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ABSTRACT: This paper presents an overview of India's pharmaceutical industry and its evolution from almost non-existent to one of the world's leading suppliers of generic drugs. The Indian pharmaceutical industry was allowed to take off when India met its WTO TRIPs obligations and amended its patent laws with the passage and implementation of the Patents (Amendments) Act 2005. When India re-instituted "product" patents, it effectively ended 36 years of protection for Indian companies and terminated legal reverse engineering or copying of patented foreign pharmaceuticals drugs. To meet the short fall in revenues, many of India's leading pharmaceutical companies turned to foreign acquisitions and exports, especially to the United States. Indian companies benefit from a greater acceptance of generic drugs among the U.S. public, tremendous pressure on healthcare providers to reduce costs, and impending expiration of patents on drugs with annual sales of $50 billion. India's major pharmaceutical companies are positioning themselves to offer generic versions of these drugs and some have predicted that they will capture at least 30 percent of the U.S. generic replacement market. However, Indian companies face severe price compression in the U.S. for their generic drug market and stiff competition from domestic U.S. generic manufactures and suppliers from other low-cost countries.

Abbreviations

AIDs	Acquired Immune Deficiency Syndrome
API	Active pharmaceutical ingredient
ANDA	Abbreviated New Drug Application
Assocham	Associated Chambers of Commerce and Industry of India
CAGR	Compound annual growth rate
CII	Confederation of Indian Industry
CIS	Commonwealth of Independent States
CNS	Central nervous system
CRAMS	Contract manufacturing and research services
DMFs	Drug Master Files
DPCO	Drug Price Control Order
FDI	Foreign direct investment
GSK	GlaxoSmithKlein
HIV	Human immunodeficiency virus
HTS	Harmonized Tariff Schedule
IPR	Intellectual property rights
M&A	Mergers and acquisitions
MNC	Multinational corporation
NCE	New chemical entities (new patented drug)
NDA	New drug applications
OTC	Over-the-counter drugs (dispensed without prescription)
R&D	Research and development
TB	Tuberculosis
TRIPs	Trade-Related Aspects of Intellectual Property Rights
US FDA	United States Food and Drug Administration (FDA)
UNICEF	United Nations Children's Fund
WTO	World Trade Organization

Definitions[1]

Abbreviated New Drug Applications (ANDAs): an application submitted to the U.S. Food & Drug Administration by a generic drug manufacturer challenging a patent held by an innovator company. Once approved, an applicant may manufacture and market the generic drug product of an existing formulation to the American public.

Active pharmaceutical ingredient (APIs): the primary, active ingredient(s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities.

Biologicals: medical preparation made from living organisms and their products, such as insulin, erythropoietin, and vaccines.

Blockbusters: industry term referring to drugs with very large sales, generally in excess of $1 billion.

Branded generics: generic drugs for which a drug manufacturing company has attached its brand name and may have invested in its marketing to differentiate it from other generic brands.

[1] Sources: Department of Chemicals & Petrochemicals, Government of India, MedicineNet.com, U.S. Food and Drug Administration, KPMG, Pharmabiz.com.

Brand name drugs: innovator drugs patented by MNC pharmaceutical companies to prevent them from being copied or reverse engineered by other companies.

Bulk drugs: the active chemical substances in powder form, the main ingredient in pharmaceuticals - chemicals having therapeutic value, used for the production of pharmaceutical formulations. Major bulk drugs include antibiotics, sulpha drugs, vitamins, steroids, and analgesics.

Drugs: there are two types of drugs: bulk drugs (intermediates) and formulations.

Drug intermediates: these drugs are used as raw materials for the production of bulk drugs, which are either sold directly or retained by companies for the production of formulations.

Drug Master files (DMFs): generic registration applications filed with the U.S. FDA in order to allow the active pharmaceutical ingredients (APIs) to appear in marketed drugs.

Essential drugs: Drugs classified as essential by the Indian government consist of antibiotics, antibacterials, anti-TB, penicillin and its salts, anti-parasitic, cardiovascular drugs, erythromycin and its preparations, vitamins and pro-vitamins, vaccines (polio, human and veterinary), preparations containing insulin, caustic and other hormones, and tetracycline and its preparations. Indian companies dominate this class of drugs with a domestic Indian market share of 71 percent. These drugs are subject to government price controls.

Formulations: drugs ready for consumption by patients (generic drugs) sold as a brand or generic product as tablets, capsules, injectables, or syrups. Formulations can be subdivided into two categories: generic drugs and branded drugs.

Generic drugs: copies of off-patent brand-name drugs that come in the same dosage, safety, strength, and quality and for the same intended use. These drugs are then sold under their chemical names as both over the counter and prescription forms. Also, referred to as unbranded formulations.

Hatch-Waxman Act (Drug Price Competition and Patent Restoration Act**):** passed in 1984, it established the ANDA process that permits the U.S. FDA to approve generic versions of approved innovator drugs without supplying clinical trials or New Drug Application (NDA) performed by the innovator company.

Innovator drugs: are drugs with patents on their chemical formulation or on their production process. They have been tested and approved by the U.S. FDA after extensive clinical trials.

New Drug Applications (NDAs): the vehicle through which drug innovators formally propose that the U.S. FDA approve a new drug for sale and marketing in the United States.

Pharmaceuticals: are used to prevent, diagnose, treat, or cure diseases in humans and animals.

Plain vanilla generics: commodity generics that are “off-patent” in the regulated markets. They offer little or no innovative value over the innovator’s product.

Prescription drugs: medicines that encompass two classes, innovator drugs and generic drugs.

Proprietary drugs: drugs that have a trade or brand name and are protected by a patent.

West/ Western: the United States, Canada, and Western Europe.

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Overview

The Indian pharmaceutical industry is one of the developing world's largest and most developed, ranking 4th in the world in terms of production volume and 13th in domestic consumption value.[2] India's industry, valued at $5.3 billion in 2005, represents less than one percent of the global pharmaceutical industry ($550 billion).[3]

India's Pharmaceutical industry in 2005

Share of global sales:	Value 1%, Volume 8%
Global ranking:	4th in volume, 13th in value
Domestic market:	$5.3 billion
Exports:	$3.7 billion
Imports:	$985 million
Bulk drug production:	$2.1 billion
Employment:	5 million direct, 24 million indirect.
Capital investment:	$1.2 billion
Production costs:	Among the lowest in the world, estimated to be 70% less than the West.

Source: OPPI.

Over the last 30 years, India's pharmaceutical industry has evolved from almost nonexistent to a world leader in the production of high quality generic drugs. India has garnered a worldwide reputation for producing high quality, low cost generic drugs. The industry currently meets India's demand for bulk drugs and nearly all its demand for formulations, with the remainder supplied by foreign multinational corporations (MNCs).

India's pharmaceutical industry is one of the fastest growing segments of the Indian economy with an average annual growth rate of 14 percent during 2002-2005. Overall, the Indian market for pharmaceuticals is projected to grow at an average annual rate of between 15 and 20 percent during 2005 - 2010. The surge in production has been driven by legislative reforms, the growth in contract manufacturing and outsourcing, value added foreign acquisitions and joint ventures, India's mastery of reverse engineering of patented drug molecules, and India's efforts to comply with its World Trade Organization (WTO) Trade Related Intellectual Property Agreement (TRIPs) obligations.

When India joined the WTO in 1995, its pharmaceutical exports were valued at less than $600 million. By 2005, its exports had grown to $3.7 billion and accounted for more than 61 percent of industry turnover. Currently, Indian pharmaceutical companies produce between 20 and 22 percent of the world's generic drugs (in value terms) and offer 60,000 finished medicines and nearly 400 bulk drugs used in formulations.[4]

With changes in India's patent laws in the early 1970s, Indian drug producers became experts in 'reverse engineering' and increased its supply of less expensive copies of the world's best-selling patent-protected drugs. India's pharmaceutical industry grew and prospered in a highly regulated environment with government price controls on a significant number of formulations and bulk drugs. In January 2005, India amended its patent laws governing pharmaceuticals, bringing them into conformance with the WTO TRIPs agreement. Under the new patent law, Indian drug markers can no longer manufacture and market reverse-engineered versions of drugs patented by foreign drug producers. To replace sales lost to TRIPs compliance, many of India's leading pharmaceutical producers have increased their exports of generic drugs to the United States and Western Europe and entered into research and development agreements, mergers and acquisitions, and other alliances with foreign pharmaceutical firms.

[2] *National Pharmaceutical Policy, 2006,* Department of Chemicals and Petrochemicals, Government of India, Dec. 28, 2005.

[3] "India gears up for unprecedented manufacturing growth," *in-Pharma Technologist.com*, Aug. 8, 2006.

[4] "Cuts Drug Prices, Else Face Action, Paswan Tells Industry," The Associated Chambers of Commerce and Industry of Industry, Nov. 29, 2006.

India's Pharmaceutical industry: independence to 2005

At the time of independence in 1947, India's pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. The Indian pharmaceutical market remained import-dependent through the 1960s until the government initiated policies stressing self-reliance through local production.[5] At that time, 8 of India's top 10 pharmaceutical firms, based on sales, were subsidiaries of MNCs. To facilitate an independent supply of pharmaceutical products in the domestic market, the government of India founded 5 state-owned pharmaceutical companies.[6] Today, India is the world's fifth largest producer of bulk drugs.

Government policy culminated in various actions including: the abolition of product patents on food, chemicals, and drugs; the institution of process patents; the limitation of multinational equity share in India pharmaceutical companies, and the imposition of price controls on certain formulations and bulk drugs. Subsequently, most foreign pharmaceutical manufacturers abandoned the Indian market due to the absence of legal mechanisms to protect their patented products. Accordingly, the share of the domestic Indian market held by foreign drug manufacturers declined to less than 20 percent in 2005. As the MNCs abandoned the Indian market, local firms rushed in to fill the void, and by 1990, India was self-sufficient in the production of formulations and nearly self-sufficient in the production of bulk drugs.

Regulatory environment

To end the dominance of foreign drug companies, the Indian government enacted a series of policies designed to foster self-sufficiency in the production of basic drugs. Because these measures lowered barriers to entry, thousands of medium and small Indian pharmaceutical companies entered the market challenging the MNCs for control. These actions laid the foundation for today's highly competitive domestic industry that is capable of offering some of the lowest drug prices in the world. These policies ended India's dependence on expensive foreign drugs, fostered the development of a competitive pharmaceutical industry, and guaranteed the Indian public access to inexpensive drugs. Nonetheless, the Indian pharmaceutical industry also became one of the country's most heavily regulated. The industry currently faces restrictions on imports, high tariff rates, ration requirements, and equity ceilings for foreign participation.

The Patent Act, 1970: The Act's stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs.[7] The Act replaced intellectual property rights laws left over from the British colonial era and ended India's recognition of Western-style "product" patent protection for pharmaceuticals, agricultural products, and atomic energy. Product-specific patents were disregarded in favor of manufacturing "process" patents that allowed Indian companies' to reverse engineer or copy foreign patented drugs without paying a licensing fee. This allowed the domestic industry build up considerable competencies and offer a large number of cheaper "copycat" generic versions legally in India at a fraction of the cost of

[5] Devinder Sharma, "When death becomes cheap," *Deccan Herald*, Apr. 16, 2005.

[6] The Bengal Chemical and Pharmaceutical Works (1930) as India's first public sector drug manufacturer; The Hindustan Antibiotic Ltd. (1954) with the assistance of the United Nations and UNICEF; Indian Drugs and Pharmaceutical Ltd. (1961) with assistance from the former Soviet Union; Bengal Immunity Ltd; Smith Stanistreet Pharmaceutical; and the Indian Drugs and Pharmaceutical Corporation.

[7] *The Patent Act, 1970*, Office of the Controller General of Patents, Designs, and Trademarks, Government of India.

the drug in the West, as long as they employed a production process that differed from that used by the patent owner. The Act protected process patents for 7 years instead of the usual 15 years needed to develop and test new drugs.

Drug Price Control Order, 1970 (DPCO): The order was introduced when most of India's drugs were under strict price controls. Since its introduction, the number of bulk drugs under price controls gradually declined from 347 in 1987 to 163 in 1994 to 74 in 1995.[8] In 2005, the government capped prices on 74 bulk drugs and 260 formulations that account for approximately 25 percent of India's retail pharmaceutical market (attachment).[9] Trade margins for these drugs were capped at 8 percent for retailers and 16 percent for wholesalers. The National Pharmaceutical Pricing Authority, founded in 1997, is responsible for monitoring prices using the DPCO to fix ceiling prices on drugs and ensure that no Indian company in a monopoly position takes advantages of its monopolistic position by profiteering. In June 2006, the National Pharmaceutical Policy 2006 (Part A) proposed to add price controls on 354 specific drugs listed as essential medicines.[10] The new policy will cap margins on generic drugs at 15 percent for wholesalers and 35 percent for retailers. It will also enforce a 5 percent price cut on more than 75 commonly-used medicines resulting from import duty reductions of 5 to 7.5 percent on certain active pharmaceutical ingredients (APIs).[11] The NPPA controls ceiling prices for controlled bulk drugs in all intra-industry transactions as well as the retail ceiling prices for controlled formulations.

