6. Building Contract Manufacturing Industry

6.1 Contract Manufacturing Opportunity

Three major developments suggest that Indian drug manufacturers are set to benefit from an outsourcing boom. First, an upsurge is taking place as a number of top-selling drugs come off-patent in the next 5years and the pressure on profitability and differential in cost structures are expected to force the Pharmaceutical companies to outsource (refer table 21 & chart 20). Second, after India has become TRIPS compliant, the discussion is what to source to India than whether to source. India's capability with respect to APIs or formulation production cannot be ignored. Although it is painful to shut down plants or shift products to either India or China, today's CEOs have no choice other than reducing the overheads of their local manufacturing divisions.

Table 22: Comparison of Cost Advantage in India (%)	
Costs in the Western Countries	100.0%
Production costs	50.0%
R&D Costs	12.5%
Clinical Trials Cost	10.0%
Source: Pharmexcil Research	

The global market for contract manufacturing of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 billion, although the over-the-counter medicines and nutritional products sector will show the fastest growth. Asia has recently been challenging North America and Europe's traditional domination of the global pharmaceutical contract manufacturing market. India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates.

India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system. Although, most will be unable to develop the financial muscle necessary to embark on R&D for innovative new products, but the scientific, technical and manufacturing skills, developed under the country's 35-year process patent system, perfectly matches the requirements of global drug manufacturers who are increasingly seeking to offshore many manufacturing activities previously performed in-house.

Indian successes in this area have already created some significant international developments. Several Indian firms like Jubilant Organosys, Dr Reddy's, Nicholas Piramal, Shasun Drugs, Bilcare, etc, have made acquisitions in this area.

Pharmaceutical production costs are almost 50 percent lower in India compared with western nations. India's long-established manufacturing base also offers a large, well-educated, English-speaking workforce, with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers with 1,500 PhDs. These English speaking capable science graduates or postgraduates can be employed on the shop floor in India as Indian manufacturers can afford them. The understanding of chemical/manufacturing processes is so good that India has won significant number of regulatory approvals from world's best agencies.

However, unlike IT services, it is difficult to shift Drug manufacturing activities from existing locations to India. A product outsourcing or relocation decision means approvals of the product from the new contract facility, necessitating substantial costs and investment in lot of scientists' time in proving the equivalence, in each and every country where the product is approved. This by no means is an easy task. However, there are compelling reasons to outsource, such as significantly low manufacturing costs or cost of refurbishing obsolete facilities or shut down decisions due to patent expiries of branded drugs. Obviously, such market capture although is tedious it is long lasting. India's competence with regulatory skills and other technical and human resource capacities qualifies it to capture the first movers' advantage in this respect.

Although the opportunity is very large, currently the sector is dominated by only API business deals. Global leaders need considerable capacity at a single unit to outsource formulations. For example, if a company out sources ten formulations to ten plants in India, all ten will require inspections by several country regulatory agencies and it is considerably expensive and risky. As global leaders' requirements are huge, outsourcing capacity available for such companies is inadequate at a single point. This is the reason that the Industry has been investing heavily on capital expenditure in the last few years in augmenting their capacities.

Practically all economies with either high wage cost for scientific staff or having insufficient population and consequent economies of scale are willing to outsource from India. In the API segment, issues are less complicated and the sourcing is intense. In the long run integrated services of supplying APIs as well as formulations will help manage inventories, logistics and cost structures. Capacity building, Increased testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories will draw contract manufacturing to India than China.

Investing in Key Links to Accelerate Outsourcing Business

Government should promote capacity building in testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories urgently through policy action, appropriate incentives and venture capital. Such facilities can be made available to SMEs at subsidised rates to reduce entry barriers and encourage competition from start-ups in drug discovery and other key growth segments.

6.2 Challenges for Contract Manufacturing Industry

By its nature, the contract manufacturing segment needs intense capital expenditure, high scientific skills in managing regulatory compliance and meeting international environment standards. The decision of outsourcing in large corporates is a serious one and it has to meet corporate objectives along with economic motives. There are several tax efficient locations in world and the segment is well understood by China as also by certain European nations. However, once contract manufacturing moves to the country, the business is secure for several decades. This aspect has to be understood and necessary concessions have to be given.

API and formulation SEZs consciously built will be able to compete in the global market. Due to peculiarities of the industry, it takes three to four years to set up the facility, validate it, get inspected and obtain marketing approvals. The costs in terms of filings, inspections, government fees for products, etc., continue for several years until a broad portfolio of products and markets take place. The commercialization is slow. Generally a twenty year business view is taken for such decisions.

