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Outsourcing in Biopharmaceutical Industry: India's Value Propositions

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Outsourcing in Biopharmaceutical Industry: India’s Value Proposition

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Abstract: In this paper, we discuss the rationale behind biopharmaceutical outsourcing. We then discuss the benefits, challenges, current trends, and market opportunities. From January 2005, India has agreed to comply with the product patent protection in accordance with the obligations under the TRIPS Agreement of the WTO. This has created new opportunities as well as challenges for the Indian biopharmaceutical companies. We analyze the value proposition of India as a suitable destination for outsourcing in biopharmaceutical industry in the current business scenario. This research will help managers to understand the benefits of biopharmaceutical outsourcing along with its challenges under the current business scenario. Hence, this study is timely and relevant from both an academic and a practitioner’s perspective.

I. Introduction

In today’s global economy, outsourcing has become a very common phenomenon (Alvares et al., 1995; Greenes, 1999; Squires, 2004). While outsourcing has been studied in traditional manufacturing and information technology sectors (Burt, 1996; Hirschheim and Lacity, 1993; Lacity and Willcocks, 1995), it is still in the nascent stage when applied to the biopharmaceutical industry (Ball, 2003; McCreery, 2000). By outsourcing, management can focus their critical resources and competencies on developing new drugs through research and development, improving market share, gaining competitive advantage, generating more profits, and achieving higher customer satisfaction (McCreery and Fracassa, 2003). Many large pharmaceutical companies have outsourced many of their business processes. Factors such as lower costs, improved productivity, higher quality, higher customer satisfaction, time to market, and ability to focus on core areas are some of the benefits of outsourcing. However, there are many challenges and risks associated with biopharmaceutical outsourcing.

There are three major aspects under proposed research that are summarized by the following questions.

1. What are the benefits of outsourcing in biopharmaceutical industry?
2. What are the major factors that contribute to risk in global biopharmaceutical outsourcing?
3. What is the value proposition of India as a suitable destination for outsourcing in biopharmaceutical industry?

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Globalization and Competition

Technological advances, especially in the areas of communications and transportation, have had a profound impact on the business and geographic scope of organizations. Additionally, the opening up of previously closed economies and the emergence of new markets such as India, China, and the former Eastern bloc countries along with a proliferation of multi-lateral trade agreements are presenting tremendous opportunities for firms in their constant quest for increasing efficiencies and profits. Hence, previous limitations on the boundaries of firms are made practically non-existent and tasks that could be accomplished earlier only within the firm are now possible by coordinating with vendors or cooperating with a customer regardless of geographical distance.

Vertically integrated and internal value chains within atomic organizations are now being replaced almost entirely by unit-firm cooperation on a broad and far-reaching scale with the objective of achieving greater efficiencies and returns on investment. Within the pharmaceutical industry, projects are now carried out across several organizations by larger teams of researchers with varied skills and backgrounds from different countries to solve complex problems and make rapid advances in drug discovery, genomics, bioinformatics and pharmaceutical manufacturing (Valazza, and Wada, 2001). As a result, new products, new technologies and services are developed more quickly and meeting the specific needs of the firm by taking advantage of global cooperation in the form of strategic joint ventures, outsourcing, or some variants of teams having complementary skills and lower costs (Valazza, 1998).

Collaboration

For the present day pharmaceutical industry, collaboration is an increasingly important and essential business model. Vendors work with clients to share the development work and hence the associated risk to improve newly created products, custom products, technologies and services. This is particularly important for bioinformatics tools vendors as it is not always possible to create ubiquitous software tools that cater to different customers as there is always a need for customization and tweaking during technical development to suit individual requirements (Kim and Buchanan, 2003).

For biotechnology and pharmaceutical companies, the magnitude in the cost of development of viable products is extremely prohibitive to restrict selling only to local markets. Hence, there is a real need for access to new markets to sustain profits and long term growth. There is a global market for similar health concerns in every part of the world such as hypertension, diabetes, obesity, allergies, and life extension etc., presenting opportunities for firms in developing countries in terms of partnerships and outsourcing vendor relationships with North American and European drug firms which have had a head start over the former (U.S. Department of Commerce, 2003).

Bio-Pharmaceutical Industry Problems

High cost drug discovery economics is only a part of the problem faced by the pharmaceutical industry which is also characterized by escalated investment expenses for research and development, lengthy time for FDA approval and time to market and higher commercialization costs (Stofka, 2001). The total investment

2. Benefits of Outsourcing in Biopharmaceutical Industry

The pace of new techniques in drug discovery are invented faster than can be mastered by any individual company, and planning carefully the scope of outsourcing within the research and development agenda can have excellent payoff in terms of utilizing locally non-existent technology, cost and overall product development time.

