health care, and increased sensitivity to the needs of the ultimate consumer - the individual who uses the medicine.

The changes in the pharmaceutical industry have been driven by a number of influences, most of which pertain to health care cost containment measures. During the 1980s and through the 1990s health care expenditures in developed countries have been intensely scrutinised. Governments and third party payers began, and continue to seek ways of ensuring that health care dollars are spent effectively. This scrutiny has had profound effects on the way health services are organised and delivered.

The pharmaceutical industry has not escaped the spectre of cost containment. As the 1980s progressed, the growth of managed care began to affect pharmaceutical demand: insurers were no longer willing to pay top dollar for drugs without proof of therapeutic and cost effectiveness. The recent explosion of pharmaco-economic research, which applies economic tools to analyse pharmacotherapies, is testimony to the continued cost-cutting efforts of benefit providers. Governments, hospitals and American HMOs have also been able to exert powerful demand side pressures to curtail the expense of drug therapies through mergers and buyer groups. During the evolution of managed care, a specialised industry of pharmaceutical benefits managers (PBMs) developed to help American HMOs manage their pharmaceutical costs. These influential companies use purchasing might and information finesse to achieve phenomenal savings for HMOs. The growth of PBMs in the U.S. has promoted the growth of American generic drug manufacturers while putting the squeeze on branded manufacturers profit margins. PBMs' formula for cost cutting success in the U.S. will soon be copied elsewhere, and eventually will take some form in Canada.

In sharp contrast to the current situation, pharmaceutical manufacturers had it made in the 1980s. Innovative new products were coming down the research and development pipeline; more

consumers than ever had some form of prescription drug insurance; demand grew steadily; and profits were high. Organisations that thrived in this era were not infallible. For example, few pharmaceutical companies were left with much more than a bad taste in their mouths after venturing into the cosmetics industry with minimal consumer product marketing knowledge. Mistakes of this nature may have cost the companies, but they occurred, perhaps, at a time when the pharmaceutical industry could afford it.

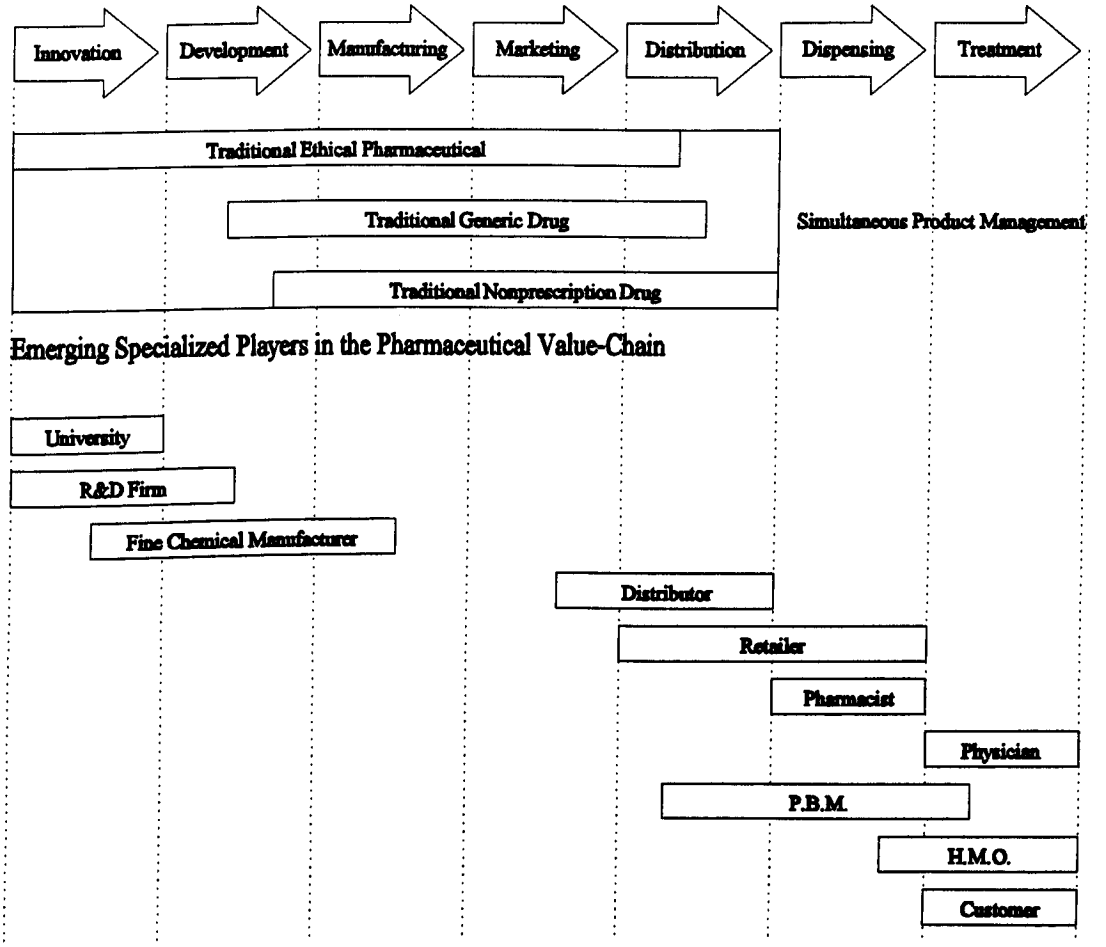
Today, with profit margins under pressure, the risks of poor management are far greater. For example, heavy investment in me-too product development instead of commitment to long-term growth through innovative research is now believed to be taking its toll on some firms in the industry. The management of a product from inception through to delivery is now, more than ever, critical for the success of branded multinational pharmaceutical companies. These firms need not only to manage a product along a value chain, but also to manage it across categories. Within the context of the value chain model, companies must manage branded prescription, generic, and OTC-switch versions of their innovative drugs; each version evolves along a value chain with emphasis on different areas. A company will now strive to control more of the value chain for a new prescription drug, by way of vertical integration from research to retail; it will also integrate horizontally, simultaneously managing generic and OTC versions of its product, by forming relationships with experienced companies in these categories.