Patents (Amendment) Act 2005:[12] To meet its TRIPs obligations, India amended its patent law on March 22, 2005, abolishing its "process" patents law and reintroduced Western style "product" patents for pharmaceuticals, food, and chemicals.[13] This action effectively ended 36 years of protection for Indian pharmaceutical companies and stipulated that Indian companies selling copycat drugs must pay foreign patent holders a "reasonable" royalty for copies sold in the Indian market. The amendment made reverse engineering or copying of patented drugs illegal after January 1, 1995. The Act allowed for only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995. At present, nearly 97 percent of all drugs manufactured in India are off patent and therefore will not be affected by this Act. It also introduced a provision establishing compulsory licenses for exports to least developed countries with insufficient pharmaceutical manufacturing capacities.

The Amendment grants new patent holders a 20-year monopoly starting on the date the patent was filed and, without a compulsory license, no generic copies can be sold during the duration of the patent. The WTO also required India to establish a "mailbox" where patent applications could be filed between January 1, 1995 and 2005. The Act encouraged significant numbers of foreign pharmaceutical

[8] "India's new product patent law: challenges and opportunities for local drugmakers," *Pharma Market Letter*, Dec. 6, 2004. *The Indian Pharmaceutical Industry: Collaboration for Growth*, KPMG, 2006.

[9] Sanjay Kumar, "India to extend price controls on drugs," *BMJ Journal*, Aug. 14, 2004. "The Cloning of Viagra," Asia Week.

[10] "New policy adds 354 to the list of controlled drugs," *domain-b.com,* July 1, 2006.

[11] "Government to enforce 5-per cent cut in prices of 75 drugs," *domain-b.com*. March 27, 2007.

[12] Novartis (Switzerland) recently challenged India's patent laws before the Chennai High Court alleging that India's refusal to grant a patent on its leukemia anti-cancer drug, Gleevec, violated the WTO's TRIPs agreement. In Jan. 2006, India's patent office rejected the patent application insisting that Gleevec was only a new form of an existing drug and was therefore not patentable in India. Amy Yee, "Novartis in Indian patent dispute," *Financial Times*, Dec. 22, 2006. "Novartis contests India's patent law," *Chemistry World*, Feb. 15, 2007.

[13] The Indian Patent Act, 1970 was amended by the Patents Amendment Ordinance, 2004 (the thirds amendment), which was amended by the Patents Act, 2005. *Important Changes Incorporated in the Patent (Amendment) Bill, 2005 As Compared to the Patents (Amendment) Bill, 2003*, Press Information Bureau, Government of India, March 23, 2005.

companies to participate in the Indian market and, in 2005, foreign drug producers filed approximately 8,926 patent applications to cover their patented drugs sold as generics in the Indian market. Roche (Switzerland) became the first foreign company to win a patent under India's new product patent regime and that patent, granted in March 2006 for a drug to treatment of hepatitis C (Pegasys), will be valid for 20 years from May 15, 1997. Pfizer (US) has submitted the largest number of patent applications (373) followed by Johnson & Johnson (262) and Procter & Gamble (187). [14]

Industry production

Thirty-five years of protection has enabled the Indian pharmaceutical industry to perfect its scientific and manufacturing capabilities, allowing many of its leading companies to move up the value-added chain. India's pharmaceutical industry consists of large, medium, and small companies and is one of the world's most price competitive. It is also highly fragmented with more than 20,000 domestic production units. Because of low barriers to entry and low capital requirements, the number of domestic pharmaceutical firms engaged in the formal and informal sectors expanded dramatically from 2,257 in 1970 to more than 20,000 in 2005 (table 1).[15] Because many of these companies focus of producing similar generic drugs, with possibly hundreds of companies producing the same drug, the industry is characterized by fierce competition and high volumes, razor-thin profit margins, overcapacity, and declining prices. According to FICCI, there are only 6,000 firms participating in the formal sector that have received drug manufacturing licenses from the Indian government.[16] India's pharmaceutical firms can be differentiated by size, annual sales, function, export markets, and R&D capabilities (table 1).

Table 1: India's pharmaceutical firms, by size, sales, function, exports, and R&D capabilities

Grouping	Number of firms	Description
Group 1	100	Largest firms, includes both wholly-owned Indian firms and subsidiaries of MNCs; have annual revenues of at least $650,00; have brand recognition and are engaged in developing R&D capabilities; responsible for recent wave of cross-border acquisitions and alliances; export to regulated, semi-regulated, and unregulated markets.
Group 2	200	Mid-size firms with annual revenues between $210,410 and $650,000; they have limited investment capabilities and primarily serve the domestic Indian market. They are generic drug producers that subsist mainly on reverse engineering of patented and off-patent drugs (primarily bulk drugs and APIs); also includes niche players specializing in contract research (CRAMS) and contract clinical trials in segments of the market where they have a competitive advantage; export to semi-regulated and unregulated markets.
Group 3	5,700	Smallest firms with annual revenues of less than $210,410;.primarily perform contract manufacturing services for MNCs or domestic firms. Many have been adversely affected and have been forced to close their doors due to revised Good Manufacturing Practices set by Schedule M of India's Drug and Cosmetic Act, 1940 that came into effect from July 1, 2005. Those affected cannot meet production standards of regulated market regulators and their production will be limited to the domestic, semi-regulated, and unregulated markets.

Source: Padmashree Gehl Sampath, *Indian Pharma Within Global Reach?*, United Nations University, 2006-031.

[14] KG Narendranath, Patent mailbox opens, Pfizer is top applicant," *The Financial Express*, March 20, 200__.

[15] D.K. Nauriyal, *TRIPS-Compliant New Patents Act and Indian Pharmaceutical Sector: Directions in Strategy and R&D*, Indian Institute of Technology, Roorkee. "Pharmaceuticals: Getting the Dose Right," *Pharmacy Choice*, Nov. 2, 2006.

[16] All drug production requires a government license. Staff interview with FICCI officials, Apr. 23, 2007.

The vast majority of India's pharmaceutical firms are small by global standards with annual revenues of less than $5 million. The Confederation of India Industries (CII) estimates that approximately 80 percent of them are engaging in some type of contract manufacturing or outsourcing.[17] The largest 250 companies control nearly 70 percent of the domestic market with the top 10 controlling approximately 40 percent. The domestic Indian pharmaceutical industry consists of both domestic companies and subsidiaries of MNCs. In the 1970s, the vast majority of foreign pharmaceutical companies abandoned the Indian market during the "process" patent era due to inadequate product protection, government price controls, growing domestic competition, and declining prices and profitability. Consequently, the share of India's market controlled by multinationals dropped to less than 20 percent by 2005.[18] In the absence of government protection, India's leading drug producers are moving toward new drug discovery rather continuing to rely solely on copying patented foreign drugs. Industry experts project that by 2010, Indian firms will produce 6 of the top 10 drugs scheduled to lose their patent protection in developing countries.[19]

Indian pharmaceutical companies now supply nearly all the country's demand for formulations and nearly 70 percent of its demand for bulk drugs. Indian firms produce nearly 60,000 generic brands in 60 therapeutic categories and between 350 and 400 bulk drugs. Approximately 80 percent of domestic production consists of formulations, and more than 85 percent of those formulations are sold in the domestic market, whereas at least 60 percent of bulk drug production is exported. Nearly 97 percent of India's drug market consists of second-and-third generation drugs no longer subject to patent protection in the developed world. Some under-patent, lifesaving drugs continue to be imported, primarily from developed countries, especially the United States, Germany, the United Kingdom, and France.

India has the world's third-largest API manufacturing industry valued at nearly $2 billion in 2005. Currently, India's drug industry produces more than 400 different APIs and is among the world's top 5 API producers accounting for approximately 6.5 percent of the world's API production. Italy's Chemical Pharmaceutical Generic Association (CPA) projects that India's share of the world API market will grow to 10.5 percent by 2010 as patented blockbuster drugs lose their patent protection. The CPA also expects that the domestic Indian market for APIs, both generic and branded, will rise from $755 million in 2005 to $1.9 billion in 2010.[20] According to the Assocham, the leading APIs were anti-infectives, and gastrointestinal, cardiovascular, and respiratory drugs (table 2). In terms of volume of sales, the gastrointestinal and cardiac segments saw the highest rates of growth and accounted for the largest number of new drug launches.

[17] Sasikant Misra, *CRAMS (Contract Research and Manufacturing services)*, Confederation of Indian Industry (CII).

[18] "Indian Healthcare: A growing market," *Economist Intelligence Unit*, June 22, 2005.

[19] "Pharma Cos must be globally competitive," *The Financial Express*, May 28, 200x...

[20] Generic APIs are expected grow by nearly 20 percent to $1.6 billion in 2010 and branded APIs are expected reach $285 million while growing at an annual rate of approximately 25 percent. Patrician Van Arnum, "The Changing Fortunes for APIs," Pharmaceutical Technology, Jan. 2, 2007.

Table 2: Major therapeutic segments (2004)	
Category	**Market share (percent)**
Anti-infectives	14.7
Gastrointestinal	10.7
Cardiac	11.1
Respiratory	10.5
Vitamins-minerals-nutrients	9.2
Pain-analgesics	9.6
Dermatological	5.4
Gynecology	5.0
Anti diabetics	4.6
Others	13.8
Source: Assocham.	

Leading Indian pharmaceutical manufacturers: India's leading pharmaceutical companies are striving to compete not only in the domestic Indian market, but also in the global market for both generic drugs and original products. Sales for India's largest 200 pharmaceutical companies grew from $7.9 billion in 2004 to $8.6 billion in 2005, or by 9 percent.[21] By 2005, 9 of the top 10 Indian drug makers were Indian-owned firms accounting for more than 44 percent of total industry sales. India's top five pharmaceutical companies, in terms of sales, are Ranbaxy Laboratories, Dr. Reddy's Laboratories, Aurobindo Pharmaceutical, GSK-India, and Cipla (table 3). These companies manufacture a wide range of generic drugs (branded and non-branded), intermediates, and active pharmaceutical ingredients (APIs) (table 4).[22]

Table 3: India's top 10 pharmaceutical company sales ($million)

Company	Sales turnover		Share of market	
	2004-05	2005-06	2004-05	2005-06
Ranbaxy Laboratories	776.8	1,176.0	23	19
Dr. Reddy's Laboratories	387.3	534.5	11	9
Cipla Ltd	534.3	719.0	16	12
Nicholas Piramal India	323.7	344.7	9	6
Aurobindo Pharmaceuticals	258.0	380.3	8	6
GlaxoSmithKline	202.1	342.9	6	6
Lupin Laboratories	329.3	395.5	10	6
Sun Pharmaceuticals	159.3	375.2	5	6
Cadila Healthcare	248.4	254.2	7	4
Wockhardt	188.5	217.5	6	4
Sub-total	3,407.7	4,739.8	73	76
Total	4,662.0	6,205.0		

Because of rounding figures may not total 100 percent. FY2005-06: $1=Rs 44.2735; FY2004-05: $1=Rs 44.9315.
Source: Economic Times, Orbis, Stock Market Quotes, and Company Research.

In terms of total sales, Ranbaxy Laboratories is India's largest pharmaceutical company and one of the world's top ten generic drug makers. In 2005, exports accounted for nearly 80 percent of Ranbaxy's sales and the United States is Ranbaxy's largest market. Ranbaxy accounts for 23 percent of

[21] Economic Times, Stock Market Quotes and Company Research.

[22] For more detail see Appendix A.

India's pharmaceutical industry revenues.[23] Ranbaxy is a vertically integrated company with a presence across the pharmaceutical value chain, offering a range of unbranded and branded generics, active pharmaceutical ingredients, and biotechnology products. Ranbaxy markets its products in more than 100 countries, a sales presence in 23 of the world's top 25 pharmaceutical markets, and has manufacturing facilities in 8 countries. Cipla, India's second-largest pharmaceutical company, is best know for its anti-AIDs drugs, and Dr. Reddy's Laboratories, India's third-largest pharmaceutical company, also rely heavily on exports as its revenues.

