Analysis of the Indian Pharmaceutical Industry

With Emphasis on Opportunities in 2005

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The Indian Pharmaceutical Industry is expected to undergo phenomenal change after 1 January 2005, when international patent laws will be implemented. India's domestic pharmaceutical companies have experienced a significant increase in R&D spending to be competitive in the world market. Although the Indian pharmaceutical market is very small and does not have enough funding for drug discovery programs, India has well-educated scientists, a well-established computer industry, and technological know-how for the manufacture of bulk drugs and formulations. This article discusses various challenges of India's pharmaceutical industry and how it could tie to the American pharmaceutical industry.

Recent globalization and the development of the information superhighway have brought the countries of the world closer. From a business perspective, the world is one marketplace. The American pharmaceutical industry has played a pioneering role in the development of the drug industry through in-depth, timely, and useful research and bulk manufacturing of drug products. Although the US pharmaceutical industry is enjoying the leadership position, it can no longer be content to focus only on the US, Japanese, and European markets.

Two recent articles that analyzed the Chinese and Hungarian pharmaceutical markets showed that during the 1990s, the Chinese pharmaceutical market experienced overestimated demand and severe undercapacity use, and the Hungarian pharmaceutical market suffered setbacks in the same decade and was forced to adopt new strategies to revive the industry (1,2). India, being the second largest country in the world in terms of population, is also attracting attention for future business potential. The purchasing capacity of approximately 300 million middle-class individuals cannot be easily overlooked by global

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pharmaceutical companies. This market potential will be increased by Indian officials' decision to honor international patent laws by 1 January 2005. After having made a similar move, the Korean pharmaceutical industry grew tremendously, and the doors to foreign investments swung open (3).

This article analyzes the current information available about the Indian pharmaceutical industry (IPI). It discusses the IPI's preparation for 2005 so that it will not lose market share after multinational companies enter the Indian pharmaceutical market. It also discusses some strategies that the American pharmaceutical industry may choose to ensure smooth entry into the IPI.

Table I: Health statistics of India (6).

Subject	Year of Reference	Particulars
Population	May 2000	1000 million
	2050*	1533 million*
Crude birth rate (per 1000 population)	1998*	26.4
Crude death rate (per 1000 population)	1998*	9.0
Expectation of life at birth: male	1996–2001	62.4
Expectation of life at birth: female	1996–2001	63.4
Number of medical colleges in India	1999–2000	167
Total admission capacity for medicine	1998–1999	17,000
Number of pharmacy institutions imparting degrees in pharmacy	1999–2000	112
Number of pharmacy institutions imparting diplomas in pharmacy	1999–2000	325
Total admission capacity for pharmacy	1997–1998	5610
Number of doctors registered	1994–1995	489,189
Number of hospitals	1994–1995	13,692
Number of qualified nurses	1998–1999	607,376

*Estimated.

Current global pharmaceutical market

Pharmaceutical products consist of two main components— the active pharmaceutical ingredient (API) or bulk drug and the formulation (i.e., a suitable final dosage form). Generally, APIs are either produced by chemical synthesis or are of plant, animal, or biological origin. Patents are critical aspects in the development and marketing of pharmaceutical products. A patent can be obtained for a new drug molecule, a new indication for an existing molecule, or for a new drug delivery system of an existing product. The World Trade Organization (WTO) has decided to enforce a product patent life of 20 years in all countries. In other words, if drug development and FDA approval takes approximately 10 years from the first disclosure of the molecule, a pharmaceutical company gets only 10 years of exclusivity to market the formulation. The excessive cost of drug development forces drug prices to remain high while the drugs are protected by patents. In addition, not every project leads to a marketed product, so successfully marketed products must cover the costs incurred for the failed projects.

The current pharmaceutical market is worth more than $317 billion (4). The major contributing regions are the United States, Japan, and Europe. GlaxoSmithKline, Pfizer, and Merck are the top three companies in the pharmaceutical market, with annual sales of $23.5, 22.6, and 20.2 billion, respectively. Pfizer has the largest R&D budget, which is hovering at $4.4 billion. Most of the major US pharmaceutical companies showed double-digit growth in 1999 (4).

Drug prices vary from country to country. Citizens of developing countries cannot afford expensive medicines that are under patent. Multinational companies (MNCs) must either choose to sell a product at a low price in these countries or face the challenge of piracy or parallel trade. Types of diseases in Third World countries may vary from those in developed nations. However, because of the lack of sizable profits from distributing pharmaceutical products in Third World countries, MNCs are reluctant to conduct research to develop new drug molecules to treat these diseases.

The pharmaceutical market in India

Historical background. India received independence from Britain in 1947. In the early years following that event, MNCs were allowed to export drugs—mainly low-priced generics and a few high-priced specialty items. When the Indian government increased pressure against the import of finished products, MNCs developed formulation units in India and exported only bulk drugs to that country. In the early 1960s, the Indian government encouraged the indigenous manufacture of bulk drugs. In the following decade the Indian patent act prevented the granting of product patents for substances used in foods and pharmaceuticals. Only process patents were allowed for five years from the date of granting a patent or seven years from the date of filing the patent. Drug price control order (DPCO) was introduced during the same period to prevent undue profiteering from essential medicines. MNCs were compelled to reduce their holdings to 40% in their Indian ventures. In the 1980s–1990s, domestic pharmaceutical companies flourished. As a result, the market share of MNCs fell to the current 35%, down from 75% in 1971.

Types of drug systems in India. Ancient civilization allowed India to develop various kinds of medical and pharmaceutical systems. In addition to the allopathic system, which is prevalent in the United States, Japan, and Europe, the following types of medical and pharmaceutical systems are used by the Indian people: ayurvedic, unani, siddha, and homeopathy (5).