We now examine in detail the true benefits of outsourcing as a strategic business decision to acquire specialized and complementary assets, technologies not existent within the firm.

Reduce R&D Costs and Improved Margins

Major pharmaceutical industries spend up to 20% of the total sales in R&D and have traditionally sought to reduce spending by engaging in selective outsourcing of fundamental research activities to universities, government laboratories and research institutes. Hundreds of independent new-generation biotechnology companies have been innovating new technologies aimed as drug discovery and development, outmaneuvering the total number of pharmaceutical products available in the market (Dougall, 2002).

Biotech firms have strategically repositioned themselves as "drug discovery tools companies" aiming to provide research services to drug discovery companies, and research spending by biotech firms alone was estimated to be about $1 billion in a report prepared by Ernst & Young for the Biotechnology Industry Organization (Ernst & Young, 2005). It is practically impossible for any single medium and small sized pharmaceutical company to keep the pace of innovation at the applied research level and stay ahead of the external firms creating innovation in their respective core competencies.

and almost double to sustain previous double digit growth rates. Price containment tactics imposed by medical insurance companies, rising consumer unrest over the high prices, and increased competitive intensity have exacerbated market pressures on pharmaceutical firms to decrease costs of drugs, research and development investments, while generating higher and higher returns on investments (Dahms et al., 2003).

The traditional "biggest-the-better" model of pharmaceutical companies with massive investments in the organization and waiting for the discovery of the next blockbuster drug, casts serious doubts on the sustainability and longevity of such organizations in the present business conditions in spite of favorable outlook on the growth of this industry (Polastro and Tuckman, 2003). The most difficult challenge is the impending expiry of patent rights in several of the blockbuster drugs in the market, potentially resulting in severe loss of revenue for the original innovators. Furthermore, many companies seem to be operating on borrowed time in anticipation of the next blockbuster drug. According to industry sources, drugs accounting for almost 25% of the total sales translating to nearly 80 billion dollars are set to lose patent rights in the next 5 years and are open for competition from generic drugs. The pressure is higher than ever for the need to shorten drug development time and speed-to-market (Robbels, 2000).

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When the Swedish biotech firm Kabigon decided to make its foray into genetic engineering for the manufacture of pharmaceutical products, they did not have any resident expertise but were keen to miss the commercial potential of this new technology. Kabigon decided to jump start into the new trajectory by contracting R&D work to Gencentech, who had developed research competencies and different genetic engineering techniques. Kabigon essentially funded Gencentech to create new scientific techniques and absorbed that knowledge in-house. Without such innovative contracting, it would not have been possible for Kabigon to move quickly into the commercial trajectory of using genetic engineering into its pharmaceutical production system (McKelvey, 2000).

When the task of sequencing the human genome was launched thirteen years ago, the complexity of this project originally estimated to take approximately 30 years. However global collaboration and utilization of global competencies among 16 research laboratories worldwide made it possible to complete this colossal task within 13 years since it started.

Most new innovations in any industry are dependent on computing power and software. No single R&D entity in the world can predict all the possible combinations of applying software and computing power to innovate all possible new products and processes.

A few can strive to gain competitive advantage over its counterparts by discovering sources of lower cost or differentiation in any of its activities (Cullen, 2001) from any part of the world such as:

- New ideas and technologies
- Source of raw materials
- Efficient manufacturing capabilities
- Lower labor cost in other countries
- Lower R&D cost in other countries

Refocusing on Core Competencies

Diversified corporations aim to create and increase shareholder value by strategically orienting themselves either focused on creating new and innovative products or as a services company adept at efficient business processes focusing on cost effective manufacturing solutions and logistics. The pharmaceutical industry is research and development intensive and hence product driven.

The U.S. Patent law allows patenting of newly discovered drugs but not the extraction process of the drug, without enforcing protection from imitation by a difference in just a single molecule. Product differentiation and advertising placed high importance on the adoption and market demand. Hence pharmaceutical companies invested in their own manufacturing capabilities, sales and distribution channels as some of these segments were easily available in the market at competitive prices.

