

Adaptive strategies in the Indian Pharmaceutical Industry

T.R. Madanmohan^{*} and R.T. Krishnan^{}**

*** Asst. Professor (Technology & Operations)
Indian Institute of Management Bangalore**

**** Asst. Professor (Corporate Strategy)
Indian Institute of Management Bangalore
Bannerghatta Road, Bangalore.
560 076**

The authors sincerely acknowledge the comments and insights offered by senior managers of various units. Specifically, we are indebted to Dr. D.B.A. Anantha Narayana, Dabur Research Foundation; Dr. B.B. Lohray, Dr. Reddy's Research Foundation; Anil Agrawal, Indian Herbs, and Gopalakrishnan, formerly German Remedies Ltd for their critical inputs on the R & D strategies. Special thanks are also to Prof. A.V. Rama Rao, former Director Indian Institute of Chemical Technology (IICT), Hyderabad, Dr. J.S. Yadav, Deputy Director, IICT; Dr. B.S. Srivatsava, Central Drug Research Institute (CDRI), Lucknow; Dr.O.P. Asthana, CDRI, Lucknow, and Dr.G.S. Nataraj, Bangalore Medical College, Bangalore for their deliberations on developments in the organic compounds and clinical trials in the Indian pharmaceutical industry. This study has been supported by Indian Institute of Management Bangalore vide faculty development fund project no.52 10 53. The usual disclaimer stands.

* corresponding author

Introduction

How do firms react when an industry faces increased competitive pressures due to trade liberalisation? Firms are believed to bring about changes in their technology, marketing and organisation by reorganisation and redeployment of resources, often through exit process (Buffie and Spiller 1986, Ross 1988). Pavitt's (1990) analysis of technological opportunity and innovations, Ettlie and Bridges's (1982) analysis of environmental uncertainty and its impact on technological performance seem to support this. Many research results have observed that environment can affect firms' strategies (Jemison 1981, McArthur and Nystrom 1991), and under conditions of increased uncertainty firms employ innovative strategies (Paine and Anderson 1977). However, evaluations are not so clear in a science-based industry such as Pharmaceuticals, especially if it is an oligopolistic domestic industry and imports are only imperfect substitutes for local production. Innovations are endogenous to the science-based industries and the firms have high technological options: one of diversifying into horizontal related products or altering the basic technological platforms themselves (Pavitt, 1990). This paper looks at adaptive behaviour of the Indian pharmaceutical firms during the period of trade liberalisation.

Such a study is timely. A number of developing countries had begun to dismantle trade barriers and several free trade agreements are being implemented. Over the seven years that have followed the initiation of major economic reforms in June 1991, the Indian economy has undergone a remarkable transition. For the pharmaceutical industry, it began with dispensing of industry licenses for the drugs and pharmaceutical industry, except in some limited sectors reserved for the public sector. Similarly, relaxing of the norms for foreign equity participation and collaboration have changed the environmental context of the industry. The most important change however came in the form of signing up of the GATT agreement by India. This entails fundamental and far reaching changes in the Indian Patents Act, 1970. First-important change likely to come into being is recognition of product patents as against only the process patent. The second important proposed change has been increasing of the life of the patent from existing 7 years to 20 years. The challenge before the industry is to make a transition from era of protectionism to an era of global competition. Innovation activity in these industrial sectors is endogenous and product innovations from this sector enter a wide range of sectors as capital and intermediate inputs. For example, a new fermentation process may not only affect the basic industries but could also be a useful process innovation at formulation end. As the year 2005, the deadline for the product patents regime to come operational approaches, industry's mission to enhance the growth bears a tremendous and yet unexplored potential. This study is an attempt to understand how a science based industry such as pharmaceuticals responds to these environmental changes.

In the following section, we trace factors contributing to the turbulent environment in the 90's. In the next section, potential development perspectives as currently provided by the theoretical discussion on organisational adaptation to change are presented. In the last section, the route of adaptation currently being pursued by the firms is presented and the results are highlighted.

Indian Pharmaceutical Industry: changing facets of competition.

The Indian pharmaceutical industry is nearly a century old. Indigenous production of allopathic drugs started in 1901 with the establishment of Bengal Chemical and Pharmaceutical Works by Prof. P.C. Ray. From a mere 800 formulators and 125 bulk drug firms two-and-a-half decades ago, the industry has grown to over 15,000 formulators and 600 bulk drug manufacturers in 1990. In 1995-96, the total number of units in the country was estimated at over 23,000, of which more than 95 per cent were with a turnover of less than \$ 5 million. Table 1 and 2 present the product market and major segments of the sector.

In the Second Plan (1955-60) the pharmaceutical industry was placed under the government's control on sale prices of drugs in 1962, when it became obligatory for the manufacturers to publish the production prices and for traders to display them. This was followed by Drugs (Control of prices) Order that pegged the prices of drugs at the levels prevailing as on 1st April 1963. Two significant developments in 1970's: the Drug Price Control Order (DPCO) and adoption of Patents bill in 1970 were significant in terms of impact and shaping of the industry. The DPCO had three main elements: a) prices of bulk drugs were controlled, b) prices of selected formulations were controlled and c) for the first time, a ceiling on overall profit on molecular level was introduced.