Ayurveda. Ayurveda translates as the "science of life." It encompasses fundamentals and philosophies about the world and life, diseases, and medicines. The knowledge of ayurveda is compiled in *Charak Samhita* and *Sushruta Samhita.* The curative treatment lies in drugs, diet, and general mode of life.

Siddha. The siddha system is one of the oldest Indian systems of medicine. *Siddha* means "achievement." Siddhas were saintly figures who achieved healing through the practice of yoga. The siddha system does not look merely at a disease but takes into account a patient's age, sex, race, habits, environment, diet,

physiological constitution, and so forth. Siddha medicines have been effective in curing some diseases, and further work is needed to truly understand why this system works.

Unani. The unani system originated in Greece and progressed to India during the medieval period. It involves promotion of positive health and prevention of disease. The system is based on the humoral theory, i.e., the presence of blood, phlegm, yellow bile, and black bile. A person's temperament is accordingly expressed as sanguine, phlegmatic, choleric, or melancholic. Drugs derived from plant, metal, mineral, and animal origin are used in this system.

Homeopathy. Homeopathy flourished in Germany in the seventeenth and eighteenth centuries. In India, it is one of the commonly used methods to treat diseases. Physicians in the time of Hippocrates (400 BC) first observed that some substances produce symptoms of conditions that they were then used to treat. On the basis of this finding, a homeopathic medicinal agent, which can produce artificial symptoms in healthy human beings, can cure a similar set of symptoms of natural diseases. It normally uses a single medicine, and the dosage is minimal—just enough to cure the disease.

Yoga and naturopathy. Yoga and naturopathy are ways of life. In naturopathy, one applies simple laws of nature. It advocates proper attention to eating and living habits. It also involves hydrotherapy, mud packs, baths, massage, and so forth. Yoga consists of eight components: restraint, observance of austerity, physical postures, breathing exercises, restraining of the sense organs, contemplation, meditation, and samadhi.

Increasing interest exists in revisiting these ancient drug systems. The Department of Indian Systems of Medicines and Homeopathy was established in 1995 as a separate department in the Ministry of Health and Family Welfare. One of the organization's goals is to prepare standards for ayurvedic, unani, sidhha, and homeopathy drugs. Good manufacturing practices for ayurvedic drugs is at the final stage. The department is actively pursuing a proposal to establish a medicinal-plant board to enhance the availability of quality raw materials, prepare a database of medicinal plants, and collect information from ancient texts.

Health statistics of India. Table I summarizes the health statistics of India (6). India is the second largest country in the world, with a population of approximately 1 billion. The population is

Table II: Value of production of bulk drugs and formulations in India during the past decade (6).

	Bulk Drugs			Formulations		
Year	Value Rs. in Crores	Value in $ Millions**	% Growth	Value Rs. in Crores	Value in $ Millions**	% Growth
1991–92	900	183.7	24.0	4800	979.6	25.0
1992–93	1150	234.7	27.8	6000	1224.5	25.0
1993–94	1320	269.4	14.8	6900	1408.2	15.0
1994–95	1518	309.8	15.0	7935	1619.4	15.0
1995–96	1822	371.8	20.0	9125	1862.2	15.0
1996–97	2186	446.1	19.9	10494	2141.6	15.0
1997–98	2623	535.3	20.0	12068	2462.9	15.0
1998–99	3148	642.5	20.0	13878	2832.3	15.0
1999–00*	3777	770.8	16.7	15860	3236.7	12.5
2000–01*	4344	886.5	15.0	17843	3641.5	12.5

* Estimated.
**Currency exchange rate: Rs 49 = US $1.00 or Rs 1 crore = $0.204082 million.

Table III: Total value of imports and exports of drugs and pharmaceuticals from 1991–1992 to 1999–2000 (6).

	Total Imports			Total Exports		
Year	Rupees in Crores	$ Million	% Growth over Previous Year	Rupees in Crores	$ Million	% Growth over Previous Year
1991–92	807.4	164.8	—	1489.5	304.0	—
1992–93	1137.4	232.1	41	1541.5	314.6	3
1993–94	1440.0	293.9	27	1991.7	406.5	29
1994–95	1527.0	311.6	6	2465.3	503.1	24
1995–96	1867.0	381.0	22	3443.2	702.7	40
1996–97	1039.2	212.0	−44	4340.0	885.7	24
1997–98	1447.1	295.3	39	5353.0	1092.5	23
1998–99	1446.8	295.3	−0.02	6153.0	1255.7	15
1999–2000	1502.0	306.5	4	6631.0	1353.3	8

Currency exchange rate: Rs 49 = US $1.00 or Rs 1 crore = $0.204082 million.

Table IV: Exports of formulations and basic and crude drugs with value and growth percentages from 1990–1991 to 1998–1999 (6).

	Formulations			Basic Drugs			Crude Drugs		
Year	Rupees in Crores	$ in Millions	% Growth over Previous Year	Rupees in Crores	$ in Millions	% Growth over Previous Year	Rupees in Crores	$ in Millions	% Growth over Previous Year
1990–91	985.5	201.1	118	157.8	32.2	−55	111.3	22.7	27
1991–92	508.7	103.8	−26	838.7	171.2	431	142.1	29.0	28
1992–93	965.5	197.0	90	409.5	83.6	−51	166.5	34.0	17
1993–94	1310.8	267.5	36	530.8	108.3	30	150.1	30.6	−10
1994–95	1505.5	307.2	15	760.1	155.1	43	199.7	40.8	33
1995–96	2044.8	417.3	36	1132.9	231.2	49	265.5	54.2	33
1996–97	2414.8	492.8	18	1664.5	339.7	47	260.7	53.2	—
1997–98	2926.8	597.3	21	2214.8	452.0	33	211.4	43.1	−19
1998–99	3101.4	632.9	6	2870.4	585.8	30	181.2	37.0	−14

Currency exchange rate: Rs 49 = US $1.00 or Rs 1 crore = $0.204082 million.

expected to grow to about 1.5 billion by 2050. Life expectancy at birth for males and females is 62.4 and 63.4 years, respectively, which is much lower than that of the United States. The total admission capacities for medical and pharmacy institutions of higher learning are 17,000 and 5610, respectively. India has approximately 14,000 hospitals. The number of registered doctors and nurses is about 490,000 and 600,000, respectively.