The critical task for the management in the most simplified terms is to create new drugs that almost have no side effects, and inventing new drugs fast customers need, but none exist in the market. Thus of course is a highly difficult and deceptive task. The changing market conditions have given rise to a wave of diversified companies specializing in different segments of the drug discovery process creating a highly competitive atmosphere which the entry of generics has further intensified the competitive nature.
Refocusing on core competencies allow to compete vigorously, for some companies it might be more suitable to outsource their marketing, sales and distribution functions, while other companies find it more suitable to license drug compounds from other companies and capitalize on their own brand equity, established marketing and sales networks and geographical reach. For example, Novartis Pharma, a Swiss pharmaceutical major signed a license with a lesser known company Sigma Tau to develop, manufacture and commercialize the drug compound Gunstatem having therapeutic values for the treatment of cancer (Novartis Media Release).

Time to Market

Time to market is a very critical factor and is often the biggest deciding factor between success and failure of the product as first-to-market wins the allegiance of the market. For example, Pfizer’s Viagra generated sales of 1.9 billion dollars in 2003 alone and still owns a major share of the market. For example Pfizer’s Viagra generated sales of 1.9 billion dollars in 2003 alone and still owns a major share of the market. For example Pfizer’s Viagra generated sales of 1.9 billion dollars in 2003 alone and still owns a major share of the market.

In the biotech and pharmaceutical industry, the early phase of the research can be isolated into its constituent steps of computational power and automated high throughput screening by opportunistically outsourcing relevant areas can result in shorter development times.

Many of the phases that are typically executed in a serial fashion can be done in parallel, by outsourcing operations management to companies that excel in providing efficient drug development timelines by conducting as many steps in parallel. This ability of the external company to detect toxicity of specific compounds and perform target validation efficiently can save time and speed up the process. Outsourcing makes it possible for the sponsoring company to concurrently run multiple promising projects due to the additional resources pooled up from the vendor.

In terms of timing to reduce the time span of the product development life cycle, much potential results from new technological innovations that are made available almost continually by vendor biotech companies focused on innovating tools for drug discovery and establishing outsourcing alliances with such organizations can lead to successful completion of project within or exceeding timelines.

3. Risk Factors

In this section, we discuss various risk factors that are specific to biopharmaceutical outsourcing.

Protecting IP through Patents

In the biotech and pharmaceutical industry, firms hope to earn money through new innovations and creating new technologies through real product differentiation unlike in other industries such as consumer goods or automobiles where innovations are more easily duplicated and they rely on product value competition. Patents are highly effective and remain the single most effective strategy of biotech companies to protect their intellectual property rights.

The U.S. Patent system is a "give and take" bargain agreement between the inventor and the government. The inventor has to fully disclose to the public the invention in exchange for a government protected exclusive right to exploit the invention in the U.S. for a limited time period (Blaug, et al., 2003). Patenting allows the inventors to fully exploit the commercial potential of their inventions without risking theft of their R&D effort by other competing firms.

Given the higher levels of investment and risk needed for the development of commercially viable inventions and processes related to drug discovery and development, the time period of patent protection for patients involving drugs is much higher (20 years) and a request for a further extension of patent rights for a few more years can be filed when nearing the end of patent life.

FDA Regulations

Biotech and pharmaceutical companies choosing to take advantage of contracting firms for outsourcing any activity in the drug development need to be cautious in ensuring the compliance of regulatory requirements of FDA. Vendor firms provide a means of access to resources and expertise without high capital investment costs in equipment. It does not necessarily mean that the FDA regulatory requirements are adhered to unless specified in the contracts and the contract firm has inherent capabilities and methodologies in place for such compliance requirements.

If the contract firms violate FDA regulations, there are potential implications of significant liability to the client and there is a risk of attracting legal sanctions and involves product seizure, court injunction and penalties. To mitigate such risks, the client company should take precautionary measures of reviewing references, review the vendor’s regulatory files and establishment inspection reports at the FDA and consider track records of earlier dealings with the FDA (Kim and Buchanan, 2003).

Maintaining Quality

A quality agreement between the contractor and the client, clarifying in significant detail the quality and regulatory compliance obligations is an important instrument in maintaining quality concerns during outsourcing. The agreement must specify the documents that are expected from the contractor, address the communication of deviations and responsibilities of corrective actions, roles and responsibilities of audits and inspections, and communication of complaints and recalls of raw materials etc. “Guidance for Industry – Cooperative Manufacturing Arrangements for Licensed Biologics” document published by the FDA provides some excellent examples of Quality Agreements in the biotech industry (FDA, 1999).