The pharmaceutical value chain may be used to understand the ways in which pharmaceutical companies are evolving and specialising in the industry. Figure 5.1 shows the way firms relate along and across the value-chain.

Survival techniques for the brands have already been heavily employed. Multinational branded manufacturers can, and will continue to, push for OTC status because the majority of OTC customers buy products based on brand names, rather than ingredients. As brand names enjoy lifetime copyright protection, the profit erosion of a well managed switch can be much slower than a prescription equivalent. The prescription drug market is susceptible to erosion when low-cost generic manufacturers seize market share post patent expiry. Providers of prescription drug benefits ensure that upon entry of a generic competitor, only the lowest cost drug is supplied. The OTC switch is also promoted by governments and insurers who view self-medication as a less costly way of treating minor illnesses, particularly when OTC versions of popular medications are delisted from their coverage formularies.

From the perspective of the value chain, switches involve the simultaneous development of a second product. This product will require less investment in the early research stages, but will require expertise in the sales stages and increased communication with the ultimate consumer. The prescription drug manufacturer can facilitate this transition by developing relationships with companies who have expertise in consumer products. Unlike the experience with cosmetics, few pharmaceutical companies are venturing into the OTC realm without hiring marketing savvy. For those companies already endowed with experienced consumer product divisions, the increase in

Figure 5.1 The Evolving Pharmaceutical Value-Chain



switch related products is driving internal restructuring. Traditionally, consumer products and pharmaceutical divisions of multinational companies have been distinct entities. These divisions are now being brought closer together in many firms; in some cases they will be merged into a single organization. Advantages from the coordination of the consumer products and pharmaceutical divisions include synergies in distribution and sales calls; reduced costs in areas such as finance, regulation and administration; and integration of product design, manufacturing and market research for the Rx and OTC versions of the drug.

Cost containment measures are also influencing the generic segment of the industry. Canada has a long history of encouraging generic competition as a means of reducing the cost of prescription medicines. The 1969 amendments to the compulsory licensing provision of the

Canadian patent act precipitated the growth of the Canadian industry. Since then, the generic drug industry has grown substantially in Canada. Growth in the American generic drug industry was slow until the introduction of the Waxman Hatch Act of 1984. This act substantially lessened the regulatory requirements for generic drug approval. Generic profitability in both countries depends heavily on the speed with which manufacturers can get their products on the market following patent expiry.

