

**Opening Up to the World:
India's Pharmaceutical Companies
Prepare for 2005**

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Abstract

In 2005, India will implement new intellectual property (IP) laws that recognize product patents on pharmaceuticals. Because India's 1970 Patent Act only recognizes process patents, Indian drug companies have been free to copy molecules from multinational companies (MNCs), to sell within India and other nonpatent conforming markets. New laws, such as the Exclusive Marketing Rights amendment to the 1970 Patent Act (ratified on April 19, 1999), will substantially alter this practice. This paper discusses what companies are doing to prepare for 2005 and beyond. As is the case today, Indian and MNCs alike will figure prominently in the future of the pharmaceutical sector, albeit in somewhat altered form. Although the new patent regime has the potential to reward MNCs at the expense of Indian firms, local companies will likely benefit from stricter laws. In fact, it is plausible that the 2005 laws will vault some Indian pharmaceutical companies into globally prominent positions.

Preface

Until 1991, India's industrial policy regime was among the most inward-looking anywhere. Dilution of the restrictive policy regime began in the 1980s, but June 1991 marked the turning point of India's policy regime toward the world. Since then, technology imports have been essentially uncontrolled. A wide range of products (including most industrial, and some consumer products) can be freely imported at tariffs which dropped from an average of 200 percent in 1990 to 30 percent in 1996, where they have stayed, approximately, ever since. At long last, the Indian policy regime sees the rest of the world as something to engage, not keep out. As part of this overall integration with the global economy, India has also acceded to the GATT/WTO Intellectual Property Rights (IPR) regime, and is progressively passing legislation that amounts to repeal of the 1970 Patent Act. These changes appear in dramatic relief when set against India's own past. Compared with other countries, India still has a long reform agenda pending. However, the broad direction of policy reform, very hesitant at times, is toward liberalization and integration with the global economy.

Much work has been done on liberalization in India, but no systematic, academically rigorous investigation of the impact of liberalization on technology in Indian industry has yet been undertaken. This is troubling, as no issue will more surely determine the long-term success of industry than the technical capability of Indian firms. Technical capability comes from learning, and from technical effort. Four decades of protection and inward-looking policies fostered much technical effort on the part of Indian firms. How much of this work has been useful in building the technical capabilities necessary for internationally competitive firms? In 1998, the Asia/Pacific Research Center initiated a study to consider these questions. This report on the pharmaceutical industry, which is based on interviews with a dozen of India's leading pharmaceutical companies, represents the first output of this ongoing study.

The pharmaceutical industry in India provides an excellent case study of Indian industry as a whole: of inward-looking policies fostering the growth of many similarly inward-looking local firms. However, India's pharmaceutical industry differs from other industry in one key respect. The Indian Patent Act of 1970 had little impact on most of Indian industry, but has significantly affected the pharmaceutical sector. In the years since 1970, a large

number of firms began to form—at over one thousand manufacturing firms, the industry is among the most fragmented in the world—alongside the leading multinational company (MNC) subsidiaries that were then operating in India. Between 1970 and 1991, private Indian firms increased their share of the Indian drug market from less than 20 percent to 60 percent, primarily taking market share from the MNC subsidiaries. A wide range of drugs is now produced in India, and sold at prices (determined through a price control regime) that are among the lowest in the world. Under the 1970 Patent Act, the leading Indian pharmaceutical firms grew by legally reverse-engineering internationally patented drugs. After 2005, this alternative for new product innovation will no longer exist.

This study, conducted by Sean Eric Smith, with input from Harry Rowen and Naushad Forbes, studies the impact that the events of 2005 are likely to have on the Indian pharmaceutical sector. Will leading Indian firms be taken over by MNCs that will again dominate the Indian pharmaceutical market? Will the remaining Indian firms hang on as low-cost manufacturers of off-patent generics? Will Indian firms thrive as low-cost manufacturers of off-patent generics, selling them internationally through MNCs, or even directly, as Indian-branded products? Or indeed, will Indian pharmaceutical MNCs themselves emerge with their own branded and internationally patented drugs?

This study does not pretend to answer these fundamental questions about the future. However, by analyzing the current strategies of some Indian firms, we can safely hypothesize that the future will not be one in which MNCs simply take over Indian firms. Consider the following points, highlighted in this report. First, around 80 percent of the Indian drug market consists of off-patent drugs. These, and other drugs whose patents expire by 2005, will continue to be available to Indian firms with no IPR of their own. It is striking that over 95 of the top 100 drugs listed by the World Health Organisation are off-patent. Second, the price-control regime means that Indian firms are highly efficient manufacturers, as is shown by the 40 percent share of output being exported. This figure will grow as Indian firms become increasingly active overseas, and our study reveals that many firms are already pursuing such involvement—6 of the 8 Indian firms we studied had established their own foreign subsidiaries as of 1998. Third, a few Indian firms have determinedly moved away from their origins as reverse-engineers of patented medicines, and are now investing a growing R&D budget in their new drug discovery programs, aimed at building their own internationally patented IPR. Two firms, Ranbaxy Laboratories and Dr. Reddy's Laboratories (DRL), have already filed their first molecules internationally, and in 1999, received the all-important FDA approval to conduct clinical trials upon them. These companies have also indicated that they have discovery pipelines that enable them each to file for one molecule per year.

As encouraging as these developments are, they must be tempered by the sobering realization that the combined research budget in dollars of *every* Indian pharmaceutical firm would add up to under 10 percent of the budget of a Glaxo-Wellcome or a Merck. (However, as our report indicates, the Indian firms claim that they are much more efficient as drug discoverers.) Is our optimism for the future of India's pharmaceutical sector warranted? Only life beyond 2005 will tell, but our research demonstrates that Indian firms have built up significant technical capability, and several of these display both the ambition and the commitment to become major players.

This analysis of the pharmaceutical sector can also instruct a more general understanding of the impact of liberalization on Indian industry. As reform has proceeded, many in India have called for a "level playing field" for Indian firms, which amounts to a demand for

continued protection. The most strident of these voices came from the so-called Bombay Club group of industrialists, which in turn resonated in the Swadeshi rhetoric of the last Indian government. It is encouraging that, in 1999, the same re-elected government quietly dropped the inward-looking rhetoric of its first term. But our study convinces us that the pharmaceutical firms investing more in research and development (R&D) at home and building operations abroad—such as Ranbaxy, DRL, and Nicholas Piramal (NPIL)—will benefit most from opening up to the world. These firms understand that 2005 represents an opportunity for them to become MNCs in their own right.

If these firms had the soft option available—if they could continue to look inward, and to focus on the Indian market for reverse-engineered on patents and off-patent generic drugs—would they accept it? We are optimistic that forcing Indian firms (pharmaceutical or otherwise) to compete—inside India, but at international tariff levels—with the best international firms and products will encourage them to seek MNC status themselves, and to compete *outside* India. Perhaps this approach will bring about the demise of the protectionism that still swathes so much of Indian industry. If the pharmaceutical sector is representative, however, we believe it will also usher in a new period of Indian firms as significant actors and competitors on the global industrial stage.

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1. Introduction

India's pharmaceutical sector has been the subject of much conjecture recently because evolving intellectual property (IP) laws are sure to alter the status quo. As a knowledge-driven industry, pharmaceuticals are especially sensitive to regulatory changes that affect IP. In the past, Indian pharmaceutical firms have derived considerable revenues by selling copies of Western companies' patented products. In 2005, this practice will likely come to an end, when India implements stronger IP protection laws. What is less obvious is how the industry will react in the post-2005 environment. Existing research has analyzed 2005 from a number of angles, ranging from consumer-focused to investor-focused, and used both theoretical (top-down) and company-specific (bottom-up) methods.

By focusing on the strategic activities of twelve influential companies, this paper makes projections about how the Indian pharmaceutical industry might develop in the coming decades. It can be argued that this method puts too much emphasis on the role of the firm in the larger industry context, and overlooks other factors such as patent enforcement, market segmentation, and demand. However, given that firm strategies are derived from assessments of external factors, it is reasonable to invest some confidence in them. Furthermore, the extent to which pharmaceutical companies control their own destinies must be observed. Consider, for example, the prospect of creating new drugs in India. India's capacity to produce its own IP is very much contingent on the success of firms such as Dr. Reddy's Laboratories (DRL) and Ranbaxy.

1.1 Structure of paper

The principal objective of this paper is to project the effects that 2005 IP laws are likely to have on the Indian pharmaceutical industry. Section 2 provides background on pharmaceuticals in India, while section 3 strikes at the heart of the issue in question by reporting and analyzing how companies are preparing for 2005.

1.2 Summary of findings

This research supports a number of conclusions about the impact of reforms on the pharmaceutical industry. Increased patent protection need not spell disaster for Indian

pharmaceutical companies, even though the current practice of profiting from other companies' IP will likely cease to be a strategic option. The future success of Indian pharmaceutical companies hinges on their ability to find productive roles for themselves in the post-2005 environment.

The most publicized reaction of Indian firms to 2005 has been the development of drug discovery programs by companies such as DRL, Ranbaxy, Wockhardt, and Dabur, who plan to use product patent protection as an incentive to produce their own IP. To be sure, Indian drug discovery programs are still in their infancy and there remain considerable obstacles on the horizon. Indian companies have neither the capital bases nor the experience of their multinational company (MNC) competitors. On the other hand, odds are high that some firms in India will succeed in drug discovery within the next few years. If successful, India will be the one of the first emerging economies to produce cutting-edge technology.

Not all Indian pharmaceutical firms possess the resources, the will, or the know-how to initiate drug discovery, but there is hope for lesser-endowed companies after 2005. Consider the following points. First, 90 percent¹ of the Indian pharmaceutical market consists of second and third generation drugs that are no longer subject to patent protection in the developed world. After 2005, Indian companies will be able to continue to produce such drugs. It has even been suggested that the market for these older drugs will increase as the prices for newer, on-patent drugs increase. Some companies have already established themselves as exporters of generic drugs to the developed world, and 2005 patent legislation does not pose a threat to these revenue sources. Second, Indian drug companies have advantages over MNCs in the Indian market in a number of nontechnological areas, including marketing, distribution, and traditional medicines. Some Indian companies are leveraging these nontechnological strengths (and even building entire businesses around them) as they approach 2005. Third, mergers and acquisitions (M&A) have become increasingly common. By matching companies with complementary strengths, the M&A process promises to better equip Indian companies to compete with MNCs in years ahead. To the extent that M&A activity has occurred between Indian and multinational firms, the distinctions between the two groups are increasingly blurred.

