India has been newsworthy as a result of its indigenous pharmaceutical industry selling low-cost AIDS cocktails to South Africa in direct competition with drugs manufactured by multinationals. These triple combination antiretroviral entities were thought to be protected by product patents through multilateral trade negotiations (TRIPS). Impoverished markets offer little incentive to highly profitable multinationals to provide drugs there. The resultant controversy over intellectual property rights—patents, copyrights, trademarks, and trade secrets—and a suitable strategy to prioritize relief for the mounting suffering in Third World nations from AIDS, malaria, tuberculosis, and a dozen other causes of vast morbidity and mortality, has led AIDS activists to claim that “Patents Kill.”

The Economist has written that patents have been the preserve of western multinational companies, “allowing them to establish monopolies, drive out local competition, divert research and development away from the needs of poor countries and force up the price of everything from seeds to software. In the process, patents prevent poor people from getting life-saving drugs, interfere with age-old farming practices, and allow foreign ‘pirates’ to raid local resources, such as medicinal plants, without getting permission or paying compensation.”

At least four Indian pharmaceutical firms stand ready to sell generic AIDS drugs to governments in the least-developed nations at steep reductions (around $350 per year of therapy). Such an action (and what it has helped to prompt in multinational pharmaceutical companies’ price reductions, drug donations, and the dropping of concerted legal action in South Africa), along with the AIDS epidemic worldwide, is forcing a profound alteration in the global pharmaceutical marketplace.

Indian firms are expected to play a more pronounced role in the U.S. market as well as the developing world. It is therefore crucial that we in the United States have more information and insight into India’s pharmaceutical industry.

India’s Economy

During the time span from independence in 1947 until the early 1990s, India was a closed market, insulated from the global marketplace and characterized by Fabian socialism, central planning, and slow economic growth. In 1991, reforms initiated by the Congress Party government led to a sea change in economic activity, with foreign direct investment and exports rising phenomenally. The following decade saw a growth rate of 7% to 8% a year. In spite of a recent slowdown, India still ranks among the fastest-growing economies in Asia, second only to China, which recorded a growth of 8.1% for fiscal 2001.

There are broader forces pulling India into the global economy. Indian democracy has not historically yielded a direct forward force toward economic liberalization that would let this country run alongside the other Asian tigers. When in power, the Congress Party lowered trade barriers that had discouraged India from buying almost anything from or selling to the rest of the world. According to The Economist, “Economic growth, after a brief wobble, picked up, making India one of the world’s fastest-growing economies of the 1990s. Foreign direct investment rose from next to nothing to well over $2 billion a year. India’s share of world export of goods, which had fallen from 2% at independence to 0.4% in 1980, climbed to 0.7% in 2000.”

Consumer price inflation fell and a new dynamic export industry was born, with many poor Indians being drawn from the margins of the society into jobs. Indian manufacturers of consumer goods have discovered internal rural markets and flooded them with goods—including pharmaceuticals.

Yet there remains considerable doubt about India’s competitiveness in the global economy. There are also grounds for questioning the integrity of its institutions, the quality of its infrastructure, and the present zeal for further reforms. Pressures are upon the now BJP (Bharatiya Janata Party) national government to adopt policies that rekindle the excitement in the economy of the early 1990s.
The uneven development of India is also problematic. Higher-growth Indian states tend to have higher private investment, and there are clear links between economic growth and certain kinds of infrastructure, especially electricity and telecommunications. Shortcomings in infrastructure are of two types: the traditional sort of roads, power grids, telecommunications, and so on; and what might be called the human kind, such as courts, bureaucracy, and politics. Failures in each have similar consequences, for they both raise costs, slow transactions, and deter investment. They also feed on each other, and outside observers very often maintain that the current infrastructure leaves much to be desired.

Health care expenditures as a percentage of GDP are very low at 5.6%.

The annual per capita drug expenditure is $3, even lower than Pakistan and Bangladesh at $7 each. Only 3% of the population has medical insurance, so consumers bear the brunt of a large percentage of health care expenses. Other glaring facts are that India has 16% of the world’s population, 18% of the world’s mortality, and 1% of the world’s health care investment.

India’s “new economy” has more bearing on the nation than first impressions might suggest. It extends far beyond the software industry, which has been its most visible sector internationally.