Pitfalls to Avoid

• "One size fits all", every outsourcing contract is unique and different.
• Outsourcing is not an opportunity to offload internal problems, not knowing what to expect will only lead to uncertainty in evaluating the level of success of the result.

4. Tapping Offshore Resources – India

Western multinational companies are attracted to India today more than ever before as it offers a way to reduce costs in every industry, from software development to insurance claims-processing, and from customer care call centers to income tax.
returns preparation. The second most important reason most large companies propose to expand abroad is in search of specialized capabilities that are not available locally.

A study by a group of researchers (Chung et al., 2002) finds "knowledge seeking" is highly prevalent among companies associated in Research & Development-intensive industries such as pharmaceuticals, semiconductors and electronics. In fact, their research shows that drug makers are twice as likely to seek knowledge abroad as companies in any other industry.

Bio-pharmaceutical industry in India – a Background

India is one of the largest and cheapest producers of therapeutic drugs in the world; it stands foremost among the third world and has excellent technology, R&D and production facilities; a wide range of quality medicines are made locally for most medical conditions ranging from common fever to specialized antibiotics and vaccines (Maria, Ruet and Zerab, 2003).

- Traditionally the industry has been only excelling in reverse engineering and tweaking of drugs focused to sell in the domestic market. However, with the product patent rights regime going into effect from 2005, the major players in this industry are forcibly undergoing a strategic shift in their business models. They are moving from being copycat generic drug manufacturers to innovative drug firms in order to move higher in the value chain of the industry and have woken up to realizing the importance of original R&D work that could lead to filing for internationally patentable New Chemical Entities (NCE) to retain competitiveness.

Pursued with the success of the IT services industry, the government is actively engaging to promote the biopharmaceutical industry by focusing efforts on R&D for creating new molecules, microbial enzymes, gene expression technologies, and a range of genomics and proteomics related activities targeting export markets in drug discovery and development.

India has access to vast resources of well educated and talented workforce and a slew of research centers and world-class laboratory facilities. There are a number of research activities in progress. Biocon, Dr. Reddy's Laboratories, and Ranbaxy are some of the leading companies that have filed for international patents as shown in Table 1. Indian companies have begun to successfully create strategic alliances with global heavy-weight pharmaceutical companies in the areas of drug discovery, development, and manufacture. In addition to high growth rates (Table 2), as shown in Figure 1 India is also quickly emerging as a preferred destination for contracting research in biotech products such as recombinant techniques, enzymes aimed at drug discovery, diagnostics and contract manufacturing (Chengalur et al., 2001).

The presence of a large pool of research community that is fluent in English language (largest outside of the U.S.), biodiversity (presence of a large number of diverse ethnic population), a growing technologically sophisticated pharmaceutical industry (the industry is poised to grow at a rate of 25-30 percent) and India's signing of TRIPS with a pledge to fulfill the agreements, has triggered a large number of western alliances with local Indian pharmaceutical and biotechnology firms and this trend is expected to continue. Some of the high profile partnerships are described in Table 3.

Smaller and intermediate size companies trying to make a foray into India must explore the possibilities of forming a strategic and gainful partnership based on complimentary capabilities; success is hard to come by without such alliances as Indian firms are highly competitive, price and service-capability wise.

Table 1: Key Bio-Pharmaceutical Companies focusing on Research & Development in India

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Headquarters</th>
<th>Specialization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocon</td>
<td>Bengaluru</td>
<td>Drug Discovery</td>
</tr>
<tr>
<td>Dr. Reddy's Laboratories</td>
<td>Hyderabad</td>
<td>Drug Development</td>
</tr>
<tr>
<td>Ranbaxy Laboratories</td>
<td>Mumbai</td>
<td>Drug Manufacturing</td>
</tr>
</tbody>
</table>

Figure 1: Pharmaceutical Market Revenue Breakup (Source: CIBER-OPPI)
There is an enormous scope for outsourcing and cooperative joint ventures in the areas of contract research for drug discovery, design, synthesis and manufacture (of pre-designed combinatorial libraries, formulation development, chemistry and biology services, clinical trials and technical documentation writing according to regulatory guidelines, contract manufacturing of drugs coming off patent (sunset drug compounds) etc.,

Many of the Western biotech and pharmaceutical majors have large libraries of therapeutic compounds and molecules but never prioritized for commercial development because of its lower market potentials. Strategic partnerships with Indian companies can bring low cost clinical trials and manufacturing capabilities yielding new revenues with minimal investment and risk.

