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Globalisation of biotech offshoring

Thursday, December 21, 2006 08:00 IST

Stephanie Finnegan & Karl Pinto

There are about 3,000 biotechnology companies in the world; only 100 have approved products. The rest rely on private and public equity capital markets for their survival - until they can sustain business with one or two approved products. Building manufacturing capabilities is in most cases inefficient and in many cases not viable at all. Thus, numerous contract manufacturing organizations (CMOs) have emerged to satisfy a demand for outsourced manufacturing.

The biotech CMO industry gained significant momentum in 1997 with the US FDA Modernization Act, which eliminated ELA and PLA (establishment license and product license applications) and combined them into a BLA (biological license application). A product's sponsor became its sole license holder. The use of outsourcing became possible because a manufacturing site no longer had to be in on the ownership or sponsorship of a product, and each product sponsor was deemed "the manufacturer," even if manufacturing was outsourced.

For a decade, that has served the industry well. Nearly all biotech companies outsource to some degree. A handful of companies with robust product pipelines and one or two approved products find that it makes economic sense to build or acquire their own manufacturing capability for those products. The rest (some 97% of companies) find that some degree of development and manufacturing outsourcing is necessary. The United States, Canada and Europe have been dominant sites for biopharmaceutical product discovery and development activity - and accordingly, for contract manufacturing. Companies such as Avecia, Lonza, Boehringer Ingelheim, DSM and Diosynth have become dominant. Those giants of the CMO arena serve Phase-3 and licensed products well. Together with mid-sized, niche CMOs including Cambrex, Laureate, Avid, Apptech and Goodwin, the universe of CMOs offers fully integrated process development and GMP manufacturing service offerings for products from preclinical through product approval.

Cost of goods as an industry driver

The biotech industry, though still young by most standards, has reached a point that is critical to all maturing industries: the need to meet market demands for reduced cost. As a

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discovery activities in India" The Bangalore-based Aurigene Discovery Technologies Limited, an independent subsidiary of Dr Reddy's, is now competing in a mature contract research organization space in the country.

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case in point, while the direct material cost of goods of many pharmaceutical (small molecule) commercial products is between 3% and 8%, the direct material cost of biotech products can be as high as 45%.

Biotechnology is also finally facing the challenge of lower cost "me-too" products (biogenerics or biosimilars), which will inevitably drive prices down. More so than classical pharma, we need to drive down costs of even novel therapeutics. Otherwise, managed health care in developed nations and a lack of social services, dollars and infrastructure resources in underdeveloped countries will keep many biotech products from much of the global population.

Many industry experts and well meaning bureaucrats have entirely misunderstood the way to ensure provision of novel and life-saving biotherapeutics to the masses. They speak of "price controls." But underappreciated is the fact that profit incentives are what enables the United States to develop four times as many drugs as the rest of the world combined. History has shown that 'price controls' cause an immediate and profound retraction and reduction in pharmaceutical R&D budgets. Biopharmaceutical companies must continue to make satisfactory margins and recoup their R&D expenses, but cost of goods must come down. The industry must find an efficient business model to lower prices while maintaining margins.

The industry recognizes that need. Every biopharmaceutical conference showcases enabling technologies to improve yields through cell line engineering, media optimization, cell culture methods, purification improvements, and protein production by less expensive bacterial or transgenic expression systems. Such technology platforms are the much-heralded subjects of licensing transactions announced in the biotech news press almost daily. Important strides are being made in improving productivity.

Outsourcing to reduce cost of goods

The make-or-buy decision was a hot topic in the 1990s, but that argument has long been settled. It is accepted that unless a company has one (preferably two) approved products and a strong clinical pipeline, outsourcing is a more economical way for it to manufacture than in-house production.

Even with a CMO's profit markup, its optimized spreading of fixed costs across a number of clients lowers the cost of goods for each product sponsor as compared with construction and fixed-cost maintenance of a captive biopharmaceutical manufacturing facility operating beneath its break-even capacity use. And it is widely accepted in all industries that any strategy that converts fixed costs to variable costs is a savvy way to handle periods of market

softness or economic downturn.

