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The Indian Pharmaceutical Market

By **Todd Clark**

The Indian pharmaceutical market is the world's fourth largest by volume (8% of global total) and thirteenth largest by value (less than 1% of global total). Although prices are the lowest in the world, 70% of the population does not have access to drug therapy and 2002 per capita consumption was only $3.33. The lack of pharmaceutical patents means that there is an average of 200 brands for every molecule on the market.

Imports face significant difficulties in accessing the Indian market. Aside form intellectual property issues, problems include a tariff rate over 40% and a lack of transparency in the regulatory process. Multinationals with a local presence control approximately 35% of the market, but true imports have only a 5% share. However, the government has taken steps to remove barriers to foreign investment. Revisions contained in the 2002 Pharmaceutical Policy allowed 100% direct foreign ownership (and eliminated the need for government approval) for the first time. In 2002, three of the leading ten companies were foreign-owned (See Table 1). Table 2 shows the top ten products in the Indian market in 2003 (four of which are antibiotics).

Table 1 - Leading Companies 2002

Company	2002 Sales $Mil	% Market Share	% Growth 2001-2002
GSK Pharma	231.3	5.9%	4.9%
Cipla	205.2	5.3%	22.9%
Ranbaxy Labs	180.9	4.6%	15.6%
Nicholas Piramal India	132.6	3.4%	15.0%
Sun Pharma	114.3	2.9%	23.4%
Dr.Reddy's	109.6	2.8%	28.6%
Zydus-Cadila	94.4	2.4%	23.4%
Aventis Pharma	91.2	2.3%	5.3%
Abbott India	90.5	2.3%	13.8%
Wockhardt	82.9	2.1%	15.6%
Totals	**1,332.8**	**34.1%**	

Source: ICICI Securities Ltd.

Table 2 - 2003 Leading Products

Brand Name	Generic	Category
Corex	Chlorpheniramine Maleate	Allergy
Voveran	Diclofenac Sodium	NSAID
Becosules	Vitamin B Complex, Vitamin C	Supplement
Taxim	Cefotaxime	Antibiotic
Human Mixtard	Insulin	Diabetes
Althrocin	Erythromycin	Antibiotic
Sporidex	Cephalexin	Antibiotic
Asthalin	Salbutamol	Asthma
Betnesol	Betamethasone	Anti-inflammatory
Cifran	Ciprofloxacin	Antibiotic

Source: OPPI

Without a doubt, compliance with the 20-year product patent protection requirements of TRIPS (scheduled for January 1, 2005) is the biggest issue in the Indian pharmaceutical market and one that has international as well as domestic implications. (Details on current and anticipated patent and related legislation can be found in the Intellectual Property section. *See end of article*.).

The country has been making a gradual (and many would say half-hearted) transition toward protecting intellectual property for close to a decade. After joining the WTO in 1995, India agreed to offer five year exclusive marketing rights (EMR) to products which were: 1) patented in another WTO member state after 1995 and; 2) had received marketing authorizations in both India and the patent-issuing country. EMRs are supposed to be valid for a period of five years or until a patent is issued. However, no EMRs were issued until the second half of 2003. At that time, one was issued for Novartis' oncology drug, Glivec and another for Nadoxin, an antibiotic from the local company, Wockhardt. Due to the lack of existing patent protection, local companies were already making copies of Glivec and have contested Novartis' EMR.

Continues on next page…

Regardless of the governing legislation, regulators and domestic suppliers are unlikely to drop their resistance to patents overnight. The Indian Drug Manufacturing Association (IDMA), which represents the local industry, stated the position of its members towards the upcoming patent regime as follows:

- 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 is 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.

Other factors that will work to slow the impact of TRIPS compliance include an enormous backlog of applications, understaffing at the patent office and problems with data exclusivity and other ancillary issues. Finally, with virtually all drugs (even those patented elsewhere) already available as generic copies, it will be sometime before the IP changes have a significantly positive influence on multinational share. A report from ICICI Securities indicates that products with EMRs and patents will have essentially no impact until late 2007 / early 2008 and will achieve a maximum share of 10-12% by 2010.