Four of the twelve firms in the sample for this paper were MNC subsidiaries. Accordingly, the paper also offers insights into these companies' 2005-related strategies. Most MNCs that already have a presence in India are building up the capacity to localize further their post-2005 Indian operations, pending the specific nature of the new patent environment. The recently passed Exclusive Marketing Rights (EMR) amendment to India's patent act has demonstrated to MNCs that the government will try to accommodate their interests in coming years, but the post-2005 scenario for patent protection is still far from clear. Section 3.3.7 details the currents that underlie localization decisions for MNCs. MNCs without Indian presence will undoubtedly enter the market after 2005. It is likely that a considerable share of new entrants will rely on co-marketing arrangements with local companies and other MNCs to distribute their products.

In the final analysis, changes in the Indian pharmaceutical sector will permanently alter its structure. Fears that MNCs will capitalize on increased patent protection and wipe out local competition appear to be exaggerated, although consolidation is inevitable—with 16,000 companies, the Indian pharmaceutical industry is currently one of the most fragmented in the world. However, the industry is certain to grow increasingly efficient and productive in the coming years. India may become a center of global importance in pharmaceutical production and research and thereby, enhance its position in the world economy.

2. Overview

This section provides the background to strategic issues discussed in section 3. It is comprised of four subsections, each of which offers different perspectives on pharmaceuticals in India. Section 2.1 highlights major developments in the industry over the past century; section 2.2 presents a functional model of the pharmaceutical product cycle; and section 2.3 examines the regulatory environment in which pharmaceutical companies operate. Finally, section 2.4 considers the evolution of domestic demand for drugs.

2.1 A Brief History (1900–1999)

The Indian pharmaceutical industry traces its roots to the 1903 formation of Bengal Chemical and Pharmaceutical Works in Calcutta by Professor P.C. Roy. During the first half of the twentieth century, however, and despite modest efforts on the part of the colonial government to spur local production, India remained largely dependent on the UK, France, and Germany for medicines.

The new and independent government in 1947—which emphasized industrialization to achieve self-reliance—invested heavily in pharmaceuticals (among other industries) and curbed imports.² Yet, in contrast to its policies toward other sectors, the government did not discourage foreign firms from competing in India. In other sectors, self-reliance was pursued at high cost, but pharmaceutical policies emphasized national health. Because there was no local substitute for MNCs' technology, the government did not discourage their presence in the country. In fact, until 1970, the Indian pharmaceutical industry consisted almost entirely of MNCs, most of which maintained minimal physical operations in India.

The government took its first concrete steps toward self-reliance in pharmaceuticals with the establishment of Hindustan Antibiotics Ltd. (HAL) in 1954 and Indian Drugs and Pharmaceuticals Ltd. (IDPL) in 1961. IDPL (in spite of its grossly inefficient character) became instrumental in the development of the industry by serving as the vehicle for a comprehensive Soviet-sponsored program in which Russians supplied machinery, personnel, and technical know-how to produce antibiotics. The IDPL development program helped self-reliance in several ways. First, it showed that it was possible to produce drugs in India at competitive costs. Second, it developed human and physical capital, some of which moved in due course to other companies. Third, it spurred the existence of a network of support institutes, pharmacy colleges, and up and down stream businesses.

The IDPL program alone was insufficient to jumpstart local industry. Local companies needed a way to compete with more experienced and better endowed foreign firms; only then would the industry have the critical mass to sustain itself. The 1970 Patent Act made headway toward this end by recognizing patents on processes but not patents on products, which in turn enabled local firms to legally produce compounds that were patented elsewhere. Consequently, scores of Indian pharmaceutical companies evolved to reverse-engineer and cheaply sell copies of all major drugs. Although many Western observers criticize the 1970 Patent Act on ethical grounds, it cannot be denied that the legislation helped to develop India's pharmaceutical industry. Over the next thirty years, the industry would grow from a handful of MNC players to today's 16,000 licensed pharmaceutical companies.³

From 1970, local Indian firms reverse-engineered bulk drugs, which they either sold wholesale or processed into simple formulations. Meanwhile, MNCs—reluctant to expose their IP in such a lawless market—limited their exposure to India. By 1997, MNCs had come

to account for 30 percent of bulks and 20 percent of locally produced formulations.⁴ Most MNCs did the bare minimum needed to stay in the Indian market (such as producing simple formulations from imported bulks), while awaiting the arrival of stronger patent protection. The few MNCs that have been bullish toward India over the past thirty years have local managers to thank for their aggressive posture.

Even without strong patent protection, the Indian pharmaceutical industry matured during the 1980s. In particular, local companies grew less reliant upon reverse-engineering for revenues. By increasingly focusing on attributes such as novel delivery systems, Indian firms were on their way to creating revenues based on their own added value. Companies also started to produce products better tailored for their markets than typical MNC products. For example, Lupin Labs introduced its AKT-4 kits, which combined four antituberculosis (anti-TB) drugs that were generally administered together into a single package. The AKT-4 kits were well received by TB patients, who no longer had to worry about the lack of availability of any one drug. (Selective discontinuation of anti-TB drugs can lead to resistance and even relapse in TB patients.)

While impressive in terms of growth and development, the past thirty years have been relatively uneventful for the Indian pharmaceutical industry. However, as 2005 approaches, fundamental structural changes are likely, if not inevitable. As of 2005, India has agreed to enforce product patents on drugs. Consequently, it will no longer be possible for companies to collect rents on competitors' IP.

At present, there are many questions surrounding the post-2005 patent regime. Industry participants wonder about both the will and ability of patent courts to implement and enforce decisions. They also worry about the potential for price controls to limit the profitability of first generation drugs (see 3.1.1 and 3.1.2). However, the proposed (and already enacted) changes to which India agreed by signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁵ on April 15, 1994, have been sufficient to motivate much change within the industry. Some companies will continue in their old ways for as long as possible, but others are in the midst of transitions that will enable them to remain profitable in a changed industrial environment.

2.2 The Pharmaceutical Production Cycle

Pharmaceutical production consists of a number of discrete activities. Because different phases of the pharmaceutical production cycle require different types of resources and levels of funding, it is useful to examine firms' strategies within their operational contexts. In fact, many of the conclusions drawn in section 3.3.1 are relevant only within certain phases of the product cycle. This paper assumes that the product cycle has four main components: 1) discovery, 2) clinical trials, 3) production and manufacturing, and 4) marketing and distribution. Large MNCs typically have activities that span all of these areas. However, smaller companies—in India and elsewhere—often specialize in one or more functions.

2.2.1 *Discovery*

In principle, discovering new drugs is a straightforward process. First, chemists supply research scientists with compounds for testing, a process referred to as lead generation. Generally, such compounds are closely related molecules within a given disease area. In the West, because the success of a discovery operation is at least partially contingent upon the number of leads, drug companies have recently turned to combinatorial chemistry in order to accelerate the lead generation process. (Combinatorial chemistry, with its high costs and

unproven effectiveness, has not yet gained widespread acceptance in India.) Second, scientists screen molecules in a lab environment by conducting *in vitro* (petri dish) tests. Next, compounds with attractive medical qualities are advanced to an “animal house” for *in vivo* tests. *In vivo* tests are used to determine the minimum dosage necessary to produce the intended results (efficacy) and the maximum nonlethal dose (toxicity) of the drug in question in animal subjects. Companies usually file for patent protection of promising compounds midway through *in vivo* testing. Additionally, research scientists note any side effects that may be associated with the drug’s administration. Following the completion of *in vivo* tests, companies may apply to conduct clinical trials on their compounds in their desired markets. Permission to conduct clinical trials depends on the results of both the *in vitro* and *in vivo* tests, and their conformity to generally accepted standards, as they are determined in individual countries.

In practice, drug discovery is not as simple as the preceding summary suggests. First, government drug authorities around the world mandate that tests be conducted in controlled conditions that often entail the construction of specialized facilities and the procurement of highly-trained personnel. Second, lab tests on new drugs typically take five years to administer. Third, only a very small percentage of lead compounds advance through the entire testing process; successes are generally accompanied by large numbers of failures. Finally, the profitability of a new drug is contingent upon the size of its distribution network. That is, companies without global distribution contacts are less likely to benefit from discovery than well-positioned MNCs. For these reasons and others, new drug discovery is a difficult line of business for pharmaceutical companies to enter. Discovery requires sizable capital investments, the assumption of large amounts of risk, and the establishment of global marketing strategies.

It is not surprising that large pharmaceutical companies with global reach have traditionally carried out most drug discovery. However, opportunities still exist for smaller firms in the discovery realm. In the Silicon Valley, for example, a range of small biotech companies has evolved in accordance with the venture capital funding model. When viewed in isolation, the financial prospects for small, discovery-oriented companies are bleak because they lack the resources to pursue enough projects to reduce their risk to acceptable levels. Venture capitalists, however, are not concerned about the success of individual companies. Rather, they focus on the economic viability of their overall portfolios. By investing in a large number of companies, their risk approximates that of major pharmaceutical companies, which—by simultaneously engaging in a number of projects—internalize their own risk.

India’s pharmaceutical industry does not, yet employ much venture capital funding. But some Indian companies have entered drug discovery without being very large. They have done so by contracting other phases of the product cycle, such as clinical trials and marketing, to established foreign and domestic companies. These topics are pursued in greater detail in section 3.3.

2.2.2 Clinical Trials

While testing on animals provides valuable and necessary insights into a drug’s medical characteristics, regulatory authorities in virtually all markets require comprehensive clinical trials on human subjects before granting production and marketing approval. The standards for clinical trials are considerably more stringent than those for animal testing. Doctors and other professionals who administer trials are required to pass reviews that are administered by independent Institutional Review Boards (IRBs).⁶ Trials must employ double-blind test procedures. Production facilities should be in accord with Good Manufacturing Practices

(GMP) as determined by the relevant regulatory authority.⁷ This list is not exhaustive; clinical trials are exacting and, consequently, expensive to administer. Furthermore, since different countries have different standards, it is necessary to conduct clinical trials in multiple locations (or at least simultaneously in the same location) to achieve global distribution.⁸

Several analysts have suggested that India is well suited for clinical trials because it has a strong university system capable of producing low-cost human capital, and a large population of poor and relatively disease-ridden potential test subjects. Some local companies—namely Cadilla and Ranbaxy—have begun to fill this role. However, the issues alluded to above still prevent global clinical trials from being a viable option for most Indian pharmaceutical companies. Therefore, while MNCs may begin to use India for clinical trials in the near future, local companies will likely enlist other firms to assist them in this capacity as they discover new drugs.

2.2.3 Production and Manufacturing

Pharmaceutical production consists of bulk drug manufacturing (in which active compounds are synthesized on an industrial scale) and formulation manufacturing (in which active and inactive ingredients are packaged into tablets, capsules, liquids, and injectibles). Bulk drug manufacturing is more technology-intensive than formulation manufacturing because, while the former draws from reverse-engineering skills and requires knowledge of chemical processes, the latter merely approximates the job of the local pharmacist on a larger scale. Indian companies have proven themselves capable in both areas, as barriers to entry are modest and domestic manufacturing guidelines are liberal. However, to export products to developed markets, companies must bring their factories into conformance with GMP standards (see section 2.3.1). U.S. Food and Drug Administration (FDA) and UK Department of Health and Social Services (DHSS) sanctioned factories are consequently premium assets in India. According to D.M. Gavaskar, managing director of Knoll Pharmaceuticals, GMP-compliant facilities are 25-30 percent more valuable than noncompliant facilities. This cost premium renders it difficult for smaller companies to compete in manufacturing.

