PHARMACEUTICALS

The Indian Pharmaceutical Industry:

Collaboration for Growth

INDUSTRIAL MARKETS

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1 Letters of Introduction

India's pharmaceutical sector is currently undergoing unprecedented change. Much of this is due to the country's introduction, on January 1, 2005, of a system of product patents; before that, only patents for processes were permitted to be issued, a fact that has been instrumental in the domestic industry's huge success as a worldwide exporter of high-quality generic drugs.

The new patent regime has also led to the return of the pharmaceutical multinationals, many of which had left India during the 1970s. Now they are back, and looking at India not only for its traditional strengths in contract manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services.

Both multinational companies (MNCs) and domestic players are also examining the prospects offered by the local market as the government moves forward with initiatives aimed at providing India's more than one billion inhabitants, for the first time, with access to the life-saving drugs they need. A further huge boost to the local market is coming from the rise of India's new affluent consumers, who lead more Western-style lives and are demanding innovative drugs to treat the chronic illnesses that these changing lifestyles may produce.

India's leading drug manufacturers are becoming global players, utilizing both organic growth, through the gradual development of their business, and mergers and acquisitions (M&A) as they seek to boost their presence in existing markets and open up new ones.

However, there are significant obstacles ahead, and overcoming them will require new commitment by both industry and government, and unprecedented levels of partnership between them. This report examines how these opportunities can be realized and the challenges met. Our research includes invaluable insights provided by a number of the industry's leading figures. We thank them for their contributions.

John Morris
Global Chair
KPMG's Pharmaceuticals Practice

India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system on January 1, 2005. Most will be unable to develop the financial muscle necessary to embark on R&D for innovative new products, but their scientific, technical and manufacturing skills, developed under the country's 25-year process patent system, perfectly match the requirements of global drug manufacturers that are increasingly seeking to offshore many research and manufacturing activities previously performed in-house.

At the same time, a number of the country's largest pharmaceutical companies are attaining global-player status as existing markets expand, and new ones open up, for high quality, affordable generic drugs. Indian firms have embarked on an unprecedented shopping spree of overseas acquisitions to establish themselves in these highly lucrative markets and boost their capacities, as demand continues to grow.

Partnerships will also be key for Indian firms' development in their home market. Multi-national companies that have re-entered the market since the new product patent system seek out the domestic industry's skills and infrastructures to boost their research and manufacturing activities in the subcontinent and also open up this vast, virtually untapped market.

However, India's market development will depend, more than anything, on government moves to increase the population's access to medicines, which is now extremely limited. Further price controls are not the answer; Indian prices for essential drugs are already the lowest in the world. Instead, the solution lies with pro-active measures such as public-private partnerships and encouragement of R&D; for example, through industry-academia collaborations and an official system of grants, which have proved to be of great benefit to industry and patients elsewhere in the world.

A number of leading industry figures generously gave their time to provide unique industry insights for this report. We would like to thank the following people for their contribution: Ranjit Shahani, vice chairman and managing director of Novartis India Ltd, and president of the Organisation of Pharmaceutical Producers of India; Kewal Handa, managing director of Pfizer India; Satish Reddy, managing director and chief operating officer of Dr. Reddy's Laboratories Ltd; Ajay Piramal, chairman and managing director of Nicholas Piramal; and Pankaj Patel, chairman and managing director of Zydus Cadila.

Sanjay Aggarwal
Pharmaceutical Sector Leader
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2 Executive Summary

India's pharmaceutical industry has been growing at record levels in recent years but now has unprecedented opportunities to expand in a number of fields. The domestic industry's long-established position as a world leader in the production of high-quality generic medicines is set to reap significant new benefits as the patents on a number of blockbuster drugs are scheduled to expire over the next few years. In addition, more and more governments worldwide are seeking to curb their soaring prescription drug costs through greater use of generics. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the U.S. and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, and Eastern and Central Europe.

In addition, India's long-established position as a preferred manufacturing location for multinational drug manufacturers is quickly spreading into other areas of outsourcing activities. Soaring costs of R&D and administration are persuading drug manufacturers to move more and more of their discovery research and clinical trials activities to the subcontinent or to establish administrative centers there, capitalizing on India's high levels of scientific expertise as well as low wages.

Both multinational and local drug manufacturers could eventually benefit from the market potential of India's population of over one billion. A large market will likely open up as the result of a projected boom in health insurance, an area in which the country is currently woefully underdeveloped. New government initiatives seek to enable the majority of the population to access the life-saving drugs they need, while even greater opportunities may be presented by the rise of the new Indian consumer. This group-urban, middle class and wealthy-live fast-paced, Western-style lives and, as a result, they are beginning to suffer from Western, lifestyle-related illnesses, for which they want, and can afford, innovative drug treatments.

This untapped domestic market is also highly attractive to the pharmaceutical MNCs, which recently have returned to India in large numbers (many had left when the regime allowing process patents only was introduced in the early 1970s). Now, MNCs and domestic companies are starting to work together, utilizing each other's strengths for their mutual benefit. For the foreign firms, this includes not only the Indian companies' research and manufacturing capabilities and their much lower operational cost levels, but also comprehensive marketing and distribution networks operating throughout India's vast territories.

There are, however, a number of uncertainties, particularly the effects of India's new product patent system, which was introduced on January 1, 2005. Previously, only process patents were granted, a situation that led to India's current role as a world leader in the production of high quality, affordable generics. The new regime may spell the end for the domestic sector's smaller players, while for others it could represent unprecedented opportunities.

Nevertheless, the domestic industry is still spending far too little on R&D, which must change quickly if it is even to begin to address these new opportunities and challenges. On the international front, the industry still has some catching up to do in terms of quality assurance while, on the local market, pricing remains a problem.

There is a need for regulatory reform in India to encourage leading global players to continue and accelerate the outsourcing of their R&D activities-beginning with discovery research-to the subcontinent. This is particularly urgent in the face of the strong competition from China, where the government has been particularly proactive in encouraging foreign investments in pharmaceuticals and biotechnology.

In India, the industry is now awaiting developments following the January draft publication of the government's National Pharmaceuticals Policy for 2006. The document contains proposals for far-reaching initiatives aimed at boosting the domestic industry's global competitiveness, as well as improving the population's access to medicines. Indian government ministers have also promised MNCs concrete action soon on speeding the patent approval process and other crucial issues, such as the definition of patentability and compulsory licensing.

Action is required soon, if India wants to be a significant player in the global pharmaceutical arena.

3 The Indian Pharmaceutical Industry

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall.[1] Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value,[2] and its drug exports have been growing 30 percent annually.[3]

The "organized" sector of India's pharmaceutical industry consists of 250 to 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75 percent of India's demand for medicines is met by local manufacturing.[4]

According to the German Chemicals Association, in 2005, India's top 10 pharmaceutical companies were Ranbaxy, Cipla, Dr. Reddy's Laboratories, Lupin, Nicolas Piramal, Aurobindo Pharma, Cadila Pharmaceuticals, Sun Pharma, Wockhardt Ltd. and Aventis Pharma.[5] Indian-owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994.[6]

India's potential to further boost its already-leading role in global generics production, as well as an offshore location of choice for multinational drug manufacturers seeking to curb the increasing costs of their manufacturing, R&D and other support services, presents an opportunity worth an estimated $48 billion in 2007.[7]

Over-the-Counter Medicines

The Indian market for over-the-counter medicines (OTCs) is worth about $940 million and is growing 20 percent a year, or double the rate for prescription medicines.[8] The government is keen to widen the availability of OTCs to outlets other than pharmacies, and the Organisation of Pharmaceutical Producers of India (OPPI) has called for them to be sold in post offices.

Developing an innovative new drug, from discovery to worldwide marketing, now involves investments of around $1 billion,[9] and the global industry's profitability is under constant attack as costs continue to rise and prices come under pressure. Pharmaceutical production costs are almost 50 percent lower in India than in Western nations, while overall R&D costs are about one-eighth and clinical trial expenses around one-tenth of Western levels. India's long-established manufacturing base also offers a large, well-educated, English-speaking workforce, with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers, with 1,500 PhDs.[10] The industry provides the highest intellectual capital per dollar worldwide, says OPPI.

India's top 10 branded drugs 2004:

Corex (chlorpheniramine maleate, codeine phosphate)
Human Mixtard (insulin)
Voveran (diclofenac sodium)
Becosules (vitamin B complex, vitamin C)
Taxim (cefotaxime)
Asthalin (salbutamol)
Sporidex (cephalexin)
Digene (aluminium hydroxide, magnesium hydroxide)
Betnesol (betamethasone)
Althrocin (erythromycin)

India's largest-selling drug products are antibiotics, but the fastest growing are diabetes, cardiovascular and central nervous system treatments.