Clinical Trials

Conducting clinical trials forms a significant portion of the drug development costs and is time intensive. A heterogeneous pool of genes and the availability of a large number of patients have attracted a number of companies such as Pfizer and GlaxoSmithKline to conduct clinical trials in India. According to estimates by Kotak Securities (2003) it is 40-50% cheaper to conduct clinical trials in India compared to developed markets due to the availability of a large number of physicians, good clinical practices training and the speed of patient recruitments.

However, while most multinational companies conducting clinical trials in India, do so through their fully owned subsidiaries, the design and the protocols of the clinical trials is still not done in India but in their other facilities. Only tasks with clearly defined inputs and outcomes are executed in India. Pfizer, Eli-Lilly, Astra Zeneca are few of the international companies that are successfully conducting clinical trials in India. The sponsoring client company has to take the initiative to design the protocols, monitoring criteria, and predefine data management guidelines. There are very few independent Contract Research Organizations that are already

Table 2: World Pharmaceutical Market Growth by Region (1998-2002)

<table>
<thead>
<tr>
<th>REGIONS</th>
<th>CAGR 1998-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>9.8%</td>
</tr>
<tr>
<td>Europe</td>
<td>5.8%</td>
</tr>
<tr>
<td>Japan</td>
<td>6.9%</td>
</tr>
<tr>
<td>Latin America &amp; Caribbean</td>
<td>8.2%</td>
</tr>
<tr>
<td>Southeast Asia/China</td>
<td>11.0%</td>
</tr>
<tr>
<td>Eastern Europe</td>
<td>8.6%</td>
</tr>
<tr>
<td>Middle East</td>
<td>10.6%</td>
</tr>
<tr>
<td>Africa</td>
<td>3.7%</td>
</tr>
<tr>
<td>Australia</td>
<td>9.8%</td>
</tr>
<tr>
<td>CIS</td>
<td>6.7%</td>
</tr>
<tr>
<td>Total World Market</td>
<td>8.0%</td>
</tr>
</tbody>
</table>

(Source: IMS HEALTH Global Pharma Forecast 1998-2002)

Table 3: Foreign Partnerships with Indian Pharmaceutical and Biotechnology Firms

Table 4: Advantages and Disadvantages of doing Clinical Trials in India

<table>
<thead>
<tr>
<th>Advantages:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Large patient pool with a wide gene pool, quick patient recruitment and recruitment costs sharply reduced</td>
</tr>
<tr>
<td>- Incentives: 10% discount for R&amp;D-investments and no customs duty on materials imported for clinical trials</td>
</tr>
<tr>
<td>- Availability of a large number of western-trained clinical pharmacists, good clinical practices training and the speed of patient recruitments</td>
</tr>
<tr>
<td>- Low costs (patient recruitment costs, infrastructure costs and personnel costs are lower)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disadvantages:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Intellectual property protection challenges</td>
</tr>
<tr>
<td>- Issues on data sharing and the ability to access data</td>
</tr>
<tr>
<td>- Documentation standards are not uniform (for EU, USA, India)</td>
</tr>
<tr>
<td>- Reforms on regulatory affairs are slow</td>
</tr>
<tr>
<td>- No single window clearance, need to deal with multiple agencies</td>
</tr>
</tbody>
</table>

Clinical Trials

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capable of doing these tasks from start to finish without handholding. If a client is seriously pursuing clinical practices in India, the following are the leading companies specializing in this area and can be explored for potential joint venture partners or outsourcing:

- Syngene International Pvt. Ltd.
- Lotus Lab Pvt. Ltd.
- Sirc Genomics

Advantages and disadvantages of doing clinical trials in India are listed in Table 4.

Contract Research Services

The Department of Biotechnology (DBT) in India has been instrumental in creating bioinformatics facilities to accelerate R&D in the areas of molecular biology and modern biotechnology. Numerous national laboratories and university grants have resulted in a large number of fundamental research projects in the areas of functional genomics, microbial genomics, human genome diversity, pharmacogenomics, proteomics, stem cells, bio-computing etc., and has resulted in a large pool of talented research (Patel, 1997; Rudolph and Molitor, 1996).

The programs initiated by the DBT have developed screening programs for a wide range of prevalent genetic diseases such as sickle cell anemia, thalassemia etc., and also resulted in several indigenous diagnostic technologies using genomic information for diseases such as AIDS and vectors for rabies and malaria. Reliance Life Sciences and the National Center for Biological Sciences are among the 8 institutions in 5 countries that have been identified by National Institute of Health (NIH) in US as sources of embryonic stem cell eligible for U.S government federal funding.