2.2.4 Marketing and Distribution

Since fixed costs—such as those for R&D and clinical trials—represent a considerable portion of the total costs for developing drugs, pharmaceutical profit margins are largely contingent upon the number of customers reached. Therefore, companies strive to build their reputations with doctors who prescribe pharmaceuticals and the patients who use them. The largest pharmaceutical companies in India use field sales forces, ranging in size from 500 to over 2,000, to bring their products to the domestic market. According to Uday Bhansali of Arthur Andersen, Indian companies have a decisive edge over MNCs in terms of distribution because they better understand the nuances of the Indian market for drugs.

Until recently, the Indian market alone provided sufficient profitability for Indian pharmaceutical companies. But as this market becomes more congested and the costs for producing new products grows, it is increasingly necessary for companies to look for customers beyond India and the developing world. Unfortunately, most Indian companies do not produce enough products to justify investments in global marketing and distribution. Established MNCs, on the other hand, enjoy rapport throughout the world's pharmaceutical markets. When Merck develops a new product, for example, it can insert it into a large distribution system. In order for India's pharmaceutical companies to match the distribution capabilities of the major international players, they will likely have to join their own local forces, or enlist the support of MNCs to supplement their efforts.

2.3 Regulatory Environment

It is almost impossible to engage in a discussion about pharmaceuticals without addressing regulation. This is true for two reasons. First, since drugs affect the health and well being of so many citizens, government has an interest in assuring their adherence to medical standards (see section 2.3.1) and availability (see section 2.3.2). Second, in light of the fact that patentable research can represent up to ten percent of a given drug company's cost structure, IP protection is essential to provide firms with incentives to develop new drugs.

2.3.1 Approval Process

Unlike other products, drugs must undergo extensive approval procedures before they may be marketed. India's domestic approval standards are quite low, but export products must comply with standards in all destination markets. Approvals are required for both products and processes. After a new drug is developed, regulatory authorities oversee clinical trials, which determine efficacy, toxicity, and side effects (see section 2.2.2). Companies are free to manufacture and formulate all approved products for which they have production rights (whether newly patented molecules or off-patent substances) as long as the relevant authorities determine that their production facilities comply with global GMP standards. GMP standards apply to equipment, sanitation, and documentation.

Indian pharmaceutical companies often employ foreign consultants to help bring factories into GMP compliance. Because India's own regulations are less stringent than those of the FDA in the United States, or the DHSS in the UK, many Indian firms have opted to limit their operations to domestic sales and exports to other countries with approval standards similar to India's.

2.3.2 Price Controls

Price controls are not nearly as important in today's pharmaceutical sector as are other regulatory issues. This is partly because market-clearing prices for controlled drugs have typically fallen at or below price-controlled levels since the late 1970s. In cases where price controls did pose problems, companies simply adjusted their product portfolios accordingly, toward noncontrolled drugs. But price controls are still worthy of mention insofar as past price control orders have shaped current pharmaceutical operations. Furthermore, it is plausible that price controls will assume a role of increasing importance in the near future.

In 1970, the government introduced the Drug Price Control Order (DPCO) to guarantee public access to "essential" drugs, to provide a reasonable rate of return to companies, and to ensure quality.⁹ In response to the DPCO, many firms concentrated on production of (nonessential) drugs outside its scope. Some even divested themselves completely of controlled drugs. In this sense, the DPCO undermined its own objective of providing public access to essential drugs, which were more difficult to procure after it was introduced. Another derivative effect of the DPCO was that it exempted smaller firms from price controls, thereby encouraging them to participate in the pharmaceutical industry.¹⁰ Not surprisingly, this caused small companies to be represented more prominently than might otherwise be expected.

To address the aforementioned problems (e.g., the lack of incentive to produce essential drugs and the overrepresentation of small companies), while still adhering to its objectives, the government issued a revised DPCO in 1995. The 1995 DPCO declassified 70 out of 146 drugs, dropped some clauses that favored small companies, and exempted newly (locally) produced products from price controls.¹¹

Recent evidence suggests that, as it enacts new patent legislation, the government may be positioning itself to backtrack on the progress made in the 1995 DPCO. New price controls would arguably serve to defend consumers and local companies against the potentially destabilizing effects of India's obligations under TRIPS. The EMR amendment, for example, contains explicit provisions for compulsory licensing and fixing prices of newly registered drugs.¹² Insofar as the EMR amendment provides insights into New Delhi's agenda, it is reasonable to assume that price controls may emerge as a new menace to producers of patentable drugs in the future.

2.3.3 Intellectual Property Protection

Prior to 1970, India employed Western-style patent legislation, and recognized product patents in addition to process patents on drugs. Under that environment, MNCs prospered while local companies lacked the resources to enter the industry. The 1970 Patent Act, which represented a change in favor of local producers, consisted of the following key clauses:

- 1) No pharmaceutical product patents are admissible, only process patents are acknowledged;
- 2) The term for a process patent is fourteen years;
- 3) Three years from filing, patents are deemed to be endorsed as license of right;
- 4) Patents must be worked within three years of filing;
- 5) The Indian government may use or authorize others to use the patented invention.¹³

By ignoring product patents, the 1970 Patent Act permitted companies to reverse-engineer their (MNC) competitors' products. In addition to India, such products are freely sold in Russia, the Commonwealth of Independent States (C.I.S.), Africa, China, and South America. Furthermore, Indian companies were free to ship reverse-engineered drugs to patent-recognizing countries on or after the day of expiry (with no lag time). Such a liberal patent environment benefited Indian firms at the expense of MNCs, causing some MNCs to opt for minimal presence in India.

In 1995, the government amended the 1970 Patent Act to conform to the TRIPS accord of the Uruguay round of GATT. The main provisions of the 1995 ordinance were:

- 1) The recognition of product patents;
- 2) Exclusive marketing rights (EMR) for new products from 2000–2005;
- 3) A mailbox provision for filing product patent applications during the transitional period from 1995–2005;
- 4) Twenty-year patent life;
- 5) Shifting of the burden of proof to the alleged infringer;
- 6) The extension of protection to include imported materials and products.¹⁴

Thus far, the EMR clause and the mailbox provision have been officially incorporated into India's patent legislation. Although it is too early to evaluate the effectiveness of the EMR amendment, U.S. and EU officials were reasonably pleased with the April 19, 1999 legislation, and the U.S. delegation that advised India on EMR felt the amendment adequately addressed its concerns.¹⁵

The 1995 ordinance caused an enormous rift in the pharmaceutical industry. Firms immediately aligned themselves according to their positions on IP. In particular, two major industrial associations in the Indian pharmaceutical sector—the Indian Drug Manufacturers

Association (IDMA) and the Organization of Pharmaceutical Producers of India (OPPI)—locked horns. The two associations share similar agendas, except on the subject of IP: the IDMA opposes to stringent IP protection, while the OPPI favors it.

The IDMA was victorious over the OPPI in 1995 because it was able to hold the ordinance in suspension, but the dynamics of the current global economy bode well for the OPPI in the future. First, the Uruguay GATT resolution established a ten-year grace period for developing countries to implement protection. In light of the grace period clause, it was inevitable that less developed countries would delay implementation of new patent laws to allow producers time to reorient themselves. After 2005, however, delays will no longer be permissible, and India will have to comply with GATT/TRIPS requirements, or risk a return to isolation. Since the second scenario is unlikely and undesirable, the industry can probably look forward to product patent protection in 2005. The precise future of India's drug patent regime remains hazy, but stronger protection is presumably on the horizon

2.3.4 Other Regulatory Issues

Aside from approvals, price controls, and patent policies, the Indian government has used other tactics to regulate the pharmaceutical and other sectors. These are primarily those of classic protectionism (e.g., tariffs on imports, mandatory licensing, restrictions banning imports, etc.). Liberalization efforts of 1991–1992 sought to disassemble protectionist barriers and allow foreign firms to compete on more even footing with their Indian counterparts. The main components of this 1991–1992 liberalization included:

- a) MNCs treated as equal to Indian companies.
- b) Automatic approval for 51 percent foreign equity proposals.
- c) Automatic approval for foreign technology agreements.
- d) Most bulk drugs (and their forms) delicensed.
- e) Provision for a higher rate of return for companies undertaking production from basic stages.

Interviews with firms, as well as supporting literature suggest that, aside from the important move to GATT/WTO compliance, the pharmaceutical industry was largely unaffected by liberalization. Several explanations seem relevant. First, because it valued health more than industrial self-sufficiency, the government had never kept foreign firms wholly out of the pharmaceutical sector in the first place. Second, industry-specific regulations are simply far more important than classic protectionist measures to the pharmaceuticals sector.

2.4 The Indian Market

The previous three subsections have dealt primarily with factors pertaining to pharmaceutical supply. This section examines the characteristics of pharmaceutical demand. There is much anticipation concerning the future of the Indian market for pharmaceuticals. With a population of 950 million and a plethora of diseases, India is a desirable market for drug companies. Furthermore, in spite of their low incomes, Indian consumers have exhibited extraordinary pharmaceutical purchasing habits. According to Ranjit Shahani, managing director of Novartis India Limited, even though the dollar value of the Indian drug market is still too small to warrant serious attention, the market is one of the largest in the world in terms of volume. For the Indian market to justify large pharmaceutical investments, incomes

and drug prices need to rise, and it is safe to assume that this will occur. Barring unlikely political collapse, India is bound to maintain its course of rapid development. IMS Health estimates 8.6 percent annual growth for the Indian pharmaceutical market between 1998 and 2002, and forecasts that the Indian market will be worth \$7.8 billion—its figure for the North American drug market is \$169.1 billion—in 2002.¹⁶ Despite the apparent precision of such projections, several unknowns complicate the marketing initiatives of pharmaceutical companies. In particular, there is insufficient information about: 1) the time frame of India's rise to economic prosperity, 2) the market reaction to liberalization (i.e., customers' willingness to tolerate price increases), and 3) the structure of the post-2005 market.¹⁷

These ambiguities have implications for pharmaceutical companies' future product selection. If it appears that market demand will support the higher prices likely to result from patent protection, then companies have reason to invest in new and expensive products. Shahani's firm, Novartis, belongs to this school; it is betting that Indian customer tastes are converging with its global market. Other companies, such as Knoll Pharmaceutical, Lupin Laboratories, and Nicholas Piramal India, are more skeptical, and will likely continue to focus on less expensive—and less risky—second and third generation drugs following 2005. D.M. Gavaskar of Knoll believes that most MNCs are overly optimistic about future consumption patterns because they underestimate demand elasticity. "Indian consumers are much more price-sensitive than Western consumers," he reasons.¹⁸ Most of the companies interviewed for this paper have not taken a decisive stand on demand issues. The common pattern seems to be to invest in both upmarket (first generation and/or high margin) and downmarket (older and/or high volume) product lines. This tendency reflects an uncertainty about future conditions as well as a belief that the Indian pharmaceuticals market functions not as one market, but as an aggregate of many smaller markets.