Mandatory substitution rules put in place by provincial governments and third-party insurers have also facilitated the growth of the generic drug industry in Canada. As a result of the historically favourable regulatory climate, Canadian generic drug manufacturers built a reputation for quality and production efficiency. The two leading companies in the industry boast massive sales, domestically and internationally, and among the broadest spectrums of products offered by drug manufacturers worldwide. Currently, however, growth of generic manufacturers in Canada has been stifled by Bill C-91. Although patent protection is something that Canada is obligated to provide, the regulatory amendments and export restrictions in Bill C-91 are believed to be "nightmarish". Without reconciling these portions of the bill, Canadian generics will export production, research and profits - a trend, as several companies have stated, which has already begun.

Production efficiency continues to play a major role in the delivery of generic products to the post C-91 domestic market. This is because generic manufacturers deliver value by being the lowest cost supplier to their customers. Domestic companies must also invest heavily in the development and distribution stages of the value chain. For domestic generic firms to grow, it is important for develop many generic products. By building a broad spectrum of products, generics better serve their customers, the pharmacies. Establishing relationships with pharmacies and serving them with the range of products they need is critical for the growth of generic manufacturers in Canada.

The largest Canadian generics have already tapped into the growing multi-source markets worldwide. For the large, established firms, exporting product is one of the few remaining areas of growth potential. Another such area is innovation. The major players have accumulated enough mass to begin the expensive search for innovative products, something that has traditionally been the domain of branded multinational firms. Finally, generic drug manufacturers can secure sales by licensing-in the production of products for branded firms. These controversial relationships between independent generics and branded firms are expected to continue as branded firms license out the production of their branded-generics. Even branded firms are now producing generic products for other branded firms within Canada.

The American market for multi-source drugs has also grown substantially. In the U.S., the generic industry grew rapidly in the early 1990s due, in part, to the efforts of PBMs. PBMs' use of mandatory substitution and counter-detailing for their managed formularies ensure that generic drugs are used whenever a multi-source drug is prescribed. As a result of the ongoing

erosion of branded manufacturers market shares, these companies have become major players in the American generic industry, as well as the global multi-source industry. Branded manufacturers have been producing their own generics, or developing generic subsidiaries, to compete with the independent generic manufacturers. It is felt that branded generic manufacturers in the U.S. have helped rebuild the reputation of the generic drugs after the generic drug scandal in the late 1980s. This involvement of branded companies in the generic industry is another example of integration across products, or managing multiple drugs along the value chain.

The blur of pharmaceutical products and integration of pharmaceutical manufacturers is creating a much more integrated pharmaceutical industry. The nature of the value delivery in this industry is increasingly dependent on the ultimate consumer. It is the consumer who has demanded that costs be contained and a greater role in their health care. Companies such as HMOs and PBMs are providing services for consumer that are aimed at increasing the efficiency of the pharmaceutical component of their health care. Manufacturers, recognising the need to attend to the later stages of the value chain, are also becoming more involved with the ultimate consumer as they move towards promoting self-medication. Additionally, pharmaceutical companies are forming relationships with health service providers (e.g., HMOs, PBMs, and hospitals) in order to broaden their role in the pharmaceutical value chain and, thus, increase profitability.

Trends in the pharmaceutical industry are global in nature. The evolving pharmaceutical industry is no longer bound by geographical borders. While the scale of the industry in Canada is relatively small, there is enormous potential for growth by Canadian firms in the globalized marketplace of the 1990s. For generic drug manufacturers, regulations need to be improved for Canadian production to be exported - thus enhancing job opportunities within Canada and domestic growth of Canadian firms. Similarly, improved regulations should foster increased growth of the nonprescription segment as the trend to Rx-to-OTC switches continues and the provincial and federal governments more closer towards harmonising retail-centred regulations.

To summarise, firms in both segments of the Canadian industry will continue to operate based in an increasingly global environments. As industry representatives all agreed, there will be continued consolidation and integration which will force some firms out of business. Rationalisation will also mean reductions in the scale of activities in Canada vis-a-vis the United States, and will contribute to a sharper, more detailed focus on certain market segments. Some of the smaller firms, such as Genpharm and Buckley, will continue to benefit from niche market specialisation while others, such as Apotex and Novopharm, will continue to expand globally with an already diverse product line. Central to success in the Canadian context, however, irrespective of head office strategy is the role of regulation.