Source: OPPI, 2004.

The industry's exports were worth more than $3.75 billion in 2004-05 and they have been growing at a compound annual rate of 22.7 percent over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006. The Policy estimates that, by the year 2010, the industry has the potential to achieve $22.40 billion in formulations, with bulk drug production going up from $1.79 billion to $5.60 billion: "India's rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second-largest English-speaking group worldwide, after the USA."[11]

The Indian Pharmaceutical Industry in 2004

Turnover:	$6.02 billion, up 6.4 percent year over year
Exports:	$3.72 billion
Imports:	$985.3 million
Bulk drug production:	$2.10 billion, with over 400 bulk drugs produced. Over 60,000 formulations produced, in 60 therapeutic categories
Capital investment:	up 14.8 percent to $1.16 billion
Employment:	5 million direct, 24 million indirect

Source: OPPI, 2004.

VAT

In April 2005, the government introduced value-added tax for the first time and abolished all other taxes derived from sales of goods. So far, 22 states have implemented VAT,[12] which is set at 4 percent for medicines. This led to pharmaceutical wholesalers and retailers cutting their stocks dramatically, which severely affected drug manufacturers' sales for several months.

4 Opportunities

The main opportunities for the Indian pharmaceutical industry are in the areas of:

- generics (including biotechnology generics)
- biotechnology
- outsourcing (including contract manufacturing, information technology (IT) and R&D outsourcing).

Generics

Prescription drugs worth $40 billion in the U.S. and $25 billion in Europe are due to lose patent protection by 2007-08. Indian firms will likely take around 30 percent of the increasing global generics market, the Associated Chambers of Commerce and Industry of India (Assocham) forecast. Currently, the Indian industry is estimated to account for 22 percent of the generics world market. Low production costs give India an edge over other generics-producing nations, especially China and Israel, says Assocham's president Mahendra Sanghi. He suggests that it will be easier for Indian firms to win larger generics market shares overseas than at home, particularly in the U.S. and Europe.[13]

Indian drug manufacturers currently export their products to more than 65 countries worldwide.[14] Their largest customer is the U.S., the world's biggest pharmaceutical market. The use of generic drugs is growing quickly in the U.S. due to cost pressure by payers and the introduction on January 1 this year of the Medicare Part D prescription benefit, giving seniors and people with disabilities prescription drug coverage for the first time. With 74 facilities, India has the largest number of U.S. Food and Drug Administration (FDA)-approved drug manufacturing facilities outside the U.S. Indian firms now account for 35 percent of Drug Master File applications and one in four of all U.S. Abbreviated New Drug Application (ANDA) filings submitted to the FDA.[15] Analysts at Credit Lyonnais Securities Asia say they expect the number of generic drug launches by Indian companies in the U.S. to increase from 93 in 2003 to over 250 by 2008.[16]

In January 2006, the Indian exporters' representative body, the Pharma Export Promotion Council (Pharmexcil) said it planned to raise a number of concerns with the U.S. government over what it sees as barriers to trade with them. One is a U.S. regulation that disqualifies Indian firms from bidding for government contracts, and another is the requirement Indian drug manufacturers submit separate applications for each U.S. state (there is no U.S.-wide regulatory requirement), even when the firms have FDA-approved products and facilities.[17]

ANDA Filings for Indian Mid-sized Companies

Company	FY04	FY05	FY06
Glenmark	–	7	14
Zydus Cadila	12	13	6-18
Orchid	–	18	18-30
Wockhardt	5	7	12-13
Aurobindo	2	22	3

Source: Cygnus Consulting & Research. *Industry Insights-Pharmaceuticals*, November 2004.

However, India's traditional lucrative export markets may be becoming a little less secure, for a number of reasons. For example, generic prices have not been rising in the U.S.; the seniors' advocacy group AARP (formerly the American Association of Retired Persons) says that, of the 75 generic drugs widely used by older people that it monitors on a quarterly basis, none had had a change in manufacturer list price during third quarter 2005 and only three had had increases in list price at any time during January to September 2005.[18] Also, new competitive threats have arrived, such as authorized generics produced by major drug producers, new mid-sized players, Chinese and Eastern Europe manufacturers, and fully integrated generics firms, which are less reliant on Indian "back-end" businesses.

The U.S. continues to be an attractive market for Indian firms, despite the challenges of price erosion and the launch of "authorized generics" by innovator companies, says **Ranjit Shahani**, vice chairman and managing director, Novartis India Ltd, and President of the Organisation of Pharmaceutical Producers of India. He does not see any increase in non-tariff barriers there, and in fact feels that trade between India and the U.S. is "set to rev up following President George W. Bush's visit to India on March 1, 2006, with both countries going all out to liberalize market access." The major concern of the U.S. FDA appears to be the entry of counterfeit drugs, he says, but he does not believe this to be an obstacle for reputable Indian manufacturers. Moreover, while the World Trade Organization (WTO) Doha Trade-Related Aspects of Intellectual Property rights (TRIPs) national emergency/compulsory license agreement presents an exporting opportunity for Indian firms, Shahani stresses that the firms must have anti-diversion measures in place in order to protect their reputation.

"The European generics market," he says, pointing to Dr Reddy's recent acquisition of Betapharm of Germany for $570 million, "holds more promise." Indian companies have acquired over $1 billion worth of pharmaceutical companies overseas in the past year and a half and should increasingly look more aggressively at countries like Brazil, Russia and the

Commonwealth of Independent States, and Japan, where the markets are mature and remunerative, despite some regulatory hurdles, he notes.

Also, he says, Indian firms should move up the value chain to produce innovative "super generics" as the once-a-day Ciprofloxacin product developed by Ranbaxy and licensed to Bayer, move up from producing "generic generics" to branded generics.

Biotechnology Generics

Firms based in India and China could be among the first to bring biogenerics (generic versions of biological products) to the regulated markets and faster than expected. The first biogeneric product was approved by the European Medicines Agency (EMEA) which refers to these products as "biosimilars," in April 2006.

IMS estimates that biotechnology products accounted for 10 percent of global pharmaceutical sales in 2004, or about $55 billion in worldwide sales for the year.[19] By 2003, the U.S. accounted for 62 percent of the global biotech drugs market, while in that year Japan's share of the total had fallen to 7 percent from 28 percent in 1994.[20] Patents on the first generation of blockbuster biopharmaceuticals are beginning to expire, and the high cost of these products means the generic versions will find large markets among hard-pressed governments and other payers. Sales of biogenerics are flourishing in the unregulated markets. The only regulated-market approvals so far are in Australia, granted in October 2004 for the recombinant DNA growth hormone Omnitrope, manufactured by Sandoz, as well as in the EU, granted in April 2006.

No U.S. approvals are likely until 2009, says market research company Datamonitor. The company has identified six key product classes-insulin, human growth factor, epoetin, colony stimulating factors (CSFs), interferon alpha and interferon beta-as being at risk from biogeneric versions of these products and estimates that global sales of the latter should total over $2 billion by 2010.[21]

An early beneficiary when the regulated markets finally establish frameworks for biogenerics is likely to be Wockhardt.[22] This pharmaceutical and biotechnology company was one of the first Indian drug manufacturers to enter the European market, achieving this through a series of acquisitions; it now has three subsidiaries in Europe, acquiring first The Wallis Laboratory in 1997 and CP Pharmaceuticals in 2003, both in the UK, then Esparma of Germany in 2004.

Biopharmaceuticals are central to Workhardt's growth strategy, and the firm expects this area of its business to take off in 2006. Reporting at the end of December 2005, it says it has more than 55 registrations for biopharmaceuticals pending, and 26 approvals in 18

countries. According to analysts at SSKI India, Wockhardt is one of the few players in India, and even globally, to have the requisite capabilities in biogenerics production.[23]

Export Import Bank Chairman T.C. Venkat Subramanian believes the patent expiries on 11 major drugs this year could help bring a "biotechnology revolution" to India. He forecasts that biotechnology could potentially generate revenues of $5 billion and create one million jobs by 2010, through products and services.[24]

Biotechnology

In 2003-04, biopharmaceuticals accounted for 60 percent of India's total biotechnology market, which was worth an estimated $709 million-up 39 percent over the previous period. Investment in the sector was up 26 percent to $137 million-and exports accounted for 56 percent of industry revenues. The domestic biopharmaceuticals sector grew 38.5 percent and had the largest local market share, at 76 percent, followed by bioagriculture at 8.4 percent, bioservices at 7.7 percent, and industrial products at 5.5 percent and bio-informatics at 2.5 percent.[25]

With 200 biotech companies and total revenues of $500 million annually, India's biotechnology sector is still in the relatively early stages of development. However, it is growing fast, with an initial emphasis on vaccines and bioservices. The industry is situated mainly in Karnataka, although there are operations in Andra Pradesh, Hyderabad, Kerala, Maharashtra and West Bengal. The top 10 players in terms of revenues in 2004 were Biocon, Serum Institute of India, Panacea Biotec, Nicholas Piramal, Novo Nordisk, Venkateshwara Hatcheries, Wockhardt, GSK, Bharat Serums & Vaccines, and Eli Lilly & Co, reports Burrill & Co, the U.S.-based life sciences merchant bank. As is generally the case worldwide, most biotech companies in India have developed along the contract or collaborative research models.