Services are making a noticeable contribution to GDP, and new economy firms present an example to enterprises throughout India. The Economist claims that, “Whether you are peddling software or other services, India offers the same deal: work done to global standards, and often at a faster pace, at Indian cost.”

Opportunities in the Indian stock market are attracting foreign capital. The past crisis brought down valuations, but investors as recently as summer 2001 snapped up low-tech companies that make their money in India and are protected from a global economic recession. The Indian pharmaceutical sector should additionally lure more attention.

The Pharmaceutical Industry

In the early years after independence, the sole players in the industry were multinationals such as Glaxo, Pfizer, and Parke-Davis. The companies both imported and manufactured formulations. The industry saw the emergence of domestic companies after the passage of the Indian Patents Act in 1970, which offered protection against patent violation charges. Thus was born in India the phenomenon of “reverse engineering,” whereby altering some stage in the process of manufacturing a molecule made it possible to secure an Indian process patent. As a result, domestic firms copied Western products overnight. Inherent domestic advantages included the availability of skilled scientific personnel; the low cost of raw material, production, and labor; and government policy (such as exemption from excise duties) that supported indigenous production in the private small-scale industry (SSI) sector. The speed at which new product technologies were adopted and effective distribution systems and effective distribution systems has been phenomenal.

The Indian pharmaceutical market is presently valued at U.S. $5.4 billion, of which domestic sales account for U.S. $3.8 billion and exports for U.S. $1.6 billion. Today, the market accounts for 8% volume of production worldwide, representing 1.8% of the global pharmaceutical industry. Over the last decade, the Indian pharmaceutical industry has recorded a compounded average growth rate (CAGR) of 15%, compared to a world industry rate of 8%.

The industry can be divided into the organized sector and the SSI sector. The Indian pharmaceutical industry is highly fragmented, with 15,000-plus licensed manufacturing units. About 300 are in the organized sector, of which multinationals account for about 40%. Together, the top ten industry players account for only 30% of market share; the top company, Glaxo—Wellcome, has only 5.7%. The market share of multinationals has decreased from 75% in 1971 to approximately 35% at present, while that of Indian companies has increased to 65%. While in 2001 the top five multinationals grew at a rate of 7.2%, the top five domestic companies grew at 14%.

A report by McKinsey predicts that the industry will further grow at a CAGR of 19% to reach $25 billion in revenue by 2010. It is expected that $18 billion to $19 billion will come from existing operations and the rest from new drug discovery and research services. The market capitalization of Indian pharmaceutical companies is projected to grow dramatically to $150 billion from the present $15 billion to $20 billion.

The Organization of Pharmaceutical Producers of India (OPPI) and the Indian Drug Manufacturers Association (IDMA) are the two major associations in the industry. The OPPI has both multinational and Indian members, but is considered to reflect chiefly the multinational viewpoint. The 450 members of the IDMA—the “technocrat entrepreneurs”—on the other hand, are all Indian, so it is considered the voice of the Indian sector.

The new Indian Pharmaceutical Alliance (IPA) consists of 11 leading domestic companies, including Dr. Reddy’s Laboratories, Ranbaxy, and Cipla. They contribute about 30% of the country’s pharmaceutical exports and share over 30% of the domestic market. Their annual R&D accounts for 92% of total pharmaceutical R&D expenditure in the private sector. The alliance was formed primarily to lobby the government on policy issues, such as price regulation, evolution of a patent regime that will honor TRIPS, and upgrading the regulatory framework to prepare Indian companies for international competition.

Products and Performance

The two main categories of Indian products are bulk drugs and formulations. India produces about 70% of its bulk drug requirement and 90% of its requirement for formulations. About 60% of total bulk drugs are exported, making them a major foreign exchange earner for the country. India is now the fourth largest bulk drug producer globally, after the United States, Western Europe, and Japan.
Multinationals have had a strong presence in the manufacturing of formulations but some Indian companies, Reddy’s, Ranbaxy, Cipla, and Wockhardt among others, are growing steadily (see Table 1). These companies have already consolidated their domestic position and are preparing themselves to achieve the same internationally, especially in the generics market.

Price control has been a major deterrent to growth in the Indian pharmaceutical market. The Drug Price Control Order (DPCO) has been amended three times, with the latest version in 1995 reducing the number of products under price control to 76. This number is expected to decrease drastically with the passage of the New Drug Policy in 2002. Companies often withdrew certain products that fell under price control, introducing others that did not. The resultant shortages hurt consumers and triggered an increase in spurious drugs.