Finally, there are several issues that have emerged from this study that require closer examination. It has been beyond the scope of this report to answer these questions but they are critical if we are to fully understand the competitive issues impacting on firms in the industry. These include the following:

1) What is the impact of the mosaic of regulatory requirements in the retail environments across the country (e.g. marketing and scheduling regulations) ?

2) What is the impact of the regulatory approval process on corporate competitiveness? Will the move towards a cost recovery approval process lead to greater efficiencies?

3) What are the implications of increasing levels of rationalization by global pharmaceutical firms on the Canadian pharmaceutical industry?

4) How will managed care impact on the competitive structure of the pharmaceutical industry in Canada?

5) How will provincial drug plans evolve in light of the transformations in health care and what will be the impact of this on the Canadian pharmaceutical industry?

6) Given that consumers are the ultimate end-users of pharmaceuticals how will their perception, education and awareness affect the market structure for generic and OTC drugs?

APPENDIX A GLOSSARY OF TERMS

Abbreviated New Drug Application (ANDA) ANDAs are used to gain approval to manufacture a copy of an existing *dosage form* by proving pharmacological -equivalency and/or bio-equivalency with the original drug known as the Canadian Reference Product.

Behind-the-Counter Drug (BTC) Behind-the-counter (BTC) drugs, or pharmacist-monitored nonprescription drugs, are available for sale without a prescription under the condition that they be sold only by a pharmacist who is physically present at the point of sale. Moreover, the product must be stored in an area where there is no opportunity for self selection (e.g. the dispensary).

Branded Drug Manufacturer A branded drug manufacturer is a company that produces and markets *branded drugs*. Branded drug manufacturers are usually international companies that have the requisite capital to sustain large scale marketing efforts. These companies were traditionally known as *R&D-based firms*.

Branded Drugs Branded drugs are drugs marketed under names other than the proper name of the drug. Branded products are supported by large-scale consumer direct marketing in the case of *nonprescription drugs*, or physician and pharmacist direct marketing in the case of prescription drugs.

Branded Generic Drug Manufacturer This is a term used to describe *generic drug manufacturers* that are partly or wholly owned by branded manufacturers.

Dosage Form The dosage form of a drug is that which is marketed for sale to the consumer/physician/pharmacist. Dosage form describes the level of active and inactive ingredients combined in a tablet, capsule, liquid, injectable, spray, cream, ointment, etc.

Drug As stated in the Food and Drugs Act, Glossary of Terms (Feb 1990), a drug includes any substance or mixture of substances manufactured, sold or represented for use in: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof, in man or animal; (b) restoring, correcting or modifying organic functions in man or animal; or (c) disinfection in premises in which food is prepared or kept. For the purposes of this report, the term drug will refer to points (a) and (b) for human use only.

Drug Identification Number (DIN) A drug identification number (DIN) identifies the status of a drug. All nonprescription drugs must be approved by the Bureau of Nonprescription Drugs and are assigned an 8 digit number preceded by DIN or GP (*general public*). Products designated with DIN are available for sale through pharmacies only.

Ethical Drug A product (usually prescription drug, but occasionally nonprescription) which is advertised only to health professionals, not to the general public.

Fighting Brand Fighting brands are generic drugs manufactured by an *innovating firm* from within its own facility, or under license with its *branded generic* company. A fighting brand is positioned to compete with other generics in order to capture the price-sensitive segment of market. A fighting brand is often released into the market prior to the expiry of the innovator's patent - a tactic that is under review by U.S. and Canadian regulators.

Fine Chemical Fine chemical usually refers to active ingredients. These are the ingredients that are combined with non-medical ingredients to make the *dosage form*.

General Public (GP) General public (GP) is an approval status of a drug. All nonprescription drugs must be approved by the Bureau of Nonprescription Drugs and are assigned an 8 digit number preceded by DIN (*drug identification number*) or GP (general public). A drug approved for the general public is designated with GP and is available for sale in all retail outlets.