Faced with the move toward a product patent system, Indian producers have largely been forced to choose between three business strategies:

- Become a contract manufacturing organization for larger, international companies.
- Undertake the high risk, high cost process of developing original drugs.
- Pursue generic markets in developed countries.

Of these, the sale of generics in developed markets appears to be the most promising approach and the one that presents the greatest threat to the research-based industry. The increasingly aggressive behavior of Indian producers (discussed in more detail in the Generics section) has resulted in serious legal challenges to blockbuster drugs that were believed to enjoy years of remaining IP protection.

Counterfeit drugs have been estimated to account for 16 to 30% of all products in the market. To address this issue, the death penalty was introduced for counterfeiters in late 2003. Another illegal but common practice is the dispensing of ethical pharmaceuticals without a prescription. The practice has led to widespread misuse (particularly of antibiotics).

R&D / Clinical Trials

In the past, lack of intellectual property protection has created little incentive for Indian companies to fund R&D. Historically, investment levels have represented only 2% of revenues – the lowest levels of any major industry in the world. As the product patent system approaches, this is changing somewhat. Some major companies are already spending 6% on R&D and the industry as a whole is expected to reach 5% within a few years.

Clinical trials are another area where India stands to benefit from the post-2005 patent regime. The clinical trials sector is currently valued at $70 million and is forecast to reach $200 million by 2008. A huge population, a high number of treatment naïve patients, and (as a result of longer life-spans) the increasing prevalence of chronic disease are attractive factors for drug researchers. The patient pool includes an estimated 40 million asthmatics, 34 million diabetics, 30 million with cardiovascular disease, 8 million epileptics and 1.5 million with Alzheimer's. Further, trial costs are estimated to be 50 to 60% less expensive than in the United States with bigger discounts for the more expensive, later stage studies.

India's government has taken steps to increase the country's attractiveness for drug researchers: import duties on studied drugs have been eliminated, ICH Good Clinical Practice regulations are now mandated, and protocol approval times have been cut to approximately 12 weeks. Due to fears about exploitation of a largely poor population, it is necessary to conduct Phase II and III trials after they have been conducted elsewhere in the world. Phase I trials (used to establish basic safety profiles) are not allowed at all. It seems highly likely that, at a minimum, the delay on Phase II/III trials will be dropped in the near future. (Note that trials involving placebos are often rejected as unethical but this is not an official position.)

Lack of data exclusivity is probably the major restraint to continued growth of the clinical trials sector. Multinationals must weigh the benefits of conducting research in India with the possibility

that lax IP protection will result in loss of trade secrets. Proponents claim this should not be a concern because data collected in India will actually be analyzed and filed in developed markets first. (See Patents & IP section for details. *See end of article*.)

Generics

To speak of generics and the Indian pharmaceutical market is largely redundant. Since the government has only recognized process patents, domestic producers have relied largely on reverse engineering of branded drugs and have offered these imitations at low prices. This has undermined demand for higher-priced branded versions. In any case, multinationals have been reluctant to release new copies of their high value products for fear of imitation. Although some expect this situation to change dramatically after patents are introduced in 2005, the problems discussed under the Pharmaceutical Market section are likely to mean that India will evolve only gradually toward a mixture of original and generic drugs.

As we've seen, the country's pharmaceutical industry was built on the reverse engineering of drugs which were created and patented elsewhere. With that option soon to be closed under TRIPS, many of the threatened companies are targeting the generic markets in developed countries. Of particular interest to multinationals is the fact that Indian companies are not always waiting for patent expiration before seeking marketing approval. In the US, for example, Dr. Reddy's received approval to sell a copy of Pfizer's Norvasc although that product had three years of remaining market exclusivity. At this writing, it appears that this particular decision will be overturned in the courts, but it is a clear sign that Indian companies intend to exploit any potential loophole to ensure continued viability post-2005. (The mechanism through which these early challenges are being launched is discussed in more detail in the US section. *See end of article*.)