International pharmaceutical companies however have been very apprehensive of realizing any significant R&D investments in India, mainly because of earlier bad experiences with weak intellectual property protection laws. There is a change in attitude and mind set since the signing of WTO and there is a large pool of talent. Bioinformatics vendors specializing in it.

While the global bioinformatics market is estimated to be $9.8 to $14.6 billion (U.S. Department of Commerce), the Indian market is estimated to be a miniscule $2.2 million (Confederation of Indian Industries). The Indian bioinformatics market is estimated to grow to approximately $15-20 million by 2006 (Prabhu and Bhargava, 2003), and IDC India predicts a more exponential growth to nearly $130 million mainly from distributed computing, storage and data handling, data mining, genotyping, DNA-Sequencing applications, and software services.

India’s Advantages in Bioinformatics

The numbers indicate that the bioinformatics industry in India is clearly still in its infancy state but the business conditions offer a tremendous opportunity in view of the presence of the strong Information Technology knowledge and skills and the local presence of a large number of biotechnology and pharmaceutical companies that are hungry for innovative low cost bio-informatics solutions targeting a range of activities from drug discovery to data management.

The government has been careful not to miss the bio-informatics opportunity and was instrumental in establishing the Department of Biotechnology India (DBT) way back in 1986 to oversee the establishment of necessary infrastructure by creating the Biotechnology Information System (BTIS) network that connects 57 research centers across the country to provide state of the art tools, education, and information in bioinformatics. Many specialized educational programs have been introduced in the universities by DBT to meet the challenge of skilled technical professionals.

India’s Challenges in Bioinformatics

The key to realizing the bioinformatics revolution in India is the technical expertise and skill of manpower, vertical knowledge in IT and superficial knowledge of life sciences is not enough. Substantial levels of development skills are necessary to integrate diverse fields of life sciences, mathematical knowledge with the latest in information technology. The management challenges of such complex projects are not trivial either. There is a shortage of this highly specialized workforce to be able to duplicate the low cost process stream in standalone IT applications.

The entry barrier to small companies are high and the venture capital and other sources of funding are difficult to attract since product development times and Return-on-Investment (ROI) are longer. Bioinformatics outsourcing activity is mainly done

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internationally competitive prices and there is a large pool of scientific talent and engineering base.

Bioinformatics and IT Services

Bioinformatics and IT services are extensively used in all the phases of drug discovery and development, as the services and standards are beginning to be mastered with well defined processes in place, bio-pharmaceutical firms are beginning to view ‘bio-informatics’ as a more standardized component not related to their core competency (drug discovery) and are outsourcing bio-informatics projects to vendors specializing in it.

According to OPPI, there are about 60 (FDA Approved) drug manufacturing plants in India which is ranked second only to the U.S and correspondingly the world no. 2 in Drug Master Filings (DMF), which is manufacturing of bulk drugs for supplying to other large generic drug makers and for self consumption. KPMG Securities reports, India accounted for 34% of the global DMF filings in 2003 (compared to 2.4% in 1991). India offers an excellent manufacturing base at
within the US, mostly by small and medium size businesses as large companies tend to have the capability within the firm. Convincing companies to outsource projects to India can prove a significant marketing challenge.

Intellectual Property (IP) Development and Protection

The Indian Patent Act was passed in 1970 to protect intellectual property, the laws were formed to limit the influence of powerful multinational drug firms from monopoly, and there were many elements of safeguards introduced to make easier access to drugs by common people. Product patents were not protected and only the duration of such patent enforcement existed only for 7 years instead of 14 years elsewhere.

It allowed India to produce generic drugs at a fraction of the cost compared to Europe and America, leading to a rapid increase in the domestic production of generic drugs and bulk formulations, many of which were reverse engineered and molecular level tweaked copies of blockbuster drugs. The domestic pharmaceutical industry has grown its market share from 25% in 1970 to almost 70% presently.

The loopholes in the patent laws largely prevented global pharmaceuticals to view Indian market with scepter and have preserved any significantly large deals in the subcontinent. India’s entry into the WTO fold in 1995 and its agreeing to ratify all the obligations of patent laws from 2005 has forced a paradigm shift in the perspectives of the global biotech and pharmaceutical multinationals.

See Tables 5 & 6 for relevant Indian laws and the implications of India’s ratification in the WTO.