The patent bill (which replaced the original act, Patents Designs Act 1911), made several changes that affecting R & D and investments in this sector. The main were: a) patent protection limited to the process of manufacture only, and b) patent expiry term limited to 5 years from the date of sealing of the patent or seven years from the date of filling of the complete specifications, whichever period was shorter. The emphasis on process patents had given a definite policy push so that many Indian firms could exploit the development of a known compound (without incurring the cost of identification and standardisation of the molecule). Table 3 lists some of the key molecules manufactured. While the process patent did offer the intended effect of reduced entry barrier, it also had an unintended effect of proliferation of drugs. While Pharmacology has provisions for only a maximum of 500, a recent estimate puts the number of medicines in the Indian market at over 60,000 (CFA, 1997). The therapeutic equivalents command larger market share than the patented molecules as shown in Table 4.

In a reducing cost industry (at molecular level), fragmented prices have started hurting the industry profits. Ciprofloxacin, used in the treatment of typhoid, has seen its prices come down steeply mainly because of increase in the number of players in the field, with less than six per cent nearer to minimum efficient scale. With the result, firms are witnessing volume growth, especially if the drug happens to be DPCO controlled. Table 5 lists DPCO controlled drugs selling below the announced price.

Reduced demands either due to more potent or cost effective drugs has been another threat confronting the industry. For example, Ampicillin, which has been showing a negative growth rate, has virtually no market in the developed countries and developing countries are using it to a limited extent. Over the last three years (1993-96), the growth

of Ampicillin has dropped by 7.9% and its market share has fallen to 1.4% from 3.2% in the antibiotic segment. With a large international base and declining prices, imports have become cheaper. Increasing MES and competition have reduced the margins and thus increasing the exit rates (Madanmohan, 1997). Lupin and Gujarat Themis Biotech are the two main manufacturers of Rifampicin and Ethambutol, with global scale plants. Around 50% the world capacity for this drug is expected to be in India while 25% will be in China. Unchecked dumping of bulk drugs, especially from China has been hurting the industry. More than 30 bulk drug-manufacturing units in Southern State of Karnataka have closed down during 1993-1995 due to unchecked dumping of bulk drugs. The other development, that has far reaching importance, was the government decision to sign GATT agreement on intellectual property, paving way for the introduction of the product patents for Pharmaceuticals. By doing so, India joined other nations of World Trade Organisation in committing itself to strengthening and protecting IPR. It is under obligations to amend Indian Patent Act 1970 to provide for product patents for food, drugs and chemicals. Indian pharmaceutical companies are recognising the need for R&D to survive in post 2005, when product patent are expected to come into force.

New Drug Policy

The first Drug Price Control Order (DPCO) was announced by the government in May '70. This was followed by DPCO, 1979, which was later revised as DPCO, 1987. Restrictive conditions in the licensing (such as a fixed ratio between quantity of bulk drug and formulation that could be produced, and the mandatory supply to other manufacturing units with a percentage of bulk drug produced) were abolished. Changes were also made on the price control policy. DPCO, 1995, specifies that drugs which have an annual turnover of over RS. Four Crores and a total of five bulk manufacturers and 10 formulators should be kept away from price control, provided no single produced has more than 40% market share. To avoid a monopoly situation, the policy also lays down that a drug with sales of RS. One core or more would come under price control if a single formulator has more than 90% market share. Formulators are provided a mark-up-dubbed Maximum Allowable Post-manufacturing Expenses (MAPE) - of 100% over the ex-factory price of the bulk drug. DPCO, 1995, came into effect on 6 January '95. The main features of this order are as follows:

- * the number of drugs under price control has been reduced from 145 to 76
- * span of control for a price-controlled drug has been reduced from 70% to 50%
- * the government has set a time limit for clearing applications made for price revision
- * the government has announced a 4% higher rate of return for bulk drugs produced from the basic stage - 18% on net worth (from 14% earlier) or, alternatively, 26% on capital employed (from 22% earlier)

* industrial licensing has been abolished, except for five drugs which are reserved for Public Sector Units- Vitamin B1 and B2, folic acid, tetracycline and oxytetracycline.

A new regulatory pricing body, the National Pharmaceutical Pricing Authority (NPPA) has been created to oversee drug-pricing functions. This body constituting of members both from industry and the government started functioning from 1 September 1997. The NPPA is expected to adopt the single window scheme for price fixation and revision.

How the Indian pharmaceutical industry is responding

Theoretically, there is a spectrum of perspectives on the ability of the firm to transform itself in response to environmental challenges. The resource-based perspective (Penrose, 1959; Teece, 1982) proposes a primal-dual relationship between firm resources obtained from factors markets and product markets. Firms are supposed to accumulate the required resources and then exploit them in product markets to generate more revenue. The non-linearity and imperfections built into the market for the firm's productive resources determine when these resources can only be obtained as a bundle through acquisition rather than through efficient markets for individual assets (Capron et al., 1995). This diversification-oriented integration strategy may often be to exploit economies born from marketing or technological concentricity (Kay, 1982; Richardson, 1972). In case of science based industry such as pharmaceuticals, the joint exploitation of activities utilising connected knowledge assets (say between an organic and inorganic drug route for a particular disease) offers economies of scope. This diversification may be at the segment level or technology routine, or both. The segment diversification in pharmaceutical sector may involve positioning a low-cost low-price solution in place of a high-cost high-performance treatment/dosage. Technological routine here refers to the habituated form of activities in a firm (including learning). Nelson and Winter (1982) suggest these routines are quite stable over time, thus emphasising stickiness of strategic resources, in that they are intertwined within the firm and are accumulated as a result of path-dependent actions.