Generic Drug Manufacturer A generic drug manufacturer sells copies of other drugs. Generic drug manufacturers do not invest heavily in consumer-direct or physician-direct marketing, thus enabling them to compete by serving as the lowest-cost provider in *multi-source drug* categories. Traditionally, these were considered non-R&D based firms. In Canada, however, generic drug manufacturers conduct varying amounts of *dosage form*, delivery system, and process-based R&D.

Generic Drug By definition, generic drugs can only compete in *multi-source drug* categories, as they are copies of existing *dosage forms*. From a packaging perspective, a generic drug is a copy of another drug packaged under the *proper name* of the drug, without consumer direct marketing. From a regulatory perspective, a generic drug is any drug which receives its Notice of Compliance (NOC) based on an *Abbreviated New Drug Application (ANDA)*, including identical *branded drugs*, generics, and *house brands*.

House-Brand House brands are *generic drugs* marketed by large retailers under a house name. These products are common *nonprescription drugs* labelled according to therapeutic class (as opposed to proper names). For example, "Life" is Shopper's Drug Mart's house brand; "Life-Allergy" is their allergy medicine containing Terfenadine - also found in branded allergy products.

Innovating Firm The firm that discovers a drug is called the innovating firm. Innovating firms almost always market their drug under a brand name.

Line Extensions A line extension is an addition of a new *dosage form* to be sold under a brand name. Line extensions are usually modified dosage forms of existing medications (e.g. Claritin Extra Strength versus Claritin Regular Strength), or combinations of active ingredients to add new "actions" to a medicine (e.g. DM cough syrup versus the regular form). There are increasing numbers of line extensions that have little similarity to the original product by which the line is branded (e.g., Tylenol Allergy versus Tylenol - pain relief).

Me Too Drug A "me too" drug is a product that is nearly identical to an existing drug on the market. Me too drugs are "discovered" by testing the pharmacological properties of minor variations of the original molecule then patenting the "new chemical entity". This form of research is common among branded firms as well as generics because it is an effective way of getting around an existing patents, while marketing the drug based on the (minor) differences in pharmacological profiles.

Multi-Source Drug A multi-source drug is a *drug* that is marketed by more than one manufacturer. Or, in the case of *fighting brands*, where a manufacturer sells differently packaged versions of the same drug.

Nonprescription Drug A nonprescription drug is available for sale without a prescription (or renewal of a prescription) from a doctor. Nonprescription drugs may be designated for sale in pharmacies only, or in general retail and convenience locations. The in-store location of nonprescription drugs designated "pharmacy only" is determined by provincial pharmacy practice regulations. For example, pharmacy only nonprescription drugs may be designated *over-the-counter* or *behind-the-counter* (pharmacist monitored) classes.

Off/Non Patent Drug Drugs for which there is no patent, most likely due to patent expiration. Off-patent drugs may be manufactured and sold by branded and generic companies. The most common usage of this term is to describe the expiry of a drug's patent. For example, Seldane came off patent in 1994 when Marion Merrell Dow's patent on Terfenadine (the active ingredient) expired. Thus, Contact Allergy and Life Allergy, both of which were manufactured with Terfenadine under license with MMD since 1991, also came off patent in 1994.

Over-the-Counter (OTC) Drug OTC drugs are *nonprescription drugs* available in an area of the pharmacy (*DIN* and *GP*) or other retail outlets (GP only) where there is opportunity for self-selection.

Patented Medicine Patented medicines are drugs for which there is an active patent. Patented medicines may only be sold by, or under license with, the patent holding firm.

Private Label Private label products are produced for retailers and are marketed under the retail name, or a name that is exclusive to that particular retailer. These are common nonprescription drugs known also as *house brands* (for example, Shoppers Drug Mart's Life Brand).

Proper Name The proper name of a drug is sometimes called its generic name. Drugs often have three names; the scientific name of the active ingredient, a proper name, which is a less scientific name for the active ingredient, and a brand name assigned to the *dosage form* product by manufacturers. The proper name for a drug makes it easier for manufacturers to market to physicians. For example, *fluticasone propionate*, the proper name of Glaxo's Flonase corticosteroid nasal spray, may seem complicated, but it is a great simplification of its chemical name: *s-fluoromythyl 6alpha,9alpha-difluoro-11beta-hydroxy-16alpha-methyl-3-oxo-17alpha-propiony-loxyandrosta-1,4-diene-17beta-carbonate.* Drug names can create a great deal of confusion, particularly in the over-the-counter market. The problem arises at the brand name level. The proper name, which always represents the same molecule, may be sold under different brand names, or generically. For example, in 1991 Marion Merrell Dow licensed the use of Terfenadine (an antihistamine) to SmithKline Beecham. As a result, consumers could choose between identical drugs packaged under different brands -Seldane (MMD) or Contact Allergy (SB). Consumers who take the time to read the proper name on the drug (manufacturers are required to print the proper name of the drug on labels), would discover that the two products are identical.