Table 4: Principal products of India's leading drug manufacturers

Company	Principal products: bulk and generic drugs	Percent of sales
Ranbaxy Labs	Anti-infectives, cardiovascular, gastrointestinal, central nervous (diazepam, midazolan), ophthalmic & ointments, urologicals, nutritionals, sex hormones, analgesics, anti-asthma, cough & cold, vaccines.	Bulk: 22%, Generic: 78%
Dr. Reddy's	Cardiovascular, gastrointestinal, anti-infectives, pain management	Bulk: 40% Generic: 60%
Cipla	Antibiotics, anti-asthmatics, anti-AIDs and TB drugs, anabolic steroids, analgesics-antipyretics, antacids, anti-arthritis, anti-inflammatory, anti-cancer, antidepressant agents, anti-diabetic, anit-epileptic, anti-fungal, anti-malarial.	Bulk 7%, Generic: 93%
Wockhardt	Anti-infectives, pain management, nutraceuticals	Bulk drugs: 19%, Generic: 81%
Pfizer India	Nutritionals, cough syrup, anti-arthritis, anti-infectives, cardiovascular	Generic: 100%
Sun Pharma	Neuro-psychiatry, cardiovascular, gastrointestinal, diabetic, gynecological, anti-allergic, antidepressants, cholesterol reducers, anti-asthma, Parkinson, ADD, pain.	Bulk: 18% Generic: 82%
GSK	Anti-infective, anti-inflammatory, analgesic, gastro-enterological, anti-allergic, dermatological.	Generic: 100%
Lupin	Tuberculosis medication, antibiotics, cardiovascular.	Generic: 100%
Cadila	Cardiovascular, gastrointestinal, anti-inflammatory/analgesic, antibiotics/anti-infectives, vaccines/immunomodulators, anti-diabetics; vitamins.	Generic: 100%
Nicholas Piramal	Analgesics-anti-inflammatory, antibiotics, antifungal, antihistamines, antiseptics, cardiovascular, central nervous system, diabetic, dermatologic, endocrinologic, gastro-enterological, vitamins, pulmonary-respiratory, trauma-emergency, gastrointestinal, NSAIDs.	Generic: 100%
Aurobindo Pharmaceuticals	Antibiotics, anti-retrovirals, cardiovascular, central nervous system, gastro-enterological, anti-allergy.	Generic: 100%

Sources: Union Budget 2006-07.

MNC presence in India: Many of the world's leading pharmaceutical companies have subsidiaries or other operations in India. Multinational companies like GlaxoSmithKline (GSK) Baxter, Aventis, Pfizer, Novartis, Wyeth, and Merck have been active in India's pharmaceutical market mainly

[23] Amanda Chater, "Indian companies gain traction in U.S. generics market," *Drugstore News*, Sept. 25, 2006, pp. 34-35.

through subsidiaries. The re-introduction of product patents precipitated the return of a large number of other MNCs, some of whom left during the process patent era. MNC pharmaceutical companies have also been attracted by tax holidays, the deduction of capital R&D expenditures, and other financial incentives offered by the Indian government. Industry sources indicate that the most significant challenges facing MNCs are the uncertainly over pharmaceutical price controls and data exclusivity.[24]

There are approximately 34 foreign drug companies engaged in the Indian pharmaceutical market and among them are 15 of the world's 20 largest pharmaceutical companies. According to FICCI, although MNCs have not launched new products they have invested in new production facilities and R&D centers and many are engaged in contract manufacturing, clinical trials, and other forms of outsourcing.[25] In 2005-06, MNCs invested more than $172 million in India's pharmaceutical industry and FDI has grown by a compound annual growth rate (CAGR) of 62 percent during 2002-06.[26] However, many industry experts believe that the return of the world's leading pharmaceutical companies will gradually erode India's cost advantages. According to the Organization of Pharmaceutical Producers of India, multinational drug companies currently command 24 percent of the domestic Indian market, through their share could rise to 40 percent by 2010.[27]

GSK-India, a 51 percent subsidiary of GSK Plc (UK), is the largest foreign company in India's pharmaceutical market, its fourth largest pharmaceutical company, and leading prescription drug supplier. GSK-India operates two Indian manufacturing plants and controls approximately 5.9 percent of the domestic Indian market. GSK-India is among India's leading suppliers of anti-infective, anti-inflammatory, analgesic, gastro-enterological, anti-allergic, and dermatological drugs. GSK-India announced plans to extend its product line by launching several antibiotic, cancer, and cardiovascular products in India in the near term. Likewise, MNCs dominate India's OTC (over the counter) drug market, with Pfizer accounting for 5.1 percent of the market, Sanofi-Aventis for 5.0 percent, and Johnson & Johnson for 4.8 percent. These companies offer analgesics, cough and cold preparations, indigestion medicines, skin care products, and vitamins and minerals. Other foreign multinationals active in India's pharmaceutical market include: Bristol-Myers Squibb, Eli Lilly, Boehringer, Bayer, Chiton Corp, Abbott, AstraZeneca, Janssen, and Roche.

Recently, Teva Pharma (Israel), the world's leading generic drug manufacturing company, acquired a bulk drug manufacturing and intermediate facility in the State of Uttar Pradesh, announced plans to add two more units, and more than triple the value of its exports from India by the end of 2007. Teva also opened an R&D facility in India and announced plans to register between 10 and 15 bulk drugs per year in the United States from its Indian facilities.[28]

Industry structure

Mergers, acquisitions, and other alliances: The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a 'nearshore-offshore' option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets

[24] "GSK Pharma Net Up 16.3% yoy," *India Infoline*, Feb. 19, 2007.

[25] Staff interview with FICCI officials, Apr. 24, 2007.

[26] "Indian pharma mkt to grow at 13.6% from 2006-10: Assocham," *India Infoline.cim*, Nov. 13, 2006.

[27] "India's drug sector tackles new patent regime," *in-Pharma Technologist.com,* Feb. 14, 2005.

[28] Gauri Kamath, "Is the pharma dream run over?" *Business Week*, June 16, 2004.

of Western Europe and the United States. Indian companies without significant R&D capabilities for drug discovery are also purchasing Western drug discovery companies.

In 2005-06, 18 Indian companies spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico.[29] These companies included Ranbaxy, Dr. Reddy's Labs, Nicholas Piramal, Sun Pharmaceutical, and Jubilant Organosys (table 5).[30] Although eleven of these transactions were for medium-and-small sized companies valued between $5 million and $30 million, several have been significant acquisitions valued in excess of $500 million. To date, Dr. Reddy's purchase of Betapharm Arzneimittel of Germany for $572 million is the industry's largest overseas acquisition. Other significant deals include Ranbaxy's purchase of Terapia (Romania) and RPG Aventis (France) and Matrix's acquisition of API of Belgium. With these acquisition; Dr. Reddy's became Germany's fourth largest generic drug company and Ranbaxy became Romania's third largest generic drug company and one of Belgium's top 10 generic providers.[31] India's pharmaceutical industry should witness a significant decline in the number of smaller companies that either leave the market or are acquired by larger Indian or foreign companies. Since 2000, a number of smaller Indian pharmaceutical companies have been acquired by larger companies including Wockhardt's acquisition of Merind and Tata Pharma; Ranbaxy's purchase of Crosland; Nicholas Piramal's acquisition of Roche, Boehringer, and Sumitra Pharma, and Glaxo-Wellcome's merger with Ciba-Sandoz. Matrix, one of India's and the world's leading producers of APIs, was acquired by Mylan (US) in January 2007 for $546 million. Mylan, one of the largest generic drug producers in the United States, acquired Matrix to expand its manufacturing capabilities, gain a foothold in key markets, and gain access to Matrix's technical and scientific expertise.

Since 2005, Europe has become a counterweight to the U.S. market and its growing pricing pressures. In exploring Western Europe for acquisitions, Indian pharmaceutical companies found a wider range of companies available at more reasonable valuations.[32] The new patent regime is also forcing the Indian pharmaceutical market to consolidate, and only firms with a global presence and significant R&D capabilities for drug discovery, drug delivery systems, and technology licensing will prosper into the future.

[29] Ravi Krishnan, "It's Europe for Ranbaxy," *The Financial Express*, Apr. 1, 2006.

[30] "Indian pharma firms expand global footprint in 2006," *The Economic Times*, Dec. 25, 2006.

[31] "India Pharma Inc - Competing Globally," Pharma Summit 2006, Sept 14, 2006, KPMG.

[32] Europe's three major generics markets are Germany, France, and the United Kingdom.

Table 5: Selected international acquisitions and foreign tie-ins by the Indian pharmaceutical industry		
Company	**International acquisition (s)**	**Foreign alliances, JVS, and other tie-ins**
Nicholas Piramal	Pfizer-Morpeth (UK), Avecia Pharma (UK), Dobutrex brand acquisition (US), Rhodia's inhalation business (UK) , Biosyntech (NPIL Pharma) (Canada), Torcan Chemical (Canada), 51% of Boots (S. Afruica), Bio Syntech	Ethypharm (France), Genzyme (US), Eli Lilly (US), Biogen Idec (US), Chiese Farmaceutici (Italy), Minrad (US), Pierre Fabre (France). Gilead Sciences (US), Allergan (US), Hoffmann-La Roche (Switzerland)
Ranbaxy	Terapia (Romania), Allen -GSK (Spain & Italy), Ethimed (Belgium), Betapharm (Germany), RPG Aventis (France), 40% stake in Nihom Pharmaceuticals (Japan), Brand-Veratide (Germany), Efarmes (Spain), Be-Tabs (S. Africa), Akrikhin (Russia), Basic (Germany), Ohm Labs (US)	GlaxoSmithKline (UK), Janssen-Ortho (Canada), IPCA Labs (US), Zenotech (India), Sonkel (S. Africa), Cephalon (US), Gilead Sciences (US), Schwarz (Germany)
Dr. Reddy's	Betapharm Group (Germany), Trigenesis (US), BMS Laboratories and Meridian Healthcare (UK), Roche's active ingredients business (Mexico), BMS Labs (UK)	Novo Nordisk, Bayer AG (Germany), Par (US), Novartis (Switzerland), Merck (Germany), Clin Tech, Pharmascience (Canada), ICICI (India), Merck (Germany), Schwartz ( )
Marksans	Nova Pharmaceuticals (Australia)	NA
Aurobindo	Milpharm (UK), Pharmacin (Netherlands)	Gilead Science (US), Citadel (India)
Sun Pharma	Able Lab (US), Caraco (US), Valeant Pharmaceuticals (US & Hungary), ICN (Hungary), Caraco (US), MJ Pharma	Dyax
Dishman	I03S Ltd (Switzerland), Synprotec (UK), Carbogen Amcis (Switzerland), Solutia's Pharma (Switzerland)	Azzurro (Japan)
Orchid	Bexel Pharma (US)	Stada, Alpharma, Par, Apotex
Biocon	Nobex (US)	Centre of Molecular Immunology (Cuba)
Wockhardt	Wallis Labs (UK), CP Pharma (UK), Esparma (Germany), Pinewood Laboratories (Ireland), Dumex (India)	Pharma Dynamics (S. Africa)
Cadila	Alpharma (France-formulations), Dabur Pharma Redrock (UK)	Schering (Germany), Boehringer Ingelheim (Germany), Viatris (Germany), Novopharm (Canada), MCPC (Saudi Arabia), Cipharm (Ivory Coast), Geneva (US), GSK (UK), Ranbaxy (India), Mallinckrodt (US), Mayne (Australia), Shinjuki (Japan), Zydus Atlanta
Jubilant Organosys	Target Research Associates (US), PSI (Belgium), Trinity Laboratories (US)	NA
Matrix Labs	22% controlling stake in Docpharma (Belgium), Explora Lab (Switerland), MCHEM (China), Fine Chemicals (S. Africa), API (Beligum)	Aspen, Emchem, Doc Pharma, Explora Labs
Glenmark	Kinger Lab (Brazil), Uno-Ciclo (Brazil), Srvycal (Argentina), Medicamenta (Czech), Bouwer Bartlett	Forest Labs (US), Lehigh Valley Technologies (US), Shasun (India), KV, Apotex (US)
Source: IBEF, Ernst & Young, The Economic Times, individual company web pages.		

Contract research and manufacturing, outsourcing, and other services: The passage of the Patents (Amendment) Act 2005 has significant implications for both Indian and multinational companies competing in the Indian market. Leading Indian companies are moving away from a reliance on the domestic market to the development new drugs, exports to regulated markets, and cooperative agreements with MNCs. Facing lagging sales of patented drugs by MNCs in their home markets, declining R&D revenues, and rising costs, many MNCs have turned to contract manufacturing and research services (CRAMS), co-marketing alliances, outsourcing of research and clinical trials to reduce costs, increase development capacity, and trim the 'time to market' for new drugs. These strategies permit MNCs to focus on their core profit making activities (competencies), such as drug discoveries and marketing, rather than on manufacturing. India has emerged as the principal destination for global pharmaceutical companies across the pharmaceutical value chain.

Indian pharmaceutical companies have two basic options: compete with MNCs for vanilla generics and new chemical entities (new drugs) or co-operate (table 6). Subcontracting in India has gradually moved up the value-added chain from intermediates and APIs to new drug discovery, clinical trials, marketing, and sales. According to India's Federation of Indian Chambers of Commerce and Industry (FICCI), many Indian companies, especially those without the resources for R&D, are embracing custom manufacturing, contract research, and marketing alliances to remain profitable.[33] Others are planning to manufacture and export vanilla generics to regulated markets before eventually producing either more difficult to manufacture generics or new chemical entities (proprietary drugs).