The Indian pharmaceutical market. Value of production, exports, and imports. India's pharmaceutical market may not be impressive by international standards, but considering the total Indian economy, it is one of the major economic sectors in India. According to the Indian Drug Manufacturers' Association (IDMA) annual publication, the estimated value of production of bulk drugs and formulations in India during 2000–2001 was approximately Rs 22,187 crores (~$4.5 billion) out of which Rs. 4344 crores is for bulk drugs and Rs. 17,843 crores for the formulations (currency conversion rate used is Rs 49 = US $1.00 or Rs. 1 crores = $0.204082 millions) (6).

Table II summarizes the value of production of bulk drugs and formulations during the past decade. The bulk drug production increased by nearly 20% every year, whereas the value of formulations increased at an average rate of 15% per year. Table II clearly indicates the rapid growth of the pharmaceutical sector in the Indian market. Table III shows the total import and export values of drugs and pharmaceuticals during the past decade. The value of imports and exports increased two-fold and four-fold, respectively, during 1991 and 2000. For the years 1999 and 2000, the value of imports and exports was $306.5 million and $1353.3 million, respectively. Table IV shows the export values in terms of formulations and basic and crude drugs between 1990 and 1999. During the year 1998–99, the value of exports of formulations, basic, and crude drugs was $632.9 million, $585.8 million, and $37.0 million, respectively. The export of bulk drug underwent dramatic growth in the past decade, coming in at nearly 40% each year. A comparison of values shown in Tables II and IV shows that ~80% of the formulations produced are consumed indigenously, whereas the majority of the bulk drugs manufactured are exported. Table V lists the top 10 countries to which India exports drugs and pharmaceuticals. The ranking is based on the export figures of 1999–2000. Russia and the United States are the top two importers of bulk drugs and pharmaceuticals from India ($100.7 million and $137.9 million, respectively). However, countries such as Brazil, Singapore, and Iran experienced a tremendous growth in the import of pharmaceuticals from India in recent years.

Major players in the pharmaceutical industry in India. Two types of companies exist in the Indian pharmaceutical sector: companies of Indian origin (domestic) and foreign MNCs. Table VI lists the rankings of the major players based on their sales figures (7). GlaxoSmithKline, Cipla, Dr. Reddy's Laboratories, and Ranbaxy are the top four companies in terms of gross sales. Other companies' sales values are very similar, and the rankings can change with time. The top MNCs with a presence in India are GlaxoSmithKline, Hoechst Marion Roussel, Knoll Pharma, and Pfizer. Approximately 20,000 pharmaceutical units exist in India. Ranbaxy, the leading domestic company, reported sales of Rs. 1745.9 crores ($356.3 million, assuming that $1.00 = Rs 49) during 2000. Glenmark Pharmaceuticals, Cadila Healthcare, Ajanta Pharma, and Elder Pharmaceuticals are among other upcoming companies.

India's preparation for 2005

After the signing of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Trade Agreement in Marrakech, Morocco, in April 1994, WTO was created. WTO is an institution rather than an agreement such as GATT. It sets rules governing trade between its 132 member countries. It has allowed member countries until 1 January 2005 to make necessary adjustments before they are required to abide by WTO rules. Three major conventions exist to protect patents and intellectual property rights: the Paris Convention, which includes the United States and 100 other countries; the Inter-American Convention, which includes the United States and Latin American nations; and the Madrid Arrangement, which includes 26 European nations (8). The World Intellectual Property Organization (WIPO), a part of the United Nations, is responsible for promoting the protection of intellectual property as well as administering various multilateral treaties. Despite all the treaties and rules, policing patent infringement and piracy has become a monumental task. Each country is required to take measures

to address these problems. The secondary outcome of these efforts could be to develop technology and promote patenting in every country, which will automatically help protect international patents.

Likewise, India is making efforts to develop modern technology in the pharmaceutical industry. The key task is to promote R&D that is on par with the technology in other advanced countries. After 2005, the globally harmonized patent system would prohibit the production and marketing of patent-protected new drugs. Indian officials want to ensure that Indian people do not suffer in terms of high costs of medicines after 2005. The goal is to prevent the American, European, and Japanese pharmaceutical monopolies from exploiting the Indian population.

Basic needs for the development of the pharmaceutical sector are funds, infrastructure, R&D management, and human resources. The Indian government and the IPI have been focusing their efforts so that these necessities are ready for 1 January 2005.

Efforts by the Indian government. The Indian government is encouraging private and public sectors as well as foreign investors to increase investments in pharmaceutical R&D. Some positive steps taken by the Indian government in recent years include

- recognition of the pharmaceutical industry as a knowledge-based industry
- reduction in interest rates for export financing
- additional tax deductions for R&D expenses
- reduction in the price control of pharmaceuticals.

As an example, the import duty surcharge of 3.5% on vaccines and life-savings drugs has been removed. A 10% surcharge on custom duty has also been scuttled (9). Small-scale industry exemptions have led to the proliferation of small formulation manufacturers and low-cost drug manufactures.