Meyer and Roberts (1988) state that a firm's ability to recognise and nurture the technologies (knowledge) required in the evolving of designs of its product families is an important aspect of managing technological innovation in the firm. The technological basis is the product 'platform', which defines the core technological strengths, from which derivatives or follow-on-products may be efficiently generated. Product platforms are renewed and reinvigorated to develop successive products. In case of a pharmaceutical firm, the product platform can be at many levels. For example, an aggregated classification may be the firm as organic or inorganic molecule pursuer for a specific disease. Alternatively, it may also be a specific technological route within this broad classification, for example Organo-metallic or Carbohydrates. Knowledge domain strategy is ideal when the local search process builds on previous knowledge that can be transferred to new fields, and the transfer of learning across platforms is not costly, and, there are too many technological options available for exploration (Kim and Kogut, 1996).

Another strategy available to firms is to increase profitability through integration (Scherer and Ross, 1990). The value creating drivers in such a strategy include increase in efficiency (scale and scope economies, and transfer of resources) and market power (Stigler, 1964; Capron et al., 1995). Plant-level and multi-plant economies follow from the disposition and rationalisation of redundant assets; attainment of minimum efficient scale, the use of more specialised or cost effective technologies, and spreading of the fixed cost over a large sales volume. These acquisitions considered as a strategy to enhance control through the value chain allow the firms to respond to non-desired developments or changes that evolve outside the realm of the industry. While attending economies of scale can be a relevant consideration, expanding firms scope of actual and potential products in the market are added criteria.

In pharmaceutical sector integration aimed at achieving economies of scale and scope at manufacturing and marketing end are attained by gaining control of value-chain, or multi-media (multi-segment) applications of the molecule. The value-chain strategies involve capacity addition, brand acquisition, vertical integration and logistical integration. Given that the per capita consumption of drugs in India is just US \$ three per head (the lowest in the world), while Japan, Germany, the US, UK and Canada spend from US \$ 100 to 400 per head the demand side integration strategies look promising. The vertical integration in the industry can be at intermediates level, marketing channels or R & D. The multi-media strategy involves spread from say intra-muscular (IM) to intravenous (IV) or low end-potency to high-end potency.

Vertical Integration, Capacity additions and acquisitions strategy

Integration and capacity addition in Indian pharmaceutical industry has been driven by considerations of 1) transaction cost, 2) economies of scale or 3) economies of scope at marketing or manufacturing end. Acquisitions in the industry have been motivated by considerations of 1) exploiting complementary nature of product segments or R & D, and 2) broad basing product technology. The former is more evident in firms with dominant market share in at least one product form, say tablets.

Ranbaxy bought a 30% stake in Vorin labs thereby gaining control over a key supplier of the raw materials and intermediates for Ciprofloxacin, one of its key products. The major advantage of the backward integration would be evident once the patent on Ciprofloxacin expires in 2001 (Ghangurde 1996). Ranbaxy also acquired control of Crosslands Research Laboratories Ltd, a specialist firm in dermatological products. This acquisition conjures an enviable position of market leadership with 5.2 per cent in domestic formulations market to Ranbaxy (Business Line, 1997a).

Wockhardt took over the RS. Six crores Chennai-based intravenous fluid manufacturer R R Medi Pharma. Wockhardt's take-over of R R Medi Pharma helps the Mumbai-based Company to reduce the cost of transporting the bulky intravenous fluid to the southern parts of the country (Economic Times, 1995). It recently acquired Merind from Tata's, a major player in animal health business especially animal vaccines. This acquisition is

expected to allow easy spread of its biotechnology R & D costs over both human and animal vaccine markets.

By acquiring Boehringer in October 1996, Piramal gained access to the multinational's expertise in the diagnostic segment. The group merged Sumitra Pharma in October 1995 to add large capacities for bulk drug manufacturing (Mukerjea, 1996). Unlike Ranbaxy and Wockhardt, Sun has adopted acquisition route to expand its product portfolio. The acquisition of M J Pharma and Gurajat Lyka has helped it add a new dosage form, injectibles, to its present specialty markets of anti-cancer and psychotropic drugs. Its acquisition of Tamil Nadu Dadha Pharmaceuticals Ltd (TDPL), is expected to offer Sun a ready entry strategy into speciality areas of oncology, gynaecology, and pain management (Business Line, 1997b).

Brand acquisitions strategy

Firms find brand acquisition as an easy way to acquire the market share and probably access to different media applications (say, injectibles and tablets). However, for MNCs and their subsidiaries operating in India it is not so easy. Care has to be taken so as to abide by stringent patent laws prevalent in the nation of its parent. This means they can not target companies that derive major turnover from the patented drugs and hence their choices are largely confined to brand acquisitions of off-patent drugs. Even though brand name drug manufacturers currently account for only about 33 per cent of the generic market and brand acquisitions are a preferred strategy compared to say acquire for the following reasons.

- Buying brands is an easy way to cover more therapeutic segments and increase Disease coverage. For instance, a firm with a popular OTC cough syrup by acquiring Metacin (a popular paracetamol brand) may augment the companies present in general patient care segment. Dr. Reddy's by acquiring Riflux, an antacid, has supplemented its existing range of anti-ulcer products.
- Established brands help companies' side-step brand-building expenses. For example, Ranbaxy's acquisitions of Mox, a Rs.300 crores brand of Amoxycillin drug.
- Brand acquisition is hassle free and does not saddle the firm an excess workforce or other loss-making problems.
- Market share augmentation by 100% subsidiaries of multinationals. Consider the cases of SmithKline Beecham and Parke-Davis. While their parents control about 40% of each firm, they also have wholly owned subsidiaries in India. Brand acquisitions, especially of off patent products, by units in which they have a 40% stake may prove to be successful strategy to gain market share in domestic markets and cheaper sources of bulk drugs for transnational business.