Table 6: Strategic options for Indian companies

Option to compete	Option to cooperate
* Market and sell plain vanilla and speciality generics. * Develop low risk NDAs * Develop follow-on biologics * Challenge IPRs on regulated markets * Invest in R&D for proprietary NCEs.	* Provide contract manufacturing for MNCs * Supply APIs to MNCs * Partner with MNCs for their sales channels * Provide clinical outsourcing for MNCs * R&D collaboration

Source: The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India China, DFID Health Systems Resource Centre 2004.

Contract research and (custom) manufacturing services (CRAMS): CRAMS can be divided into 3 basic segments: the production of intermediates, active pharmaceutical ingredients for new chemical entities, and the manufacture of generic drugs. India has emerged as one of the world's leading CRAMS providers for MNC innovator companies and now accounts for between 6 and 7 percent of the global market and many expect India will command at least 15 percent of the market by 2009-10. Although CRAMS is still in its nascent stages in India, it represents a significant opportunity for medium-sized Indian pharmaceutical companies.

In 2005, the Indian CRAMS market was estimated at $532 million with contract manufacturing accounting for nearly 84 percent of the total.[34] The remainder consisted mainly of contract research (not including clinical trails). Both contract research and contract manufacturing grew by more than 40 percent in 2005 compared with 2004 and industry experts maintain that Indian companies have the capacity to gain between 35 percent and 40 percent of the global CRAMS market.[35] The Associated Chambers of Commerce and Industry of India (Assocham) projects that the domestic Indian CRAMS

[33] FICCI.com.

[34] "Domestic pharma to grow 13.6% in 2006-10: Assocham," P*harmabiz.com*, Nov. 31, 2006.

[35] *CRAMS: The Gateway to Indian Success*, *Focus Reports.net*, Sept. 2006.

market will reach $900 million by 2010 and the demand for contract clinical trials will grow from $100 million in 2005 to $200 million in 2007 and to $1 billion by 2010.[36]

India's competitive advantage lies in its lower production and research costs, its large pool of low cost technical and scientifically trained personnel, and the large number of U.S. FDA certified plants.[37] Other important factors include the popularity of outsourcing non-critical business functions to India by MNCs, the reintroduction of product patents for pharmaceuticals, the growing importance of R&D related to drug discovery by Indian drug companies, and the growing demand for generic drugs in developed markets. It is estimated that manufacturing costs in India are between 30 and 40 percent lower than those in the United States and Western Europe and labor costs are one-seventh of that in the United States.[38]

Nicholas Pirmal India Ltd. is India's leading contract manufacturer with CRAMS contracts valued at $250 million (table 7).[39] At present CRAMS accounts for approximately 30 percent of Nicholas Piramal's total revenues in 2005 and plans to increase it to 50 percent by 2010.[40] In 2006, Nicholas Piramal signed a 5-year, $350 million agreement with Pfizer for 12 products. The agreement made Nicholas Piramal Pfizer's largest custom manufacturing partner.[41] To augment its global contract manufacturing capabilities, Nicholas Piramal purchased Pfizer's contract manufacturing facility in the United Kingdom (Morpeth) and Avecia Pharmaceutical. Its deal with Pfizer could potentially produce much as $350 million for Nicholas Piramal by 2010. Likewise Jubilant Organosys booked contracts worth $65 million for 2006 and 2007, and Shasun Chemicals and Drugs, India's leading producer of ibuprofen, bought the CRAMS business of Rhodia Pharma Solutions (France).[42] Dishman Pharma and Divi specialize in contract manufacturing of patented drugs and custom synthesis; Shasun and Matrix specialize in generics; and Shasun, Jubilant Organosys, Torrent, and Morepen specialize in old generics. MNCs like Aventis, Bayer, and Roche have announced plans to make India their regional hub for APIs, bulk drugs, and clinical research.[43]

[36] Sanjiv Kumar, "Drug cos on a high!," *Mumbai Mirror*, Nov. 12, 2006.

[37] Mithun Chandra G, "Sector Momentum Update - Pharma," Birla Sun Life, June 16, 2005.

[38] The Confederation of Indian Industry (CII) estimates that it costs between $100 million and $200 million to develop a new drug in India as compared to $500 million to $900 million in the United States. Sasikant Misra, *CRAMS (Contract Research and Manufacturing services)*, Confederation of Indian Industry.

[39] Nicholas Piramal.com

[40] Jeetha D'Silva, "Drug cos bet on contract manufacturing," *The Economic Times*, July 25, 2006.

[41] MG Arun, "Druggists swallow phoren pills to open new vistas," *The Financial Express*, June 28, 2006.

[42] Jeetha D'Silva, "Drug cos bet on contract manufacturing," *The Economic Times*, July 25, 2006.

[43] *Pharmaceuticals*, IBEF.

Table 7: Selected CRAMS, contract research, and outsourcing deals in India		
Indian company	**CRAMS partner**	**CRAMS product(s)**
Lupin Labs	DMS (US) . . . . . Fujisawa (Japan) . . . . . Apotex (Canada)	API for cephalosporins Cefixime Cefuroxime, Axetil, Lisinopril
Nicholas Piramal	AMO (US) . . . . . Allegran (US) . . . . . AstraZeneca (Sweden) . . . . . Advanced Medical Optics (US) Pfizer (US)	APIs and formulations Bulk drugs and formulations Intermediates and APIs Eye products API's-formulations for veterinary products
Wockhardt	Ivax (US)	Anti-ulcer
Dishman Pharma	Solvay Pharma (Belgium) . . . . GSK (UK) . . . . . AstraZeneca (Sweden) . . . . . Merck (Germany)	APIs and formulations Intermediates and API Nexium Losartan
IPCA Labs	Merck (Germany) . . . . . Tillomed (UK)	Bulk drugs Atenelol
Orchid Chemicals	Apotex (Canada) . . . . . Bexel (US)	Cephalosporin and other injectables Drug discovery research in metabolic diseases
Sun Pharma	Eli Lilly (US)	Cardiovascular products, anti-infective drugs and insulin
Kopran	Synpac Pharma (US)	Penicillin
Cadila Healthcare	Altana Pharma (Germany) . . . . Boehringer Ingelheim (Germany) . . . . . Mayne (Australia)	Intermediates and APIs Gastrointestinal and cardiovascular products JV for producing patent drugs Intermediates for oncology products
Biocon	Bristol Myers Squibb . . . . . Pfizer (US) . . . . . AstraZeneca (Sweden)	Contract research for bulk drugs Contract research for bulk drugs Contract research for bulk drugs
Bharat Biotech	Wyeth (US)	Vaccine and bio-therapeutics
Shasun Chemicals	Eli Lilly (US) . . . . . GlaxoSmithKline (UK) . . . . . Reliant Pharma (US) . . . . . Alpharma (US) . . . . . GSK (UK) . . . . . Boots (S Africa)	APIs APIs APIs Generics & APIs API's for Ranitidine, nizatidine and cyclosorine API for Ibuprofen
Jubilant Organosys	Eli Lilly (US) . . . . . Novartis (US)	New chemical entities: CVS, CNS, diabetes, oncology. Intermediate and API
Matrix	GSK (UK)	APIs
Divi	Merck, Abbot, GSK	Custom chemical synthesis
Sources: Assocham, rediff, Economic Times, Business Standard, Financial Express, IBEF.		

Contract outsourcing: Western pharmaceutical companies are now outsourcing a wide range of activities including: the manufacture of APIs, chemical intermediates, and formulations; clinical research and clinical testing; and packaging and labeling. The Indian market for contract outsourcing has been driven by the need of leading MNC pharmaceutical companies to reduce production costs and increase revenues. These companies have shifted portions of the production, research & development, clinical trials, packaging and labeling, stability testing, and other types of drug development and discovery activities to India. In 2004, India's drug outsourcing sector was valued at $470 million and was expected to grow by 30 percent per year to $800 million in 2005. Leading drug firms like Pfizer, AstraZeneca, Novartis, and Eli Lilly have already begun shifting a portion of these activities to India.

According to India's Chemical Pharmaceutical Generic Association, the domestic contract research market is growing between 20 percent and 25 percent per year and was valued at $120 million in 2005 and is projected to grow to $200 million by the end of 2007. The Chemical Pharmaceutical Generic Associations also predicted that this segment will reach $1 billion by 2010.[44] The Association indicated that India dwarfs its nearest rivals, Italy ($60-$70 million) and Spain ($25 million to $33 million), and projected that contract research in India will grow at an annual rate of between 20 percent to 25 percent. Clinical trials represent 65 percent of this market and new drug discovery makes up the remaining 35 percent.[45] Companies active in India's contract research market include: a limited number of multinational corporations, subsidiaries of large international contract research firms (Quintiles, Covance), joint ventures and tie-ins between Indian and foreign companies, and stand-alone and offshoots of Indian companies. Several multinationals active in the Indian market have designated India as a hub for their production of active pharmaceutical ingredients and finished formulations. Divi Labs, Shasun Chemicals & Drugs, and Dishman Pharmaceuticals are among India's leading contract research firms.

Research and development (R&D): With the reintroduction of product patents, leading Indian pharmaceutical majors are altering their business strategies by placing greater focus on R&D and the discovery of new chemical entities. Traditionally, the vast majority of India's pharmaceutical R&D spending was concentrated on reverse engineering and the adaptation of patented foreign drugs to the Indian market. Most of the industry's funding went to research rather than to new drug discovery and development. Low levels of industry productivity and the relatively small size of India's pharmaceutical companies limited funding for R&D as they dedicated only less than 2 percent of their annual turnover to R&D compared with between 15 percent and 20 percent allocated by Western innovator companies.

After 2005, India's leading drug companies recognized that they could not survive as global players without significant R&D capabilities. Since 1995, total industry R&D spending has grown from nearly $30 million to more than $495.3 million in 2005-06 (table 8).[46] The vast majority of the industry's R&D spending is conducted by 15 companies whose R&D spending rose to $192.3 million in 2005 from $131 million in FY2004, representing an increase of 47 percent. R&D expenditures are expected to gradually rise to between 9 percent and 10 percent of total industry spending by the end of 2007.[47]

Likewise, the vast majority of the industry's R&D expenditures on new drug discovery and development is conducted by a limited number of companies, with Dr. Reddy's and Ranbaxy at the forefront. In 2005, Dr. Reddy's committed 14 percent of its annual sales to R&D, whereas, Ranbaxy

[44] "Domestic pharma to grow 13.6% in 2006-10: Assocham," *Pharmabiz.com*, Nov. 31, 2006.

[45] Clinical trials represent between 50 to 60 percent of a new drug's development costs. By using India and other low-cost countries, Western drug innovators can potentially reduce their costs per patient by 40 percent to 60 percent. Michael Block, Ajay Dhonkhar, Shanker Narayanan, "Pharma leaps offshore," McKinsey Quarterly, July 2006.

[46] "From Copycats to Innovators," India Report, Focus Reports, Sept. 2006.

[47] Ranbaxy Laboratories.

allocated approximately 7 percent. Ranbaxy announced that it will gradually increase its R&D spending to between 9 and 10 percent of sales by the end of 2007. Others with significant R&D expenditures include Nicholas Piramal, Aurobindo Pharma, and Glenmark Pharma.

Table 8: India's pharmaceutical R&D expenditures ($million)

FYear	Value	Percent change
2000-01	97.8	
2001-02	130.5	33
2002-03	175.3	34
2003-04	280.0	60
2004-05	392.4	40
2005-06	495.2	26

Source: Assocham.

Driven by the dynamics of the market, leading foreign pharmaceutical companies have entered into R&D agreements with India's leading drug companies. Facing spiraling costs and patent expiries for blockbuster drugs at home, many are looking to India as a low-cost alternative, especially due to the large number of U.S. FDA-approved plants located in India. MNCs have been attracted by India's low costs for new drug discovery and many of these firms have founded state-of-the-art research facilities in India. Whereas new drug discovery costs between $100 million and $200 million in the West, the same process in India only costs approximately $10 million.[48] Likewise, clinical trials in India cost approximately $20 million while the cost abroad would ranges between $300 million and $350 million.[49]

Strengths and weaknesses of India's pharmaceutical industry: India's comparative advantages lie in its cost competitiveness, its reverse engineering experience, its large pool of less expensive English-speaking scientific and engineering workers, and its well-developed chemical industry infrastructure (table 9). India's pharmaceutical companies can also operate at much lower profit margins that their Western counterparts. Today, India produces some of the cheapest drugs in the world, especially because labor costs are 50 to 55 percent cheaper than in the West.[50] Industry experts indicate that infrastructure costs are 40 percent lower and fixed cost are estimated to be 12 percent to 20 percent less that in the United States and Western Europe. Consequently, India can produce bulk drugs that cost 60 percent less that in the West and can open a production plant in India 40 percent cheaper than in developed countries. Because of this, India has become a hub for pharmaceutical research and development and clinical trials for many leading foreign pharmaceutical companies.