Discussing the development of the domestic biotechnology market, **Ranjit Shahani** of Novartis India points out that, globally, most small and medium-sized biotech enterprises are acquired by MNCs as the quickest route into this market, and India is no exception. Government incentives are important, particularly in terms of regulatory reforms, tax incentives for R&D, the development of biotechnology parks and Special Economic Zones, etc. While India's 2005 Biotech Policy should spur investment, U.S.-style industry-academia partnerships and cluster models are worth emulating. To this end, he says, India's February 28, 2006, National Budget was a disappointment for the pharmaceutical industry, as it offers very little in the way of incentives for R&D, which is becoming increasingly important in the post-IPR regime.

In a report published last September, the Organisation for Economic Cooperation and Development (OECD) pointed to a current lack of focus on biotechnology in India, due in part to a lack of consensus on a definition, and also that the large number of government

agencies that deal with biotechnology have led to a duplication of research funding and poor coordination. This needs to be addressed urgently, said the report, which also called for initiatives to attract India's best scientists back to the country, and more support for small and medium-sized enterprises to enable them to face competition from the MNCs.[26]

Observers also warn that India's nascent biotechnology sector could face particularly strong competition from China, the only developing country to participate in the international Human Genome Project.[27] Also, massive levels of state investment mean Chinese firms are now producing hepatitis vaccines, recombinant insulin, interferon and other generic therapeutic biologics. As is the case throughout the industry, India is regarded as having the edge over China in terms of qualified, English-speaking employees, intellectual property rights, and judicial and quality standards. However, if China does emerge as the dominant biotechnology player, this could have very serious implications for India.

Outsourcing

IT Outsourcing

India's status as an information technology superpower, with access to specialist skills and 24/7 work hours, is a huge advantage as it strengthens its position as the destination of choice for contract research, including drug discovery. Eighty-two percent of U.S. companies overall rank India as their first-choice IT outsourcing destination, says leading international clinical research organization Chiltern International,[28] adding that IT and IT-enabled services (ITES) companies have been expanding their activities in India to new business segments such as bioinformatics and life sciences; those doing so or planning to include Accenture, Intel, Satyam, Cognizant, IBM, Oracle and TCS. Wipro Spectramind, India's largest third-party offshore business process outsourcing provider, is conducting bioinformatics work for global pharmaceutical companies.

"India is considered a highly promising outsourcing IT and clinical data management destination because of its rich talent pool, technological innovation, creditable quality, operational flexibility, cost effectiveness, time-to-market and competitive advantage," says Dr. Umakanta Sahoo, general manager of CRO Chiltern International in India. While India previously relied on cost-effectiveness to attract customers, quality and fast response are now dominating the business processes, adds Dr. Sahoo.[29]

MNCs that have already entered into off shoring contracts include Pfizer India, which has signed a preferred provider contract for its biometrics division with Cognizant Technologies India and is also working with SIRO Clinpharm; Wyeth, working with Accenture in clinical trial data management; GSK, whose biomedical data sciences and clinical data management centre in Bangalore supports studies for the group worldwide; and Novartis, which has a software development centre for specialized drug development programs.

India's Other Advantages for Off shoring

- Low-cost skill base
- Current Good Manufacturing Practice (cGMP) and U.S. FDA compliance levels
- High visibility in generics
- High-quality, compliant manufacturing
- Strong financial position with ability to scale up
- Manufacturing capacity
- Access to new technologies
- Cost efficiency and track record
- Industry position
- Recognition of product patents

Contract Manufacturing

The global pharmaceutical market is estimated to represent a $48 billion opportunity for India by 2007[30], in terms of:

- manufacturing outsourcing-supply of active pharmaceutical ingredients (APIs) and intermediates
- development outsourcing-conducting preclinical and clinical trials
- customized chemistry services-contract research services for compounds pre-launch.

Worldwide revenues for pharmaceutical industry contract manufacturing and research services (CRAMS) totaled $100 billion in 2004 and will grow at an average annual rate of 10.8 percent to reach $168 billion by 2009, say analysts at Frost & Sullivan. Within this total, the global market for contract manufacturing of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 billion, although the over-the-counter medicines and nutritional products sector will show the fastest growth.[31]

The Asian region has recently been challenging North America and Europe's traditional domination of the global pharmaceutical contract manufacturing market: India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates.[32]

Two major developments suggest that Indian drug manufacturers are set to benefit from an outsourcing boom. First, such an upsurge in business always occurs when a number of top-selling drugs come off-patent, as is about to happen. Second, the arrival of India's product patent regime has increased international companies' confidence in India's outsourcing industry. At the same time, those Indian firms that will not have the ability to invest in R&D will be able to exploit the strengths they have developed as the world's leading suppliers of affordable essential drugs.[33]

Key Contract Manufacturing Agreements

Indian Company	International Partner	Outsourced Products
Cadila Healthcare	Altana	Two intermediates for Altana's under-patent molecule Protonix (pantoprazole)
Hikal Limited	Degussa	Hikal has signed an agreement with Degussa for supplying pharmaceutical intermediates and active pharmaceutical ingredients
Nicholas Piramal	AMO	Neutralizing tablets and sterile FFS packs (product names not disclosed)
Nicholas Piramal	Allergan	APIs for Levobunolol (Betagen) and Brimonidine (Alphagan and Alphagan - D)
Nicholas Piramal	Pfizer	7-year agreement relating to R&D services under which Nicholas Piramal will provide process development and scale up services to Pfizer's animal health division from the latter's facilities in India
Dishman Pharma	Solvay	6 projects; the main one being for starting material and advanced intermediate for Tevetan (eprosartan maleate)
Dishman Pharma	AstraZeneca	Intermediate for Nexium (esomeprazole)
Dishman Pharma	Merck	Intermediate for Losartan (to be supplied to its contract manufacturer in Japan)
Shasun Chemicals	GlaxoSmithKline	Ranitidine API
Shasun Chemicals	Eli Lilly	Nizatidine, metohexital and cycloserine APIs

Source: Citigroup Analyst Report, October 10, 2005.

Indian successes in this area have already created some significant international developments. For example, last year, Jubilant Organosys, which has the largest CRAMS business in India, acquired Target Research Associates plus 64 percent of Trinity Laboratories and its wholly owned subsidiary Trigen Labs, all U.S.-based firms. Another large Indian firm, Bilcare Ltd, acquired its first manufacturing facility in the U.S. last year, with the purchase of Philadelphia-based proClinical Inc.

Contract Research

Ajay Piramal, chairman and managing director of Nicholas Piramal, expects to see significant growth in India's custom manufacturing business, as a result of high and rising costs to innovative manufacturers in Europe and the U.S., and also forecasts that there will be a

growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D (including drug discovery and clinical trials), co-marketing and manufacturing.

India and China's drug outsourcing discovery markets combined are currently worth around $7.3 billion and, driven by government initiatives to diversify the drug discovery portfolio and develop infrastructure, are set to reach $19.8 billion in 2011, say analysts at Frost & Sullivan.[34]

In September 2004, a global innovation survey by the Economist Intelligence Unit identified India as an R&D "hotspot," defined as a place where (1) companies are able to tap into existing scientific and technical expertise networks, (2) there are good links to academic research facilities, (3) the environment supports innovation and (4) it is easy to commercialize. Costs of pharmaceutical innovation in India are estimated as low as one-seventh of their levels in Europe, and the country's clinical research industry is currently worth $100 million and growing around 40 to 50 percent annually, although some forecasts say it could be worth as much as $1 billion to Indian firms in 2008.[35]

Examples of R&D Inward Investments

- AstraZeneca is conducting research into tuberculosis (TB) at the AstraZeneca Research Foundation India in Bangalore. India's estimated 8.5 million TB patients[36] mean clinical trials can be conducted easily and economically. Although the revenue potential for anti-TB drugs is limited as the disease mainly affects poorer nations, the reduced research costs of developing the drug in India and the goodwill associated with helping to eradicate a major disease in developing countries still present a good business opportunity for AstraZeneca.
- GSK and Ranbaxy have set up an early-stage partnership in drug research, under which GSK will provide the Indian firm with leads, Ranbaxy will conduct lead optimization and animal trials, and GSK will take the drug through human trials. GSK will have exclusive rights to sell any resulting product in developed-world markets, and the two firms will co-promote it in India.
- Pfizer is exploring the establishment of an R&D facility and setting up an Academy for Clinical Research in Mumbai.