3 Impact of 2005 on Firm Strategies

This section explores how Indian companies are reacting to anticipated changes in patent protection following 2005. It will be demonstrated that firm strategies are contingent upon expectations about and capacities to adapt to the new patent environment.

3.1 Expectations

There are still many unknowns concerning the anticipated patent legislation in 2005. Even if (as is expected) the new patent law nominally complies with WTO guidelines, much uncertainty persists about its specific operation. For example, the law may be interpreted in a manner that favors Indian companies over MNCs. Furthermore, courts might be unwilling or unable to enforce decisions.

3.1.1 *New Delhi's will to affect change*

In evaluating the degree to which the New Delhi government will support stronger patent protection, it is useful to consider its standpoint with respect to the costs and benefits associated with patent protection. If perceived costs, such as increased prices and local firms' weakened competitive position, outweigh the benefits associated with innovation, then New Delhi will be inclined to choose weak legislation and enforcement. If the government believes

that strong patent protection will contribute positively to India's overall social and industrial welfare, the reverse will be true.

A number of factors suggest that New Delhi will support patent legislation that has minimal effect on the status quo, though the success of their efforts remains to be seen. Most notably, during the past two decades of debate about universal IP norms in pharmaceuticals, India has led other less developed countries (LDCs) in vehemently opposing developed countries' efforts to implement global standards. They have endeavored to block such standards on the grounds that strong IP rights put local industry at a disadvantage to foreign competition and, more importantly, cause drug prices to escalate to unaffordable levels. Taken to its logical conclusion, this position suggests that strong patent protection sacrifices the health of India's vast population. The following quote from Indira Gandhi's much-publicized remarks at the 1982 World Health Assembly illustrates the crux of the LDCs' argument, then and now. "The idea of a better-ordered world," Mrs. Gandhi asserted, "is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."

The anti-patent school has recently wielded a great deal of influence in New Delhi. Consider, for example, that the parliament prevented the original 1995 act from passage and insisted on a ten-year grace period. Given such negative sentiments, it is reasonable to assume that the government is not fully committed to increased patent protection. To appease the WTO, it will do the bare minimum necessary, while still loading its legislation with safeguards to protect existing national interests.

Less influential, but still vocal, the pro-patent position has also garnered some support in New Delhi, and its proponents argue that strong patent legislation will benefit India. Yale economist Jean Lanjouw points to three sources of dynamic gain from patent protection. First, by providing monopoly profits to inventors, the law will give companies incentives to develop new drugs. Second, the law's disclosure requirement will fuel continuing R&D by documenting all patented products. Third, product patents may improve industry productivity by inducing firms to contract and ally with one another based on complementary strengths. Of course, support of the pro-patent position assumes that these gains outweigh the static losses to society, which take the form of higher drug prices. Many locals appear skeptical of this assumption; they point out that most gains from patent protection are likely to benefit MNCs and foreign drug designers, whereas price increases and local firms' reduced competitive position will cost India dearly. The pro-patent faction's most notable success of the position is New Delhi's recent ratification of the EMR amendment, which offers firms *de facto* patent protection on products released on or after 2000.

History is on the side of the pro-patent school. That is, based on the experiences of other developing countries, strong patent protection has been an outgrowth of the development process. Countries develop their own incentives to protect IP in parallel with their capacities to produce IP. This phenomenon has already occurred (or is occurring) in the majority of Latin American, Eastern European, and Asian newly industrializing countries (NICs).

3.1.2 *New Delhi's ability to affect change*

Even if the 2005 patent law fully complies with OPPI specifications, it will be ineffective without proper enforcement. Patent examiners possess skills not easily attainable in India, and they generally command premium compensation. Lanjouw estimates that the Indian patent and trademark office (PTO) currently spends \$330,000 per year, whereas its U.S. counterpart operates on a \$300 million budget.¹⁹ Obviously, New Delhi will have to allocate more resources to its PTO if it is to function effectively. In addition, India lacks other

complementary private sector features that are required of a well-functioning patent system, such as patent attorneys and a general appreciation of IP issues.²⁰

3.1.3 Firms' views

In the final analysis, patents will probably not be as strong or as well enforced as the OPPI firms and Western governments want, but the post-2005 scenario—against the apparent wishes of New Delhi—is sure to represent a significant departure from the status quo. The potential range of possible outcomes poses significant problems for firms attempting to draft post-2005 strategies. Several of the MNCs covered in this study have decided to refrain from making a judgement about 2005 until after the fact, but have devised expansion plans to distribute higher revenue, easily prepared, first generation drugs in India. Other firms, such as Sun Pharmaceuticals, have made detailed guesses about the degree of patent protection they will receive, and have initiated costly, irreversible investments based on their assumptions. A third set of firms, such as Wockhardt, is more forward-looking than the first group, but places a higher value on workable contingency strategies than the second.

At this stage in time, it is all too easy to misdiagnose the effects of the 2005 legislation on company profitability. Even if a given firm makes incorrect assumptions about 2005, it is still likely that its new strategies will be more profitable than those that they replace.

3.2 Capabilities

Because different companies have different strengths and weaknesses, two companies may well put forth identical analyses of the post-2005 patent environment, yet react in completely different ways. This subsection attempts to highlight some of the features that differentiate companies from one another. Figure 1 presents a qualitative snapshot of the functional capabilities of the companies that comprise this paper's sample. According to the sample, in all four areas of the product cycle, the most prominent Indian companies are competitive with MNCs in the domestic market. Indian companies excel particularly in domestic marketing and distribution. For the MNCs, the domestic figures may be somewhat misleading, because MNC subsidiaries often rely upon their parent companies for assistance in specific areas, rather than duplicating work themselves.

Figure 1: Functional Capabilities

	Discovery		Clinical Trials		Bulk Manufacture		Formulation Manufacture		Marketing & Distribution	
	India	Global	India	Global	India	Global	India	Global	India	Global
<u>Indian Firms</u>										
A	3	1	2	1	2	2	2	1	3	2
B	2	1	0	0	2	1	1	1	2	1
C	2	1	0	1	2	1	2	1	3	1
D	3	2	3	2	3	3	3	2	3	2
E	1	1	0	0	3	2	2	2	2	2
F	2	1	0	0	3	2	2	1	3	2
G	1	1	0	0	3	2	2	2	3	2
H	1	1	0	0	3	2	2	1	3	1
<u>MNCs</u>										
I	1	3	0	3	2	3	2	3	1	2
J	1	2	0	3	2	3	2	3	3	2
K	1	3	0	3	3	3	2	3	2	3
L	1	3	2	3	3	3	2	3	2	2
Indian Average	1.88	1.13	0.63	0.50	2.63	1.88	2.00	1.38	2.75	1.63
MNC Average	1.00	2.75	0.25	3.00	2.50	3.00	2.00	3.00	2.00	2.25

Legend: 0 = None; 1 = Minimal; 2 = Moderate; 3 = Extensive. Global ratings for the MNCs apply to the parent companies of the Indian subsidiaries interviewed for this paper.

3.3.1 Size

Historically, large companies have dominated the global pharmaceutical industry. This has been the case primarily because certain phases of the product cycle (see section 2.2), such as clinical trials and (global) marketing, require substantial investment. In India, three factors have reduced the importance of companies' size, as compared with elsewhere in the world. Local companies did not have to engage in discovery and clinical trials, limited their operations to India and its neighbors, and finally, were offered substantial protection under the drug price control order (DPCO). For these reasons, bigger did not necessarily mean better in India.

Figure 2: Size Comparison

	Total Assets	Market Cap	Turnover	Employees
<u>Indian Firms</u>				
Ranbaxy	500,141*	880,283*	333,425#	5,104@
DRL	101,756*	3,756*	82,900#	
Wockhardt	260,230*	194,385*	79,113*	2,400@
Lupin	18,564*		17,957*	3,000#
NPIL	185,172*	122,013*	117,150*	1,500#
Dabur	121,875#		176,700#	
Sun	6,578#		7,043#	
<u>MNCs</u>				
Glaxo	8,526,000@		13,087,000@	54,000@
Merck	31,853,400@		26,898,200@	57,300@
Novartis	34,552,000#		21,134,000#	87,239#
HMR	55,899,000@		22,346,000@	97,100@

Legend: All monetary figures in USD (\$1,000s). * = 1996 or 96–97 (36 INR/USD); # = 1997 or 97–98 (40 INR/USD); @ = 1998 or 98–99 (43 INR/USD).

However, the advent of product patent protection may induce India’s small firms to alter their strategies. If the industry is overtaken by new drug discoverers (a dubious assumption), then small companies may be forced to merge or align themselves with other companies, to focus on specific phases of the product cycle, or simply to grow larger in order to survive. In the more likely scenario, the new drug discovery market will merely complement much larger markets in older generation branded generic drugs, thereby allowing smaller firms to pursue derivatives of their current strategies if they so choose. In fact, many industry experts expect that demand for older drugs will *increase* as a result of stronger patent protection: Indian consumers want cheaper drugs and will be unwilling and unable to pay the higher prices that newer products command.

3.2.2 Markets

Some of the companies covered in this study, such as Lupin Laboratories, Dabur Research, and Knoll Pharmaceuticals, sell the vast majority of their products within India. Others, such as Sun Pharmaceuticals, sell large percentages of output to India and other emerging markets that have low approval and patent standards. A third group sells bulks and branded generic formulations all over the world.

The geographic markets a given company serves today will influence its post-2005 strategies. For example, companies with particularly strong distribution and marketing

capacities in India, such as Knoll or Lupin, might leverage those strengths after 2005 by contracting to sell other companies' products. Similarly, companies with established international distribution networks, such as DRL and Ranbaxy Laboratories, might concentrate on forging positions for themselves in other markets, in order to support new investments.

Perhaps more important than geography, however, is the product mix from which companies have historically derived their revenues. Companies with large percentages of soon-to-be illegal current products have a more urgent need to change course than those that rely on off-patent drugs for the majority of their revenues.

3.2.3 Present Technological Capabilities

Technological competence is developed gradually. Therefore, firms that already have technologically intensive operations have a better chance at rising to the level of their MNC competitors than those that do not.

3.3 Strategies

This section evaluates some of the measures companies are adopting to ensure solvency after 2005.

3.3.1 Technological Strengthening

The most common strategic concern that 2005 has raised for Indian pharmaceutical companies is the perceived need for technological strength. Companies are faced with the realization that the only way they can continue to sell first generation drugs (in the absence of licensing or distribution agreements) is by discovering and developing them indigenously. For Indian firms, there are two routes to this end. They can either latch onto the skills of MNCs or they can embark on programs to develop their own technical capacities.