[48] Drugs & Pharmaceuticals, CII.

[49] Ibid.

[50] Ashok Ram Kumar, "Impact of TRIPs on Indian Pharma," *Pharmabiz*, Dec. 2, 2004.

Table 9: Strengths and weaknesses of India's pharmaceutical industry	
Strengths	**Weaknesses**
* Cost advantages (development, manufacturing, R&D, clinical trials, and labor). * Large pool of highly trained manpower. * 2nd largest number of U.S. FDA approved facilities (61). * TRIPS compliance. * Lower operating margins. * Drug cost a fraction of the cost in the West. * Growing biotechnology industry. * Reverse engineering skills. * Largest number of DMFs. * Bio-diversity. * FDI up to 100 percent. * Strong IT skills for research data management. * Political stability. * Strong marketing and distribution network. * Well established network of laboratories.	* Low level of investment in R&D. * Highly fragmented industry. * Government price controls. * Low margins. * High tariffs and taxes. * Substandard drugs and counterfeiting. * Most Indian companies are small by world standards. * High logistics costs. * Lack of experience in drug discovery. * Industry concentrated at lower end of value chain. * Corruption. * Weak domestic market. * Low levels of per capita medical expenditure. * High logistics costs. * Lack of experience in drug discovery.
Source: CII, Intec.net, Financial Express, Bain & Company.	

Indian Market

The Indian pharmaceutical market is small, both by Western standards and in terms of per capita consumption. Although India is the world's leading producer of generic drugs, its annual per capita consumption of pharmaceuticals is among the lowest in the world at approximately $4.50 per person, as compared with $820 in the United States and $13 in China in 2006. The value of India's pharmaceutical industry nearly doubled from $3.2 billion in 2000 to more than $6.2 billion in 2005, or by an average of 12 percent annually (table 10). According to the Associated Chambers of Commerce and Industry of India (Assocham), the Indian pharmaceutical market is expected to grow at an average annual rate of 13.6 percent during 2006-2010 to reach $9.5 billion in sales by 2010.[51] This growth is expected to be driven by: access to low cost, high volume generic drugs; mergers and acquisitions: industry consolidation; and India's growing importance as a pharmaceutical contract manufacturing and services location.[52] Approximately 80 percent of domestic industry production consists of formulations, with the remainder consisting of bulk drugs.

Table 10: Indian pharmaceutical market ($million)		
Year	**Total**	**Percent change**
2000	3,244	0.5
2001	3,260	15
2002	3,735	10
2003	4,088	14
2004	4,662	15
2005	5,344	16
2006	6,205	
Sources: U.S. Census Bureau; Economist Intelligence Unit; and World Trade Atlas.		

[51] "Domestic pharma to grow 13.6% in 2006-10 'Assocham'," *Pharmabiz.com*, Nov. 30, 2006.

[52] "Indian pharma mkt to grow at 13.6% from 2006-10: Assocham," *India Infoline*, com, Nov. 13, 2006.

In the post-product patents era, India's domestic market is changing, reflecting rising disposable incomes in urban areas and changes in India's demographic profile. Leading drug companies are putting more emphasis on meeting a growing demand for high value low volume, Western-style "lifestyle"drugs for wealthy urban customers who make up approximately 12 percent of the market.[53] This highly lucrative market segment includes drugs for "chronic" or "lifestyle" diseases have grown from 10 percent to 20 percent of the market in the mid-1990s to between 25 and 35 percent of the market today.[54] The demand for these drugs is growing at a faster rate, at 18 percent, than domestic demand for the acute drug segment (12 percent). India has often been called the world's diabetes capital and the rates of aliments like hypertension and high cholesterol are increasing annually. According to Sanjay Kaul, General Manager of Mankind Pharma's Product Division, the lifestyle drug segment will fuel the growth of India's pharmaceutical industry and includes anti-diabetes, anti-ulcer, anti-depressants, cardiovascular, hypertension drugs, Alzheimers disease, osteoarthritis, and cancer.

Intense domestic competition, a growing reliance on exports by the largest producers, and India as a growing market for contract manufacturing, contract research and development, and clinical trials, were among the forces behind the industry's growth. Prescription drugs dominate the Indian market, accounting for 85 percent of India's pharmaceutical production in 2005. The Indian pharmaceutical industry accounts for the second largest number of Abbreviated New Drug Applications (ANDAs), is the world's leader in Drug Master Files (DMFs) applications with the U.S. Food and Drug Administration, and has the largest number of FDA-approved manufacturing plants (75) outside of the United States. Many of India's leading Indian pharmaceutical companies have also been certified by regulatory authorities in Australia, South Africa, and the EU.

Imports: India's consumption of imported pharmaceuticals accounts for only a tiny portion of the world's production. Its imports consist almost entirely of life-saving drugs and new generations of formulations that are under patent by innovator companies. These include anti-cancer, cardiovascular, and anti-hypertension drugs imported primarily by major global pharmaceutical companies for sale in the Indian market. Within these categories, leading imports consisted of penicillin (13 percent), antibiotics for combating stomach infections (9 percent), and other medicines for retail sales in dosage form (19 percent). Life saving drugs can be imported into India duty free, whereas all other pharmaceutical imports faced a base duty rate of 30 percent and an effective duty rate of 56.8 percent in 2002, compared with "zero" duty in the United States.[55] India's imports of finished pharmaceutical drugs, intermediates, and APIs nearly tripled in value from $516.1 million in 1999 to more than $1.3 billion in 2005 (tables 11 & 12).

[53] Estimates range between 80 million and 100 million potential consumers that can afford expensive 'lifestyle' medicines.

[54] Khomba Singh, "Pharma cos see future in chronic medicines," *The Economic Times*, Apr. 9, 2007.

[55] Ames Gross and Sunil Patel, Indian Pharmaceutical Industry: Market, Regulatory, Import and Investment Regime, Pacific Bridge Medical, Inc., May 2002.

Table 11: India's pharmaceutical imports, 2005 ($million)		
Year	**Value**	**Percent change**
1999	516.1	
2000	547.1	6
2001	593.5	8
2002	847.1	43
2003	954.3	13
2004	1,050.2	10
2005	1,346.3	28
Source: World Trade Atlas.		

Table 12: India's pharmaceutical imports by product group (2005)				
Year	**HTS No.**	**Imports by product group**	**Value**	**Percent of total**
1999	2941	Antibiotics	421	31
2000	2942	Antibiotics for stomach	384	29
2001	3004	Other medicines	249	18
2002	2937	Hormones	89	7
2003	3002	Blood, vaccines	71	5
2004	2936	Vitamins	35	3
2005	3003	Mixtures, not in dosage form	27	2
Source: World Trade Atlas.				

India's top 7 import source countries accounted for approximately 32 percent of the total during 2005, down from 37 percent in 2004 (table 13). India's leading import suppliers included Switzerland (8 percent), Germany (6 percent), the United States (7 percent), and France (3 percent). Although India's pharmaceutical market is relatively small, at least 45 MNC pharmaceutical companies are serving the market through subsidiaries, other tie-ins, and imports. India's imports from Switzerland, the United States, and Germany consisted primarily of other medicaments in dosage form for retail sales (HTS. Subheading 3004).

Table 13: India's pharmaceutical imports from top 7 countries, by value ($ million)						
Country	**2002**	**2003**	**2004**	**2005**	**Jan - June 2005**	**Jan - June 2006**
Switzerland	92.6	95.7	82.8	109.2	63.3	115
Germany	57.6	52.6	61.9	85.3	58.1	51.3
United States	62.6	76.0	77.2	97.2	48.3	53.5
France	33.6	30.2	23.1	36.8	22.5	25.5
Denmark	31.4	33.3	24.3	42.7	17.7	13.9
Belgium	9.6	15.7	10.0	21.9	13.6	22.0
United Kingdom	24.9	25.6	40.6	34.9	22.9	24.5
Total	312.3	329.1	319.9	428.0	246.4	305.2
Source: World Trade Atlas.						

Exports: After nearly 30 years of focusing inward, India's pharmaceutical industry has emerged as a global player satisfying a significant portion of the world's generic drug needs. Attracted by high drug prices in the West, India's pharmaceutical exports grew from $1.9 million in 1999 to $5.2 billion in 2005 (table 14). In the last 5 years, India's exports more than doubled and account for approximately 40 percent of total industry production and nearly 30 percent of its revenues. India also enjoyed a trade surplus that increased from $3.1 billion in 2004 to $3.8 billion in 2005, or by 23 percent. India's exports should continue to show strong growth through 2010 as $60 billion worth of patented drugs lose their patent protection in the United States and Western Europe.[56] Assocham predicts that Indian companies will capture at least 30 percent of the replacement market of generic drugs.

Table 14: India's pharmaceutical exports ($million)

Year	Value	Percent change
1999	1,913.0	
2000	2,053.2	7
2001	2,311.2	13
2002	2,860.9	28
2003	3,514.8	23
2004	4,188.7	19
2005	5,150.1	23
Jan.-June 2005	3,349.1	
Jan.-June 2006	4,074.1	22

Source: World Trade Atlas.

According to Assocham, the importance of exports has grown dramatically over the last 5 years due to declining profit margins and the extremely price-competitive nature of the domestic Indian pharmaceutical market. Exports have grown to constitute a major revenue source for India's major pharmaceutical companies including Ranbaxy, Cipla, and Dr. Reddy's. Collectively, regulated markets accounted for more than 50 percent of their total annual revenues. In 2005-06, Ranbaxy derived nearly 80 percent of its sales revenues from exports, while exports and international acquisitions accounted for 66 percent of Dr. Reddy'sales and 50 percent of Cipla's. The successful penetration of the U.S. and EU markets has encouraged a growing number of Indian "copycat" companies to enter these markets.

India's exports to the regulated Western markets are expected to remain strong in the mid-term, event though Indian companies will be challenged by declining prices in the U.S. market, declining profit margins, growing competition from other low-cost countries, parallel launches of authorized generics by Western innovator companies, and the increasing power of large distributors in the U.S. and European markets. About $60 billion in blockbuster drugs will open to generic competition between 2002 and 2010 and Indian companies are expected to vie for a significant percentage of that business.

India exports pharmaceuticals to more than 200 countries and on a country-wise basis, India's five largest export markets are the United States (28 percent), Russia (11 percent), Germany (10 percent), the United Kingdom (8 percent), and China (7 percent) (table 15). All of India's major pharmaceutical companies are looking at the global market to accelerate their growth. They are looking at all markets with potential including the regulated markets of the United States, Japan, and Europe; the semi-regulated markets of BRIC countries; and less regulated markets of Africa, Middle East, and Southeast Asia. India has also become a very important source of generic drugs for the developing world and is the leading supplier of AIDs drugs to the world. Indian companies like Cipla and Ranbaxy have driven the

[56] "India Healthcare: Ranbaxy ready to take on the world," *Financial Times*, Oct. 11, 2006.

down the annual cost of anti-retroviral treatment from $15,000 per patient in 1995 to $200 in 2005.[57] Other leading exporters include Dr. Reddy's, Wockhardt, Sun Pharma, and Lupin Labs.

The vast majority of India's exports, by value, are destined for the developed economies of the West, particularly the United States, Germany, the United Kingdom, and France. Exports to these countries consist primarily of bulk drugs that account for nearly 60 percent of India's pharmaceutical exports. The remainder, mostly formulations, are exported to the countries of the former Soviet Union (CIS) and developing countries (Southeast Asia, Africa, and Latin America). India continues to be a leading supplier of less expensive antibiotics, cancer therapy, and AIDs drugs to the developing world. In 2005, more than 90 percent of India's exports are of drugs that are no longer protected by patents.

India's largest single export market continues to be the United States, which is the world's largest generic drug market. Exports to the United States grew from $429 million in 2003 to $589 million in 2005, or by 37 percent. The percentage of total exports represented by the United States declined slightly from 12 percent in 2003 to 11 percent in 2005. This decline can be attributed to the introduction of authorized generic drugs by domestic U.S. pharmaceutical giants, lagging profits and declining generic drug prices, and growing competition from other low-cost countries, particularly Israel, China, Korea, and those from East Europe.[58] To offset revenue losses from total sales in the United States during 2005-06, India's leading exporters have been aggressively shifting their attention to Europe and Africa. Europe, the world's third largest pharmaceutical market, behind the United States and Japan, had generic sales of approximately $100 billion primarily in the UK, Germany, and France. As previously stated, Indian pharmaceutical companies have made a number of acquisitions in Europe to gain a foothold in its markets. European generics markets considered to be under served include Spain, Italy, and France, and are expected to be important and growing markets for Indian exporters in the next 5 years.

Table 15: India's pharmaceutical exports to top 15 countries, by value ($million)

Country	2003	2004	2005
United States	421	497	575
Russia	129	157	219
Germany	165	172	211
United Kingdom	81	104	165
China	73	80	139
Brazil	70	173	121
Nigeria	71	94	110
Canada	60	84	100
Italy	45	54	81
South Africa	26	41	80
Netherlands	52	55	80
UAE	43	52	68
Turkey	28	40	67
Ireland	12	52	57
Total	1,276	1,655	2,073

Source: World Trade Atlas.