The brand acquisition in Indian Pharmaceutical market was set rolling by Dr Reddys laboratories acquiring the anti-ulcerate brands, Clamp and Raflux, from Sol Pharma.

This trend continued with Ranbaxy picking up the entire range of antibiotic and dermatological brands of Gufic Laboratories (Economic Times, 1997). SmithKline Beecham Pharmaceuticals has acquired Duphar Interfrans money spinning OTC brand Crocin, with annual sales of Rs.30 crore. Piramal by acquiring Nicholas Laboratories (now Nicholas Piramal) in 1988 gained immediate access to established brands such as Analgin and the pain-relieving cream Multigesic. Similarly, it took over Roche Products (now renamed Piramal Healthcare) in 1993 in order to add to its kitty well known brands such as Supradyn and Valium (Mukerjea, 1996).

Marketing channels integration

One another adaptive strategy pharmaceutical firms are pursuing are entering into business relationships to increase market contact. Here the objective is to have access to international markets and technology, and to create critical mass to support R&D and marketing in the future. For this purpose, some of the leading Indian companies have formed alliances with international drug companies, like the Ranbaxy with Eli Lilly, Torrent with Novo Nordisk of Denmark and with Sanofi of France, the Lupin with Merck and Max with Geest Brocades. Some have even set up or acquired generic drug companies abroad.

The drive for internationalisation of Indian Pharmaceutical firms has been triggered by changes in European Patent laws. The \$ 3 billion US generics market, till recently catered to largely by Italian and Spanish companies, is set open after the tightening of European patents laws with the adoption of the Supplementary Protection Certificate (SPC). The SPC dictates that no European producer can make even the small quantities of patented bulk drugs required for US formulators (typically less than 1 tonne) and they have to submit to the authorities in their ANDA (abbreviated new drug application). Companies used to be allowed to produce patented drugs on a small or pilot scale, if only to generate samples for submission. These samples have to be submitted four years before the drugs goes off patent, and so the adoption of the SPC in effect chokes the US new generic market off for European producers. Italy is expected to stop production of these bulk generics by 1998, and Spain by 2002. Europe accounts for 80% of \$ 3 billion US bulk generic sales, and of this Italy used to produce seventy percent. There are only two major independent US producers of bulk generics, Gaines Inc and Wyckoff Chemical Company Inc, and at present, they account for only 1% of US generic sales.

Mumbai-based Rs.55 Crore Pharmaceutical Products of India Ltd (PPIL) have opted for a 50:50 joint venture with Wickoff. Under the terms of the agreements, PPIL is to make advanced intermediates in India, and ship them out to Wyckoff-PPIL in the US, where the finishing will be done at Wyckoff's Michigan unit. Wyckoff is the second largest player in U.S. generic market. The PPIL-Wyckoff tie up is seen as working to the advantage of both parties. While Wyckoff gets access to inexpensive R & D (Indian Ph.D. holder come at one-tenth the price of their US brethren) and production base for bulk drug intermediates, PPIL can break into the US market through Wyckoff which claims to have a well-established clientele including Upjohn and Abbott. Wyckoff and

Gaines hope to take 10% to 15% of the generic market by the end of the century, leaving the rest up for grabs.

Dr. Reddy's which exported generics - ibuprofen bulk and intermediates worth Rs.45 crore to the US in 1996, has an arrangement to supply bulk drugs to Pharmaceutical Resources Inc, a small generics player in the US. A sister company, Cheminor Drugs, holds a 75% stake in a joint venture marketing outfit in the US, Reddy Cheminor Inc. The products that are supplied to PRI will be manufactured by Cheminor which has one 100% export oriented formulations plant and three bulk drugs manufacturing facilities which conform to US current good manufacturing practices (cGMP). Another major Indian player, the Rs.445 crore Lupin Laboratories, has a tie-up with Merck Generics to market its dosage forms abroad (Aiyar, 1997).

Wockhardt, as a part of its globalization drive, has set up manufacturing joint ventures in China and Saudi Arabia. Wockhardt holds 50% equity in Saudi joint venture, Wockhardt Middle East Ltd. Two local partners, Al-Mintakh and MAS between them hold the remainder of the \$ 10 million equity of the company. With its manufacturing site at Riyadh, this venture has given Wockhardt access to the over \$ 1 billion Gulf pharmaceutical market (Deshmukh, 1995). Wockhardt has also acquired world wide exclusive rights from Rhein Biotch GmbH (RBG) of Germany to develop, commercialise and license the latter's human insulin technology through an equal partnership joint venture. The research and development (R&D)-cum-manufacturing venture named Wockhardt Rhein Biopharm (WRB) will share the world wide rights with another company for developing RBG's technology to produce and market Hepatitis-B vaccine. In 1996, it floated a 100% owned subsidiary in the US to produce generic drugs. It is also operating a wholly owned subsidiary, Wockhardt Europe Ltd, in London to serve European market.