Smart outsourcing also provides for efficiencies due to core competency "right-sizing." Few companies want (or can afford) to develop multiple sites and core competencies. CRO, CMO, and CTO partners (contract research, contract manufacturing and contract testing organizations, respectively) specialize in a variety of tasks including toxicology studies, viral validation, biosafety testing and characterization, process development, early phase preclinical and clinical manufacture, late-phase clinical and licensed-product manufacture, formulation, fill and finish, and clinical trials management. Use of specialists and sites that are designed appropriately for a product's stage of development can greatly reduce the cost of goods for a product sponsor.

Global manufacturing and offshoring

Lately, the concept of outsourcing by "offshoring" has become a popular topic of discussion, and various countries are targeting biomanufacturing as a high impact industry. In view of the tremendous impetus to reduce cost of goods and especially in light of the exponential growth biotechnology promises, this industry is highly visible and has been seriously evaluated by nearly every government. The dominant players in this nascent trend are in Asia, predominantly India, China, Singapore, and South Korea, with Malaysia emerging as a candidate also.

India has already become the premier site of offshoring with overwhelming success in the "other" high-technology sector, information technology (IT). If you ask an Indian citizen to name the two greatest areas of growth for that country, the answer will most likely be "IT and BT" (biotechnology). Asia in general is a logical choice for biotechnology; in particular for outsourced bioprocessing, because of low labor costs and excellent universities that churn out more engineers and scientists than North America and Europe.

Houssain Mooraj and Colin Masson of AMR Research recently wrote, "Pharma companies have little choice but to capitalize on the dramatic cost efficiencies that can be attained by working with global CMOs and redesigning their own supply networks". Asia is named as the geographic center of global contract manufacturing in nearly every article concerning outsourcing and offshoring of biopharmaceutical production.

The benefits of manufacturing in Asia are largely accepted. But the relative advantages and disadvantages of the "most-favored nations" are subjects of wide debate. Industry wisdom suggests that most of Asia shares the key benefits of low labor cost, excellent universities, and the concomitant availability of skilled technical workers - with the most significant downside being difficulties in protecting

intellectual property (IP).

China

Eliza Zhou of BioPlan Associates has written that "with \$25 billion in excess pharmaceutical production capacity in China . . . almost half of its production facilities are standing idle". The logical strategic move for such companies is to move into bioprocessing. Such a move is perceived as a way to springboard China into international recognition for GMP compliance in biotherapeutics. China has decades of experience in the manufacture of small molecules, and its proponents would also argue that the country's university system is adept at training skilled biologists. The Chinese government strongly supports a contract bioprocessing agenda. Its administration has set forth the support and furtherance of contract manufacturing as a long-term goal. Experts perceive a cost advantage (labor, materials, and infrastructure) in China compared with the rest of Asia and expect that to be sustainable over five to ten years.

Pitfalls include a language issue that is not present in Singapore or India. IP protection is also perceived to be a greater problem in China than in India and other Asian countries. Astonishingly, counterfeiting and piracy are worth up to one third of China's GDP, by some estimates. According to biotech banker G. Steven Burrill, to gain FDA approval a Chinese CMO would need to develop a relationship with a US-based drug developer first. Key biopharmaceutical CMOs in China include Beijing Kawin Biotech Co., which produces 100 million vials of interferon annually. Others are Hangzhou Acon Biotech, Shenzhen Watsini-gene Engineering Co., and the Liuyang Biopharmaceutical Park.

Singapore was one of the first countries in Asia to consider biotechnology a high-impact industry and strategic imperative. As an "early adopter," Singapore is well along in its quest to garner success. Early on, it had the support of both its government and university system. In 2003, Singapore opened Biopolis, a \$500 million medical science park that, according to Burrill, "was conceived as a cornerstone of a broader vision to build up the biomedical sciences industry in Singapore". Government support in the form of the Agency of Science, Technology, and Research (A*STAR) is provided and funded under the aegis of the Ministry of Trade and Industry.