One of the preferred methods of penetrating the U.S. market has been by aggressively challenging the patents on blockbuster drugs. If successful, the challenger can obtain 180-day Exclusive Marketing Rights (EMR) to sell its generic version before other competitors are allowed into the market.

[57] Donald G. McNeil, "India Alters Law on Drug Patents," *The New York Times*, March 24, 2005.

[58] Gregory Roumeliotis, "India geared up for unprecedented manufacturing growth," *in-Pharma Technologist.com*, Aug. 15, 2006.

For example, Ranbaxy won an EMR against Merck for the production of a generic version of Prozac and the U.S. FDA permitted Ranbaxy to offer an 80mg generic version of Prozac for 180 days before others could offer competing generic products. Ranbaxy is also challenging patents on 6 other drugs in the United States like Valtrex (GSK's herpes drug), Nexium (AstraZeneca's anti-ulcer drug), and Actos (Tekeda's insulin sensitizer).[59] Another popular tactic is to file Abbreviated New Drug Applications (ANDAs) with the U.S. FDA.[60]

On an individual product level, India' leading exports include other medicaments packaged for retail sales (HTS subheading 3004), antibiotics, penicillin, and vitamins (table 16). Other medicaments exports more than tripled during 1999-2005, growing by $614 million to $2.2 billion in 2005. These products have traditionally dominated India's exports and their dominance has grown over the years, from 74 percent of the total in 2003 to approximately 90 percent in 2005. Exports of other medicaments were dominated by other generic and over-the-counter drugs (HTS 3004.90) that grew from $281 million in 2002 to $1.4 billion in 2005 representing 62 percent of India's exports during 2005. This Subheading includes generic and over the counter drugs such as anti-ulcer and anti-fungal medication, analgesics, drugs to treat irregular heartbeat (arrhythmia) and high blood pressure, anti-infectives, anti-seizure medication, and antacids and other gastrointestinal drugs.

Table 16: Indian pharmaceutical exports, by commodity ($million)

HTS Subheading	Commodity description	2002	2003	2004	2005	Jan-June 2005	Jan-June 2006
3004.90	Other medicaments of HTS 3004	281	827	1,011	1,391	673	757
3004.20	Antibiotics	55	165	193	271	139	179
3004.10	Penicillin and streptomycin	38	79	104	152	73	96
3004.50	Vitamins	31	62	96	128	50	69
3003.90	Other medicaments of HTS 3003	71	66	152	109	50	69
3002.20	Vaccines for human medicine	36	66	68	65	61	69
3003.20	Antibiotics	13	42	89	52	44	61
3003.39	Hormones, no antibiotics	1	50	58	34	16	25
3004.39	Other hormones, no antibiotics	10	14	16	26	12	12
3004.31	Insulin	4	3	25	22	10	9
3004.40	Alkaloids, no hormones or antibiotics	6	11	14	20	10	11
3005.90	Other wadding, gauze, bandages	3	10	10	16	8	10
3001.10	Dried glands and organs	4	7	8	13	11	1
3003.10	Penicillin	4	11	16	12	9	8
Total		557	1,413	1,860	2,311	1,166	1,376

Source: World Trade Atlas.

The role of Indian generic drugs in the U.S. market

Overview: The United States is the world's largest single market for pharmaceutical products accounting for nearly 50 percent of the value of the total world market. According to the Generic Pharmaceutical Association, U.S. retail drug sales for 2006 totaled $221 billion and generic pharmaceutical sales totaled $54.1 billion.[61] U.S. pharmaceutical sales grew by 73 percent from $128.1

[59] "Ranbaxy says it will keep attacking patents," *New York Times*, Dec. 21, 2005.

[60] ANDAs were introduced in the Hatch-Waxman Act and are used by foreign generic drug makers to challenge a U.S. patent before its expiry. If successful, the applicant gets a 6-month (180 day) exclusive right to sell its generic version. At the end that period, other generic drug companies can enter other versions of the molecule and generally the price of the generic version falls sharply.

[61] *Statistics*, Generic Pharmaceutical Association.

billion in 2000 (table 17). Together, the United States and Canada account for more than 50 percent of global sales and U.S. and Canadian generic commodity-type drug sales was estimated at $65 billion in 2005.[62]

In 2005, generic drugs accounted for approximately 63 percent of total U.S.-dispensed prescriptions and, on average, generic drugs cost between 30 percent and 80 percent less than their branded counterparts.[63] On average, the price of a generic commodity type prescriptions was $29.82 compared with the average price of brand-name prescription drug at $101.71.[64] According to the Generic Pharmaceutical Association, the U.S. market for generics grew by 23 percent in 2006 due to a greater acceptance of generics, changes in U.S. FDA's generic drug approval process, Medicare Part D, and declining prices driven by fierce price competition. Generic drug sales are projected to grow by 10 to 12 percent over the next 5 years as more blockbuster drugs lose their patent protection.

Table 17: Retail drug sales in the United States, ($million)

Year	Value ($million)	Percent change
2000	128,074	
2001	148,565	16
2002	163,039	10
2003	182,979	12
2004	194,480	6
2005	207,303	7
2006	221,059	9

Source: Economist Intelligence Unit.

U.S. pharmaceutical companies dominate the world's drug markets. Of the world's 10 leading drug companies, five are based in the United States. The top nine U.S. drug manufacturers account for nearly 70 percent of U.S. drug sales. The leading revenue earners were drugs for the central nervous system, which generated $53.9 billion, or 21 percent of the total U.S. drug market in 2005.[65] The second leading category was drugs for the cardiovascular system, which accounted for 19 percent of total U.S. drug sales, or $496 billion. Pfizer, the U.S. and world's leading research-based pharmaceutical company, controlled approximately 11 percent of the world market and 13 percent of the U.S. market in 2005.[66] Pfizer's most important products include Lipitor (the world's best selling drug) and Norvasc (the world's most prescribed anti-hypertension drug). Other leading pharmaceutical companies in the U.S. market are GSK (UK), Johnson & Johnson, and Merck (table 18).

[62] France is next spending $457 per capita followed by Japan at $339. Economist Intelligence Unit.

[63] "Express Scripts Study Shows Substantial Savings Opportunity for Consumers, states, Health Care Purchasers with Generics, says GPhA," Generic Pharmaceutical Association, Press release, Aug. 16, 2005.

[64] *2006 Chain Pharmacy Industry Profile*, The National Association of Chain Drug Stores.

[65] *Pharmaceuticals in the United States*, Industry Profile, Datamonitor, Dec. 2005.

[66] Bernard Rhee and M. June Casalmir, "Pfizer/Pharmacia Merger – The Biggest Just Got Bigger, FindLaw, May 28, 2003.

Table 18: Global sales by leading pharmaceutical companies in the U.S. market ($billion)			
Company (country)	**2003**	**2004**	**2005**
Pfizer (US)	44.7	52.5	51.3
Johnson & Johnson (US)	41.9	47.3	50.5
GSK (UK)	NA	NA	15.4
Merck (US)	22.5	22.9	22.0
Abbott Labs (US)	17.3	19.7	22.3
Bristol-Myers Squibb (US)	18.7	19.4	19.2
AstraZeneca (UK)*	8.9	10.1	11.2
* Estimated Source: 2005 and 2006 Annual Reports.			

The U.S. industry producing unbranded commodity-type generic drugs includes 9 of the world's 10 biggest generic drug companies. Generic drugs cost, on average, between 30 percent and 80 percent of their brand-name counterparts and account for approximately 56 percent of all prescriptions written in the United States, yet only 13.6 percent of every dollar spent of pharmaceuticals.[67] Sales of generic drugs grew by nearly 21 percent in 2005 compared with 2004, as generic versions of innovator blockbuster drugs lost their patent protection.[68] The initial six months following the expiry of a patent is the most profitable period for generic drug manufacturers. During that period, the price of the drug only drops, on average, by 40 percent since only one generic company has been granted exclusive manufacturing rights under an ANDA by the U.S. FDA.[69] With the loss of exclusivity after six months, the price drops, on average, an additional 40 percent as more companies enter the market and begin manufacturing the drug. Nearly $16 billion in patented drugs are scheduled to lose patent protection by the end of 2007.

Leading generic manufacturers in the United States, based on total sales in 2005, included Teva Pharma-USA, Novartis (Sandoz), Mylan, and Watson (table 19). Leading generic suppliers, based on the number of prescriptions dispensed, included Teva Pharma-USA, Mylan Labs, Novartis (Sandoz), Watson Pharma, and Ivax (table 19). Collectively, these companies accounted for more than 62 percent to total U.S. generic sales and more than 70 percent of all U.S. prescriptions dispensed in 2005. Other leading generic drug suppliers include Barr Pharma, Perrigo, Fougera, Taro, and Ranbaxy. Ranbaxy reported that its share of the U.S. generics market increased from 2 percent in 2004 to 2.3 percent in 2005 and that the in markets where it competes, it increased its share of the U.S. market from 12.2 percent in 2004 to 13.9 percent in 2005. In the dermatology segment, Ranbaxy's share of the market grew from 15.9 percent in 2004 to 21.7 percent in 2005.

Although U.S. generic sales increased in 2005, most of these companies experienced a drop in revenues resulting from price erosion, the introduction of authorized generics by innovator companies, and the entry of additional suppliers from low-cost countries into the market. Pricing pressures combined with mergers & acquisitions and consolidations, have reduced the number of companies manufacturing generic drugs in the United States over the last 5 years. For example, Teva Pharma-USA, a subsidiary of Teva Pharmaceuticals (Israel) the world's largest generic drug producer, became a major player in the U.S. market with the acquisition of Ivax in 2006 for $7.4 million.[70] Teva derives over 80 percent of its sales from the United States and Western Europe. Likewise, Actavis Group (Iceland) became a significant supplier of generic drugs in the U.S. market with the acquisition of Alpharma in 2006. As companies leave the industry there will be fewer firms producing older generic drugs.

[67] *Statistics,* Generic Pharmaceutical Association.

[68] Amanda Chater, "Generic sales soar as patents expire," *Drugstorenews,* Aug. 28, 2006.

[69] Aaron Smith, "Generic drugs concoct their next move," *CNN Money*, Feb. 9, 2007.

[70] Ravikrishnan, "It's Europe for Ranbaxy," *The Financial Express*, Apr. 1, 2006.

Table 19: U.S. Generic drug sales, 2005		
Companies	**Sales ($million)**	**Percent share**
Teva Pharma-USA	2,992	13.4
Novartis (Sandoz)	2,643	11.8
Mylan	2,003	9.0
Watson	1,425	6.4
Ivax	1,186	5.3
Par	932	4.2
Pfizer (Greenstone)	722	3.2
Actavis	677	3.0
Boehringer Ingelheim	674	3.0
Baxter Healthcare	639	2.9
Top 10 producers	13,894	62.3
Total	22,317	
Source: IMS Health, Feb. 2006.		

Table 20: Number of U.S. generic prescriptions issued (2005) (million)		
Company	**Number of prescriptions**	**Percent share**
Teva Pharma-USA	234	13.1
Mylan	213	12.0
Sandoz (Novartis)	191	10.7
Watson	158	8.9
Ivax	103	5.8
Mallinckrodt	84	4.7
Qualitest	74	4.1
Actavis	73	4.1
Par	70	3.9
Barr Labs	54	3.0
Top 10 producers	1,254	70.3
Total	1,781	
Source: IMS Health, Feb. 2006.		

Generic companies are preparing to compete for a share of the more than $60 billion worth of anti-cancer drugs set to go off-patent in the United States by 2011. Unlike other markets segments, the anti-cancer segment has not experienced significant price erosion and companies like Novartis (Sandoz), Teva Pharma-USA , Pliva, and Mayne Pharma are already offering anti-cancer drugs in the U.S. market. According to an industry source, while generic versions of most drugs are offered at prices 5 percent to 15 percent of the innovator's price, anti-cancer drugs will be offered at 40 to 50 percent of the innovator's price because only selected companies have the technical and dedicated facilities needed to produce these drugs.[71] In September 2006, Dabur Pharma was the first to gain approval from the FDA to offer a generic anti-cancer drug in the U.S. market.[72] Among the anti-cancer drugs scheduled to lose their patent protection are:

[71] Noemie Bisserbe, "Windfall for cos eyeing US oncology market," *The Financial Times*, April 11, 2007.

[72] Dabur offered a generic version of Bristol Myers Squibb's Paraplatin that went off patent in October 2004.