Costs of clinical trials in India are around one-tenth of their levels in the U.S., and it is estimated that they could be worth $300 million to India by 2010.[37] Major drug producers that are already conducting trials in India include Pfizer, estimated to have some 20 ongoing clinical trials there; GSK, with seven trials; Eli Lilly, with 17 trials; plus AstraZeneca and Novartis. As well as Chiltern, leading contract research organizations (CROs) such as Quintiles, SFBC International and ICON Clinical Research have extensive operations in India.

5 Challenges

"The three strategic drivers for accelerating growth of the pharmaceutical industry in India are intellectual property rights-its implementation in letter and spirit; liberal drug pricing policies; and regulatory (as well as labor) law reforms," according to **Ranjit Shahani** of Novartis India.

Patents and Intellectual Property Rights

India's new product patent regime is the result of the WTO's Doha Round of negotiations in 2001. Final agreement was reached on TRIPs ground rules for patent protection among WTO member countries, stating that both processes and products should be protected.

Subsequently, on March 22, 2005, India's parliament approved the *Patents (Amendment) Act* 2005, bringing in a system of product patents backdated to January 1, 2005. The new regime protects only products arriving on the market after January 1, 1995, abolishing the previous process patent system established by the 1970 *Patent Act*.

Since the introduction of product patents the MNCs have largely returned, the most recent being Merck & Co, which inaugurated its wholly owned subsidiary MSD India Pvt Ltd in July 2005 after being absent for approximately 20 years. "With passing of the patent regime in India, we thought the atmosphere was conducive for business, and we are looking at bringing our products here soon," said the subsidiary's Managing Director, **Leonard Tauro**. While the firm did not plan to set up manufacturing facilities in India within the near future, it was looking at R&D prospects in the country, beginning with clinical trials, he added.[38]

Assocham believes the new patent regime will enable the development of innovative new drugs, which will increase profitability for MNCs. It will also force domestic players to focus on R&D, which, for those who can afford to do so, will have long-term beneficial effects, it says.[39]

The draft National Pharmaceuticals Policy 2006 states that the government is committed to making India's laws and policies relating to IPR, including data protection, fully compliant with TRIPs provisions. Also, new rules are being framed under the *Patents Act* 1970 amendments introduced from April 1, 2005, for product patents, and these will be brought into law soon. "Under these rules, it would be the endeavor of the government to simplify procedures and shorten the timelines of various approvals," says the draft Policy.[40]
Kewal Handa, managing director of Pfizer India, applauds the introduction of India's product patent regime at the start of last year as a very positive move by the government in honoring its TRIPs commitments, but adds that a number of big issues remain to be addressed.

Of crucial importance is the issue of patentability, he says. The industry is keenly awaiting the publication of the Technical Expert Group, which has been set up under the chairmanship of RA Mashelkar, Director General of the Council for Scientific and Industrial Research, to examine issues such as whether it would be TRIPs-compatible for the patent regime to limit

the granting of patents to New Chemical Entities or New Medical Entities involving one or more inventive steps.

The industry is also waiting to see whether the government will follow international guidelines governing compulsory licensing, the process by which the TRIPs agreement permits governments, in special cases, to waive the patent on a particular medicine. Elsewhere in the world, the trade treaty allows compulsory licenses to be issued in response to a national emergency, but in India they may currently be invoked due to factors such as the reasonability of a product's price, and its potential for export and local manufacturing, among other issues. Government policy in this area needs to be more clearly defined, said **Handa**.

Pfizer is one of the longest-established MNCs in India and was the first to set up R&D facilities there, but he believes that, for R&D activities to expand as the government wishes, the industry must have high levels of confidence in the country's regulatory framework. A major drawback is that India offers no data protection (although it is provided by China, which also has a good patents protection regime and a bigger domestic market than India). A further disincentive is that drug prices on the Indian domestic market are the lowest in the world.

All of this means that "people are talking about India but investing in China," says **Handa**.

India's First Pharmaceutical Patent Goes to Roche

In March 2006, Roche became the first company in India to receive a patent under the product patent regime. The product patent has been granted for Pegasys (peginterferon alfa-2a) for the treatment of hepatitis C, under the country's "mailbox" facility for post-1995 inventions. The patent is valid for 20 years from May 15, 1997, during which time no other firm can launch a generic version in India.

Girish Telang, managing director of Roche Scientific India Pvt Ltd, forecast the development would "usher in the next wave for the Indian pharmaceutical space, by way of a flow of newer innovative molecules in the Indian market, complemented by increased investments in R&D towards drug development efforts."[41]

Ranjit Shahani of Novartis India still sees some areas of concern with respect to IPR, despite the arrival of the new product patent regime. Areas of concern include narrowing the definition of patentability only to NCEs (New Chemical Entities); broadening the scope of compulsory licensing to include affordability; and the lack of data protection. He calls for an early resolution of these issues by the various committees now considering them, in order to help increase domestic as well as foreign direct investments. He also welcomes the Policy's

proposal for a centralized National Drug Authority, rather than state-by-state FDA control; this will help uniform implementation of the law throughout the country, he says.

Pricing Issues

The prices of 74 bulk drugs and their formulations, which account for around 40 percent of the retail pharmaceutical market, are controlled by the *Drug Price Control Order (DPCO)* of 1995. The government's 2002 Pharmaceutical Policy would have reduced the numbers of price-controlled drugs still further, but this proposal is currently under judicial review in the Supreme Court. If it is approved, the number of price-controlled drugs is expected to drop to 25. [42]

A new DPCO is expected to be introduced by the end of 2006, which will take account of two recent major reports-one on drug pricing, produced in November 2004 by a government panel headed by GS Sandhu, joint secretary of the Department of Chemicals and Fertilizers, and the September 2005 report of the Prime Minister's Task Force on Drug Affordability, headed by Pranob Sen, Chief Adviser to the Planning Commission.

Looking to the future of the domestic market, as envisioned by the provisions of the government's newly proposed National Pharmaceuticals Policy for 2006, **Kewal Handa** of Pfizer India says that the market will be defined by the manner in which the prices of patented products are controlled and, therefore, it is critical that the government gets this right.

Having provided product patent protection, the government must now look at the holistic picture and decide where value is to be created-through controlling prices or encouraging manufacturing and research, he says.

As the government's draft National Pharmaceuticals Policy, published in January 2006, is under discussion with all, the industry hopes the last several years' trend of reducing the number of price-controlled drugs will continue, says **Ranjit Shahani** of Novartis India, and he calls for a move away from micro-managing price controls to price monitoring. The Indian market is highly competitive and its prices are now the lowest in the world, at almost 10 percent of U.S. prices.

Zydus Cadila Chairman and Managing Director **Pankaj Patel** describes the draft National Pharmaceuticals Policy as confusing, noting that it emphasizes R&D but also price controls and keeping drugs cheap. Implementation of the latter will keep the industry from moving forward, he warns.

"It's tough to move ahead by looking into the rearview mirror, and that's exactly what's happening," he says, adding, "On one hand, there is emphasis on R&D in the Policy, which is futuristic, but at the same time it does not address the issue of price controls, which will tie the industry down and not allow it to accelerate the pace of growth and move forward."

Discussing the issue of compulsory licensing in India, **Pankaj Patel** notes that, globally, it has always been a practice to approve new drugs on the basis of safety, efficacy and, lately, the economic value of drugs. India is also looking at economic criteria as well as national importance for to the reasons why it could permit compulsory licensing. But it is important, he adds, that India's government has in fact never invoked these criteria, not even in the case of Roche's anti-flu drug Tamiflu, which it could have done while still remaining TRIPs-compliant. "The provision is, therefore, more of a safeguard to ensure optimal pricing for Indian patients, taking into account the heavy disease burden and purchasing power of people in India," he says.

Regulatory Reforms

While he feels it is premature to discuss the proposals contained within the government's draft National Pharmaceuticals Policy, **Ajay Piramal** of Nicholas Piramal stresses that the government must take steps to make the domestic industry more robust and create an environment that is conducive to research. The pressure to reduce prices must end, he says. Instead, the government needs to provide incentives and allow companies to make additional profits that they can plough back into research.