Cadila Pharmaceuticals, the Ahmedabad-based manufacturer of herbal therapeutic products, has entered into an open-ended partnership with Murdock madaus Schwabe (MMS) of Utah, the US. In April last year, the Ahmedabad-based Rs.298 crore Torrent Pharmaceuticals set up a 50:50 joint venture with Sanofi Pharma, an international healthcare giant belonging to the \$ 40 billion Elf group. It needs access to the multinational's R & D since Indian pharmaceutical companies will be allowed to make only patented drugs from the year 2005 when product patents become compulsory in India under the General Agreement on Tariff and Trade (GAT). Ranbaxy expanded its presence internationally by acquiring Rima Pharmaceuticals in Ireland and Ohm Laboratories in USA, both makers of generics (Economic Times, 1996). It has a subsidiary in Netherlands, Ranbaxy (Netherlands), targeting European markets. It also became the first Indian company to manufacture and sell its products in China. It has joint venture holding Ranbaxy (Guangzhou China) manufacturing and marketing antibiotics and other drugs (Dhar, 1995).

The Mumbai-based Cipla has technology licensing agreements with Canadian generics manufacturer Novopharm, Saudi formulations maker MCPC and Cipharm in the Ivory

Coast, Africa. MCPC has set-up a \$ 50 million formulations project based essentially on Cipla's technology in the Middle East, while Novopharm and Cipharm are utilising Cipla know-how for their generics and tablet and suspension production respectively. Besides, Cipla will receive royalty from its Egyptian venture with Heliopharm and on a supply arrangement with US generics manufacturer, Geneva Pharma, which is now a part of Swiss multinational, Novartis (Shankar, 1996). Aotukang Cipla (in which Cipla has a 55% stake) located in the Jinhua economic development zone in central Zhejiang province, China manufactures a range of antibiotics, life-saving infusions and anti-cancer drugs (Business Standard, 1995). Cipla also has a marketing joint venture with Genpharm of Australia, as part of its strategy to consolidate its global presence.

R & D integration strategies

Changes in their basic R & D strategies from Product to process or across different 'technological' platforms are known to be the typical adaptive strategies firms pursue. A technological platform refers to the core technology based on which many a products be offered. For example, an aluminium continuous casting firm may be offering several products to automotive, air lines, hospitals and distilleries. The basic technological platform here is the 'continuous casting technology', which limits particular volume of production, product shape and physical properties and so on. For pharmaceutical firms the strategies can be improvement or discovery strategies. The improvement strategies involve drug delivery systems and expansion to multi-media. The emphasis in drug delivery systems is in improving the effectiveness of an existing drug (say in terms of dosage, length of treatment, bio-degradability). Many Indian pharmaceutical firms, with a proven track in reverse engineering of a patented drug, see this strategy as risk-free strategy. Drug delivery improvements do not impinge the product patents and the cost of stage I and II trials for an improved drug cost almost 1/10 of a new drug. Importantly, an improved version of an existing drug also assures reasonable market success, unlike a new molecule. Multimedia applications refer to leveraging product know how in a particular form to another. Application from a tablet to injectibles or vice versa, and shift from ointment to lotion are the examples of multi-media strategies. Here again the pharmaceutical firms can pursue either a niche media expansion strategy (thus sharing little of manufacturing or drug delivery process) or media expansion across disease segments (only leveraging horizontally key generic delivery system or manufacturing).

Pfizer Ltd launched a new anti-hypertensive medicine Minipress XL for the treatment of low blood pressure, cholesterol and blood sugar levels. Minipress XL incorporates a novel drug delivery system called GITS (gastro-intestinal therapeutic system) manufactured by using laser technology. The drug can be used by a range of patients including smokers and patients suffering from various co-existing illnesses. The new drug is targeted at the Rs 270 crore anti-hypertensive market which is growing at a rate of 30% per annum. The Indian drug giant - Ranbaxy Lab Ltd - has tied up with Central Drug research Institute, Lucknow, for R&D projects aimed at screening new drug delivery systems and compounds to develop drugs against infectious diseases, especially tuberculosis.

The discovery of new molecules can be by pursuing same technological platform or shifts to another technological platform. In their quest to adapt to the changes in the 1990s, pharmaceutical firms are affecting changes in the 'product platforms'. Traditional inorganic bulk drug producers are expanding their R & D platform to include organic molecules. There are both economic and technological reasons for the drug manufacturing firms' interest in natural products. A growing fascination with 'alternative' streams of medicines, a desire for self-care using natural products to improve health, and a growing respect for the wisdom gleaned over the centuries by different cultures the world over has triggered interest in the herbal medicines. In 1990 U.S.A spent US \$530 millions on herbal medicines, while U.K and France expended US\$ 104 million and US\$ 210 million. Germany, the largest importer of herbal medicines is estimated to have spent US\$ 790 millions in 1990. According to a United Nations Development Program (UNDP) report of 1994, the annual value of medicinal plants derived from developing countries is approximately \$ 32 billion. There are about 47 major modern pharmaceutical plant based drugs already in the world market and the market share of these drugs is expected to rise. Table 6 shows some of the important plant derived drugs that are in use. Indian herbal medicines are particularly well known in therapeutic categories like vitamins, bowel regulators, vitality drugs and balms (Choudary, 1996).

From point of view of R & D, the discovery of a inorganic drug for global markets (considering stage III trials and regulatory enforcement) costs as much as \$ 125 million, and may involve a time lock-in period of 10 years. On the other hand, developing a new variety of medicines from herbs and aromatic and medicinal plants is estimated to cost \$ 4 million and the drug is available within the space of a year. Given that the cost of discovering new routes in inorganic is becoming extremely uneconomical, pharmaceutical firms are turning their attention to organic molecules (Fairley, 1998). Indian medicinal sector, which follows many alternate medicine systems like Ayurveda, homeopathy, and Unani, is considered to be a potent source for drug identification and development (Exim Bank Of India, 1997). Many European companies have earmarked significant investment for this sector to become a major force in herbal drugs within the next three to four years. Chinese companies have not have had any major herbal brand successes except for the age old Ginseng, the vitality drug, and a few balms. Besides many of their products are based on animal extract rather than plant extract and hence cannot be sold in the West.