Promoting SEZs to Accelerate Contract Manufacturing

SEZs should be promoted consciously in the area of formulations and APIs to ensure that Indian industry compares at par with international locations.

In reality contract manufacturing means inputs for conversion are given by the third party and the processing charges only are actually billed. However, in India in reality the inputs are purchased and imported by the contractors and finished drugs are sold to the concerned party again. The customs clearance permit bond system needs to be reviewed as it has not helped contract manufacturing for a variety of reasons. In this system, the working capital burden is intense for the contractors. Moreover, while developing a new location, MNCs cannot change the locations of input and output at the same time. Hence, inputs come from the current approved locations while the output location changes. Subsequently, there will be motivation to change the input location also to India. There are procedures

available to do real contract manufacturing in international market, where inputs come from outside and go back after conversion.

Resolving Hurdles in Contract Manufacturing

The Government may look at developing a practical and operable system, which should be adopted by contract manufacturers where in the goods come for processing without paying any duty and go back with out any duties except for the processing costs or value addition. The system should have compliance of Drugs & Cosmetics Act as such manufacturing requires lot of documentation meeting the regulatory requirements of various destination countries. Typically, the inputs come from a country and the output will have to go to several countries. Even in standard contract manufacturing, there are issues of free sale certificates, etc. hence there is a requirement for an interdepartmental action to appreciate the issues involved and develop appropriate departmental notifications.

Another important challenge is the lack of bargaining power with respect to various obligations imposed in agreements. For example, in the current structure, the manufacturing and compliance responsibility lies with Indian contractor. There are natural business risks like inspection failures or supply failures, etc. Many small scale or medium scale manufacturers do not have enough legal acumen or access to legal capacities to understand the issues in various clauses such as reputation damages, consequent damages, price fluctuations guarantees, etc.

Pharmexcil's Role in education on Intricate Issues in International Contracts

In the interest of manufacturers, Pharmexcil should develop standardized agreements and caution on various clauses and their implications to the firm in the long term. A one time effort employing international experts will raise the standards of understanding in this regard.

In the context of contract manufacturing, economies of scale are achievable when certain product or product groups are produced for various countries. In this context, unlike past, the same product gets registered in different countries in different forms in different brand names or in different colours or shapes as per the strategies of the international firm. The contractor stands a good chance of economies of scale if the firm can source applications of the product from several firms to increase production volume. In this context the same product may need multiple brand name or generic licenses for different firms matching their individual needs. Each importing country demands free sales certificates, CPP, etc. Necessary clarifications or orders empowering regulatory bodies should therefore be undertaken. If required appropriate changes in law may be made.

Often high level executives of importing organisations from various countries visit facilities before giving business. In China, governmental representatives are commonly invited when major buyers visit. These government representatives assure international businessmen in case of any aspersions on infrastructure and conditions of production and some times resolve difficulties expeditiously. There is a perception problem in the minds of global business men over handling of bureaucracy. A proactive role for the government in this sphere is clearly made out.

Often contract manufacturing relationships with big firms may take up significant management time if appropriate positioning does not take place from the beginning. It would be tempting to say that Indian companies may tie up with large multinational companies for contract manufacturing and the same would always be profitable for them. In reality however, the last few years have seen pharmaceutical alliances become more and more complicated, requiring significant resources simply to manage. According to a survey 85 percent of senior officials of the pharmaceutical industry expect the number of alliances to increase over the next few years.[12] In order to enter into an effective partnering with the outsourcer companies, Indian CMOs need to adopt any one of three kinds of commercial arrangements:

(i) Long-term supply agreement for pure contract manufacturing with total transparency in the pricing structure (such arrangement works well with professionally managed long-term players)

(ii) Using the capabilities of the partner for process technology development and utilize their facilities for scaling-up and further commercialization; and

(iii) Work on a contract research basis with laboratory space dedicated to the purpose of research on a full time equivalent (FTE) basis, where the innovator has the complete freedom of research design and process (such arrangement works well when the Indian partner is capable of providing world class infrastructure at a competitive price)

Intricacies in Negotiation of Contract Manufacturing

Pharmexcil should organize learning module on contract manufacturing negotiations and help small and medium scale entrepreneurs appreciate the issues of short term and long term. There exists a case to evaluate whether company law provisions have to be amended to bring in exclusive licensing of substantial capacity on par with hiving-off substantial assets.

[12] Ameet Mallik, Brett Zbar, and Rodney W. Zemmel, "Making Pharma Alliances Work", 2004 (1) *The McKinsey Quarterly*, available at **www.mckinsey.com**.