DPCO came into existence in 1970 and thereafter was revised in 1979, 1987, and 1995. DPCO controls the domestic prices of major bulk drugs and their formulations (10). In 1970, all drug prices were controlled by DPCO. The numbers of drugs ruled by price controls were 370, 143, and 76 in 1979, 1987, and 1995, respectively. DPCO oversees all formulations containing bulk drugs specified in the first schedule. DPCO 1995 gives a uniform maximum allowable postmanufacturing expense (MAPE) of 100% as compared with earlier MAPE of 75% for some of the drugs. The retail price (RP) of a DPCO formulation is calculated by the following formula

$$RP = (MC + CC + PM + PC) \times 2 + \text{excise duty}$$

in which MC is the material cost, including cost of bulk drugs/excipients and process losses; CC is the conversion cost; PM is the cost of packing material including process losses; and PC is the packaging charges. DPCO applies only to allopathic drugs.

Table V: Top 10 countries in export of drugs and pharmaceuticals from India (6).

Country	1995–96	1996–97	1997–98	1998–99	1999–00
Total Exports	3443.2 (702.7)*	4340.0 (885.7)	5353.0 (1092.5)	6153.0 (1255.7)	6631.0 (1353.3)
United States	423.8 (86.5)	500.1 (102.1)	591.4 (120.7)	709.8 (144.9)	671.8 (137.1)
Russia	303.6 (62.0)	386.6 (78.9)	393.7 (80.3)	185.9 (37.9)	493.2 (100.7)
Hong Kong	191.9 (39.2)	262.0 (53.5)	282.7 (57.7)	383.0 (78.2)	356.2 (72.7)
Germany	341.8 (69.8)	368.3 (75.2)	415.6 (84.8)	367.5 (75.0)	325.2 (66.4)
Nigeria	119.9 (24.5)	126.4 (25.8)	153.4 (31.3)	205.4 (41.9)	257.7 (52.6)
United Kingdom	114.2 (23.3)	149.2 (30.5)	222.6 (45.4)	187.7 (38.3)	256.8 (52.4)
Singapore	86.8 (17.7)	170.3 (34.8)	147.9 (30.2)	179.0 (36.5)	245.2 (50.1)
Netherlands	143.6 (29.3)	139.1 (28.4)	194.0 (39.6)	209.7 (42.8)	219.2 (44.7)
Iran	63.4 (12.9)	94.0 (19.2)	104.8 (21.4)	72.3 (14.8)	179.6 (36.7)
Brazil	17.0 (3.5)	33.5 (6.8)	57.9 (11.8)	105.4 (21.5)	162.7 (33.2)

Currency exchange rate: Rs 49 = US $1 or Rs 1 crore = $0.204082 million.
*Values in parentheses are in $millions.

Efforts by the Indian pharmaceutical industry. The IPI, seeking to take full advantage of benefits offered by the government, has been allocating money to R&D. Its focal points are drug discovery, development of drug delivery systems, biotechnology, and bioinformatics. Companies are reevaluating their strengths and emphasizing product segments that are profitable to the company. Many companies are trimming their portfolios to focus on particular therapeutic segments.

Pharmaceutical marketing is also changing rapidly, and pharmaceutical companies are making elaborate marketing efforts. Companies such as Sun Pharma, Nicholas Piramal, and Dr. Reddy's Laboratories have opted for brand/company acquisition to increase therapeutic reach and market penetration. Such specialization would make the entry of MNCs difficult. Some theorize that companies with a strong marketing force would be attractive for possible take-over. Many pharmaceutical companies are entering into marketing arrangements such as Hoechst Marion's agreement with Nicholas Piramal and Ranbaxy's pact with Cipla, Glaxo, and Hoechst Marion.

Recent mergers and acquisitions include Nicholas Piramal's acquisition of Roche Products, a company mainly involved in diagnostic products and Zydus Cadila's acquisition of German Remedies in India. Sanofi Synthelabo, the second largest pharmaceutical company in France, will buy out Ahmedabad-based Torrent Pharmaceuticals. Very recently, Dr. Reddy's Laboratories signed a definitive agreement to acquire 100% of Meridian Healthcare and BMS Laboratories, whose primary busi-

Table VI: Sales of major domestic and foreign multinational companies in India (7).

Rank*	Company Name	Gross Sales in Rs Million*	Gross Sales in US $ millions*
	Domestic Pharmaceutical Companies		
1	Ranbaxy	17,459	356.3
2	Cipla	10,475	213.8
3	Dr. Reddy's Lab	9841	200.8
4	Nicholas Piramal	5667	115.7
5	Wockardt Ltd.	5583	113.9
6	Lupin Labs	5437	110.9
7	Cadila Healthcare Ltd.	5087	103.8
8	Sun Pharma	4764	97.2
9	Alembic Ltd	4738	96.7
10	Morepan	4297	87.7
	Multinational Pharmaceutical Companies		
1	Glaxo-Wellcome	9346	190.7
2	Hoechst-Marion-Roussel	5505	112.3
3	Novartis India Ltd.	4384	89.5
4	Knoll Pharma	3333	68.0
5	Pfizer	3272	66.8
6	Smithkline Beecham Pharm. India	3195	65.27
7	E Merck India Ltd.	3134	64.0
8	Wyeth Lederle Ltd	2947	60.1
9	Rhone-Poulenc India Ltd.	2629	53.7
10	German Remedies Ltd	2307	47.1

Currency exchange rate: 1 US$ = Rs 49/- or Rs 1 million = $0.0204082 million

*Rankings and gross sales values will change accordingly with time.

ness is manufacturing and marketing generic pharmaceuticals in the United Kingdom (11).

Strengths, weaknesses, opportunities, and threats (SWOT) analysis of the IPI

SWOT analysis can be gainfully used to examine the IPI and determine where its greatest opportunities lie. This section examines these factors.

Strengths. Most people in India, especially those who are educated and have advanced degrees, are fluent in English. This aptitude allows them to communicate with most of the outside world, which is an important asset to the IPI. The health statistics of India make it clear that India produces a sufficient number of medical and pharmacy graduates, which contributes to the strengthening of the IPI.