Marketing

On average, manufacturers devote 9% of revenues to marketing – a figure that translates to approximately $310 million for 2002. Multinational companies, which tend to offer branded, patented products, have 50% higher selling costs than their Indian counterparts. Efforts aimed at physicians rely heavily on direct sales forces, which, given the thousands of manufacturers in the market, face a highly competitive environment. Both multinationals and domestics regularly engage in physician-directed marketing activities, including borderline bribery, which would be highly questionable in other parts of the world.

Most sales representatives are unionized. Their organization, the Federation of Medical and Sales Representatives of India, has called several strikes in recent years to protest layoffs caused by mergers and changes in the patent regime.

Given dispensing pharmacists' importance in product selection decisions (see Distribution section. Order the PharmaHandbook for complete information.), marketers generally feel compelled to direct significant efforts in their direction. Most often, this takes the form of providing discounts aimed at increasing pharmacy profit margins. As they provide numerous incentives for misuse, these promotions have been widely criticized. However, the manufacturers respond (with justification) that pharmacies will otherwise refuse to stock their products.

[Please see next page for a summary of Indian Pharmaceutical Market Statistics.]

Abstracted from PharmaHandbook™ 2004 Edition.

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Indian Pharmaceutical Market Statistics

General	Data	Source
Population (Millions)	1049.55	WHO
2002 GDP US$ Millions (PPP Method)	2,664,000	GlobalEdge
2002 GDP Per Capita US$ (PPP Method)	2,538	Calculated
2002 GDP US$ Millions (Exchange Rate Method)	515,012	WorldBank
2002 GDP Per Capita US$ (Exchange Rate Method)	491	Calculated
GDP Rank (ExchRate Method All Countries)	11	WorldBank
GDP Per Capita Rank (ExchRate Method All Countries)	111	WorldBank
Local Currency to US$ Exch Rate (2003 Avg)	0.02151	Oanda.com
PPP to Exch Rate Ratio	5.17	Calculated

Healthcare	Data	Source
2002 Total Healthcare Spending US$ Millions (PPP)	135,864	Calculated
2002 Total Healthcare Spending US$ Millions (ExchRate)	26,266	Calculated
2002 HC Spending as % GDP	5.1%	WHO
Public % of HC Spending	10.0%	TPUK
Private % of HC Spending	90.0%	WHO
Private Health Ins as % of HC Spending	1.0%	VOI Estimates
HC Spending per Capita (PPP)	129.4	Calculated
HC Spending per Capita (ExchRate)	25.0	Calculated
% of Population Fully Insured	15.0%	CII-McKinsey
% of Population w / Some Insurance (a)	50.0%	TPUK
% of Population w / Private Insurance	0.4%	EIU
Number of Pharmacies	230,000	Various
Number of Physicians	503,784	WHO
Number of Hospital Beds	870,000	EIU

(a) based on public sector health network which is often spotty and of poor quality.

Pharmaceutical	Data	Source
2001 Total Sales US$ Millions	3,463	Est from ICICI
2002 Total Sales US$ Millions	3,910	Est from ICICI
2003 Total Sales US$ Millions	4,109	Est from OPPI
2001-02 Growth Rate	12.9%	Calculated
2002-03 Growth Rate	5.1%	Calculated
2002 Per Capita Consumption US$	3.73	Calculated
Pharma Spending as % GDP (ExchRate 2002) *	0.8%	Calculated
Pharma Spending as % HC Total (ExchRate 2002) *	14.9%	Calculated
Public Payment as % Total Sales	7.0%	VOI Estimates
Private Payment as % Total Sales	86.0%	VOI Estimates
NGO & Similar Payment as % Total Sales	7.0%	VOI Estimates
Foreign Co. Share of Market	35.0%	EIU
Domestic Co. Share of Market	65.0%	EIU
Drugstores as % of Total Sales	83.0%	VOI Estimates
Physician Office as % of Total Sales	10.0%	VOI Estimates
Hospital as % of Total Sales	7.0%	VOI Estimates
Branded as % Total Volume	6.0%	Est from EIU
Branded as % Total Sales Value	18.0%	Est from EIU
Generics as % Total Volume	94.0%	Est from EIU
Generics as % Total Sales Value	82.0%	Est from EIU

* Prescription Drugs Only / Ex-mfr prices.
TPUK = TradePartners UK
EIU = Economist Intelligence Unit

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