Some Indian pharmaceutical firms like Dabur, Getin Pharma, Ajanta Pharma and over 50 small and medium companies have successfully tapped the world-wide herbal drugs market with sales of around Rs.250 crore. Cadila Pharmaceuticals phytochemistry team has been engaged in the development of new herbal formulations, backed on Ayurveda. This team has developed over 30 herbal formulations. Karnataka Antibiotics & Pharmaceuticals have set up an RS. Six crore R&D center for ayurvedic medicine. The Hoechst Marion Research (HMR) Center, Mulund has developed significant compounds such a Forskolin and Trequinsin (biochemical tools), Mulundocandin, (a micro-organic anti-fungal), Flavopiridol (a synthetic derivative based on natural compound) and Rohitukine, an anti-cancer compound. The center has worked on the isolation of natural products from microbial and plants sources, total synthesis of novel chemical substantial

and modifications of natural products. The firm has already taken six patents on *Coleus Forskohlii*, a herb traditionally used for treatment of cardio-vascular disease, abdominal colic, respiratory disorders, painful urination, insomnia and convulsions. Very recently, Piramal has acquired this lab though HMR holds 140 odd patents. The quarter century old center is the largest private source of natural product research in India and it is expected to add more than reverse-engineering skills to Piramal. "Memory Plus", a drug for memory enhancement made from the time-tested 'Brahmi' creeper strongly recommended in Ayurveda, was developed by the Central Drug Research Institute (CDRI), Lucknow. Ace Laboratories Ltd, a multi-location and multi-technology company markets this drug. Cipla Laboratories are developing a new anti-asthma drug, based on a derivative of black pepper. Lupin, has introduced four products- 1B, a stress reliever, Sofotovac, a laxative; Apivate, an energy provider, and Fibrin, a laxative (Tiwari, 1998).

Another knowledge integration strategy adopted by Indian firms is their attempt to acquire biotechnology skills. The success of indigenously developed genetically engineered Hepatitis B vaccine by M/s Shantha Biotechnics Pvt. Ltd, Hyderabad has triggered R & D interests of several pharmaceutical players. Advanced Biochemical has invested Rs.24 crores in an R&D center at Sinnar in Maharashtra to focus on molecular biology, downstream process development and new applications for enzyme development. Cipla's Rs. Five crore-biotechnology research center at Kurkumbh near Pune became operational in 1997. Cipla had also R&D facilities in Bangalore for molecular biology cloning, screening and product characterisation. However, unlike the European or U.S drug companies no formal business relationships have sprang up between Indian pharmaceutical and biotechnology industry. This may be because a large portion of Indian biotech industry is constituted of government and research labs, and the major focus of private biotech industry is agriculture related, for example tissue culture (Madanmohan and Balaji, 1996). Wockhardt's bio-technology programme started five years ago. It currently involves R & D for development of Recombinant DNA products such as R-insulin, interferons, peptide drugs, fermentation-based drugs and identification of new molecules from the plants and development of drugs from them. Wockhardt intends to launch at least three indigenously produced biopharmaceuticals in the country during the next two years. These are Human insulin, Hepatitis-B vaccine and erythropoietin.

Conclusion

This article has shown that vertical and horizontal mergers and acquisitions are the pharmaceutical companies answer to the turbulent environment of the 1990s. We consider this consolidation process as an attempt to stabilize the business environment, and thus to gain control over the pharmaceutical market with few competitors. Brand acquisitions may allow firms to consolidate market share in few critical 'disease' segments. Based on the causal observations, we emphasize that developments in the directions outlined in the paper reveal a move towards increased vertical integration and economies of scale. Thus we expect mature firms to increase their bargaining strength through concentration to cope with changing institutional arrangements.

Reference

- Aiyer, S. (1997), Lupin Labs pact with Merck, Fujisawa. Business Line, 28 January.
- Bellur, V.V, Chaganti, R, Chaganti, R and Singh, S.P. (1985), Strategic Adaptation to Price Controls: The case of Indian Drug Industry, Journal of Academy of Marketing Science, 13 (1-2), 143-159.
- Buffie, E and Spiller, P.T. (1986), Trade Liberalisation in Oligopolistic Industries: The Quota Case, Journal of International Economics, 20(3). 65-81.
- Business Line (1997a), Croslands, Ranbaxy merger at 3:7 ratio, page 2,
- Business Line (1997b), TN Dadha to merge with Sun Pharma, page 1, May 15.
- Business Standard, (1995), Cipla seeking joint ventures abroad, March 1.
- Capron, L, P. Dassuage and W. Mitchell (1995). "Resource deployment following horizontal mergers and acquisitions in Europe and United States, 1988-1992". Paper presented at the BPS division of the Academy of Management Conference, Vancouver.
- Dosi, G. (1982). "Technology paradigms and technological trajectories", Research Policy, 11, 147-162.
- Dhar, P. (1995), Ranbaxy joint venture in China starts production, page 2, 30 May.
- Deshmukh, J, (1995), Wockhardt to set up 3 plants to make drug formulations, Business Standard, 25 March.
- Economic Times, (1995), Wockhardt to acquire stake in R R Medi, 14 March.
- Economic Times (1997), Ranbaxy acquires all of Gufic's major pharma brands, 14 January.
- Ettlie, J.E. and W.P. Bridges, (1982). "Environmental Uncertainty and Organizational Technology Policy," IEEE Trans Engineering Management, E-29, 2-10.
- Exim Bank of India, (1997), Indian Medicinal Plants: A Sector Study, Occasional Paper No.54,
- Fairley, P. (1988), Drug Discovery, Chemical Week, 160, 5, April 22, page 27-30.
- Ghangurde, A. (1996), Vorin Labs: Ranbaxy seeks open offer exemption, Business Line, 6, December.