The Patent Act and Drug Price Control Order of the 1970s forced MNCs to shrink their operations in India, thus providing space for indigenous pharmaceutical companies to expand in the local market. As a result, in the past two to three decades domestic pharmaceutical companies have established operations and are self sufficient in all aspects. For example, Cipla Limited could provide the generic version of the AIDS triple cocktail to impoverished South African people at $350/patient/year or at a price that is one-thirtieth its cost in the United States.

Indian patent laws allowed local companies to set up operations to produce bulk drugs that are still under patent, by various synthetic routes. The prevalence of this reverse engineering is controversial, but it suggests that the IPI's chemists have a strong showing in organic/medicinal chemistry. The IPI's tremendous potential to produce bulk drugs will be a major asset in future drug discovery programs.

Highly educated people as well as low labor costs are the major strengths of the IPI. Any pharmaceutical industry needs employees from the fields of organic chemistry, biochemistry, pharmacology, pharmacokinetics, pharmaceutical science, analytical chemistry, and so forth. With a very well-developed and diverse education system, India produces students who can meet these requirements.

Banglore is considered to be the Silicon Valley of India. The Indian computer industry is on par with its American counterpart, and many companies in the world depend upon Indian programmers to develop complex software. The use of computers in the pharmaceutical industry is increasing, and in particular they are being applied to data management and drug discovery programs (12). Thus, collaboration between the computer and pharmaceutical industries will help drug discovery and development programs prosper.

The presence of other parallel drug/medical systems also would be a major strength for the IPI. It would provide a vast resource for the development of new drug molecules in the drug discovery programs.

Weaknesses. Although the IPI is large by Indian standards, on the world market its share is merely 1–2%. Even if 25% of gross sales are invested in R&D, the IPI's total R&D budget is comparatively very small. Individual R&D budgets of many US companies probably amount to much more than the cumulative R&D budgets of all the companies in India. Thus, availability of funds is a major weakness of the IPI.

Animal experiments are an essential part of pharmaceutical R&D. Every drug molecule must be screened using animals first to determine its efficacy and side or toxic effects. If Indian animal rights activists block the use of animals in R&D experimentation, the IPI will be forced to turn to other countries for animal studies. A great need exists to provide appropriate information to animal activists in India so a balance can be struck between animal rights and human rights.

A drug regulatory system is an essential part of the pharmaceutical sector. Drug discovery and drug development are risky, complex, and not fully understood. The Indian regulatory system is not set up to accomodate the drug discovery/development processes and therefore does not have the proper infrastructure, enough manpower, or financial support to effectively move drug development operations forward. As a result, one might expect delays in the approval process.

The American pharmaceutical industry has entered the era of pharmacogenomics and is venturing into the development of drug therapy tailored to individuals (13). Likewise, the Indian pharmaceutical industry is investing significant funds in biotechnology and genomics. These fields are capital consum-

Table VII: Infrastructure of selected countries (8).

Country (GDP Per Capital in US $)	Highways* (km) (000)	Railways (km) (000)	Trucks and Buses in Use (000)	Electricity Production (Million kWh)	TVs in use* (000)	Telephones in Use (000)
Brazil (4,603)	1670.1	22.1	2450	222,195	30,000	12,083
China (578)	170	58.3	4927	983,700	126,000	40,706
India (351)	1100	62.4	1839	380,100	20,000	11,970
Japan (40,689)	1115.6	26.5	22,694	857,273	100,000	61,106
South Africa (3,240)	55.4	21.4	1597	182,400	3485	3919
United States (27,540)	6243.2	214.3	42,298	3,268,200	215,000	164,624

*Values as of 1997.

Table VIII: Effect of patent protection on the pharmaceutical industry in three representative countries (16).

Country	Year When International Patent Law Became Applicable	Effect on Country
South Korea	1986	Local firm market share increased from 87.3% (1986) to 89.2% (1990). Local firms have 75% of patent applications. Now an exporter of modern pharmaceutical technology.
Mexico	1991	Tripling of investment by research-based pharmaceutical companies. Competitiveness of domestic industry enhanced by technology transfer.
China	1993	17% annual growth rate for the pharmaceutical market. Number of joint venture increased.

ing and have no guarantee of success. The biotech industry needs scientists who understand these disciplines, but it is not easy to attract qualified scientists and businessmen from abroad to work in India. Spending valuable resources in this area of science, which is in its infancy, can be suicidal to the IPI. Venture capitalists would do well to invest their money only on those projects whose success is guaranteed.

Gaining FDA approval of a drug can be a lengthy process. The organization has just enough manpower to oversee approval of products from US-based companies. The IPI's efforts to seek approval to market drugs in the United States could be time consuming because of FDA constraints, and the approval process could be a major bottleneck for India's drug development industry.

As shown in Table VII, the infrastructure in India is good but could be improved. The development of infrastructure is a key to success, and the IPI must take more definitive steps to overcome this weakness.

Opportunities. A patent is granted to an invention that is novel, nonobvious, and useful. The IPI has a clear opportunity to be part of the international patent community in the acquisition of patents. This process will stimulate economic development, provide job opportunities, and help India build a global reputation as a nation with a strong scientific community. It will also make modern medicines available to the entire Indian population. More important, indigenous R&D activities will help domestic companies discover drugs to treat tropical diseases.

In the pharmaceutical arena, patents can be granted for new molecules, new medical indications for an existing molecule, new ways to administer an existing molecule, or modification of an existing formulation with added value. Because India will not be able to produce the huge amount of capital needed to discover new drug molecules, it may be prudent to consider issuing patents for "Swiss-type" claims for new therapeutic uses of known molecules. Low manufacturing costs and process skills are the IPI's forte, and India would do well to make use of this important opportunity.

As it develops its infrastructure, the IPI can look into economies of scale. Merging with a complementary domestic or international company may provide sufficient funding and resources to manufacture formulations and bulk drugs on a large scale, which would decrease the cost of manufacture. This would help make bulk drug or formulation costs competitive in the world market, which then would boost the amount of exports.