Table 5: Laws Related To Patents for Drugs in India

  - Drug not patented is subject to patent, but may not be imported
  - Product patents are only allowed for new chemical or drug not included in period of only 7 years and compulsory licensing allowed
  - WTO (1995)
  - India’s entry to the WTO (World Trade Organization) resulted in changes in Indian laws
  - WTO guidelines required that an adequate level of protection needs to be provided for pharmaceuticals
  - The duration of patent must be consistent with 20 years, the period of the patent is extended by 5 years for clinical trials

Table 6: As a WTO signatory, the obligations to be fulfilled by India

  - 20 years for new chemical entities
  - 14 years for new drug entities
  - Use of patent specialist staff to handle quicker processing of patent applications

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Regulatory Affairs

Indian companies aiming at the global market use the USFDA guidelines for drug approvals which is considered the most rigorous approval process. There is an absolute lack of one single agency that takes the responsibility to ensure the safety, efficacy, and quality of drugs in India. There are multiple agencies that are seriously understaffed which oversee the drug approval process and they do not have an adequate number of specialists in medical science.

There have been some significant efforts to reform the regulatory affairs related to drug development and clinical trials in India on the lines of the FDA; the Indian government has made it compulsory to follow the technical requirements mandated by ICH (International Conference on Harmonization) for registering all pharmaceutical products intended for human use. Compulsory following of Good Clinical Practice guidelines for clinical researches designed to be conducted in India has been mandated.

Until recently, the Indian government regulations for drugs required clinical trials for new drugs not discovered in India must be one phase behind the rest of the world and phase II and phase III trials for new drugs were not allowed simultaneously. There have been recent amendments in the Indian drugs and cosmetics act (schedule Y) to describe newer guidelines similar to the FDA's for clinical trials and allows simultaneous Phase II and III trials. However, the recommendation to allow Phase I trials of new foreign drugs in India concurrently with those that are conducted abroad is yet to be ratified.

Key Reforms

In response to the Indian biotech and pharmaceutical industries plea, the government has taken some positive measures to increase R&D activities and encourage foreign participation in the industry. There are proposals to:

- Scrap the price control orders of the government as this is a major discouraging factor for R&D investments for new drugs which warrant huge capital investments. Price control reduces returns on investments and stretches the time span during which the costs can be recovered. However, the government is willing to reduce the number of drugs in the preview of price control and gradually move away from price control on bulk drugs.
- Allow conducting of Phase I trials in India simultaneously while being carried elsewhere as this will lead to faster access to new drugs in India and promote the growth of clinical trials business revenue in India due to significant costs saving factor.
- Reform and streamline the regulatory agencies to grant approvals in a timely predictable manner and encourage a single agency for approvals on the lines of the USFDA.
- Reform the patent protection agency by strengthening of the appropriate legal frameworks and higher penalty for violations. Increase the size of patent specialist staff which is currently grossly understaffed to handle quicker processing of patent applications.
Outsourcing in Biopharmaceutical Industry

Bioethics

In spite of the existence of some laws and legislations to protect bio-ethics for humans, India lacks the frameworks, mechanisms, and appropriate provisions for strict enforcement of the legal requirements. There have been many instances of violations of the poverty, illiteracy, and ignorance of certain sections of people to be recruited as clinical trial patients and to be treated as human subjects without proper consent and information. International companies conducting clinical trials in India need to ensure the vendor company's compliance and technical credibility of confirming to international norms in order to protect itself against public backlash due to negligence.

Great Risks and Concerns

In spite of the enormous potential for India to grow in the area of biotechnology, the immediate benefits for multinational firms may not be high. There are many challenges in securing good infrastructure such as faster transportation, power, and bandwidth. The IT industry has thrived and prevailed in spite of the enormous shortcomings by operating at small islands of prosperity by building their own captive infrastructure such as local power generation and facilities. However, the investments needed for similar operations of bio-pharmaceutical companies are much higher and the returns take much longer.

There is widespread recognition while dealing with government organizations for logistics and establishment. It is very important for smaller and medium sized firms establishing offices in India to use the services of companies that specialize in providing logistical, logistics, and tax areas. Hence, the right vendor who has historical credibility and can help make things happen, a partner with a comprehensive set of capabilities that can be customized to the client's specific needs will decide the success or failure of off-shoring endeavors. Many participants in our survey have expressed discontent with the bureaucratic problems and have had their hopes dashed by using companies from Indian origin. Table 7 lists the SWOT analysis for India and Table 8 highlights key players in the Indian pharma-biotechnology sectors.