Tax incentives are also necessary to attract more foreign investment into the country, as they have proved successful in regions such as Singapore, Puerto Rico and Ireland, he says.

The government is now starting to develop an infrastructure for clinical trials in India, with amendments made recently to Schedule Y of the *Drugs and Cosmetics Rules* of 1945 to allow for multicenter concurrent clinical trials in India and address the protection of trial participants, and the integration and quality of data. Among other developments, Good Clinical Practice guidelines have been published and made mandatory.

The draft National Pharmaceuticals Policy of 2006 says the government plans the following actions to facilitate and encourage clinical trials in India:

- Early decision on data protection
- Improved regulatory infrastructure and some form of protection for undisclosed test data
- The National Toxicology Centre within the National Institute of Pharmaceutical Education and Research to be made fully compliant with GLP norms, in order to facilitate pre-clinical trials
- Tax benefits available for R&D also to be applicable for clinical trials;
- Clinical trial samples imported into India to be exempted from payment of import duty on the basis of authorizations/licenses issued by the Drug Controller General of India
- Direct investment in the field of clinical development and data management to be made exempt from service tax for a period of 10 years up to 2015.

Source: Indian Government draft National Pharmaceuticals Policy, January 2006.

"The success of government moves to encourage further outsourcing activities will depend on both the new Policy and improvements to the regulatory framework, Kewal Handa of Pfizer India says. In terms of TRIPs compliancy, he urges the government to take a pragmatic view and create a truly level playing field so that all companies can operate on an equal footing.

The government must also focus more on health care spending and devise ways to give people access to the drugs they need. These improvements can be achieved through partnerships between the government and industry rather than subsidizing through price controls. "However," he adds, "currently there is no infrastructure in place to facilitate such developments."

R&D Spending

Satish Reddy, managing director and chief operating officer of Dr Reddy´s Laboratories Ltd, calls on the government to provide a strategy for R&D in India, with specific incentives. 'Tax breaks are simply not enough," he says. "R&D grants need to be provided in some form, and with a proper framework."

Indian manufacturers cannot fulfill their ambitions to become players on the world stage unless they make significant increases to their R&D expenditures; at 2 percent of sales, these are currently far below the global level of 10 to 20 percent. In fiscal 2005, the leading five Indian companies increased their R&D spending 47 percent overall to a total of $192.3 million from $131 million in fiscal 2004. Within that total, individual companies' spending rose as much as 90 percent, with Dr Reddy's amounting to 14.7 percent of its net sales. However, Nicholas Piramal and Cipla still spend less than 5 percent of their net sales on research, and the combined R&D expenditures of the five is still less than 3 percent of Pfizer, the world's leading research-based drug manufacturer. Moreover, the average for the leading Indian firms represented just 5.7 percent of their net sales in fiscal 2004, compared to 14.5 percent for Merck & Co. and 15.6 percent at Sanofi-Aventis.[43]

Also in 2004, the number of patent applications filed from India rose from 295 in 2001 to 784 in 2004, while the largest users from India of the Patent Cooperation Treaty were Ranbaxy, with 121, up from 66 in 2003, and the Council of Scientific and Industrial Research, with 124 applications in 2003 and 69 in 2004. Other Indian PCT filings during the year came from Cipa (32), Jubilant Oraganosys (16), Vaman Technologis (R&D) (12), Matrix Labs (12), Hetero (10) and Wockhardt (10).[44]

India's new patents regime is already producing changes in terms of greater commitment to discovery research within the industry, although a major shift for Indian firms away from reverse engineering will not be seen for three to four years, **Ajay Piramal** of Nicholas Piramal forecasts.

Generally, however, he expects that the effects of the new patent regime on the market in India will be as limited as those that followed similar changes made in Poland and Brazil around 10 years ago. Apart from some innovative therapies developed for use in niche areas, most innovator drugs provide only marginal improvements over existing products, yet they carry very high prices. Therefore, as drug prices in India are among the lowest in the world, these products will have only a very limited market available to them in the country, he says.

In what was regarded as the start of a significant new trend, in September 2004, the Indian firm Glenmark out licensed GRC-3886, a PDE4 inhibitor in development for the treatment of asthma and chronic obstructive pulmonary disease to Forest Labs of the U.S., for $190 million in staggered milestone payments and 15 percent of sales in royalties.[45]

Developing the Domestic Indian Pharmaceutical Market

Satish Reddy of Dr Reddy's Laboratories applauds the government's draft National Pharmaceutical Policy for 2006's provisions on increasing access to treatments for life-threatening diseases, but points out that Western lifestyle diseases are currently providing the major growth in the domestic market.

India currently spends 4.5 to 5.0 percent of its GDP on health care, but public spending accounts for just 0.9 percent, putting the nation among the 20 lowest-spending countries worldwide. Total health expenditures were $29.3 billion in 2004, with around 83 percent accounted for by private providers. The balance of spending is also iniquitous; while the poorest 20 percent of the population has double the mortality rates, malnutrition and fertility of the richest quintile, the latter group receives about three rupees for every one rupee spent on the former. Two-thirds of what the government spends on health care goes to secondary and tertiary care rather than basic services.[46]

Ninety-four percent of all private health spending is out of pocket, mostly at the time of the incident, and more than 40 percent of hospitalized people borrow money or sell assets in order to cover their expenses. The remaining 6 percent of spending is provided by insurance -3.7 percent social, 1.6 percent employer-sponsored and 0.7 percent private insurance. Just 15 percent of the population has some form of insurance; an estimated 800,000,000 people in India have none.[47]

The health insurance market was opened up to the private sector in 2000 and, since then, growth has been fast, with nearly 10.3 million policies sold in 2003-04 compared to 7.5 million in 2001-02. A 40 percent compound annual growth rate (CAGR) is forecast for the health insurance sector over the coming years,[48] making it a significant driver of the domestic health care market, which analysts at McKinsey believe could be worth $40 billion by 2012.

National health policy goals	By
Achieve zero growth of HIV/AIDS	2007
Eliminate kalar-azar	2010
Reduce by 50 percent mortality due to TB, malaria and other vector- and water-borne diseases	2010
Reduce prevalence of blindness to 0.5 percent	2010

Source: Sustaining Health with Innovative R&D and Health Infrastructure; presentation for the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in New Delhi, India, November 4, 2004

Rising levels of population and incomes, plus the arrival of new products, will continue to grow the domestic market around 10 percent a year, but there will be no dramatic change unless there is help to improve people's access drugs, **Pankaj Patel** of Zydus Cadila says.

In 2003, medicines accounted for just 15 percent of India's total health care spend[49] and patented drugs currently represent fewer than 5 percent of the national market. The prices of essential drugs in India are among the world's lowest, with market growth coming mainly from volume in urban markets.

Turning to the domestic market, **Ranjit Shahani** of Novartis India says the forthcoming privatization of health insurance and India's fast-growing middle class will certainly boost consumption. India's fastest-growing product segments last year were for lifestyle-related diseases, and the MNCs can produce innovative, patented treatments for these conditions, as well as develop treatments for developing-world diseases such as malaria, TB and HIV/AIDS.

Novartis's own Institute of Tropical Diseases in Singapore, where such research is being done, should have been sited in India, **Shahani** says, but the timing was wrong-before the *Patent Act* was passed. He feels that Novartis is unlikely to bring such research to India soon, although in February 2006 the firm opened a global R&D centre for OTC medicines at Thane, on the outskirts of Mumbai.

Ranjit Shahani applauds the National Pharmaceuticals Policy's proposal of public/private partnerships (PPPs) to tackle life-threatening diseases such as cancer and HIV/AIDS, but stresses that, in order for them to work, they should be voluntary, and the government should exempt all life-saving drugs from import duties and other taxes such as excise duty and VAT. He is, however, critical about a proposal for mandatory price negotiation of newly patented drugs. He feels this will erode India's credibility in implementing the *Patent Act* in

a fair and transparent manner. To deal with diabetes, medicines are not the only answer; awareness about the need for lifestyle changes needs to be increased, he adds.

While industry leaders have long called for the development of PPPs for the provision of health care in India, particularly in rural areas, such initiatives are currently totally unexplored. However, the government's 2006 draft National Pharmaceuticals Policy proposes the introduction of PPPs with drug manufacturers and hospitals as a way of vastly increasing the availability of medicines to treat life-threatening diseases. It notes, for example, that while an average estimate of the value of drugs to treat the country's cancer patients is $1.11 billion, the market is in fact worth only $33.5 million. "The big gap indicates the near non-accessibility of the medicines to a vast majority of the affected population, mainly because of the high cost of these medicines," says the Policy, which also calls for tax and excise exemptions for anti-cancer drugs.