Drug	Innovator company	Therapeutic area	Year off-patent
Zofan	GSK	Nausea & vomiting due to chemo	2007
Gemcitabine	Eli Lilly	Chemotherapy drug	2009
Xeloda	Roche	Colon and breast cancer drug	2010
Arimidex	AstraZeneca	Breast cancer drug	2008
Casodex	AstraZeneca	Prostate treatment drug	2008

Role of imports in the U.S. market: The United States is the largest single pharmaceutical market in the world and the prime focus for most exporters. U.S. imports rose 61.5 percent during the 2002-2006 period, from $38.2 billion to $61.7 billion (table 21). In 2005, U.S. pharmaceutical imports consisted primarily of generic formulations in dosage form, aromatic drugs, antibiotics, vitamins, and hormones (table 22). Imports of generic drugs have increased in the last 5 years due to cost containment efforts by healthcare providers, greater acceptance of generic drugs, streamlining of the U.S. FDA's drug approval process, the passage of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, and the implementation of Part D of the Medicare Prescription Drug Act. Generic drugs also play an important role in holding down prescription drugs prices by offering the consumer an identical therapeutic alternative at a significantly lower price. The leading sources for U.S. imports include Ireland, the UK, France, Japan, and Canada, which collectively account for 51 percent of total U.S. imports generic drugs in 2006 (table 23). Although India's exports to the United States have more than doubled, they accounted for only 1 percent of total U.S. imports in 2006. Imports of other medicaments in dosage forms and aromatic heterocyclic compounds used as drugs dominated U.S. exports in 2006 accounting for 78 percent of total imports.

Table 21: U.S. imports from the world ($million)

Year	Value of U.S. imports	Percent change
2002	38,187.5	
2003	46,814.6	18
2004	48,966.2	4
2005	52,570.4	7
2006	61,660.8	17

Source: World Trade Atlas.

Table 22: U.S. imports of pharmaceutical products from the world ($million)						
HTS No.	**Description**	**2002**	**2003**	**2004**	**2005**	**2006**
3004.00.00	Medicaments in dosage form	17,808	23,080	25,947	28,689	34,721
2934.99.30	Aromatic heterocyclic compounds used as drugs	5,666	6,489	5,917	5,403	6,499
3002.00.00	Human & animal blood, antisera, vaccines	2,024	2,736	3,190	3,761	4,677
2937.00.00	Hormones	1,404	1,789	1,723	1,695	1,754
3006.00.00	Sterile surgical catgut, suture materials, tissue adhesives, Laminaria, hemostatics, contraceptives, blood grouping agents	478	830	982	1,176	1,341
2941.00.00	Antibiotics	1,080	1,471	1,200	1,378	1,110
3003.00.00	Medicaments of mixtures, not in dosage form	685	765	685	1,215	939
2936.00.00	Vitamins	496	550	640	619	620
2935.00.00	Sulfonamide	849	665	488	658	505
3005.00.00	Bandages	186	249	325	418	468
	Total	30,676	38,624	41,097	45,012	52,634
	Percent of total imports	80	83	84	86	85
Source: World Trade Atlas.						

Table 23: U.S. pharmaceutical imports, by value ($million)					
Country	**2002**	**2003**	**2004**	**2005**	**2006**
Ireland	12,681	14,750	14,368	14,768	14,729
United Kingdom	4,170	4,537	5,518	5,960	7,010
France	2,266	3,080	3,766	4,385	4,382
Japan	2,370	2,805	2,707	2,465	1,952
Canada	1,259	1,888	2,150	2,420	3,514
Switzerland	1,618	1,880	1,911	2,272	2,789
Singapore	1,036	1,505	972	1,232	2,742
Italy	905	1,037	1,263	1,795	1,699
Israel	640	825	974	1,590	2,602
Sweden	1,281	1,165	1,725	1,288	2,313
Mexico	274	313	533	413	434
Netherlands	576	696	569	499	612
Spain	290	495	630	1,122	834
Austria	145	167	212	244	304
India	289	465	415	480	712
Other	8,388	11,207	11,253	11,637	15,33
Total	38,188	46,815	48,966	52,570	61,661
Source: World Trade Atlas.					

Role of Indian generic drugs on the U.S. market: Indian pharmaceutical companies have made tremendous strides in the U.S. market. Indian companies are exploiting their cost advantages, their strength in reverse engineering, and the largest number of U.S. FDA approved plants outside the United States. Indian companies can manufacture pharmaceuticals for less than half what it costs to manufacture them in the United States, conduct clinical trials for approximately one-tenth the U.S. cost, and conduct R&D for less than one-eighth the U.S. cost.[73] India has more than 75 pharmaceutical plants approved by the U.S. FDA and in 2006, and was very aggressive in filing ANDAs in 2004-06 to challenge patents on innovator drugs.[74] Among the drugs that lost U.S. patent protection during 2006 were Pravachol, Zoloft,

[73] Aaron Smith, "Generic drugs concoct their next move," *CNN Money*, Feb. 9, 2007.

[74] "In fiscal year 2006, OGD approved a record 510 ANDAs," *Pharmaceutical Technology*, Dec. 2006.

Zocor, Plavix,and Flonase.

As 30 of the best selling U.S. patent-protected drugs go off patent by 2010, Indian companies are positioning themselves to offer generic versions of these drugs. Also, nearly $40 billion worth of patent-protected drugs will become off patent by 2010. Assocham believes that Indian companies will capture at least 30 percent of the replacement generic equivalents. In 2006, the U.S. FDA approved a Ranbaxy ANDA application to offer generic versions of 12 formerly patent-protected drugs with annual U.S. sales of $5.6 billion in 2006. Among these were generic versions of popular drug Zoloft, Valtrex, Zocor, Cefzil, Ambien, Imodium, and Lasix. Likewise, Dr. Reddy's received ANDA approval to offer generic versions of other popular drugs like Zofran, Proscar, and Allegra that have sales of several billion dollars during 2006-07.

Competition from Indian and other low-cost countries in the U.S. market will mean cheaper prices for generic drugs and greater choice for U.S. consumers. Price competition continued to intensify in the U.S. market thorough 2006 affecting both U.S. and Indian generics manufacturers. Indian companies compete directly with Teva, Myland, and at least 13 other generic manufacturers in the U.S. market. Prices and profits were also squeezed by Wal Mart's announcement that it would offer nearly 300 generic prescription drugs at "sharply-reduced prices," or at $4 for a month supply, approximately 70 percent savings for consumers.[75]

India comparative advantages have also enabled its API manufacturers to challenge U.S. API manufacturers for market share and helped Indian companies move up the value-added chain. Competition between Indian and U.S. manufacturers will also grow as Indian companies acquire U.S. manufacturing units. Ranbaxy, for example, operates 4 dosage form plants and one subsidiary (OHM Labs) in the United States with revenues of $426 million, or 36 percent of its total global sales, in 2005. Others acquiring U.S. facilities include: Zydus Cadila (R&D facility in Atlanta); Dr. Reddy's (Trigenesis); Sun Pharma (Able Labs, Caraco, Valeant Pharma); and Jubilant Organosys (Trinity Labs, Target Research Associates). Indian companies have also entered into a variety of partnerships such as joint ventures, tie-ins, and alliances with U.S. drug companies.

Conclusion

India's pharmaceutical industry has evolved from almost non-existent to a world's leader in the production of high-quality, low-cost non-branded or generic drugs, accounting for nearly 20 percent of the world's production. India currently produces almost all its own drug needs and domestic companies control over 80 percent of the Indian market. It has made tremendous strides over the last two decades as the Indian domestic market almost doubled in value during 2000 - 2006. Because of low barriers to entry and low capital requirements, there are tens of thousands of companies producing pharmaceuticals in India. The vast majority of them are small by Western standards with revenues of less than $5 million.

With the re-introduction of product patents in 2005 and the fiercely price competitive nature of the Indian pharmaceutical industry, many smaller, less competitive producers were forced to abandon the industry as it begins slowly shifting away from vanilla generic drugs to becoming a regional hub for R&D, drug discovery, contract manufacturing, and technology licensing. In this transition, many mid-level Indian producers will turn to contract manufacturing, outsourcing, contract research, contract clinical trials, or other tie-ins with MNCs. Some Indian sources predict that MNCs will make up 60 percent of the Indian market by 2015.[76]

Since 2005, many MNCs began re-entering the Indian pharmaceutical market by setting up their

[75] This includes most commonly prescribed drugs for some of the most common illnesses including cardiac disease, asthma, diabetes, glaucoma, Parkinson's and thyroid conditions. "Wal-Mart test-markets cheap drugs," *MSNBC*, Sept. 22, 2006.

[76] DP Dubey, *Globalization and its impact on the Indian Pharmaceutical Industry*.

own manufacturing and R&D facilities. This will gradually neutralize the cost advantages enjoyed by Indian pharmaceutical majors. These alliances and millions of dollars spent on establishing domestic and foreign-based manufacturing facilities, acquiring foreign drug manufacturing firms, as well as marketing and sales networks, will enable India's leading pharmaceutical producers to re-direct large sums of their cash flow to R&D and move up the value-added chain. These foreign acquisitions will enable Indian companies to gain a foothold in Western regulated markets, diversify their portfolios, acquire recognized brands, and gain R&D capabilities.

The United States has some of the highest drug prices in the world and has attracted imports of generic drugs from India and a number of low-cost countries. However, severe price compression and growing competition from other low-cost countries is forcing Indian majors to offset their losses by shifting their attention to Western Europe. Nonetheless, Indian companies have made tremendous strides in the U.S. market and companies like Ranbaxy are major sources of generic drugs. Indian companies also enjoy comparative advantages in cost, strength in reverse engineering skills, and number of U.S. FDA approved plants located in India. Indian companies have spent millions of dollars filing ANDAs with the U.S. FDA to gain exclusive production rights for many drugs losing their patent protection in the United States. Continued price competition in the U.S. market will mean cheaper prices for generic drugs and greater choice for U.S. consumers.

APPENDIX A
Selected company profiles

Ranbaxy Laboratories

Ranbaxy Laboratories is India's largest pharmaceutical company and one of the world's top ten generic drug makers. In 2004 and 2005, Ranbaxy accounteding for 23 percent of India's pharmaceutical industry revenues.[77] Ranbaxy is a vertically integrated company with a presence in across the pharmaceutical value chain offering a range of unbranded generic and branded generics, active pharmaceutical ingredients, and biotechnology products. Ranbaxy markets its products in more than 100 countries and has manufacturing facilities in 8 countries and a sales presence in 23 of the world's top 25 pharmaceutical markets.

Ranbaxy: key indicators

- Founded in 1961 in Gurgaon.
- Total sales : $ 1.03 billion (2004), $ 1.2 billion (2005).
- Exports account for 58 percent of sales. Largest markets include: U.S., Brazil, Russia, China.
- 28% of sales are in the U.S. market.
- Sales generic drugs in over 100 foreign countries, manufacturing operations in 7 countries, and offices in 44.
- R&D budget: $75 million (2004).
- Employment: 1,700
- Merger and acquisition activities valued at $X million.

Most of Ranbaxy's sales consist of off patent generic drugs and drugs manufactured under licence from foreign pharmaceutical companies. In 2005, exports accounted for more than 80 percent of Ranbaxy's sales and the United States was its largest export market accounting for $328 million, or 28 percent of the total.[78] Sales in Western Europe amounted to $204 million and BRICS (Brazil, Russia, India, China, South Africa) amounted to $364 million and accounted for 17 percent and 31 percent, respectively, of the company's total sales. Many of Ranbaxy's crucial markets including China, the CIS, Germany, and South Africa. India registered respectable growth during 2005, whereas the sales in the United States declined by 25 percent. Ranbaxy reported that its U.S. sales declined because of a steep erosion in generic drug prices due principally to increased competitive pressures from other Indian companies and companies from other low-cost countries. Declining U.S. sales combined with increasing R&D expenditures and litigation related expenses had a significant negative impact on the company's profitability in 2005

Ranbaxy entered the U.S. market in 1994 and now ranks among the top 10 suppliers of generic drugs in the United States. It offers more than 96 different generic products and has increased its share of the total U.S. generics market from 2.0 percent in 2004 to 2.3 percent in 2005. In those segments where Ranbaxy competes, it increased its share from 12.2 percent in 2004 to 13.9 percent in 2005. In the branded dermatology segment, Ranbaxy's share of the market grew from 15.9 percent to 21.7 percent during 2004-05. Ranbaxy supplements its exports with production from its facilities in Princeton, NJ (Ranbaxy Laboratories Limited) and North Brunswick, NJ (Ohm Labs) and through a partnership with Invagen Pharmaceuticals (Hauppauge, NY).

The company is the second largest filer of AND (110 with 59 pending), second only to Teva of Israel. It is also challenging patents on 7 patented blockbuster drugs whose patents will expire within the next several years.[79] In 2006, Ranbaxy won approval from the U.S. FDA to market a number of new products including schizophrenia medication Risperiodone Cetirizine Hydrochloride syrup for seasonal

[77] Amanda Chater, "Indian companies gain traction in U.S. generics market," Drugstore News, Sept. 25, 2006, pp. 34-35.

