

Innovation In Indian Pharmaceutical Industries

Multinational corporations are searching for means to broaden their capacity for drug development while decreasing costs.

Pharmaceutical firms in India are increasingly forging partnerships with these corporations to gain revenue and to develop their own expertise. These relationships largely appear to be symbiotic.

As a result of the movement of R&D to their countries, Indian scientists are rapidly developing the ability to innovate and create their own intellectual property.

- Several Firms in India are performing advanced research and development and are moving into the highest-value segments of the pharmaceutical global value chain.

- What is noteworthy is that most of the advances in R&D in India happened over the last decade with the greatest momentum being built over the last five years.

Original proprietary research:

- Several Indian companies are developing their own proprietary drug products targeting global or regional markets, but they lack the ability to advance a drug through the entire clinical-trial process and market them worldwide.
- These companies seek licensing agreements with, or make complete drug sales (i.e. inclusive of supportive clinical data) to, multinational pharmaceutical companies that have the necessary resources.

Research partnership:

- In these relationships, a multinational corporation supplies a research partner with an early- or mid-stage drug candidate and contracts the partner to develop it further.
- The domestic companies gains access to a novel compound(s) and potential assistance from its multinational partner, which in turn expands its own drug-development capabilities.
- A number of these deals involve cost and risk sharing in exchange for joint ownership of the intellectual property.

Contract research organizations (CROs):

- These companies are typically contracted to perform specific stages of drug discovery, development, or testing, and receive a fixed payment upon reaching a predetermined milestone.
- Companies using this model do not assume any of the risk, positive or negative, associated with drug development.
- Several companies in India are specializing within specific disease types or within specific functional areas of the pharmaceutical value chain.

Generics, APIs, and manufacturing:

- India has a vibrant generics and active pharmaceutical ingredient (API) market.
- Companies that focus on this market carefully monitor the intellectual-property protection of major drug products.
- When a product comes off- patent, they explore means of mass-producing the drug using identical or similar chemical reactions.

The Globalization of Innovation:

- Indian companies are making strides in the highest-value segments of global value chains. In the lower-value segments, such as preclinical testing, animal experimentation, and manufacturing, however, Chinese companies appear to be more prevalent.
- India is regarded as a more mature destination for chemistry and drug-discovery activities than China.
- Domestic Indian companies rarely have the capital and the regulatory expertise to develop a drug beyond phase II clinical trials.
- The commercial development of new intellectual property therefore necessitates relationships with major multinational corporations.

Examples of Pharmaceutical Opportunities in India

- Indian companies like **Dr. Reddy's Laboratories, Glenmark**, are developing proprietary drug candidates, with the intent of forging marketing partnerships with pharmaceutical multinationals. Glenmark has already successfully completed several licensing agreements.
- **Dr. Reddy's Laboratories** can conduct preclinical trials for 40 to 60 percent less than the cost of comparable activities in the U.S.

- By developing drugs and selling them in markets without product-patent enforcement, **Cipla**, an Indian pharmaceutical company, has been able to provide anti-AIDS medication to India and Africa for around \$300 per patient per year, one-fortieth to one-fiftieth the cost of competing treatments.

- Indian companies appear to be able to attract U.S.-educated and -trained scientists and engineers more readily than their Chinese counterparts.
- In India, a number of pharmaceutical companies competing for regional generics markets aspire to enter new-drug development in the next five years
- Despite a leap in the number of clinical trials in India and China, the total numbers remain small compared with the U.S. and Europe.

- As of late May 2008, the National Institutes of Health's clinicaltrials.gov identifies more than 56,000 studies worldwide, including 32,410 in the U.S., 750 in China, and 670 in India. these figures include current and completed clinical trials.

When it comes to current clinical trials alone, the London-based Business Monitor International (BMI) in Asia Pacific Pharma and Healthcare Insight (May 2008) ranks Japan first in the Asia region with 406 studies, followed closely by China (389) and India (347). As recently as November 2007, BMI gave China a slender 274–260 lead over India in current clinical trials.

Two Success Stories of Indian Pharma:

Glenmark, India, has completed several licensing agreements with Big Pharma.

- In 2006, it licensed GRC 8200, an experimental diabetes drug in phase II clinical trials, to Merck. **Glenmark** was paid USD 39 million up front, with a potential total payment of USD 296 million.
- The collaboration was abandoned when Merck elected to pursue treatments for diseases other than diabetes.

In 2007, **Glenmark** completed a licensing agreement with Eli Lilly, involving a portfolio of TRPV1 receptors and a clinical compound named GRC 6211, undergoing phase II clinical trials. It was paid USD 45 million, with the potential to earn an additional USD 215 million based on milestone performance. Under the terms of the agreement, **Glenmark** will receive royalty payments if GRC 6211 is commercialized.

In April 2008, the company received FDA approval to begin phase I testing of GBR 500, a monoclonal antibody under development for potential treatment of multiple sclerosis, chronic obstructive pulmonary disease, and inflammatory bowel disease.

• **Dr. Reddy's Laboratories** is an example of an Indian company that is pursuing parallel approaches to obtaining revenue at different stages in the pharmaceutical value chain. Four-fifths of **Dr. Reddy's** discovery work is on precedented drugs; about a fifth of its research effort focuses on unprecedented therapeutic areas (i.e. new-concept drugs).

• With a global staff of more than 9000 employees, **Dr. Reddy's** seeks to advance drug candidates through early phase II trials and then license or sell their intellectual property to major pharmaceutical players.

Dr. Reddy's has already had some initial success using this strategy for a best-in-class diabetes-inhibitor molecule, which it licensed to a major diabetes company for an advance payment of approximately USD 3 million. In 1997, **Dr. Reddy's** licensed a drug candidate named Ragaglitazar, with the potential to moderate diabetic dyslipidaemia and blood-glucose levels, to Novo Nordisk. Although this drug candidate was very promising in phase I and II trials, in phase III it was identified as a carcinogen.

Dr. Reddy's continues to grow its drug-development capacity and to pursue novel research candidates.

Many companies are moving to value-sharing relationships.

Examples are:

Aurigene — Forest; Novo Nordisk; Johnson & Johnson; MerckSerono, Merck; Procter & Gamble

Ranbaxy — GlaxoSmithKline, Merck; PPD

Advinus therapeutics — Merck

Suven Life Sciences — Eli Lilly

Syngene — Bristol–Myers Squibb

Chembioteck — Forest

Jubilant Organosys — Eli Lilly and Company

GVK Biosciences — Wyeth

Nicholas Piramal — Eli Lilly and Company; Merck.