- Jemison, D.B. (1981). Organisational versus Environmental Sources of Influence in Strategic decision-making, *Strategic Management journal*, 2(1), 1981, 77-89.
- Kay, N.M. (1982). "The Evolving Firm", The Macmillan Press, London.
- Kim, Dong-Jae, and Kogut, B. (1996). "Technological Platforms and Diversification", *Organization Science*, 7(3), 1996, 283-301.
- Madanmohan, T.R. (1997). Exit Strategies: Experience of Indian Pharmaceutical Firms, *Economic and Political Weekly*, XXXII (48), M107-M110.
- Madanmohan, T.R and Balaji, G. (1996), Indian Biotechnology Industry: A Preliminary Analysis, *Productivity*, 37 (3), 482-487.
- McArthur, A.W and Nystrom; P.C, (1991). Environmental Dynamism, Complexity, and Munificence as Moderators of Strategy-Performance Relationships, *Journal of Business Research*. 23(4). 349-361.
- McDonald, H. (1992), "India's drug challenge", *Far Eastern Economic Review*, 1 October, 78-79.
- Meyer, M. and Roberts, E. (1988). "Focusing new product strategy for corporate growth", *Sloan Management Review*, 29(4).
- Mukerjea. D.N. "Piramal Enterprises: Poised For a leap", *Business World*, 13-26 November.
- Nelson, R.R. and S.G. Winter, (1982), *An Evolutionary Theory of Economic Change*, Belknap Press of Harvard University Press, Cambridge, MA.
- Paine, F.T and Anderson, C.R, (1977). Contingencies Affecting Strategy Formulation and Effectiveness - An Empirical Study, *Journal of Management Studies*, 14(2), 147-158.
- Pavitt, K. (1990). What do we Know about the strategic Management of Technology, *California Management Review*, 32 (3), 17-26.
- Penrose, E. (1959), *The Theory of the Growth of the Firm*, M.E. Sharpe, White Plains, NY.
- Richardson, G.B. (1972). The organization of industry. *Economic Journal*, 82 (327), 883-896.
- Ross, T. (1988). Movements Towards Free Trade and Domestic Market Performance with Imperfect Competition, *Canadian Journal of Economics*, 21(3), 507-524.

Scherer, F.M. and D. Ross. (1990). *Industrial Market Structure and Economic performance* (3rd Ed), Houghton Mifflin, Boston, MA.

Shanker, S. (1996), Cipla, Egyptian Co in joint venture, *Economic Times*. 31 August 1996.

Stigler, G.J. (1964). A theory of Oligopoly, *Journal of Political Economy*, 72. 55-99.

Teece, D.J. (1982), Towards an economic theory of the multi-product firm. *Journal of Economic Behavior and Organization*, 3, 39-63.

Tiwari, V. (1998), Allopathy purveyors see sense in going herbal, *Business Standard*. page 6, March 30.

Table: 1**Indian Pharmaceutical Industry: Product markets and R & D (in Rs Crores)**

Year	Product composition		R & D
	Bulk Drugs	Formulations	
1980-81	240	1,200	15.74
1981-82	289	1,434	29.30
1982-83	345	1,660	34.19
1983-84	355	1,760	40.00
1984-85	377	1,827	43.15
1985-86	416	1,945	48.00
1986-87	458	2,140	50.00
1987-88	480	2,350	53.40
1988-89	550	3,150	67.99
1989-90	640	3,420	89.35
1990-91	730	3,840	90.28
1991-92	900	4,800	100.3
1992-93	1,150	6,000	110.4
1993-94	1,320	6,900	125.0
1994-95	1,518	7,935	140.0
1995-96	1,822	8,918	160.0
1996-97	2,186	10,494	185.0

Source: Organisation of Pharmaceutical Producers of India

Table: 2**Major therapeutic segments and their market share**

Major therapeutic segments	Market share (%)
Systematic antibiotics	19.5
Multivitamins	6.0
Anti-inflammatory & Anti-rheumatic	5.30
Cough & cold preparations	4.70
Antacid+Anti-flatulent+Anti-ulcerant	4.50
Analgesic	3.10
Anti-parasites	3.0
Cardiovasculars	2.80
Anti-asthmatics	2.10
General nutrients	1.80
Psycholeptics	1.70
Anti-diarheals	1.50
Anti-diabotic	1.30
Anticholinergic Anti-spasmodics	1.10

Table: 3**Examples of Patent expired therapeutic equivalents available for some patented drugs**

Patented drugs	Patented Drugs in India Rs.Million-	Patent expired Therapeutic equivalents in Indian market	Therapeutic Equivalents Rs. Million
Ciprofloxacin	1,100	Chloramphenicol & combinations	410
Ofloxacin (antibiotic)	81	Ampicillin/Amoxycillin	2,982
		Cephalosporins	1,512
		Trimethoprim combinations	1,165
		Tetracycline & combinations	906
		Total	6,975
Norfloxacin (antibiotic)	574	Ampicillin/Amoxycillin	2,982
		Cephalosporins	1,512
		Trimethoprim combinations	1,165
		Tetracycline & combinations	906
		Nitrofurantoin	21
		Sulphonamides	18
		Total	6,604
Cefotaxime	143	Chlororamphenicols	410
		All injectables cephalosporins	211
		Total	621
Glipizide (anti-diabitics)	46	Chloropropamide,	
		Tolbutamide,	
		Glibenclamide,	
		Metformin	284
Total	284		

Source: Operations Research Group Mat, October 1992.