Most Indian firms surveyed here have decided that new drug discovery is an unfeasible short term goal and have consequently pursued more modest technological programs. Sun and Lupin fall into this category. While acknowledging that new drug discovery belongs on their long-term horizons, they have devised strategies that afford profitable operations without new drugs. Both have worked to bring more of the production process under their own control (through forward and backward integration) while simultaneously sharpening their existing R&D practices. Lupin, for example, prides itself on its innovative line extensions. Even if these companies had more capital at their disposal, they would be unlikely to pursue new drug discovery programs because their managers firmly believe that technological competence needs to be fostered gradually.

3.3.2 Redefining New Drug Discovery

Several Indian companies (e.g., Ranbaxy, DRL, Dabur, and Wockhardt) are turning the prospect of increased patent protection to their advantage by spearheading new drug discovery programs. Their efforts have attracted much attention. Skeptics assert that Indian companies are not large enough to discover and develop their own drugs successfully. Indian companies also lack the experience of the major players; leading MNCs have spent the better part of the twentieth century honing R&D skills.

Developing new drugs is time- and capital- intensive. Companies usually test thousands of substances in order to bring a single product to market. However, companies such as DRL have advanced products to the clinical trials phase only a decade after initiating new drug

discovery programs. Their costs have been substantially lower than global benchmarks—for example, Anji Reddy, chairman of DRL, estimates his research costs are one eightieth of those of his MNC competitors—and their success rate has been higher. Indian companies have yet to place their own products on global markets, but there is reason to believe that at least some of their endeavors will succeed as planned, although potential complications (such as the emergence of unexpected costs) could still result.

Even if one accepts DRL's exceptional cost claims, Indian companies are still advised to seek ways to reduce costs and risks, and thereby, to increase new drug discovery, which remains, in essence, a hit-or-miss affair. Several options are available. First, contracting with other firms to aid in various stages of the research process seems to be a preferred course of action. Both DRL and Ranbaxy have allied with foreign firms to conduct costly clinical trials in Western markets. This amounts to giving up profit potential in exchange for reducing exposure, and allows the Indian companies to devote more resources to the core of the discovery process. Firms also find relief at the front end of the research process by taking leads from public R&D centers and other companies that focus on early stage (*in vitro*) screening of new compounds. Second, some companies are considering investment in combinatorial chemistry in order to increase the volume of molecules with which they have to work. Third, some Indian companies emphasize practices that are designed to improve success rates. For example, DRL focuses almost solely on a related chain of Syndrome X diseases that have similar causes and similar cures.

Although MNCs are not convinced that Indian companies pose a serious threat to their business, at the very least, DRL and Ranbaxy have attracted sufficient attention to give them reason to reconsider their reluctance invest more heavily in Indian operations.

3.3.3 *Public research*

Most individuals surveyed for this paper were decidedly negative about India's public research facilities. In theory, public R&D labs should be an invaluable resource to India's smaller drug companies because they allow them access to lead molecules and other specialized R&D functions that they could not otherwise afford. In practice, however, the current quality of such labs is so poor that relying on them for survival, in the opinion of most experts, is one of the biggest mistakes companies can make. A notable exception to this maxim is the Indian Institute of Science (IIS), which has been quite successful at conducting clinical trials. Whether or not other public research labs can follow IIS' example remains to be seen.

3.3.4 *Leveraging Nontechnological Strengths*

On the surface, 2005 seems to call for Indian companies to become more technologically focused, and indeed, a number of India's more prominent firms (e.g. Ranbaxy, DRL, and Wockhardt) are pursuing this goal by developing U.S. FDA-approved processes and drug discovery programs. As 2005 draws nearer, however, India's pharmaceutical companies must also expand and develop their nontechnological strengths to keep pace with MNC competition.

In keeping with this broader development strategy, some companies (e.g. Sun, Lupin, etc.) are undertaking less technologically oriented initiatives. Sun, for example, recently expanded its R&D operations to place greater emphasis on developing state-of-the-art processes and novel delivery systems. Such endeavors fall short of new drug discovery, but they represent important steps toward technological self-sufficiency.

A third set of companies has chosen to concentrate on nontechnological phases of the product cycle, such as marketing and distribution, and low-technology product areas such as

traditional medicines and generic drugs. D.M. Gavaskar of Knoll refers to these focus areas as “India skills.” He believes India skills will become increasingly important after 2005, when the pharmaceutical industry will find itself saturated with foreign companies lacking the wherewithal to bring their products to market. Knoll, Nicholas Piramal, Lupin, and Dabur are all examples of companies that have adopted versions of this strategy.

Another particularly popular nontechnological strategy, related to “India skills” above, consists of local companies entering into alliances with MNCs that do not have strong India presence in order to co-market their products. Under such arrangements, Indian companies use their knowledge of Indian business conditions and relationships with doctors to maximize returns for their foreign partners. These Indian companies have become specialists in the marketing and distribution phase of the product cycle. Interestingly, Knoll, one of the most active champions of this strategy, is itself a multinational. As long as India remains foreign to the world’s leading pharmaceutical companies, there will be market need for less technologically advanced firms to perform India-specific, business functions.

3.3.5 *Growing Larger*

Section 3.2.1 demonstrated that only large pharmaceutical companies can engage in all four phases of the pharmaceutical production cycle. Indian companies—which have traditionally limited themselves to domestic production and distribution—must therefore grow larger to enter discovery and clinical trials *in addition to* their current operations, and/or to expand to developed export markets. This section reviews the means by which these companies are growing.

Mergers, Acquisitions, and Partnerships

The process of consolidation is well under way. Five of the twelve firms covered in this paper have engaged in some sort of M&A activity, while two others have purchased large assets from competitors over the past five years. Mergers have occurred between Indian companies such as DRL and Cheminor, between MNC subsidiaries such Hindustan Ciba-Geigy and Sandoz India (Novartis), and between Indian and foreign companies. With respect to acquisitions, companies such as Ranbaxy, Sun, and DRL have purchased assets from firms based in other countries in order to expand their international presence. M&A has also been motivated by the desire to shift focus, toward or away from revenues dependent on technological processes. Sun’s acquisition of Knoll’s bulk lab, for example, was motivated by the former’s technological strengthening program, in addition to the latter’s skeptical attitudes about the post-2000 patent laws.

Partnerships and marketing alliances are also increasingly common. These provide companies with the opportunity to join forces without the drawbacks and complications associated with formal marriage. Knoll is actively pursuing a strategy to court foreign multinationals without an India presence (including a fifteen year agreement with Novo Nordisk) to distribute their products after 2005. Conversely, other Indian companies are looking to international partners to market, distribute, and gain approvals for their products in foreign markets.

The consolidation process described here has led to tremendous increases in productivity. For example, sales force productivity at Novartis India Limited increased by 58 percent between 1996 and 1998, following the merger that formed the company.²¹ Although a considerable component of these gains is attributable to merged firms’ ability to cut staff (which is hard to do in India), companies that have survived the consolidation process tend to be healthier overall than they were during the pre-liberalization era.

Capital Markets

Sun Pharmaceuticals floated 50 percent of its equity on the Bombay Stock Exchange in 1994 to raise funds in support of its ambitious M&A/technological strengthening plans. DRL also issued a minority portion of its shares to the public, but has been reluctant to rely too heavily on the stock market for capital because of the owners' reluctance to relinquish control. Other companies reported similar reservations about public ownership and dilution; this sentiment may constrain growth. Of the companies surveyed here, five of twelve have issued new public equity to implement their post-2005 strategies.

3.3.6 Help from Parent Companies

Some MNC subsidiaries (e.g., HMR, Knoll, and Glaxo) have adopted a more relaxed posture toward 2005 than India-based companies. For them, adaptation consists of waiting to see where opportunity lies and then capitalizing on it by transferring resources from their parent organization.

3.3.7 Export Focus

Liberalization has substantially increased the global competitiveness of Indian pharmaceutical products, as local companies have been forced to compete alongside MNCs in their home market. Moreover, as the Indian market becomes more crowded, companies are increasingly pressured to look elsewhere in order to expand their revenues. For these reasons, the majority of the Indian companies profiled for this paper have taken specific measures to boost exports.

In the past, the vast majority of Indian pharmaceutical exports went to other developing countries with similar disease profiles and disregard for patent protection. By contrast, MNCs in India tended to limit exports to nearby emerging markets that had needs similar to India's. As 2005 approaches, however, both local and foreign-based companies have begun to export more to developed markets and less to emerging ones. Cipla, Ranbaxy, DRL, and Lupin are in the vanguard of this trend. Since these companies have agreed to comply with WTO patent norms, conflicts of interest will no longer exist with developed markets. Historically, the approvals process in the Western world has served as a major barrier to exports, but this becomes less of a factor as more and more Indian production facilities are being built to conform with GMP standards. The current practice of tying up with companies in host markets also facilitates the approvals process. Ranbaxy and DRL, for example, have adopted flexible international alliance strategies on a country-by-country basis, using joint ventures, wholly owned subsidiaries, various partnerships, and contractual agreements.

International expansion has already helped several Indian companies, such as DRL and Ranbaxy, to achieve international prominence in the generics market. In fact, Ranbaxy, with revenues from generics of \$367 million in 1997, is the eighth largest generic drug company in the world.²² Indian companies' historical aptitude for reverse-engineering is likely to translate into profitability in overseas generics markets, because they can produce generic versions of drugs shortly after patent expiry. This strategy is potentially quite lucrative; 80 percent of a drug's off-patent profits come from the first eighteen months after patent expiry.²³

MNC export strategies are motivated by an entirely different set of issues. Unlike Indian firms, MNCs have always been able to export to the West from their Indian production facilities, but exporting to developed markets was incompatible with their objectives in India, which were to retain the minimal presence needed to serve local markets. In fact, many of the products MNCs sold in India were themselves imported from elsewhere. This

situation is unlikely to change as an immediate result of liberalization. In the long run, however, some analysts expect to see MNCs producing certain drugs in India for global distribution, and local operations are obviously a necessary prerequisite for this scenario.

3.3.8 Localization of Operations for MNCs

Pharmaceutical industry experts have long argued that India is especially well suited for drug production and discovery because it possesses an abundant supply of highly skilled labor, a wide range of raw materials, and a strong domestic market. However, a considerable portion of pharmaceutical MNCs have either avoided India altogether or maintained the minimum presence necessary to gain market access.