Another area for which PPPs are proposed is for drugs to treat HIV/AIDS, India's biggest health problem. Official estimates put the number of Indians living with the disease at 5.1 million in 2003, with up to 40 percent being women and children, but others say the total is closer to 8 million.[50] Moreover, of the world's 150 million diabetic population, 33 million are in India.[51]

Among the Policy's other proposals are a 2 percent tax that would generate an estimated $1.45 billion a year to provide free medicines under health insurance schemes for the poorest Indians and also establish at least 25 "pharma parks" over the next five years: a prenegotiation pricing mechanism for patented drugs; reduced prices for bulk public drugs purchases; promoting generics by removing them from the price control regime; ceiling prices for 314 drugs to be fixed based on the weighted average price of the top three brands of each product by value at April 1, 2005; debranding of prescription drugs with clear evidence of market dominance, defined as a market share over 70 percent; halving excise duty on all medicines from 16 percent to 8 percent; a 15 to 35 percent cap to be introduced on the wholesale and retail trade margins of unbranded drugs that are not price controlled: the annual revision of the list of essential drugs; and moves to strengthen the drug regulatory system and computerize the National Pharmaceutical Pricing Authority.[52]

The Ministry of Chemicals and Fertilizers is also reported to be estimating production costs for 374 essential drugs, so that their prices can be fixed, and drawing up a list of life-saving drugs that could be brought under price control.

Many of the measures intended by the government contradict the industry's wishes for further deregulation of the Indian pharmaceutical market. The challenge remains to provide access to life-threatening diseases and, at the same time, create price incentives for the R&D investments.

6 Indian Companies as Global Players

Consolidation in the global generics industry, where the top 10 players account for 27 percent of the world market, is widely expected, and, following Teva's purchase of IVAX and the takeover of Hexal by Novartis's unit Sandoz, a vast gap has been created between these firms and the rest of the industry. Ranbaxy is widely believed to be seeking to attain the third position through an alliance with a major company. Wockhardt and Dr Reddy's are also particularly active in terms of acquisitions in the generics sector.

An enabling factor for Indian firms' activity overseas is their increased liquidity in the market, with increasing numbers of Foreign Currency Convertible Bond listings and private equity findings.

Drug manufacturers are currently the most aggressive overseas investors of all Indian industries. They are pursuing foreign acquisitions due to their need to:

- Improve global competitiveness
- Move up the value chain
- Create and enter new markets
- Increase their product offering
- Acquire assets (including research and contract manufacturing firms, in order to further boost their outsourcing capabilities) and new products
- Consolidate their market shares
- Compensate for continued sluggishness in their home market.

In the period from January 2004-when Ranbaxy formalized its purchase of RPG (Aventis) for $80 million, making it the fifth-largest generics supplier in France-until October 2005, Indian firms made 18 international acquisitions.[53] Glenmark, Jubilant Organosys, Nicholas Piramal and Ranbaxy each acquired two overseas businesses during this time, but the biggest Indian buy was Matrix Labs' acquisition of Belgium's Docpharma for $263 million in June 2005.

Eleven of the 18 acquisitions are comparatively small, worth $5 to $30 million, but the value of Indian industry purchases is rising fast, having grown from just $8 million in 1997 to $116 million in 2004, and this fast pace is expected to continue.[54]

Also, although the U.S. is the world's largest generics market, most of the purchases were in the EU. Observers believe that Indian firms consider European valuations to be more reasonable, and there is a wider price range of companies available. Use of generics is growing quickly in Europe, due to government price controls and other pro-generic measures, while the EU regulatory climate is proving a disincentive for some European firms to continue, creating buying opportunities for Indian firms.[55] The three main European generics markets are Germany, France and the UK, together worth around $3 billion a year.

Notable developments during 2005 were Dr Reddy's acquisition of Roche's API business for $59.6 million; Nicholas Piramal's buying Avecia Custom Drug Synthesis of the UK for $16.7 million; Ranbaxy's acquisition of a 40 percent stake in Japan's Nihon Pharmaceutical Industry; and Sun Pharma's completion of its buy of ICN Hungary for an undisclosed sum.

Then in February 2006, the largest-ever acquisition by an Indian pharmaceutical company was announced, when Dr Reddy's bought Germany's fourth-largest generics company, Betapharm Arzneimittel, from UK-based 3i for $573.6 million. Betapharm Chief Executive **Wolfgang Niedermaier** commented, "Dr Reddy's impressive pipeline of generic and innovative products and its high-quality standards, combined with competitive manufacturing costs, will help further develop our position in the German market and offer an entry platform for the European market."

Outlook

Price competition in generics markets is not unexpected or shocking; it is the nature of the business, and the important thing is to focus on the right product mix and optimal production processes, says **Pankaj Patel** of Zydus Cadila.

He foresees huge new potential for the company from the upcoming patent expiries in its main regulated markets-the U.S. and Europe, particularly France. The firm also has a high profile in Brazil, South Africa and Russia.

In terms of the role of Indian firms on the global stage, **Ranjit Shahani** of Novartis India points to Ranbaxy, Dr Reddy's, Nicholas Piramal, Wockhardt and Lupin as having already achieved this status; many of these firms' international sales are higher than their domestic turnover, he says.

In terms of competition with other major emerging economies, India offers the competitive advantages of an abundance of English-speaking scientific and technical staff, globally competitive IT capabilities, a sound judicial system and a vibrant democracy, which fosters innovation, creativity and cost competitiveness. The country can use these advantages strategically to beat any international competition, he says, but he believes that India's real focus should be on becoming a developed nation by 2020, and its goals should be to eradicate poverty, illiteracy and disease, rather than competing with any country.

India offers the international pharmaceutical industry very high levels of expertise, but manufacturers will not go all out to invest in the country until it also offers the right regulatory framework, warns **Kewal Handa** of Pfizer India.

Nevertheless, he is very hopeful that India will develop into a very good market for Pfizer. The company looks forward to being able to launch new products in the country

simultaneously with its global introductions, and to creating value for Pfizer globally through Indian manufacturing of formulations and APIs, enhanced clinical research and biometrics.

Within the next four or five years, the first new drug discovery made by an Indian company could arrive on the market, forecasts **Ajay Piramal** of Nicholas Piramal.
He hopes that his company will have, by that time, not only launched its own in-house developed product, but also increased the share of revenues accounted for by its international business from 30 percent at present to 50 percent, and increased its position in the domestic market, where it is currently fourth in the league of leading manufacturers.

7 Conclusion

There has never been a more important time for India's government and its drug producers, both multinational and domestic, to work together in partnership for the good of the industry and the nation. With its enormous advantages, including a large, well-educated, skilled and English-speaking workforce, low operational costs and improving regulatory infrastructure, India has the potential to become the region's hub for pharmaceutical and biotechnology discovery research, manufacturing, exporting and health care services within the next decade.

However, in order for this to happen, it is imperative that the regulatory environment continues to improve. Otherwise, India needs to look to the achievements of China, where the government's strong commitment pro-industry policies have produced a positive environment that not only offers drug manufacturers a product patent regime but also, and crucially, data protection. India's continuing failure to do so needs to be urgently rectified.

The goals set out in the Indian government's draft National Pharmaceuticals Policy for 2006 in terms of domestic market development are ambitious, and will require a positive pricing environment if the country's 1 billion people are to be able to access the life-saving and innovative medicines they need. Again, partnership is key: industry leaders are keen to work with government on issues of affordability and point out that price controls will do nothing to increase access to new and effective treatments.

For foreign investors, collaborations with India present a huge opportunity both in terms of joint production for the global market and supply of the growing domestic market.