5. Conclusions

In many large biopharmaceutical organisations, outsourcing is a very common trend and will continue to grow in the future. Some of the main benefits are reducing R&D costs, improved profit margins, establishing global alliances for contract research and well as tapping into new markets, access to global skills and time to market the product. We have discussed the major risk factors associated with outsourcing.

In addition, we also analyzed the value proposition of India as a major player in the area of biotechnology outsourcing. India provides some good opportunities for global pharmaceutical and biotechnology companies as a possible source for contract research, clinical trials, contract manufacturing, and bioinformatics. However, there are some challenges which we discussed. This research will help managers to understand the benefits of biotechnology outsourcing along with its challenges. Hence, this study is timely and relevant from both an academic and a practitioner's perspective.

Table 7. SWOT Analysis of the Bio-pharmaceutical Industry in India

<table>
<thead>
<tr>
<th>Internal</th>
<th>External</th>
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Indian companies are undergoing a major strategic shift from generics manufacturing under protectionist regimes to compete with innovative international firms in preparation for the WTO regime. There is a large gap in terms of over-
“handbolding,” the cost advantages are significant to ignore and worth the effort not in the extent where it can be totally expected to be delivered without being done properly.

offered remain an important impediment change in the near future but issues concerning infrastructure and procuring international raw materials in a timely fashion without bureaucratic delays still remain an important impediment.

Finally, the push to innovate to create new drug molecules, proteins, and intellectual property will be critical for long term success. Medium and small size firms looking towards cutting costs can definitely take advantage of many benefits offered by India, the knowledge, willingness and skills are definitely available but not to the extent where it can be totally expected to be delivered without some “handbolding,” the cost advantages are significant to ignore and worth the effort if done properly.

Table 8: Key Players in India

<table>
<thead>
<tr>
<th>Company</th>
<th>Sector</th>
<th>India Company</th>
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<tbody>
<tr>
<td>Zydus Cadila</td>
<td>Pharmaceutical</td>
<td>Acdelrys India</td>
</tr>
<tr>
<td>Dr. Reddy’s Labs</td>
<td>Pharmaceutical</td>
<td>Acdelrys India</td>
</tr>
<tr>
<td>Cipla</td>
<td>Pharmaceutical</td>
<td>Acdelrys India</td>
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<tr>
<td>Indian Drugs</td>
<td>Pharmaceutical</td>
<td>Acdelrys India</td>
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<tr>
<td>Ranbaxy</td>
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<td>Acdelrys India</td>
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<tr>
<td>Sun Pharmaceutical</td>
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<td>Isis</td>
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<td>Acdelrys India</td>
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<tr>
<td>Nicholas</td>
<td>Pharmaceutical</td>
<td>Acdelrys India</td>
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6. References

11. Food and Drug Administration (1999):
http://www.fda.gov/cber/gdhtslcoopmfr.pdf
Appendix A: Summary of Key Regulatory Agencies in India

ICMR: Indian Council for Medical Research

Role: Evaluation of new drug applications. Biotech drugs are reviewed under no expert panel.

DGCI: Drug Controller General of India

Role: DGCI is the executive head of the CDSCO and provides a number of divisions during the conducting of clinical trials. DGCI has also announced the guidelines for GCP based on ICH.

CDSCO: Central Drug Standard Control Organization

Role: Ascertain efficacy, safety and quality of drugs.

FSCA: Food and Drug Control Administration

Role: State regulatory body involved in regulating counterfeit drugs.

Appendix B: Summary of Guidelines for Drug Discovery Clinical Practices and Retail Sales

Drug and Control Act

Governs the drug approval process in India.

Schedule V: Standards about patents for proprietary therapeutic medicines

Guidelines on conducting of clinical trials for new drugs

Drugs Prices Control Order

The DPCO provides the government the power to fix the maximum retail prices of certain bulk drugs and drug formulations. It ensures that the drug is available to the population at an affordable price. The National Pharmaceutical Pricing Authority (NPPA) takes the authority to collect data and study the pricing structure to fix the ceiling prices. It is estimated that only about 35% of the total available drugs in the market are governed by the DPCO. [Source: http://www.performanceindia.org]

ICH Q7

The Good Clinical Practice prescribed by the International Conference for Harmonization

The Environment Protection Act

The EPA serves to protect the pollution of the environment by governmental and other biological pollution.
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