Focused R&D and the development of centers for clinical trials in India would allow the IPI to discover new drugs for diseases observed in tropical conditions. Such drugs could be marketed both in India and in neighboring countries with a similar tropical climate.

For the first three years of the ninth five-year plan, the growth rate for the Indian economy was 6.2% (14). To meet the target of 6.5%, the economy must grow at 7.2% during the next two years. The target growth rate for the tenth five-year plan is 9%. This sizeable increase is a clear-cut indication of the anticipated future growth of the Indian economy, which could provide good opportunities to the IPI.

Threats. Many more countries will be complying with the terms of patent laws in 2005. It means that, like India, many countries are preparing for 2005 and will be competing to market various pharmaceuticals. The Indian pharmaceutical market may face the threat of the dumping of bulk drugs and formulations by neighboring countries. The IPI would be compelled to compete with multinationals in 2005, and it remains to be seen how many companies actually will survive the competition (15). Industrialization and environmental factors

must be considered, and if proper measures are not taken up front, business growth eventually will be hampered.

Benefits to India from modernizing the IPI

At a World Intellectual Property Organization (WIPO) conference in 1999, Dr. P.V. Venugopal summarized the possible benefits to India of modernizing the IPI (16). This section discusses some of these benefits.

Social. The development of the IPI would create new jobs, but mainly it would provide access both to modern technology in the field of medicines and to medicines developed indigenously. As a result, it will be able to provide new drug formulations and improved healthcare treatments to Indian patients. In particular, new medicines would be available to treat diabetes, cardiovascular diseases, cancer, and psychological disorders. But even during the drug discovery and development phases, significant funds would be invested in local communities. For example, during Phases I to IV, normal volunteers or patients would participate in clinical trials during which they receive free medicines and are paid to participate. In Phase IV trials, patients who cannot afford expensive medicine will have the opportunity to receive modern medicines.

As a result of changes in the culture and in the social environment, new types of diseases are invading India. India must have a concrete plan to protect itself from these diseases, and the development of the pharmaceutical sector is the first step.

Economic. The development of the pharmaceutical industry would help the Indian economy produce more national wealth. Foreign investment would increase, and Indian companies would have the opportunity to collaborate with many companies from around the world. Indirectly, developing the pharmaceutical industry would also help other industries.

The related employment opportunities in various fields are no less important. If good jobs were available locally, citizens would not feel the economic pressure to migrate to the United States, Europe, or Japan. Development of clinical trial centers would provide funding from private pharmaceutical industries to local hospitals. In return, a staff of nurses and doctors would be maintained, which would benefit local communities.

According to economics historian Walt Rostow, five stages of economic development exist. The first two stages are traditional society and the preconditions for takeoff. The third stage is economic takeoff, which then matures in the fourth stage. The fifth stage is high mass consumption. The Indian economy is most likely in the second or third stage, according to Rostow's model, and is expected to take off. As an indication of this position, Indian pharmaceutical companies no longer have only domestic operations—some companies now have enterprises in the United States and other countries.

One must be aware of the relationship between economic development and the environment and thereby promote the incorporation of environmental values into economic development. This relationship is especially true for bulk drug manufacturing, in which, with the advent of drug discovery, India may experience significant growth. Increased spending for the protection of the environment would produce more-hygienic conditions for the population, and protecting the environment from the beginning would avoid the potential for future cleanup costs.

Table IX: Annual drug expenditure per capita in US $ in various countries (19).

Country	Per Capita Drug Expenditure in US $	Country	Per Capita Drug Expenditure in US $
Japan	412	Brazil	16
Germany	222	Philippines	11
United States	191	Ghana	10
Canada	124	China	7
United Kingdom	97	Pakistan	7
Norway	89	Indonesia	5
Costa Rica	37	Kenya	4
Chile	30	India	3
Mexico	28	Bangladesh	2
Turkey	21	Mozambique	2
Morocco	17		

Political. Economic growth will bring political stability to India. It will improve international credibility and create a visionary rather than a reactionary political regime. The poverty level in India stands at 27%, which is very high compared with China's 5% level, for example. Making medicines affordable to all Indian citizens is a noble goal, but one must strive for a fair distribution of low-priced medicines to the masses and high-priced modern medicines to wealthier people. The economic development that would result from growth in the pharmaceutical and computer sectors could trigger development of other sectors and indirectly lower the poverty level. India can then achieve macroeconomic growth through education, infrastructure development, improved sanitation, and enhanced public health. In a political sense, these developments will forge a win–win situation for Indian citizens and politicians.

Changing disease patterns must be understood, and policies must be prioritized for the treatment of diseases. A committee of representative physicians from various internal states, government officials, and key executives from various pharmaceutical companies could likely muster the clout required to meet the health requirements of Indian citizens as well as promote the country's pharmaceutical industry.

Opportunities and complications to the American pharmaceutical industry

The World Bank estimated that five countries—Brazil, China, India, Indonesia, and Russia—whose share of the world pharmaceuticals market is barely one-third of that of the EU will have a 50% higher market share than will the EU by 2020 (17). Thus, tremendous economic growth is expected in these five countries in the coming decades. Table VII compares the infrastructure of representative countries; certainly India is not far behind. India has well-developed road and railway systems; however, it must improve its production of electricity, which is needed by all businesses. Recent policy changes regarding power generation, telecommunication, civil aviation, and the import

of consumer goods have resulted in the entry of large MNCs such as Coca-Cola, McDonald's, and Kentucky Fried Chicken.

Table VIII compares data about South Korea, China, and Mexico in terms of positive outcomes from accepting international patent laws. After moving to honor patent laws, all three countries benefited by experiencing a boom in the pharmaceutical industry. Most likely India will undergo similar changes after 2005.