Dr. Ekkehart Hansmeyer
Head of Pharmaceuticals
KPMG in Germany

Appendix I

Indian Pharmaceutical Sector Cross-Border Acquisitions

Company	Focus Area	Transaction Date	Target	Transaction Value
Dishman Pharma	Contract manufacturing and research services	April 2005	Synprotec (UK)	US$3.5 million
Dr Reddy's	U.S. generics, specialty products, APIs, formulations, custom synthesis	May 2004	Trigenesis (USA)	US$11 million
		n/a	BMS Laboratories and Meridian Healthcare (UK)	US$16 million
		November 2005	Roche's API Business (Mexico)	US$59 million
Glenmark Pharma	Drug discovery research, formulations	April 2004	Klinger Lab (Brazil)	US$5.2 million
		March 2005	Uno-Ciclo (Brazil)	US$4.6 million
		October 2005	Servycal SA (Argentina)	n/a
Hikal	API's contract manufacturing	September 2004	Marsin (Denmark)	US$6 million for 50.1% stake
Jubilant Organosys	CRAMS, Pharma specialty chemicals, intermediates, formulations, medical chemistry and clinical services	June 2004	PSI (Belgium)	US$16 million
		July 2005	Trinity Laboratories (along with subsidiary Trigen Laboratories) (U.S.)	US$20,25 million for 75% stake
		October 2005	Target Research Associates (U.S.)	US$33.5 million
Matrix Labs	CRAMS, generic APIs, intermediates and formulations	March 2005	MCHEM (China) (JV)	n/a
		June 2005	Docpharma (Belgium)	US$263 million
		September 2005	Explora laboratories (Switzerland)	n/a
		n/a	Fine Chemicals Corp. (South Africa)	n/a

Indian Pharmaceutical Sector Cross-Border Acquisitions (continued)

Company	Focus Area	Transaction Date	Target	Transaction Value
Nicholas Piramal	CRAMS space - Contract manufacturing, APIs, branded formulations	July 2004	Dobutrex brand acquisition (USA)	n/a
		December 2004	Rhodia's inhalations business (UK)	US$14 million
		July 2005	Biosyntech (Canada)	US$6 million
		October 2005	Avecia Pharma (UK)	US$16.9 million
Strides Arcolab	Generics, OTC and nutraceuticals	July 2005	Manufacturing Plant (Poland)	US$8 million
		August 2005	Beltapharm (Italy)	EUR 1.6 million for 70% stake
Sun Pharma	Branded formulations, U.S. generics, APIs	August 2005	Two facilities from Valeant Pharma (Hungary, U.S.)	US$10 million
		n/a	Caraco (U.S.)	US$7.5 million
		December 2005	Able Laboratories (U.S.)	US$23.15 million
Ranbaxy	U.S. and Europe generic markets	January 2004	RPG Aventis (France)	US$84 million
		n/a	18 generic products of Efarmes S.A. (Spain)	n/a
		June 2005	Brand-Veratide from P&G (Germany)	US$5 million
Torrent	Formulations, European generic market	June 2005	Heumann Pharma (Germany)	n/a
Zydus Cadila	Contract manufacturing and generics	August 2003	Alpharma (France)	US$6.6 million
Wockhardt	Biogenerics, U.S. and Europe generics market, branded generics	July 2003	CP Pharma (UK)	US$20 million
		May 2004	Esparma (Germany)	US$11 million

Source: Publicly available sources of information

Appendix II

Aurobindo Pharma

Aurobindo Pharma manufactures generics and APIs in the antibiotic, antiretroviral, cardiovascular, central nervous system, gastroenterological and anti-allergy fields, and markets them in over 100 countries. In the quarter ended December 31, 2005, it reported sales up 28 percent to $93.1 million over the same quarter of 2004, with sales of formulations rising 125 percent. The firm filed 10 ANDAs and 13 DMFs in the USA in the quarter, with 70 filings in other markets, bringing its total number of formulation filings to 364.In January 2006, Aurobindo reported that the U.S. FDA had granted tentative approval for its antiretroviral Nevirapine Oral Suspension 50 mg/5 ml, qualifying the product under President George W Bush's Emergency Plan for AIDS Relief (PEPFAR) program. Also in January, the World Health Organization announced the inclusion of Aurobindo's Nevirapine oral suspension 50mg/5ml and Stavudine for oral solution 1mg/ml in its Pre-qualification list - both are used as a part of first-time line treatment in pediatric AIDS.

Aventis Pharma

50.1 percent of Aventis Pharma is held by European drug major Sanofi-Aventis and, in early April 2006, it was reported that UB Holdings had sold its 10 percent holding in the firm to Variegate Trading, a UB subsidiary. The firm's major products are in the anti-infective, anti-inflammatory, cancer, diabetes and allergy market segments and, for the year ended December 31, 2005, it reported net sales (excluding excise duty) up 9.9 percent to $181.1 million, with domestic sales up 9.1 percent at $129.8 million and exports increasing 12 percent to $51.2 million. Sales were led by 83 percent annual growth for the diabetes treatment Lantus (insulin glargine), followed by the rabies vaccine Rabipur (+22 percent), the diabetes drug Amaryl (glimepiride) and epilepsy treatment Frisium (clobazam), both up 18 percent, the angiotensin-coverting enzyme inhibitor Cardace (ramipril +15 percent), Clexane (enoxaparin), an anticoagulant, growing 14 percent and Targocid (teicoplanin), an antibiotic, whose sales advanced 8 percent.

In February 2006, analysts at SSKI India described Aventis India as a "marketing powerhouse" and forecast 13 percent and 17 percent CAGR in the firm's consolidated revenues and earnings, respectively, to 2007. The firm is well-placed to leverage on India's post-patent regime, they said, adding: "with a strong R&D pipeline, the parent's willingness to launch products in India soon after the global launch and a locally-relevant pricing strategy, Aventis is an attractive play on the growing domestic market."[56]

Cipla

India's second-largest drug manufacturer was originally established in 1935 as The Chemical, Industrial and Pharmaceutical Laboratories. Until 2000 its business was primarily domestic, but exports, to more than 150 countries, accounted for 45 percent of its fiscal year 2005 sales, giving it what is probably the Indian industry's most geographically-

diversified export base, say analysts at SKKI, who add that Cipla "has established itself as the partner of choice for generic companies globally." [57]

At the end of December 2005, Cipla signed the largest product development and manufacturing agreement in the country, when it agreed a global deal with German manufacturer Boehringer Ingelheim for the development and supply of the firm's hypertension drug Micardis (telmisartan).

The firm also announced at year-end that it planned to launch the first generic version of Roche's Tamiflu (oseltamivir), which is recommended for use against the H5N1 strain of avian flu.

In 2004, Cipla took over from GlaxoSmithKline as India's leading drug manufacturer in terms of retail sales (although, including vaccines and institutional sales, GSK still has the leading share, at just under 6.5 percent).

Dr Reddy's Laboratories

Dr Reddy's Laboratories is an emerging global pharmaceutical and biotechnology company, which was founded by chairman Anji Reddy in 1984. It operates in over 60 countries, although India and the USA each accounts for around a third of the firm's total sales. The company is already strongly present in most of the world's biggest less-regulated markets, such as Russia, China, Brazil and South Africa.

For the nine-month period to December 31, 2005, the firm reported revenues up 14 percent to $387.4 million, driven by sales of APIs (up 48 percent in the third quarter and 19 percent in the first nine months) and branded formulations (up 34 percent in the third quarter, led by growth of 34 percent in India and 35 percent in Russia). Dr Reddy's is also an innovator in the use of venture capital to maintain cash-flow for R&D, having received $57 million from ICICI Venture Funds to support ANDA filings for 18 months beyond FY2005 for royalties from sales in the USA.

Dr Reddy's made history in February when it entered the German branded generics market, the world's second-largest after the USA, not through building a business organically there but with the purchase of Betapharm, Germany's fourth-largest generics manufacturer, for $570 million. This is the largest overseas acquisition by an Indian pharmaceutical company so far.

Despite its size, the German generics market is not experiencing the pricing pressure which is currently being felt in the USA and shrinking business there. Satish Reddy from Dr Reddy's is still optimistic about prospects in the USA, pointing to the huge opportunities which will be presented there by patent expiries on major products going forward to 2010.

Before the Betapharm purchase, Dr Reddy's did not have a presence generally in the European branded generics market, although it is active in the UK pure generics market. It is now looking towards expansion in Spain, France and the rest of Europe, and also to rolling out its existing product range in major regulated markets including Australia and New Zealand.

Lupin

Lupin is one of the world's largest manufacturers of APIs and finished formulations for TB, bacterial infections and cardiovascular disease. Its products are sold in more than 50 countries. For third-quarter 2006 (ended December 31, 2005), the firm reported gross sales up 51 percent to $98.9 million, with exports up 56 percent (boosted by U.S. launches) at $46.3 million and domestic sales rising 47 percent to $51.9 million For the nine months to end-December, sales rose 34 percent to $274.7 million, with net profit up 112 percent to $29.5 million.

Nicholas Piramal

Nicholas Piramal is the flagship company of Piramal Enterprises (PEL), one of India's largest diversified business houses. It was formed in 1988 when PEL acquired Nicholas Laboratories (NPIL) a small formulations company, from Sara Lee. For third-quarter FY 2006 (ended December 31, 2005) the firm reported net sales of $78.3 million, up 9.2 percent on the second quarter, and consolidated sales were up 17.3 percent at $89.5 million. However, net profit plummeted 69.9 percent to $5.2 million, due to lower sales of the firm's leading brand, the controversial promethazine/codeine phosphate/ephedrine cough suppressant Phensedyl, which has been widely abused, and the withdrawal of two valdecoxib brands - Vah and Valto - plus a foreign exchange loss of £468,000.