Exports

The growth of the industry in India is largely due to exports. Generics are mainly exported to developed nations, the primary market being the United States, where the generics market is projected to be U.S. $18 billion by 2003. In fact, 60% of generics currently sold in the United States are imported.26 Formulations are also targeted to China, South Africa, and the CIS (Commonwealth of Independent States) countries. The ability to offer products of comparable quality at a lower price gives the Indian industry a significant edge in exports.

Cipla, the market leader in AIDS drugs in India, intends to supply the drugs to the Cambodian, Nigerien, and South African governments and plans to gain more approvals from other African governments. Brazil has also shown keen interest in buying generics from India. According to the Wall Street Journal, “reducing prices for governments made good business sense. Other generic drug companies in India say they avoid Indian excise tax, wholesale and retail markups, and fancy packaging by selling to foreign governments. That allows the drug makers to reduce prices 40% and keep the same profit. Selling to governments also means fewer problems with defaults and possibly even with patents.”18 Two other Indian firms, Hetero Drugs, Ltd., and Aurobindo Pharma, Ltd., are also pushing to export AIDS drugs through governments and international organizations.

In April 2001, 39 multinational pharmaceutical firms dropped their court challenge to prevent the South African government from importing, manufacturing, or licensing cheap copies of their patented medicines. This legal landmark may turn out to be a breakthrough in getting treatment to the 40 million AIDS sufferers worldwide. Appearing atavistic at first—up against AIDS activists and two Nobel Prize winners, Nelson Mandela and Medicine without Borders—these leading firms finally succumbed to widespread public pressure. Continuing the suit in Pretoria would have subjected the firms to an inspection of their books and records to prove their profits, and research would have been affected by the competition from Indian manufacturers.

AIDS activists and African trade ministers have taken their patent challenge against the multinational drug companies to the World Trade Organization (WTO), where developing nations represent 80% of the membership. After WTO negotiations in Seattle collapsed, it appears that prescription medicines were “the big sticking point,” according to the Wall Street Journal.19 U.S. Trade Representative Robert Zoellick may concede the intellectual property rights issue to win African support on other issues, since a large number of trade allies want to import cheaper drugs to fight rampant AIDS epidemics. In Africa 22 million people have AIDS; 14 million have already died from the disease.

There remain legitimate concerns about whether human drug trials in India are adequate, and whether drug-manufacturing factories in India and other less developed countries pass full international quality checks. If the United Nations goals for battling AIDS are to be met, health ministries and faculties of medicine and pharmacy in Asia, Africa, and Latin America must begin to play a greater role in ensuring that spurious pharmaceuticals are not allowed to create unlimited resistance to AIDS and other disease. Here policies to restrict importation to a few select Indian firms may be preferable so that they can be monitored by local and international organizations.

The Changing Scenario and Future: Post-GATT

Dramatic changes are inevitable as India moves toward 2005, when the country may be committed to honoring product patents

### Table 1: International Market Leaders

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<tr>
<td>Glaxo-Wellcome</td>
<td>Cifran (ciprofloxacin) – Ranbaxy</td>
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<tr>
<td>Cipla</td>
<td>Nexavar (nevirapine) – Cipla</td>
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<tr>
<td>Aventis Pharma</td>
<td>Taxim (cefotaxime) – Alkem</td>
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<tr>
<td>Lupin Labs</td>
<td>Becosules (vitamin B-complex) – Pfizer</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>Voveran (diclofenac sodium) – Novartis</td>
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<tr>
<td>Pfizer</td>
<td>Neurobion (vitamin B) – E-Merck</td>
</tr>
<tr>
<td>Zydus Cadila</td>
<td>Betnesol (beclomethasone) – Glaxo</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>Rabipur (PCEC rabies vaccine) – Aventis Pharma</td>
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<tr>
<td>Alkem</td>
<td>Wokadine (povidone iodine) – Wockhardt-Merind</td>
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<tr>
<td>Knoll Pharma</td>
<td>Sporidex (cephalexin) – Ranbaxy</td>
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by virtue of becoming a member of WTO and a signatory to the General Agreement on Tariffs and Trade (GATT). Indian companies have recognized that innovation and research are vital for success and survival. Current Indian R&D investment is 1.9% of industry turnover, far below that of multinationals. It is impossible at present for any Indian company to command sufficient resources to take a product from discovery all the way to market. The government has expressed support by granting a 10-year tax holiday on profits for companies investing in R&D.