Pseudo-Generic Pseudo-generic is closely related to the term *branded generic*. Pseudo-generic is most often referred to individual products produced by *branded generic companies*, and may be used to refer to a generic product produced by the brand name company within its manufacturing facility. Pseudo-generic is also used by some Canadian commentators to mean *fighting-brand.*

R&D Based Firms (Traditional) Traditionally, "R&D based firm" was a term used to describe *branded drug manufacturers* - the multinational firms whose research produced innovative prescription medicines. The distinction between R&D efforts of branded drug manufacturers and *generic drug manufacturers* is beginning to blur.

Single-source Drug A single-source drug is a drug which is sold by only one manufacturer - usually the innovating firm. Most newly approved novel drugs are single source drugs until patent expiry, or entry of a licensed competitor.

APPENDIX B
CORPORATE STRUCTURE AND STRATEGY: SELECTED CASES

- **Johnson and Johnson**

Johnson and Johnson is the world's largest diversified health company with a 3-way split between consumer health, pharmaceuticals and professional products It has five decentralized subsidiaries in the U.S. (McNeil, Advanced Care Products, J&J Consumer Products, Personal Products and J&J/Merck). Most core OTC products are handled by McNeil (UPDATE U.S.A.,06,93:177). Through a strategy of collaboration and acquisition J&J has established a presence in virtually every OTC market. Its prospect for future growth is bright given its pipeline of potential switch products, its international expansion and the ongoing collaboration with Merck. The cooperative venture itself purchased the French firm Laboratoires JeanPaul Martin as part of a strategy to expand further into the European self-medication market (UPDATE U.S.A.,10,94:309).

- **American Home Products**

Despite a presence in virtually all the major OTC markets, AHP is not regarded as an innovative OTC company. Although it has a number of switch candidates (e.g the NSAID Orudis, and the topical analgesic ingredient, Felbinac), analysts consider that the recent takeover of American Cyanamid will impact on AHP's OTC operations. Some analysts suggest that as many as 10,000 jobs could be cut from AHP and it remains to be seen just how this will affect the nature and extent of its OTC product lines (UPDATE U.S.A.,11,94:341).

- **SmithKline Beecham**

SmithKline Beecham is merging its non-European and non-North American consumer and pharmaceutical operations under one structure - SKB Healthcare International. The other divisions will still maintain their separate Rx and OTC operations. SKB has created "category management teams" to bring a global approach to OTC product groups. The focus is on GI, upper respiratory tract, oral care, dermatology and nutritional drinks. In a similar fashion to Schering with its Liberty Consumer Group, SKB formed the "Three Rivers Group" to take responsibility for mature products that are small or mid-size brands. The emphasis is to ensure these brands maintain their name recognition and market presence. SKB is also looking at expanding sales through a number of switches such as with Tagamet, Nicorette and Nicoderm, Bactroban topical antibiotic, and the anti-arthritic NSAID Relafen. The company is also working with its recently purchased Diversified Pharmaceutical Sciences to examine the cost-effectiveness of Rx to OTC switches. (UPDATE U.S.A., 05,94:135). Although it is based in the UK, almost

60% of SmithKline Beecham's OTC sales are based in the U.S. SKB's joint venture with Marion Merrell Dow in 1992 is expected to increase its market position even further.

- **Procter and Gamble**

Procter and Gamble is the largest manufacturer of household and personal care products in the U.S. It enhanced its position in the OTC segment of the industry in 1985 through acquiring Richardson-Vicks and the OTC product lines of G.D. Searle. In 1990 it attempted to align with Rhone-Poulenc Rorer but was refused permission to do so for antitrust reasons relating to the antacid market segment.