The foot-and-mouth epidemic in the United Kingdom, Ireland, and France and the scare it generated in the United States is a good example of the vulnerability of all countries. The AIDS epidemic in South Africa is another example of the fragile firewalls that separate various countries. Especially in terms of contagious diseases, a clear-cut indication exists to supply drugs to developing countries at affordable prices. Medicine as a commodity differs in comparison with items such as cars, refrigerators, and so forth. Diseases must be controlled and to that end, we must ensure an acceptable drug supply even to the poorest countries. These issues require a hard look and compel the development of strategies to benefit the American pharmaceutical industry. Current information available about the IPI as well as projections for its future indicate that the Indian pharmaceutical market also has great potential for relieving disease worldwide.

Opportunities. India is the largest democracy in the world, with a majority of its citizens fluent in English. Its GDP is $447 billion(18). India's GDP grew at an average rate of 5.5% between 1990 to 1997. During the current five-year plan, it is expected to grow at 6.4%, and in the next five-year plan it is projected to be 9%. The Indian government's policies are open to foreign investments, and the country is developing the necessary infrastructure for economic growth (18). India's huge middle class—approximately 250 million people—has a vigorous buying capacity. On average, however, per capita annual expenditure on pharmaceutical products is just $3.00 (see Table IX), a negligible amount when compared with the amounts spent in Japan ($412) and in the United States ($191) (19). An increase of only two dollars in per capita expenditure on pharmaceutical products would provide a tremendous marketing opportunity to pharmaceutical companies in India. Table IX also lists the per capita expenditure for drugs in other countries. Countries such as China, Indonesia, Pakistan, and Bangladesh also have low per capita expenditure, and importing medicines from India could help develop their drug markets. Development of the pharmaceutical sector would not only help decrease unemployment in India, but it would also help secondary industries flourish. This economic growth helps increase buying power, which in turn will make India an attractive market for US pharmaceutical giants.

Currently, Indian companies are not abiding by patent laws. MNCs have nearly two and a half years to analyze data and take steps to position themselves in the Indian pharmaceutical market. In the United States, one of the primary reasons for the merger of pharmaceutical companies is to acquire a strong pipeline. Indian pharmaceutical companies have zero or negligible drug discovery programs. Drug molecules from an Indian company may not be licensed.

The Indian government has not been open to foreign investments in the past three decades. However, now Indian authorities claim to provide a more predictable and healthy environment for businesses. Culture and business practices in India are very different than those of the western world. Thus, a strategic alliance with an Indian counterpart in which the partners' strengths complement each other would be advantageous. Many US companies are strong in technological knowledge. An Indian counterpart could provide the additional knowledge of local industry, government, banking, and marketing. A domestic company could provide local information at a faster rate, and a US company would more easily become acquainted with local norms and customs. Political turmoil, which is a possibility in any country, can affect industrial sectors, but a strong coalition with a local company would help alert the partner of potential political turmoil.

The expenditure per patient for a clinical trial in India is much less compared with that in the United States. The cost of drug development depends on the type of therapeutic segment, previous knowledge gained from a similar program, and complications that arise during the clinical study. Thus, it is difficult to pinpoint the exact cost of drug development in India, but it is much less than that in the United States. India has plenty of doctors and hospitals (see Table I). Outside companies may find it fruitful to establish an alliance with an Indian company that has its own clinical trial setup. For example, if a drug must be developed to treat a tropical disease, India could be an ideal place for conducting clinical trials.

India has the dubious distinction of being home to the largest number of people with diabetes. With a poor healthcare infrastructure, it is logical to assume that many more people remain undiagnosed (20). The occurrence of diabetes may lead to other health problems, mainly cardiovascular diseases. This reality provides numerous opportunities for pharmaceutical companies to market medicines to treat these illnesses. Several modern medicines are available in the United States to treat diabetes and related diseases, and manufacturing them in India could cost considerably less because of India's lower labor cost. Formulations production could be contracted out to local companies; thus, drugs could be sold at an affordable cost to Indian citizens. In addition, in drug discovery programs few drugs are brought forward for further development even though the backup compounds are good. Licensing these drugs to Indian companies for further development is a possible alternative to letting a new drug go by the wayside. The cost of drug development could be reduced, and the drug development program could succeed. Recently, companies such as Ranbaxy and Dr. Reddy's Laboratories are manufacturing generic drugs in India and selling them on the US market.

India's several ancient drug/medical systems (e.g., ayurvedic and homeopathic) may lead to the discovery of many valuable drug molecules that could be developed as modern formulations. American companies have an opportunity to establish alliances with Indian companies that specialize in these medicines. If they are found to be advantageous treatments, they could be brought to the US market, and the US population could also benefit.

Skinner discusses sales models for pharmaceuticals and proposes a new paradigm for sales and marketing (21). A model, which he refers to as the *customer (new millennium) model,* requires marketing personnel to ask two questions: What is best for my customers and their development? and How do these values affect marketing plans and sales objectives? We seek rewards by providing authenticity and relevance. This fact means that when an American pharmaceutical company plans to penetrate the Indian market, it must first clarify the needs of Indian physicians and customers. The new pharmaceutical products must be developed according to the needs of the Indian population. An alliance with an Indian company that has strong marketing skills would help respond to these needs. Many Indian companies export drugs to Russia and to Middle Eastern, Asian, and African countries (see Table V). Honing this type of alliance would also provide US companies with access to these markets.

WTO actions promote spreading the cost of R&D to a larger base and increasing the availability of drugs to a larger population. These actions would reduce the cost of drugs in the United States. Only two companies in India—Dr. Reddy's Laboratories and Ranbaxy—have sizable drug discovery programs. Dr. Reddy's Laboratories has licensed preclinical to Phase III compounds to Nordisk and Novartis (22). This move has given Novartis an opportunity to work with one of India's premier pharmaceutical companies. More and more alliances and mergers are expected between the US giants and domestic pharmaceutical companies in India.