When asked why they were reluctant to move more operations to India, the managers of the MNCs surveyed for this paper cited four factors: 1) poor patent protection, 2) price controls, 3) difficulty in predicting future conditions, and 4) the absence of clear microeconomic advantages to localized operations. The first three factors are related in that they are closely connected with government policy and policy implementation. The inclusion of these factors here underscores one of the major themes of this paper, that corporate strategy in India's pharmaceutical industry is contingent upon regulatory and market conditions. Assuming that patent laws and price controls continue to become increasingly liberalized, it is likely that MNCs will expand their presence in India. Such a trend would have profound implications for the industry as a whole. Even with limited local operations, MNCs have already helped bring Indian industry standards in line with global norms. (The same may be said for India's software industry in Bangalore and Hyderabad.)

The relationship between liberalization and localization is not simply a matter of cause and effect because it is necessary to consider the fourth factor outlined above, the advantages of producing in India. Many of the forecasting efforts of MNCs in India have been devoted to this issue. One firm estimates that, in addition to substantially cheaper labor costs, India's capital costs are 50-75 percent lower than those in developed countries.²⁴ India's interest rates may be astronomical, but factory equipment—the cost of which is closely linked to plant engineering expenses—remains quite inexpensive.

Localization advocates also champion the cost advantages of using India as a research base. According to Dr. Anji Reddy, DRL's founder and chairman, Indians are experts at reverse-engineering patented molecules, which the 2005 legislation will soon prohibit. Using this technique, they can develop a noninfringing process for any drug in six months or less. Dr. Reddy has shown that the same institutional characteristics that facilitate quality reverse-engineering are transferable to other areas, such as drug discovery. Reverse-engineering requires technicians to screen molecules, to use complex analytical equipment, and to create standardized test conditions, practices which all have direct applications in the discovery process.

Others are much more cautious in their optimism. They maintain that input cost-advantages are inconsequential and overstated, and will certainly evaporate as India develops.²⁵ Critics suggest that DRL's figures for new drug discovery, for example, are incomplete because they do not account for certain expenses and are based on an extremely limited set of data. Further, skeptics point out that most Indian pharmaceutical companies are unfamiliar with failure, because their past practices of selling already successful products have not required them to assume risks. Arguments concerning technical skills and human capital, however, are more difficult for the cynics to dismiss. Research comprises such a large portion of pharmaceutical companies' costs that stories of small Indian firms discovering drugs with greater success and at lower cost than global leaders are certainly cause for alarm in some quarters.

Glaxo Wellcome recently conducted a feasibility study on the localization of its Indian operations, which partially confirms the cynics' position. From that company's perspective, certain functions are best done once at headquarters and then distributed later to branch locations. Although it may be cheaper to do a given task in India than in England, it is not cost-effective if the activities in India and England are redundant. Furthermore, Glaxo found that many of India's cost advantages are either nonexistent or are offset by losses in control that occur because of the distance separating India from headquarters.

Most companies surveyed in this study have opinions on localization that fall somewhere in between the two views outlined above. Pending successful implementation of the product patent protection law in 2005, a substantial increase in MNC participation in the pharmaceutical market is likely, much of which will be supported with localized operations. Nevertheless, it will probably be some time before India becomes a global hub for the pharmaceutical industry.

4. Appendix: Company Profiles

This appendix reviews the operations of the companies surveyed for this paper. Each company is reviewed with respect to principal lines of business and strategic considerations for 2005.

4.1 Dabur Research Foundation

Dr. D.B. Ananatha Narayana, *Head of R&D*
Dr. Ravi Jain, *Senior Manager*

Dabur was founded in 1884 as a pharmaceutical company, but in the ensuing years, has greatly diversified into product lines ranging from cheeses to veterinary products. Only 5 percent of 1994 turnover was derived from pharmaceuticals, because since 1993, Dabur has consciously "undiversified" and concentrated on doing fewer things better. Still, Dabur's scope of operations is vast when juxtaposed with that of other pharmaceutical companies.

Liberalization has affected Dabur in a number of ways. First, increased competition has eroded profit margins in many of Dabur's markets. In the past, Dabur produced as many products as possible to capitalize on its distribution expertise. Now, India's infrastructure is greatly improved and specialists can sell products for less than Dabur's total cost. In response to falling margins, Dabur has abandoned failing products and pursued productivity-enhancing measures such as freight cost control, process automation, and a proposed merger with Dabur Research Foundation (at present, R&D is done a contract basis with the research foundation). Second, stronger IP protection has enticed Dabur to build up its pharmaceutical business and pursue new drug discovery. Dabur is also deliberately exploiting its nontechnical strengths by actively recruiting MNCs to market their products in India. Because Dabur is large enough to contribute substantial revenues to research and international (e.g. U.S. FDA) approvals, it believes that the "Westernization" of the pharmaceuticals sector will benefit it *vis-à-vis* its competitors. Third, liberalization—and the reduced relative appeal of the Indian market—have lead Dabur to think more about exports. At present, only 8 percent of the company's turnover is attributable to exports because Dabur

exports mostly low margin products to poor countries. Dabur plans to emphasize higher margin pharmaceuticals in wealthier export markets. Fourth, in response to increasing competition in its pharmaceutical segments, Dabur has placed added emphasis upon its ayurvedic preparations (traditional Indian medicines), an area it has traditionally dominated and also one in which MNCs are comparatively weak. Finally, Dabur plans to leverage its broad distribution capabilities by entering into marketing and distribution agreements with MNCs.

4.2 Dr. Reddy's Laboratories (DRL)

Dr. K. Anji Reddy, *Chairman*

Mr. K. Suresh, *General Manager*

Mr. T. Balamurali Krishna, *Manager*

Dr. M. Satyanarayana Reddy, *General Manager*

Mr. P.V. Sankar Dass, *Marketing Manager*

Dr. G.O.M. Reddy (DRL Research Foundation), *Vice President*

DRL was founded as a bulk drug company in 1984. It has since added formulations and new drug research to its docket of business activities. DRL prides itself on its ability to reverse-engineer *any* molecule in six months. Its product mix comprises an even balance of high volume (e.g., antibacterial) and high margin (e.g., cardiovascular) drugs. DRL's primary objective is to serve the Indian market, but it is much more involved in export markets than most of its competitors. In addition to exporting to other emerging markets, DRL exports a sizeable volume of bulk drugs to Western markets. Along with Ranbaxy and Cipla, DRL has evolved into a key player in the global generics market. DRL attempts to have a physical presence in all of its export markets, through joint venture tie-ups, wholly owned subsidiaries, and contractual arrangements. Perhaps the most notable aspect of DRL's current strategy is its vigorous support of new drug discovery in India; in this respect, it is arguably the most advanced Indian company.

Liberalization has affected DRL in a number of ways, but most changes can be categorized as being prompted either by the more intense competition at the beginning of the 1990s, or by the stricter patent regime that lies on the horizon for 2005. In the early 1990s, DRL's profit margins started to shrink at alarming rates, because of the decline in bulk drug prices and a more competitive atmosphere in general. In addition to de-emphasizing bulk drugs, DRL took other steps to increase margins and decrease risk, including a new focus on export growth, the implementation of a productivity-improving, clear results areas (KRA) system, and a more refined capital allocation algorithm.

The fall in bulk drug prices was monumental for DRL because it impelled the firm to enter the formulations market. 2005 is even more important, because it provides the impetus to launch the company into the new drug discovery business. Unlike most of its competitors, DRL has been preparing for 2005 since 1984, and Anji Reddy is convinced that long-term success for pharmaceutical companies in India is contingent upon new drug research. By 1998, DRL had advanced two molecules to clinical trials (for a fraction of global average costs), bearing out Anji Reddy's belief that discovery research will become a competitive advantage for DRL in particular and India in general. Increased patent protection, he further asserts, will benefit the industry by motivating Indian firms to pursue such new research.

Despite Anji Reddy's flair for low-cost operations, capital limitations threaten to derail DRL's expansion plans. In 1997, the company had just over \$100 million in registered

capital. Aside from proceeding with public debt and equity offerings, DRL has undertaken several initiatives to stretch its existing capital base. In the most notable of these, intended to reduce the costs and risks of doing primary research in India, DRL has contracted with foreign firms to conduct on-site clinical trials, and local firms to provide it with promising leads. Doing so allows DRL to devote a larger share of its limited capital resources to the heart of the discovery process.

4.3 Glaxo India Ltd.

Mr. Madhav B. Kurdekar, *Executive Vice President*

Glaxo's global strength has traditionally been the design and production of leading edge, high margin drugs. For the past seventy-five years, in order to participate in the Indian market, Glaxo has been forced to sell its best drugs at prices well below what it charges elsewhere in the world. Glaxo India also produces bulk drugs and formulations, and sells drugs on behalf of other foreign companies that do not have Indian presence.

Glaxo India does not sell the entire product line of its parent company, UK-based Glaxo Wellcome. Rather, it selectively markets products that are both suitable for India and do not threaten the overall profitability of Glaxo Wellcome UK. In spite of efforts to shelter and contain its India operations from the developed world, Glaxo Wellcome UK has made great sacrifices to gain Indian market share. Any time Glaxo Wellcome sells a drug on the market in India, it does so well below established global price levels. Doing so puts a strain on these global price levels and thereby hurts the parent company's bottom line.

Glaxo Wellcome (UK) believes that its competitive position in India will improve after 2005. It has made minimal strategic adjustments in anticipation of the new patent laws, preferring to wait until it understands industry currents better. However, given that the current model of using technology supplied by the parent can only be more effective with increased patent protection, it is unlikely that Glaxo India will change much after 2005.

4.4 Hindustan Antibiotics Ltd. (HAL)

Mr. M.C. Abraham, *Managing Director*

Mr. S.R. Naik, *General Manager*

Founded in 1954, HAL is a state-owned company, and one of the key building blocks of the Indian pharmaceutical industry. The company's original objectives were threefold: job creation, life saving, and technological diffusion. Today, HAL manufactures seventy-eight formulations and four bulk drugs.

HAL's corporate practices will not be affected by the advent of stronger patent protection in 2005 because—as a state-owned company—it has never engaged in semi-ethical practices such as reverse-engineering. However, other facets of liberalization and rising levels of competition have challenged HAL. As other firms become more competitive and more productive, HAL remains shackled by its intractable bureaucracy.

At present, HAL's future looks questionable. On the positive side, HAL has taken steps to detach itself from the government and to create incentives to induce its personnel to work more productively. For example, it no longer receives government subsidies. On the negative side, HAL has no choice but to carry a large work force and it is obligated to adhere to the (unprofitable) social objectives on which the company was founded.

In the future, India's pharmaceutical industry is more likely to be driven by vanguard private companies such as DRL and Ranbaxy than it is by HAL, but the industry owes much of its current health to HAL's prior contributions. Before HAL opened its doors, the domestic pharmaceutical industry was all but nonexistent. Furthermore, India's universities had no provisions for the type of specialized training required by pharmaceutical companies. HAL's founders took the initiative and laid a considerable part of the foundation that supports today's local and MNC subsidiary drug companies. HAL created a demand for inputs in the form of skilled labor, specialized capital, and relevant services, and provided the critical mass for local pharmaceutical production, created jobs for tens of thousands, spurred innovation, and sparked industrial development in up and downstream businesses. These contributions eventually rendered India a favorable environment for pharmaceutical production, research, and distribution.