NPIL's strategy of opting out of early-stage generic exports, which differentiates it from most leading Indian firms, enables it to steer clear of IP challenges and focus on partnering with global firms. Generally, contract manufacturing organizations operate only in certain segments (e.g., intermediates, APIs or formulations), but NPIL is seeking to join the rank of the few players offering the entire spectrum of services, notes SKKI.

Ranbaxy Laboratories

India's largest pharmaceutical company is ranked among the top 10 generics manufacturers worldwide and aiming to be in the top five with sales of $5 billion by 2012. However, with the firm's recent moves to increase its size through the inorganic route, it is seen as aiming to establish itself as the world's number three generics producer much sooner. It has manufacturing operations in seven countries, a ground presence in 46 nations and sells its products in over 100 countries. Ranbaxy has three state-of-the-art research facilities at Gurgaon, near New Delhi - R&D Centers I and II focus on the development of generics and novel drug delivery systems research, while the new R&D Centre III is dedicated to new drug discovery research.

The firm also has the largest R&D budget of any Indian drug manufacturer, standing at 7 percent of sales in 2004, and it plans to progressively increase this to 9 percent-10 percent by 2007.

Ranbaxy has set up a global alliance with GlaxoSmithKline in the area of drug discovery and development. Two research programs, one in the area of anti-infectives and another, in the asthma segment, are now in progress.

For the year ended December 31, Ranbaxy reported sales of $1.17 billion, similar to the previous year, but profits after tax and minority interest slumped 62 percent, largely impacted by continuing price erosion in the key U.S. market, where sales fell 22 percent to $332 million. In Europe, sales rose 5 percent to $202 million, while in the BRIC countries (Brazil, Russia, India and China) they rose 11 percent to $340 million. In January, Ranbaxy's new chief executive Malvinder Singh said the firm is looking for M&A to help it reach its $2 billion sales target by 2007; the goal for 2006 is an increase of 18 percent.

Ranbaxy follows a strategy of aggressively challenging patents of innovator firms to drive its generics business, say analysts at SKKI India, adding: "the robustness of Ranbaxy's global generic model is reflected in its presence in 23 of the top 25 markets in the world including Japan and Canada. Only Teva and Sandoz can match Ranbaxy's global generics footprint. Also, while Teva and Sandoz have built a global footprint, primarily through inorganic initiatives, Ranbaxy's growth has so far been largely organic."[58]

Sun Pharma

Sun Pharma, established in 1983, makes specialty pharmaceuticals and APIs for use in chronic therapy areas such as cardiology, psychiatry, neurology, gastroenterology, diabetes and respiratory conditions, sold in 26 markets worldwide. Its income for the quarter ended December 31, 2005 was $103.2 million compared with $73 million in the like, year-earlier period, and total nine-month income was $295.8 million. In February 2006, the firm announced the demerger of its innovative R&D programs to a new company which it has set up for this purpose. Around 25 percent-40 percent of R&D spend, which represents 10 percent-11 percent of its sales, is accounted for by innovative R&D, it said.

Wockhardt

The overseas ambitions of this Mumbai-based pharmaceutical and biotechnology-based company have already been covered elsewhere in this report, but in mid-March 2006 Wockhardt announced that it had received approval from its shareholders to raise up to $800 million, in one or more tranches, to fund further foreign purchases. Noting his company's "well-known" ability to create value through acquisitions, chairman Habil Khorakiwala said the move would "empower us to seize global opportunities quickly." The stockholders also authorized an increase in the company's Foreign Institutional Investment cap to 49 percent.

Europe has now overtaken India as Wockhardt's largest market but the USA is its fastest-growing, and it is widely forecast that much of the $800 million will be used to fund U.S. purchases.

Wockhardt's U.S. business grew more than 50 percent in the year to December 31, 2005, with six products launched there in the period, while European sales of formulations (the firm's biggest market) rose 15 percent. Indian business was up 10 percent and the firm's biotechnology sales surpassed $10 million.

Overall, net profits were up 20 percent for the year $57.6 million, with consolidated sales rising 13 percent to $316.5 million.

In February, SSKI India analysts forecast a 16 percent CAGR in Wockhardt's consolidated annual revenues to 2007, mainly led by an export-driven improvement in gross margins. "Increased proportion of sales from U.S. generics and biogenerics, where we believe realizations could be superior, will also contribute to the expansion in overall gross margins," they added.[59]

Zydus Cadila

Zydus Cadila is India's fifth largest pharmaceutical company. Cadila was founded in 1952 and, following restructuring, the Zydus Cadila Group was established in 1995. For the quarter ended December 2005, the firm reported net profits up 36.1 percent at $8.8 million, with total income ahead 17 percent at $85.5 million. The group has reported year-on-year growth of 138 percent for its exports of formulations.

During the quarter, the group received approvals for ribavirin capsules, promethazine tablets and tentative approval for gatifloxacin Tablets from the U.S. FDA. Then on February 24, 2006, the FDA granted tentative approval for sertraline (generic version of Pfizer's Zoloft). The company had already received approval from the French regulatory agency to market sertraline capsules in the French market.

Chairman and managing director Pankaj Patel is aiming for Zydus Cadila to be a top 10 global generic company by 2010, deriving half its revenues from international business, with growth led by Europe, the USA and then its other markets. Alliances and joint ventures with MNCs will be a central driver of growth for the group, both internationally where it already has arrangements with Mayne pharma, Mallinckrodt and GSK and in India, where it has tie-up with Altana, Schering AG and Boehringer Ingelheim.

Zydus Cadila has received 10 generic approvals so far and has filed a total of 30 ANDAs and 35 DMFs.

Appendix III List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
API	Active pharmaceutical ingredient
Assocham	Associated Chambers of Commerce and Industry of India
CAGR	Compound annual growth rate
cGMP	current Good Manufacturing Practice
CRAMS	Contract manufacturing and research services
CRO	Contract research organization
DMF	Drug master file
DNA	Deoxyribonucleic acid
DPCO	Drug Price Control Order
EMEA	European Medicines Agency
FDA	Food and Drug Administration (U.S.)
GSK	GlaxoSmithKline
HIV	Human Immunodeficiency Virus
IPR	Intellectual property rights
ITES	Information technology-enabled services
M&A	Mergers and acquisitions
MNC	Multinational company
NCE	New chemical entity
OECD	Organisation for Economic Cooperation and Development
OPPI	Organisation of Pharmaceutical Producers of India
OTC	"Over-the-counter" medical products
Pharmexcil	Pharma Export Promotion Council
PPP	Public/private partnerships
R&D	Research and development
TB	Tuberculosis
TCS	Tata Consultancy Services
TRIPs	Trade-related aspects of intellectual property rights
VAT	Value-added tax
WTO	World Trade Organization

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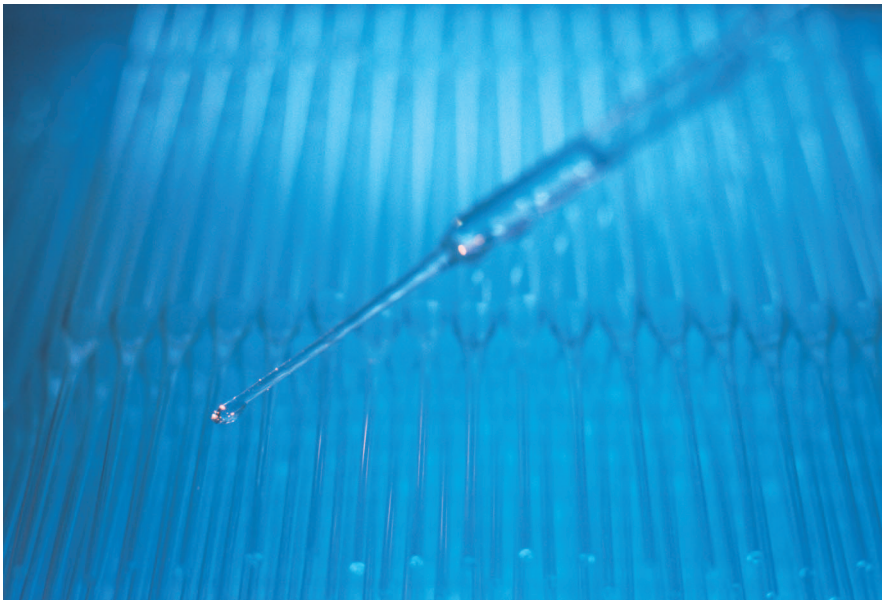

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Designed and produced by KPMG's Global Markets Design Services

Printed in the Netherlands

Publication number: 110406 May 2006