The market value of Singapore's biomedical manufacturing output was (in Singapore dollars) S\$18 billion in 2005, which represented a 10% increase over 2004. Key developments included Novartis's initiated construction of a S\$310-million tableting plant. GlaxoSmithKline began construction of a pilot plant, and Canadian CRO MDS Pharma Services opened a laboratory in Singapore to support clinical trials. Key advantages of Singapore encompass the language,

business climate, and legal system (including IP protection), paralleling that of the United States and Europe. Disadvantages include the lack of sustainable cost advantages and potential difficulties in sourcing sufficient key personnel.

Making a major splash in biotechnology headlines in 2003 was Celltrion, located in Incheon near Seoul, South Korea. Celltrion began as a joint venture between San Francisco-based Vaxgen and a group of South Korean investors. Its plant was conceived to be used for vaccine (HIV and anthrax) and therapeutic protein production, and validation was expected early this year. The intention was for Celltrion to be in part a captive manufacturing plant for vaccines but to make recombinant proteins (especially monoclonal antibodies) as a CMO. It is likely that Celltrion will be a pure CMO in the future.

South Korea is a late entrant into this field. Its government spent six years developing a "Biotech 2000" plan in which it aimed to make the country into a top-seven biotechnology producing country by 2010. Between 450 and 600 Korean companies are said to be using biotechnology in some aspect of their business, numbers that include all biotech, not just health-care applications.

India

India's well-developed pharmaceutical sector has already encountered and surmounted the challenges of quality and compliance, having engendered more FDA approved facilities than any other country outside the United States. The Indian economy is growing exponentially, significantly kindled by the country's becoming a location of choice for offshoring of IT services. As a result, India is a proven winner in the successful execution of offshored high-technology services, and there is no reason to believe that its success in IT cannot be repeated in what Indians call "BT."

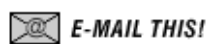
Furthermore, India enjoys an excellent university system that annually produces four times as many engineers than the United States does. This skilled workforce earns 25-40% of the average US worker. English is widely spoken in India, at least one pleasant result of the country's history as a British colony. India's business climate is friendly, and its legal system is based on the British code of law. India also has a huge and surprisingly heterogeneous population, making for clinical trials with relatively rapid patient accrual rates and cost structures of less than 25% compared with US trials. Many of the country's billion people reside in or near major urban centers and are therefore easily reached, recruited, and monitored. And most of that population qualifies as "treatment naïve." Finally, a deep rooted understanding of global GMP processes and Government

incentives (each State has a Biotech Policy) coupled with innovative Biotech Parks and biotech clusters make biotech manufacturing in India an attractive proposition.

Disadvantages of doing business in India include a governmental infrastructure that has "not caught up with growth in the technology markets". Further, IP protection is a perceived issue in spite of India's GATT obligations and requirements. The jury is still out on how such requirements will be enforced, but it appears that global pharma majors seem to be giving India the benefit of the doubt. "Over 75% of the top 50 Western biopharmaceutical companies are conducting drug development activities in India", according to Eric Meyers of Cambridge Healthtech Associates. It is also safe to assume that products in clinical development will not be subject to loss of IP protection because the reverse-engineering paradigm that India has become accustomed to has always involved commercially approved products. According to the Boston Consulting Group, "The very same multinational pharmaceutical companies that once denounced Indian pharmas now partner with them and entrust them with vital R&D".

A novel solution

In a study by Sandra Fox's High Tech Business Decisions, the concept of global offshoring of biopharmaceutical manufacturing was met with mixed opinions. The overwhelming advantage stated by respondents was cost savings. Likewise, the overwhelming objections were (perceived) lack of IP protection as well as difficulty in managing, communicating, and ensuring quality in a global relationship. As Burrill noted, Chinese CMOs will need to develop relationships with US companies to gain FDA approval. Likewise, small to mid-sized biopharmaceutical companies will not be able to confidently and economically avail themselves of Asian relationships because of the difficulties so aptly noted by the respondents in Fox's study. This would imply that only big multinationals which can afford to surmount the geographic and cultural barriers and successfully conduct business so far afield can leverage the advantages that offshoring offers, unless the CMO industry itself provides options to the smaller players. (Stephanie C. Finnegan is CEO of Goodwin Biotechnology, Inc. and Karl Pinto is chairman of Goodwin Biotechnology and a director of Wallace Pharmaceuticals.)



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