Because its role will become increasingly trivial as the pharmaceutical industry grows, it is unlikely that HAL will continue to serve India in the aforementioned capacities. Over time, public contributions to the pharmaceuticals sector will likely take other forms, such as public R&D centers, which allow Indian companies to enter drug discovery with less capital than they would otherwise require.

4.5 Hoechst Marion Roussel Ltd. (HMR)

Mr. Debabrata Bhadury, *Managing Director*

HMR is a multinational chemical company that has had operations in India since 1956. Over the past several years HMR India has abandoned its petrochemical divisions in order to focus efficiently on pharmaceuticals, a practice which mirrors the intent of its parent company. HMR's efficiency drive has also consisted of taking full advantage of economies of scale by centralizing certain functions in Frankfurt and establishing good communication throughout the HMR family. As a result, HMR India is much more closely integrated with its parent company than are most other MNC pharmaceutical subsidiaries in India.

Although it invests large sums of money to support pro-patent lobbies in New Delhi, HMR, like other MNCs, is unsure of what to expect of the post-2005 patent regime. Rather than subjecting itself to such uncertainty, it has pursued a strategy of relying on headquarters in Frankfurt for products, technology, and marketing programs on an as-needed basis. Meanwhile, it has divested itself of its local primary/bulk R&D facilities. Interestingly, HMR has filed more patents in India than any other drug company, and pending attractive patent protection, it may well reinvest in its Indian operations after 2005. Whether or not it does so will have almost no impact on the types of products it is able to produce and sell in India.

4.6 Knoll Pharmaceuticals Ltd. (BASF Pharma)

Mr. D.M. Gavaskar, *Managing Director & President*
Dr. A.V. Prabhu, *Vice President*

In 1997, BASF acquired UK-based Boots Pharmaceuticals. Subsequently, Boots India was restructured under Knoll, BASF's U.S.-based pharmaceutical subsidiary. In India, Knoll acts with considerable autonomy from its corporate parent. D.M. Gavaskar, its managing director and president, believes that autonomy is necessary for Knoll to serve its markets

adequately. Two reasons underlie this belief. First, complex matrix structures, in which employees perform both regional and functional duties, tend to inhibit distribution relationships, which are critical to success in India. Second, in many respects the Indian market differs fundamentally from the global market. For example, cough and cold medicines are currently the second largest functional segment in India, although they are of trivial importance on the world scene. Adopting a more centralized approach would weaken Knoll's individual capacity to promote cough and cold remedies. In general, a certain degree of autonomy is necessary to capitalize on Knoll's strengths—a strong distribution network and an intimate knowledge of the Indian market for drugs. Knoll does not involve itself in exports (only 3 percent of its products are exported).

Not surprisingly, Knoll's product line is heavily oriented to India's needs. Rather than selling all of its parent's products, Knoll selectively promotes formulations in anti-TB, antimalarial, and other high-demand segments. Additionally, Knoll derives 32 percent of its revenues from insulin sales.

As 2005 approaches, Knoll is moving away from, rather than toward knowledge and technology intensive practices. For example, Knoll sold its discovery lab in Goa to Sun Pharma in the belief that Indian consumers price sensitivity makes India an unprofitable place to market first generation drugs. Knoll bets that the generics and the branded-generics markets will become increasingly important. It is therefore investing in focus areas, such as marketing and distribution, to help it succeed, despite the similarity of its product line with those of its competitors. Knoll is also trying to act as a distributor/co-marketer for other MNCs that do not have operations in India. Notably, it recently signed a fifteen-year deal with Novo Nordisk of Denmark to market that company's products in India.

4.7 Lupin Laboratories Ltd.

Mr. Lalit Kumar, *President*

Mr. Shrikant Kulkarni, *General Manager*

Lupin is a twenty-seven year-old Indian pharmaceutical company. In the past, Lupin derived a considerable portion of its revenues from producing bulk and intermediate drugs with noninfringing processes, many of which were bound by product patents in more developed countries. It specializes in anti-TB medications and cephalosporins (antibiotics derived from the *Cephalosporium* genus of fungi).

With the onset of government liberalization and the prospects of increased patent protection after 2005, Lupin has decidedly changed its course in several ways. First, it has shifted focus from low-margin bulks to higher value-added products, such as novel delivery systems and niche products for selective markets. Second, it has adopted an export focus; in 1997, 55 percent of turnover came from exports. Third, Lupin has experimented with several different types of tie-ups with other firms in order to grow larger and reach new markets. For example, it has entered a joint venture with Merck, owns a subsidiary in Thailand, and maintains representative offices in several other countries. Fourth, it has increasingly resorted to capital markets to acquire the funding necessary to support its expansion.

Lupin's strengths are in marketing and distribution. Today, Lupin is the largest producer in the world of the anti-TB drugs Ethambutol and Rifampicin. The secret of Lupin's success in the anti-TB segment is its AKT-4 kit, which bundles four essential TB drugs into a single dosage pack. Doctors like AKT-4 kits because bundling helps prevent the selective discon-

tinuation that can lead to relapse or drug resistance. Lupin's demonstrated commitment to doctors and patients has afforded its brand a favorable position in India and throughout other emerging markets.

Lalit Kumar, Lupin's president, believes that the post-2005 environment will favor firms that are larger and more experienced than Lupin is at present. Lupin aspires to discover its own molecules some day, but it realizes that it does not, as yet, have the resources to do so. For Lupin, growth and learning take time.

4.8 Nicholas Piramal India Ltd. (NPIL)

Dr. A.G. Seshdrinathan, *Vice President*

Established in 1947, NPIL is engaged in the sale of pharmaceuticals and glass products for the pharmaceutical industry. Within pharmaceuticals, NPIL has a presence in the cardiovascular, anti-infective, antacid, and dermatological segments of the market. With the exception of cardiovascular, these are high-volume segments. NPIL's principal strategy is to build economies of scale in the production of high-volume drugs, which it then markets in India and other countries with similar drug markets, such as Africa, Southeast Asia, and Russia. As it is strong in marketing and distribution, NPIL has also been particularly active in marketing MNC products in India.

NPIL develops products for the Indian market. It procures its molecules from MNCs with limited presence in India and strong R&D pipelines, in addition to its own network of subsidiaries and sister companies. To facilitate its ambitious development programs, NPIL pursues a strategy of aggressive acquisitions and strategic alliances. Recent acquisitions include HMR's formulation development lab and Sumitra Pharmaceuticals & Chemicals. In total, NPIL has over twenty factories in operation, and one of its toughest challenges is the coordination of operations across its network.

NPIL does not aspire to engage in new drug discovery in the near future. Instead, it approaches 2005 with the aim of consolidating its presence in the global generics market. At the same time, the company plans to leverage its alliances with Allergan, Roche, Boots Healthcare, and other MNCs to stay ahead in the market for first generation drugs.

4.9 Novartis India Ltd.

Mr. Ranjit Shahani, *Chief Executive Officer*

Novartis India Ltd. was formed in 1997, following the merger of Sandoz (India) and Hindustan Ciba-Geigy. The old Hindustan Ciba-Geigy (India) had traditionally focused on producing formulations of its parent company's products for the Indian market, as well as a small number of export markets with conditions similar to those of India. More recently, Novartis India, as it is now called, has begun to produce bulk drugs for use in local formulations and for export to other Novartis plants.

Novartis allocates development, marketing, and distribution resources according to medical need and the number of patients for prospective products. Currently, Novartis has a strong presence in immunology, oncology, psychiatry, cardiovascular, anti-TB, gynecology, dermatology, and transplant segments.

Over the past ten years, the company has grown increasingly bullish on India, as it has become ever more apparent that the future regulatory/patent environment will complement

its strengths of a strong R&D pipeline and state-of-the-art facilities). However, Novartis will not initiate new drug discovery R&D in India until it has a clearer understanding of the post-2005 patent environment.

Novartis believes that one of the key determinants of success for pharmaceutical companies following 2005 will be brand equity, because first generation drugs will be out of reach for most consumers. Accordingly, it has devoted a considerable share of its resources to marketing, customer service, increased availability, and line extensions.

4.10 Ranbaxy Laboratories

Dr. J.M. Khanna, *Executive Vice President & Member of the Board*

Dr. Sudarshan Arora, *Executive Director (New Drug Discovery)*

Dr. M.R. Marathe, *Assistant Director*

Ranbaxy is the largest Indian drug company, second only to Glaxo India in terms of overall pharmaceutical market share. Because of its size and global ambitions, Ranbaxy has received a large amount of press in the last several years. Indeed, many analysts believe that Ranbaxy is especially well positioned to compete alongside multinationals in future decades.

Parvinder Singh—the 55 year-old chairman of Ranbaxy—is convinced that India's pharmaceutical industry is evolving in a way that will make complacency a losing strategy in years to come. He believes that Indian companies need drastically to reorient themselves to remain competitive in the post-2005 marketplace.²⁶ Ranbaxy is pursuing three initiatives in response to its changing environment: new drug discovery, globalization, and domestic strengthening. The company has also vowed not to introduce any more pirated drugs, as doing so will threaten its credibility.

Ranbaxy has been conducting new drug discovery research from its facilities in Okhla since 1994. During the past five years, the Okhla research team successfully advanced three molecules through subacute toxicity (ED50) testing procedures. Unlike DRL, however, Ranbaxy has decided to conduct clinical trials by itself in India. Pending successful completion, it will then repeat trials in the United States and Europe. This strategy will save Ranbaxy money in the short term and offer its investors a larger share of revenues from the new drugs, but it will also deny it timely access to lucrative Western markets.

Also during the past five years, Ranbaxy has established subsidiaries or entered joint ventures in fourteen countries, including the United States, Canada, Ireland, the Netherlands, South Africa, China, and Thailand. Through globalization, Ranbaxy seeks to establish overseas presence in formulation manufacture and approvals, while sourcing bulk actives from India. Ranbaxy's international product basket consists of bulks and branded generics. Ranbaxy will also sell any new drugs it discovers throughout its global network.

While Ranbaxy has developed an impressive global presence in recent years, the market it knows best is in its backyard. Ranbaxy maintains a field force of 1,800 devoted to interacting with doctors and building brand equity throughout India. Ranbaxy's new policy of nonpiracy, however, seemingly puts it at a disadvantage with its competitors, who may choose to develop patented (pirated) drugs until 2005. Therefore, in order to preserve its market share, Ranbaxy has had to act aggressively on the domestic front to increase its product offerings. First, it has acquired small firms in product segments in which it has traditionally been weak, such as dermatology and anti-inflammation, in order to gain access to their brands. Second, it has entered into licensing agreements with MNCs to manufacture

and sell their patented drugs in India. Third, it has continued to manufacture drugs whose patents have already expired.