[78] Ranbaxy Laboratories, *Annual Report 2005.*

[79] "India healthcare: Ranbaxy ready to take on the world," Pharmacy Choice, Oct. 11, 2006.

allergic rhinitis and the generic bioequivalents of a number of brand named drugs.[80]

To expand its global footprint and diversify its product portfolio, Ranbaxy raised $440 million in March 2006 to finance acquisitions and other capital expenditure requirements. During 2005, it entered into a number of alliances and other agreements with foreign innovator companies (table 5) and acquired 11 foreign generic drug manufacturing companies (table A-1). These acquisitions also enabled the Ranbaxy buy recognized brand names, obtain revenues to fund for its R&D and expansion plans, and to move up the value-added chain.

Table A-1: Ranbaxy's foreign acquisitions

Company	Country	Distinction	Value ($million)
Terapia	Romania	Romania's 5th largest generics producer	$324 million
Ethimed	Belgium	Belgium's 10th largest generics producer	NA
Mundogen (GSK)	Spain	Unbranded generics of GSK	NA
Allen SpA (GSK)	Italy	NA	NA
Eframes	Spain	NA	NA
RPG Aventis	France	France's 5th largest generics supplier	$80 million
Basics	Germany	Formerly owned by Bayer	NA
Senetch PLC	US	Auto injector device	NA
Akrikhin	Russia	NA	$110 million
Nihon Pharma (40% share)	Japan	NA	NA
Be Tabs	S. Africa	S. Africa's 5th largest generic maker.	$70 million

Sources: Rainbows Annual Report, 2005.

Rawness drug discovery program centers around infectious diseases (anti-bacterial & antifungal), urology (benign prostatic hyperplasia & urinary incontinence), metabolic diseases (Type 2 diabetes, hyperlipidemia), and inflammatory-respiratory therapeutic areas (asthma, chronic obstructive pulmonary disease and Rheumatoid Arthritis). In 2005, the company allocated $75 million, or 7 percent of its turnover.

[80] The U.S. FDA permitted Ranbaxy to introduced the bioequivalents of heart medications Tambocor (3M Pharma), Lasix (Aventis Pharma) and Zocor (Merk); anti-infectives Cefzil (Bristol Myers Squibb) and Cefzil (Briston Myers Squibb); and anti-diarrheal infective Imodium (McNeil PPC). Ranbaxy Laboratories, Ltd.

Dr. Reddy's Laboratories

Dr. Reddy's Labs: Key indicators
- India's 3rd largest drug producer.
- Revenues: $502 million (July 2006).
- 66% of revenues earned in foreign markets.
- 41% of earning derived from formulations.
- Investing 6.5% of sales in R&D.
- Employees: 7,525.

Dr. Reddy's is India's third largest pharmaceutical company. It is a vertically integrated company offering a range of generic and branded drugs and active pharmaceutical ingredients. Most of Dr. Reddy's sales are of branded drugs reversed engineered versions of drugs patented in the West. In 2005, branded drugs accounted for 41 percent of total revenues and APIs accounted for 34 percent.

Dr. Reddy's derives most of its revenues from exports and its international acquisitions that account for approximately 66 percent of total revenues in 2005-06 and is expected to reach 80 percent by the end of 2006-07. The company sells and markets its products in more than 100 countries with the United States accounting for 60 percent of the total.[81] In 2005-06, the North American market (United States and Canada) accounted for 16 percent of Dr. Reddy's revenues, Russia and CIS accounted for 15 percent, Europe accounted for 18 percent, and India accounted for 24 percent

Dr Reddy's experienced a 3 percent decline in total revenues and a decline in after tax profits of 91 percent in 2004-05 due to declining sales caused by severe pricing pressures on generic drugs in the United States. Dr. Reddy's sales in North America declined by 8 percent during this period. During 2005-06, the company rebounded reporting that revenues increased by 24 percent to $502 million and after-tax profits grew five fold. The turn around was attributed to stained growth of revenues from APIs, formulations, generics sales in Europe as well as contributions from Dr. Reddy's acquisitions in Mexico and Germany. Dr. Reddy's is increasingly viewing Western Europe, Japan, Russia and the CIS as a viable counterbalance to the volatile U.S. market, especially since its in Europe increased by 51 percent during 2005-06.

At the product level during 2005-06, formulations accounted for 68 percent of the company's revenues during 2004-05 and 69 percent in 2005-06 (table A-2). Dr. Reddy's reported that sales of APIs and formulations grew by 19 percent, revenues from branded formulations grew by 27 percent, revenues from generics grew by 13 percent, revenues from custom pharmaceutical services grew by four fold. In the medium term, Dr. Reddy's predicts that its growth will to be driven by the sale of generic drugs in Western Europe and other more profitable markets.

Table A-2: Dr. Reddy's revenue by product, 2005

Product	Value ($million)	Percent of total
Formulations	227	41
APIs	188	34
Generics	94	17
CPS	29	5
Others	20	4

$1 = Rs 43.5. Source: Annual Report 2005-06.

Dr. Reddy's expanded its presence in Europe and the United States with the acquisition of 6 foreign companies during 2005-06 (table A-3). The acquisition of Betapharm is the most significant international acquisition by an Indian company to date. Betapharm has a portfolio of 145 marketed

[81] "Dr. Reddy's profit triples, good growth seen," Reuters, Jan. 22, 2007.

products and its acquisition is expected to add nearly $200 million to the company's bottom line.[82]

Table A-3: Dr. Reddy's foreign acquisitions			
Company	**Country**	**Distinction**	**Value**
BMS Laboratories	UK	Generics maker	$14 million
Betapharm Group	Germany	Germany's 4th largest	$584 million
Arzeniemittel	Germany	generic maker	NA
Trigenesis	US	NA	NA
Roche API business	Mexico	Ingredients business	$61.5 million
Litaphar	Spain	NA	NA
Source: Dr. Reddy's Annual Report 2005-06.			

Dr. Reddy allocated approximately $50.4 million to R&D in 2005-06, representing a reduction of 24 percent compared to 2004-05. Its R&D efforts are concentrated in the therapeutic areas of metabolic disorders, cancer, inflammation, and bacterial infections, cardiovascular. To eliminate some of the risk associated with new drug discovery, Dr. Reddy's formed a $52.5 million integrated drug development company called Perlecan Pharma with Citigroup Venture and ICICI Venture.

In 2005-06, it filed 12 ANDAs with 49 pending with the U.S. FDA. The company also filed 30 DMFs for APIs, of which 17 were U.S. DMFs, 8 were Canadian, and 5 were European. Dr. Reddy's also entered into an agreement with Merck to sell two of its blockbusters (Zocor and Proscar) in the U.S. market as authorized that will soon go off-patent.[83] In 2006, Dr. Reddy's launched 6 new products in the U.S. market and is waiting on the approval 64 new drug applications from the U.S. FDA.

[82] Noemie Bisserbe, "India drug cos reel under US pricing pressure," The Economic Times, June 17, 2006.

[83] "Merck allows Dr Reddy's to sell authorised generics of blockbuster drugs," domain-b.com, Feb. 2, 2006.

Cipla

Cipla is currently India's second largest pharmaceutical company in terms of sales and it produces a range of low-cost pharmaceutical ingredients (APIs), prescription drugs, OTC products, and formulations. Cipla's domestic formulations cover antibiotics and anti-bacterials, anti-asthmatics, alimentary-metabolism, cancer, pain management, central nervous systems, and cardiovascular therapeutic segments. It offers 18 brands and 1,500 formulations and its total sales increased from $534.3 million in 2004 to $703.4 million in 2005, or by 32 percent.

Exports constitute approximately 50 percent of its sales and it markets it products in more than 170 countries. The United States is Cipla's largest single export market and accounted for 33 percent of the company's sales in 2005, followed by Africa (26 percent), Europe (20 percent), the Middle East (11 percent), and Australasia (10 percent).[84] Cipla supplies bulk drugs for a number of generic manufacturers including Watson (U.S.), IVAX (UK), Eon, and Morton Grove.[85] It also supplies budesonide inhalers to companies located in Germany.

During the July-December period of 2006, Cipla reported that its domestic sales increased by 17.3 percent and its exports grew by 26.2 percent.[86] Formulations accounted for 73 percent of Cipla's exports in 2006 and APIs accounted for the remaining 27 percent. Cipla is best know for its anti-AIDs medication that consists of a "all-in-one" pill (Triomune) that effectively cut the cost of annual AIDs treatment from $12,000 to $300, or to less than $1 per day. The company has also a major suppliers of anti-malarial drugs. Cipla allocates approximately 4 percent of its turnover to R&D activities. It filed more than 50 DMFs and 55 ANDAs during 2004-05 and received approval for 11 products from U.S. FDA.

[84] Cipla, *Sixty-Ninth Annual Report 2004-2005.*

[85] "Banking on new products," The Financial Express.

[86] *Corporate Profile*, Cipla. Com

Nicholas Piramal

Nicholas Piramal (NP) is India's 4th largest pharmaceutical company. NP's offers a diverse product line covering antibiotics, neuro-psychiatry, cardiovascular, diabetes, gastrointestinal, vitamins, neurology, inhalation anaesthesia, respiratory pain management, and dermatology. NP reported revenues of $344.5 million during 2005-06.

Nicholas Piramal
- India's 4th largest drug producer.
- Revenues: $344.5 million (2006).
- 13% of revenues from foreign markets.
- Investing 9% of sales in R&D.
- Employees: 2,000

The domestic Indian market accounts for approximately 87 percent of the company's annual sales with brands like Phensedyl, Ismo, Supradyn, Gardenal, Stemetil, Haemaccel and Rejoint that account for 67 per cent of total revenues, while secondary brands including Paraxin, Flagyl and Omnatax accounting for the remainder.[87] Nicholas Piramal operates 7 API and finished dosage production facilities in India and state-of-the art R&D facilities in Mumbai and Chennai. In 2005-06, exports, primarily APIs, accounted for 12 percent of NP's turnover in 2004-05 consisted primarily anesthesia and parenateral products used in operating rooms and critical care units. NP exports for 2005-06 grew by more than 74 per cent to $34 million (Rs 220 crore) from $17 million (Rs 126 crore).

To expand its global footprint and diversify and enhance its product portfolio, Nicholas Piramal has acquired a number of foreign and domestic companies (table A-4). In 2003, it merged with Global Bulk Drugs and Fine Chemicals (India) to obtain access to the regulated markets of the United States, Europe, and Japan. Nicholas Piramal acquired Pfizer's custom manufacturing plant located in Morpeth (UK) to supply more than 300 finished dosage forms to more than 100 markets, including the United States, Western Europe, and Japan. In January 2007, Nicholas Piramal entered into a development agreement with Eli Lilly (US) to conduct non-clinical studies and human clinical trials and gained strategic entry into Pfizer's global sourcing network to become Pfizer's largest global contract manufacturing partner.

Nicholas Pirmmal acquired 51 percent equity stake held by Boots Company in the joint venture Boots Piramal Healthcare. It also acquired the Indian subsidiaries of F. Hoffman-La Roche (Roche), Boehringer-Mannheim, Rhone Poulenc, Hoechst Marrion Roussel research center, ICI India's pharma division, and Aventis' research facilities. It also entered into joint ventures or marketing relationships with Boots Healthcare, F. Hoffmann-La Roche (Switzerland), Gilead Sciences (U.S.), Cheissi (Italy) Stryker Corporation, Allergan (U.S.), and IVAX (UK) for a wide range of products.

Table A-4: Nicholas Piramal's domestic and foreign acquisitions

Company	Country	Distinction	Value
Pfizer Morpeth	UK	Custom drug manufacturing	NA
Avecia Pharma	UK	Custom drug manufacturing	$16.7 million
Dobutrex	US	Brand acquisition	NA
Rhondia	UK	Inhalation anesthetics	NA
Global Bulk Drugs & Fine Chemicals	India	U.S. FDA approved production plant	NA

Nicholas Pirmal India Ltd. is one of the world's top 10 pharmaceutical outsourcing firms and India's leading contract manufacturer with CRAMS manufacturing revenues of $250 million in 2005, including $100 million for formulations. At present CRAMS accounts for approximately 30 percent of

[87] Company Profiles, Nicholas Piramal

Nicholas Piramal's total revenues in 2005 and plans to increase it to 50 percent by 2010.[88] In 2006, Nicholas Piramal signed a 5-year, $350 million agreement with Pfizer for 12 products. The agreement made Nicholas Piramal Pfizer's largest custom manufacturing partner.[89] To augment its global contract manufacturing capabilities, Nicholas Piramal purchased Pfizer's contract manufacturing facility in the United Kingdom (Morpeth) and Avecia Pharmaceutical. Its deal with Pfizer could potentially produce much as $350 million for Nicholas Piramal by 2010.

[88] Jeetha D'Silva, "Drug cos bet on contract manufacturing," *The Economic Times*, July 25, 2006.

[89] MG Arun, "Druggists swallow phoren pills to open new vistas," *The Financial Express*, June 28, 2006.