- **Warner-Lambert - Warner-Wellcome**

Warner-Lambert has three strategies for the OTC market: to increase consumer interest in brands through improving products and extending product delivery; to improve retail distribution and merchandising; and to exploit the global market potential of certain brands. Chairman and CEO of W-L states "....Only brand equity can win in a parity game dominated by pricing issues. Our goal is to continue to make our focus, to put resources into developing a single dominant brand, rather than to squander the company name and identification .... we select target markets and carefully cultivate them - cultivate them as if the company's life depended on it". Its recent alliances with Glaxo and Wellcome could achieve up to U.S.$200 million in the first year of sales when the Zantac and Zovirax switches go through (Scrip, 03,08,93:9; 06,08,93:10) (UPDATE U.S.A.,06,94:169).

- **Bristol-Myers Squibb**

Due to a lack of leading market brands and a large number of "second tier" products which are in very competitive markets, Bristol-Myers Squibb is seeking to expand its geographic reach. BMS has strong presence in Japan (with Bufferin - analgesic), and in France. It has also acquired the Italian company Labratori Guieu which gives it excellent distribution network in Italy and southern Europe. BMS also sees a competitive advantage potential with the effervescent technology provided by Upsa (the French firm recently acquired by BMS as part of its global expansion strategy), and plans to use this technology with other OTC applications once perfected. The company's weakness, however, is a lack of critical mass outside of the U.S., its dependency on analgesics, and few promising Rx-to-OTC switches in the pipeline. Fortuntately BMS has been adept at adding line extensions just when certain products appear vulnerable. Analysts question, however, how long this strategy can last (UPDATE U.S.A., 12,93:385; UPDATE U.S.A.,11,94:371).

- **Schering**

With increased price pressures in U.S. market, Schering sees international growth as the key to maintaining profitability along the value chain. Its strategy as of 1992, for example, was to target key markets (Canada, France, Germany, Italy, Spain and the U.K.). International business now accounts for almost 55% of total sales - up from 41% in 1991. The OTC business beyond the U.S., however, is very limited with the exception of Canada where it has had a successful subsidiary for a number of years. In the U.S. Schering is known for its expertise in taking products beyond drug stores and into food and mass merchandiser outlets, and for its experience with successful Rx-to-OTC switches.

Schering has used its Liberty Consumer Group to take over the sales and marketing for 16 older OTC products (i.e. essentially a division looking after under-profitable brands). A network of brokers was established with the idea of re-introducing these brand-name products with retailers. This is a strategy that other companies (e.g. SKB) are looking into (UPDATE U.S.A.,11,93:349).

- **Ciba**

Ciba has been undergoing "consistent and systematic restructuring" (1992 annual report) since 1990. Ciba expects to take advantage especially of its OROS osmotic technology in the OTC market. OROS delivers orally-administered drugs at a controlled rate, and is designed to minimize side effects, increase efficacy and reduce the frequency of dosing. Ciba expects to continue with a program of U.S. acquisitions, but will supplement these with collaborative inter-firm relationships (UPDATE A,07, 93:215).

Ciba's Consumer Pharmaceuticals group has expanded its OTC markets mainly through a series of acquisitions over the past 10 years. Ciba expanded in the U.S. through its acquisition of Fisons' OTC business. This had the effect of increasing sales in the U.S.by over 40%, and now the U.S. accounts for over half of Ciba's OTC sales. Its explicit strategy has been to focus on specialized market niches within the segment, which, it hopes, will lead the company to be one of the top 5 OTC players globally.

- **Other leading companies**

Few pharmaceutical companies are not looking at the OTC market for expansion. **Upjohn**, for example, although not a major player, plans to develop a dedicated OTC marketing operation in Europe within the next few years, most likely through some form of collaborative relationship. In the meantime, however, it is seen as an attractive acquisition target for some of the larger OTC players. **Hoffmann La Roche** established a new OTC division in 1992 and this has become a leading supplier of OTC products in Europe and Australasia.

Several other companies are considered somewhat slow in directing attention to the OTC. Glaxo, for example, asides from the W-L relationship, has done little to move into the OTC market. This can be explained partially by the uncertainty surrounding Glaxo's direction given the impending loss of sales when Zantac comes off-patent and the recent acquisition of Wellcome. At the moment, therefore, Glaxo's presence in the OTC world is still on hold.

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