Table: 4**Major patented drugs manufactured in India**

Chemical entity	Patent holder	Therapeutic group	Expiry date of US patent
Astemizole	Janssen-Astra (Swe)	Antihistamines	March 1999
Cefuroxime Axetil	Glaxo PLC (UK)	Cephalosporins	February 1997
Cefuroxime Sodium	Glaxo PLC (UK)	Cephalosporins	August 1994
Ceftizoxime	Fujiswa (Jap)	Cephalosporins	March 1998
Cefotaxime	Roussel (Fra)	Cephalosporins	January 1997
Ceftazidime	Glaxo PLC (UK)	Cephalosporins	May 1999
Ceftriaxone	Roche (Switz)	Cephalosporins	May 1999
Captopril	BM-Squibb (UK)	Anti-hypertensive	February 1997
Ciprofloxacin	Bayer (Ger)	Quinolones	August 2001
Enapril Maleate	Merck Inc (US)	Anti-hypertensive	December 1999
Felodipine	Hassle (Switz)	Myocardial Therapy	January 1999
Famotidine	Yamanouchi (Jap)	Anti-Ulcerant	December 1999
Ketoconazole	Hanssen-Astra (Swe)	Anti-fungal	December 1997
Ketorolac	Syntexlabs (US)	Analgesic	July 1997
Isinopril	Merck Inc (US)	Anti-hypertensive	December 1997
Norfloxacin	Kyorin (Jap)	Quinolones	January 1998
Omeprazole	Hassle (Switz)	Anti-Ulcerant	April 1999
Ofloxacin	Seiyaku (Jap)	Quinolones	April 1999
Pefloxacin	Lab R Bellon (Fra)	Quinolones	August 2001
Perindopril	SFRM (Fra)	Anti-hypertensive	September 2001
Roxatidine	Tiekoku (Jap)	Anti-ulcerant	June 2000
Roxithromycin	Roussel (Fra)	Macrolide	January 2001
Rantidine Vecuronium Bromide	Glaxo PLC (UK)	Antiulcerant	July 1997
Bromide	Akzo NV (Hol)	*Oxytoxics	August 1999
Salmeterol	Glaxo PLC (UK)	Anti-Asthmatic	April 2004
Ondansetron	Glaxo PLC (UK)	Anti-Emetic	January 2005

Source: Organization of Pharmaceutical Producers of India

Table: 5**Bulk drugs quoted below DPCO prices (Rs/kg)**

Bulk drug	Market Price	DPCO Price
Penicillin G (Per BU)	800	1,025
Cloxacillin Sodium	2,200	2,356
Ciprofloxacin	2,300	4,190
Norfloxacin	1,950	2,162
Griseofulvin	3,150	3,691
Metronidazole	425	516
Ibuprofen	405	487
Analgin	280	317
Ranitidine	1,050	1,714
Salbutanol Sulphate	5,400	8,690
Chlorpropamide	290	306
Trimethoprim	950	1,510

Some more drugs under price control as per DPCO '95

(Rs per Kg)

Cardiovascular

- * Verapamil HCl 4,662
- * Pentoxifyline 2,225

Antibiotics

- * Tetracycline HCl 1,748
- * Doxycycline HCl 4,138
- * Gentamycin Sulphate 12,740

Anti-bacterials

- * Nalidixic Acid 2,744
- * Sulphamethoxazole 415

Anti-TB

- * Rifampicin 5,220

Anti-parasitic

- * Chloroquine phosphate 1,340
- * Pyrantel pamoate 965

Vitamins

- * Vitamin C plain 539

Table: 6**Examples of Important Plant derived drugs in use**

Compound	Treatment
Ajmaline	Circulatory disorders
Ajmalicine	Clotting
Atremisinine	Malaria
Berberine	Local anaesthesia
Caffeine	Suppressant
Codeine	Blood pressure control
Colchicine	Oxidant
Digitoxin	Gastro-entomology
L-Dopa	Sleep disorders
Emetine	Skin disorders
Ergometrine	Binding agent
Glycyrrhizin	Glucose regulator
Hyoscyamine	Cuts, wounds. sever bleeding
Hyoscine	Anti-bacterial
Hesperidin	Mild digestive. Vitamic C
Menthol	Sedative
Morphine	Digestive enzymes
Papain	Skin aberrations
Podophyllotoxin	Malaria
Quinine, Quidine	High Blood pressure
Resperine	Respiratory disorders
Rutin	Inhalant
Santonin	General
Sennosides	General
Taxol	Anti-inflammatory
Vinblastine	General
Vincristine	General
Xanthotoxin	Malaria. Cough
Chemical intermediates	
Citral	
Diosgenin	
Phytosterols	
Solasodine	

Source: Express Pharma Pulse 28 November, 1996.