Complications. Accepting the international patent laws does not mean that the patent rights would be fully enforced. IDMA's stance on the patent law changes are

- to comply with specific minimum requirements and only in cases in which it is suitable
- to transfer and disseminate technology as much as possible
- to accept new developments that are conducive to the economic and social welfare of India's citizens. The Indian drug industry must be protected to serve the health of its billion people.
- not to rush into reforms and if needed, request extensions and complete the reforms in stages
- to make use of loopholes in trade-related intellectual property rights using ingenuity and imagination (6).

This stance makes it clear that the IPI will try to make use of loopholes as much as possible. The reasons may be legitimate —it is question of one's point of view. The policy seems aimed at providing standard drugs to the masses rather than making modern, expensive drugs available to a few privileged people. However, once the Indian government experiences the benefits of fully honoring the international patent laws, the situation might change. The IPI was expecting a weighted tax benefit on overseas expenses for the pharmaceutical industries such as those for clinical trials, regulatory approvals, patent filing, and litigations. The IPI also expected incentives for R&D. The 2002 budget, which disappointed everyone, may have a hidden message in it. The finance minister of India announced a scheme, called *Janaraksha,* to improve access to healthcare for rural communities, indicating that the government wants to focus on the health of poor people by providing them adequate healthcare facilities. Thus, US companies are expected to establish operations such as clinical trial facilities in India.

US pharmaceutical companies invest significant amounts of money to develop new types of formulations and drug delivery systems. For poor countries like India, the cost of drugs is a much more important factor than are fancy drug delivery systems. Local authorities are reluctant to grant approval for such formulations, which they consider to be marketing gimmicks. A recent report showed that once-a-day formulations are not successful in India—patients question the effectiveness of the medicine if only one tablet is administered per day. Such an initial setback can be wiped out by first conducting suitable clinical trials in India to prove the point and then educating patients (23).

Without doubt, India has a parallel economy, so it may be difficult to completely abolish reverse engineering and piracy of drugs. Transparent policies are essential to attract long-term investments. Healthcare reforms in India are inevitable in the current era, and they will ensure a sufficient supply of drugs, controlled prices, and the development of new products. Nevertheless, widespread corruption and a deeply integrated system of bribery make every transaction complicated and expensive.

It is very difficult for US companies to apply FDA rules to a manufacturing site in India. The process would require extensive planning, financial investment, training, and a major shift in peoples' attitude. Apart from this, FDA must inspect these sites for GMP compliance. Considering the approvals backlog in the United States and the practical difficulties in conducting inspections in a foreign country, planning of such inspections would be very cumbersome. Local private inspectors could ascertain compliance according to FDA guidance; however, no guarantee exists that the Indian FDA will agree to all the changes. Reciprocity would be needed in terms of these agreements and would undoubtedly lead to long negotiations. The Indian FDA may not approve the current paradigm of the drug development process in the United States. When it comes to GMP and GLP issues, the attitude of top management is the key parameter and thus, the US parent company would be required to provide extensive training to top management and change the culture in the Indian subsidiary.

The American pharmaceutical industry has experienced a major influx of Asian Indians, and many of them have reached high levels. In a decade, if the IPI truly flourishes according to expectations, a reverse brain drain from the United States could occur. Its effects may be experienced in the pharmaceutical schools (e.g., teaching assistants) and industry (e.g., scientist-level jobs), but no change is expected in the near future.

Business dealings with an Indian company. India's present problems are not solely economic but also are the result of political, psychological, and cultural attitudes. With Indian people migrating back from the United States, few things would change. Among its middle class are numerous college graduates, 40% of whom have degrees in science and engineering. Political, legal, and cultural factors are very critical when dealing with Indian counterparts and the government. The most important point is, don't attempt revolution, but try evolution. With the experience of British rule in its history, Indians are sensitive

about foreign people and companies trying to take over. The Indian people and government must first trust foreign companies and their motives. A US company may not want to "invent" new diseases (e.g., male erectile dysfunction) and propose medicines to the Indian people. Indians take significantly less medicines and may not accept a radical change in their medicine cabinets. Multinationals should think globally and act locally. They should adapt to local tastes and accept the laws of the land. The business pace must slow down.

One must continuously assess the political risk and for that reason, one must devise an intelligence network and early warning system, have a contingency plan ready, and seek the stability of government policies. The corruption percent index values reported for representative countries are Nigeria, 1.76; India, 2.7; China, 2.88; Brazil, 3.56; USA, 7.61; Singapore, 8.66; Finland, 9.48; Denmark, 9.94 (8). A low score signifies more corruption. Corruption and bureaucracy exist from top to bottom. An American company must examine these aspects very carefully and should have definite policies in place before venturing into the Indian pharmaceutical arena.

The 5th International Symposium on Innovation in Pharmaceutical Science and Technology will be held in Mumbai, India, 29 January–3 February, 2003. More than 30 speakers from abroad will share their experiences at this symposium. American pharmaceutical companies would be prudent to send representatives to this symposium to gain helpful cultural insight and familiarize themselves with the IPI.

Conclusions

Many countries will start honoring patent laws from 1 January 2005, and India is among the countries that will be affected. With the second-largest population in the world, a highly educated population that is fluent in English, and well-developed buying power, India has great potential for industrial growth. Its current GDP growth is approximately 6.2%. The annual per capita expenditure for pharmaceuticals is merely $3 compared with $191 in the United States. India has a strong infrastructure for pharmaceutical business environment. The IPI may not be a direct threat to the US pharmaceutical companies, but the Indian pharmaceutical market has important potential that the American pharmaceutical industry may want to explore. Cultural differences may prompt American companies to enter this market with caution; thus, it may be advisable for US companies to acquire suitable Indian companies for easy penetration of the Indian market.

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