Top companies are slowly gearing up, with R&D investment rapidly increasing. A recent success story is Dr. Reddy’s licensing of two of its antidiabetic molecules to Novo Nordisk, a Dutch company, and the sublicensing of one to Novartis for distribution in the United States, Canada, and Mexico. The proceeds are expected to be pumped back into R&D. This strategy appears to be the foundation for a slow progression from novel drug delivery systems and analog research, including combinatorial and chiral chemistry, up the value chain to basic research.

The post-GATT scenario will witness a reduction in the number of companies, with many smaller companies shutting down. Multinational interest in India is bound to be rekindled, especially with the government now allowing 100% foreign direct investment (FDI) and making a commitment to honor intellectual property rights. Several Indian firms are preparing to turn into contract research organizations (CROs) and contract manufacturing organizations (CMOs). Skilled professionals can be hired in India for one-fifth to one-tenth the cost in the West, making outsourcing a profitable option for multinationals. Thirty manufacturing facilities have already been approved by organizations such as the U.S. Food and Drug Administration, the Medicines Control Agency in the United Kingdom, and the Australian Therapeutic Goods Administration.

Another strategy in the post-GATT era is the building of strategic alliances with global giants for marketing and distribution as well as licensing. The established marketing networks and distribution systems of Indian companies have potential to be a valuable resource for multinationals. The industry in India will also make opportunities to offer technical service, such as analytical and toxicology services. An additional area with potential is the development of international clinical trial centers based on good clinical practice (GCP).

### Implications for the United States

India’s population of over a billion people includes a growing middle class of 300 million who are ready and able to consume pharmaceuticals as their counterparts do in advanced nations. The sheer size of the middle-class market and the growth of insurance reveals immense market potential for pharmaceutical products ranging from prescription drugs through a variety of OTC products. Meanwhile, higher out-of-pocket expenses are bound to force individuals into buying health insurance. Although private health insurance at present is abysmally low, the Indian health insurance business is projected to reach Rs. 170 billion (approximately U.S. $35 billion) by 2005.

Historically, multinationals have been unwilling to invest in India because Indian protection of intellectual property rights was considered inadequate, and the profit potential was relatively small. Drug regulations effective as of 2005 that will offer 20-year protections as well as the growing middle class market may shortly change their outlook. The need for financial investments may spur mergers and acquisitions within the Indian sector and between Indian and multinational firms, as is expected in post-WTO China. Multinationals see 15 to 20 blockbuster drugs going off patent within the next few years. Because Indian companies could manufacture these cheaply and provide them worldwide, vertical integration strategies may make greater sense now.

Opportunities as always go hand-in-hand with obstacles and threats. Indian drug companies are targeting the U.S. generics market. Given their advantage of low costs, they may very well pose a threat to U.S. generics manufacturers. On the other hand, bulk purchases by multinationals could sustain growth for Indian manufacturers and promote strategic alliances between the two.

One final speculation about the costs for treating AIDS: Just as Third World ministries of health balk at, for them, exorbitant prices for triple antiviral therapies, if GMP and product efficacy can be assured, Indian knock-offs might become appealing to U.S. state Medicaid directors—unless substantial domestic price breaks from the five pharmaceutical giants are forthcoming.

### Summary and Conclusions

The market for pharmaceuticals in India has immense potential. Decreased price controls and changing patent regulations will soon make conditions in India much more favorable to multinational corporations. Alliances with Indian manufacturers for marketing networks and contract research are ripe for exploration. Indian drug companies are gearing up their R&D investment. Their thrust will be on exports, especially in the generics market, and licensing of new discoveries to larger multinationals in an effort to fuel expansion and further growth.

Although scientific skill and entrepreneurship are already proven ingredients in the success of the Indian pharmaceutical industry, catalysts such as upgrading infrastructure, government support, a more efficient judiciary, a bankruptcy law, and labor reforms will speed future broadened success. It will be interesting to witness the strength of possible strategic alliances and the competition for the top echelons as the Indian pharmaceutical industry braces itself for the future.

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