Ranbaxy's future looks bright, but many challenges lie ahead. Notably, the company has invested over \$480 million per year in its international expansion, the profitability of which is contingent upon Ranbaxy's capacity to develop and market its products successfully under a wide range of circumstances. Some observers believe that Ranbaxy's strategy of establishing international operations is needlessly expensive and risky. To be sure, new drug discovery remains a large gamble for Ranbaxy and other Indian firms alike. Dr. Sudarshan Arora, executive director for Ranbaxy's New Drug Discovery program, believes it will take fifteen to twenty years for Ranbaxy to compete effectively with the global leaders in terms of drug discovery. At present, however, Ranbaxy's limited capital base (\$500 million) offsets any developmental cost advantages it may enjoy over its major competitors.

4.11 Sun Pharmaceuticals Laboratories Ltd.

Mr. Rakesh Mehta, *Vice President*

Sun Pharmaceuticals, founded in 1983, makes formulations and bulk drugs that are suitable for India's market needs and those of foreign markets with similar conditions. Within this context, Sun offers bundles of branded generics in three therapeutic areas—neurology, psychiatry, and cardiology—as well as specialized, high margin products in segments such as gastroenterology. None of these segments is subject to India's price control regime. Industry experts applaud Sun's diverse product line and its innovative marketing initiatives.

Liberalization has altered Sun's strategic course, but the company seems to be adapting well, and it could be argued that it will emerge stronger after 2005. In preparation for this event, Sun has already exhaustively redefined its operations, and continues to refine them year by year.

Two factors have forced Sun to become more productive: falling and increasingly irregular profits, and an initial public offering in 1994. Of these, the second was more influential; shareholders pressed Sun to become a much more transparent operation. In response to this scrutiny, Sun implemented two quality control units and began to measure quality and productivity. "You can't hide from shareholders," remarks Rakesh Mehta, the company's vice president.

Sun manages a broad scope of operations and actively pursues mergers, acquisitions, and other strategic tie-ups in the belief that size will be increasingly important in the coming years. The company's most notable recent activities in this capacity were its acquisition of Knoll's bulk drug facility, and its purchase of controlling stakes in Gujarat Pharma, MJ Pharma, and Caraco (U.S.). These acquisitions provide Sun with additional R&D capabilities and access to factories approved by the U.S. FDA.

The 1991 fall in bulk drug prices and the 1998 collapse of the Russian economy have shown Sun the imprudence of investing too heavily in any one market segment, whether functional or geographic. At the same time, Sun is wary that overdiversification will dilute its core competencies. For the moment, Sun has apparently solved this conundrum—its three primary therapeutic areas employ similar production technology, yet serve entirely different market segments, thereby allowing them access to the best of both worlds. It should be noted, however, that Sun is actively pursuing policies to reduce the number of products it offers, as industry analysts believe that Sun's large number of formulations will certainly become a liability when the market tightens after 2005.²⁷

In 1997, exports accounted for 18 percent of Sun's sales, and these are expected to increase in coming years. Sun's formulations are registered in twenty-six nonregulated markets, while bulks are shipped primarily to large companies in Europe and Latin America. In the future, Sun aspires to export an increasing share of its finished generic formulations to Europe and North America. Sun's recently acquired Caraco and MJ Pharma facilities are instrumental to this ambition because they are GMP-compliant and possess extensive overseas regulatory contacts.

The threat of increased patent protection has forced Sun to take corrective measures with its existing practices. For example, Sun no longer sells products with process patents that extend beyond 2005. It has also invested heavily in sales and marketing capacities with tentative plans to implement its branded generic strategy in a broad range of markets. Finally, Sun has increased its R&D spending to 4.3 percent of turnover (versus 3.8 percent in 1995). Sun is less optimistic (or more practical) than DRL about its capacity to launch primary R&D operations overnight, but shares the view that drug discovery is the key to long-term success in the industry. Mehta further points out that even with primary R&D capabilities, Indian firms will be weaker than MNCs after 2005 and should therefore concentrate on areas where MNCs are lacking.

4.12 Wockhardt Ltd.

Mr. Vinod Pabi, *Senior Vice President*

Mr. Javed Hussain, *Deputy General Manager*

Dr. M.V. Patel, *Director*

Dr. S.K. Agarwal, *Senior Scientist*

Dr. Sudarsan Jagannathan, *Scientist*

Wockhardt is an Indian pharmaceutical company engaged in the production and sale of bulks and formulations, large volume parenterals, infant foods, and agricultural products. Its specialty therapeutic segments are systemic antibiotics, cough and cold remedies, antispasmodics/anticholinergics/gastroprokinetics, analgesics, antiseptics/disinfectants, and biotechnology. For the most part, Wockhardt focuses on drugs with relatively high barriers to entry in terms of technology. Wockhardt's approach to pharmaceuticals is also disease-oriented. The company targets areas of medical need and then builds baskets of drugs accordingly.

Prior to the government's liberalization programs in the early 1990s, Wockhardt restricted itself to formulation production, using bulks purchased from other sources. Since then, it has emerged as a prominent producer of bulks in its own right, and now produces almost its entire requirement of bulk drugs. This has helped the company to achieve relatively high operating profitability compared with its competitors.

Liberalization has also helped Wockhardt to increase in size. It has taken advantage of improved access to capital markets with a GDR issue,²⁸ and pursued a strategy of mergers, acquisitions, and strategic alliances in order to boost exports, enhance R&D capacity, and gain approvals to sell its products in the United States and Europe. With respect to the last objective, Wockhardt primarily aligns itself with companies that have U.S. FDA-approved plants or prior marketing experience in the West.

In exports, Wockhardt is attempting to move from bulks to formulations because of the latter's greater profit potential. This shift entails physical presence in export markets—

witness Wockhardt's joint venture with Sidmak Laboratories in New Jersey and its two European biotechnology partnerships—because regulatory approvals are crucial.

Along with Ranbaxy and DRL, Wockhardt has also entered the field of new drug discovery at its research center in Aurangabad. In light of Wockhardt's prior emphasis on technology, the transition to new drug discovery has not been especially difficult. At present, the new drug discovery operation is constrained by the chemistry department's limited capacity to produce and screen lead molecules. To improve this situation, Wockhardt may choose to invest in costly combinatorial chemistry equipment in the near future.

Wockhardt's principal goal as it approaches 2005 is to compete with MNCs as they consolidate their operations in India. Size, exportability, biotechnology, and new drug discovery will all propel Wockhardt toward this end. The company will also continue to hone its process development skills, as growth increasingly depends upon a capacity to develop noninfringing processes for drugs whose patents are expiring. Wockhardt's current strengths are its size, its technological focus, and its experience with international regulatory authorities. Its future success is contingent upon its ability to leverage these strengths as the market tightens.

Notes

¹ According to D.M. Gavaskar, Managing Director, Knoll Pharmaceuticals.

² Felker, Greg. 1997. *The Pharmaceutical Industry in India and Hungary*, World Bank: Washington, p. 7.

³ Ibid., p. 8. Only 250 of India's pharmaceutical companies are "large-scale," in that they are monitored by the Directorate General of Technical Development.

⁴ Lanjouw, Jean. 1998. *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?"* NBER: Cambridge, MA. p. 4.

⁵ For a full text of the TRIPS accord, see *International Legal Materials*, Vol. 33, pp. 1197-1225.

⁶ *Guidance for Institutional Review Boards and Clinical Investigators: 1998 Update*, FDA web site: <http://www.fda.gov/oc/oha/IRB/toc.html>.

⁷ For more information, refer to *Current Good Manufacturing Practice Issues on Human Use Pharmaceuticals* on the FDA web site: <http://www.fda.gov/cder/dmpq/cgmpnotes.htm>.

⁸ Western pharmaceutical markets are moving toward regulatory harmonization, which will serve to reduce the costs associated with duplicating clinical trials. At present, one set of approvals is usually necessary to enter European markets, and a second to enter the United States.

⁹ Clark, Andrew. 1995. *Global Healthcare: Indian Pharmaceutical Sector*, Barings: London, p. 4.

¹⁰ Parmar, Shalin. 1996. *Drug Dealing in India*, Forbes Marshall: Pune, p. 16. Many of those interviewed in this study felt that too much has been made of price controls. For the most part, drugs have sold for less than the legal maximums.

¹¹ Clark, Ibid., p. 4.

¹² "Patents Bill Passed in Lok Sabha," *The Statesman*, March 10, 1999.

¹³ Gharpure, Y.H. 1997. "Turmoil in the Pharma Sector," *Chemical Weekly Annual*, Vol. 1., p. 168.

¹⁴ Ibid.

¹⁵ "U.S., EC Commend India for Amending its Patents Act," *Asia Pulse*, April 29, 1999.

¹⁶ "Five-year Forecast of 'Golden Age' Pharma Growth from IMS Health," *Market Letter*, January 11, 1999.

¹⁷ India's current market structure is amenable to regional and national companies because it is large and diverse. Trends toward a more homogenous structure might hurt local companies by depriving them of their regional advantages.

¹⁸ Lanjouw, p. 10.

¹⁹ Ibid., pp. 19-20.

²⁰ Stanford law professor John Barton, an intellectual property expert, is particularly pessimistic about the capacity of the Indian government to implement the new patent law.

²¹ Sales force productivity (turnover/number of sales representatives) for Novartis was 3.8 in 1994 and 6 in 1998.

²² “Annual Report: Generic Drug Industry,” *Med Ad News*, November 1998.

²³ Lanjouw, p. 16.

²⁴ Ibid., p. 17.

²⁵ Ibid., p. 18.

²⁶ Ghosh, Indrial and Dott, Namrata. “The Making of a Multinational,” *Business India*, June 15, 1998, pp. 55-60.

²⁷ This idea of the market tightening after 2005 is interesting. Rakesh Mehta, Sun’s vice president, holds the opinion that the MNCs are poised to attack (and rapidly grab market share) in 2005. This explains Sun’s urgent need to develop export markets.

²⁸ Global Depositary Receipts—also known as American Depositary Receipts (ADR)—are certificates issued by a U.S. Depositary Bank, representing foreign shares held by the bank, usually by a branch or correspondent in the country of issue. One ADR may represent a portion of a foreign share, one share, or a bundle of shares of a foreign corporation. If the ADRs are “sponsored,” the corporation provides financial information and other assistance to the bank and may subsidize the ADRs’ administration. “Unsponsored” ADRs do not receive such assistance. ADRs carry the same currency, political, and economic risks as the underlying foreign share; the prices of the two, adjusted for the SDR/ordinary ratio, are kept essentially identical by arbitrage. American Depositary Shares (ADS) are a similar form of certification. See <http://www.econofinance.com/investterms.htm> for further information.

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Interviews

Unless otherwise noted, all interviews were conducted in India by Sean Eric Smith.

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Mr. T. Balamurali Krishna, *Manager*, 7-30-98.

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