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Section: Features

Consolidation and Differentiation: Key Drivers of Change in the Global Pharmaceutical Manufacturing Industry

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Policy-driven changes in healthcare spending and the growing significance of generic competition are acting in tandem to force pharmaceutical companies to adopt more cost-effective manufacturing strategies resulting in an upsurge in the level of M&A activity in the industry as drugmakers consolidate to reduce costs, diversify product portfolios and expand geographic footprints. This whitepaper provides an overview of the pharmaceutical manufacturing landscape with a special focus on generics and biopharmaceuticals. PharmaVentures will also share unique insight gained from the divestment of manufacturing operations for some of the world's leading pharmaceutical companies.

Matching Supply and Demand in Medicine

Global spending on medicine reached US$882 B in 2011 with an expected 3-6% CAGR over the next five years [1]. Proprietary drugs (including small molecules and biologics) accounted for approximately two-thirds of global pharmaceutical spending to date (Figure 1). Nevertheless, the spending on proprietary products is expected to plateau owing to diminishing numbers of new launches, loss of patent and subsequent generic entry in the next five years. Consequently, the market expects to see an accelerated shift in spending on generics. The global generic market is forecast to rise at 11-13% CAGR to reach US$400-430 B in 2015 [1]. Price sensitivity and demand on drug supply undoubtedly have profound effects on the nature of the pharmaceutical business.

Major global pharmaceutical companies have been strengthening their revenue streams with generic product sales mainly through acquisitions or strategic alliances with generic manufacturers, such as the joint venture formed between Merck and Sun Pharmaceutical Industries in India last year [2]. The alliance allows Merck to promote the development, manufacture and commercialization of generic medicines in the emerging markets. Other leading innovator pharmaceutical companies who are also scaling up their generic business include GSK, Pfizer, Novartis and Sanofi. Amgen, the world's largest biotech company is also following the trend with the recent announcement of their US$700 M acquisition of the Turkish firm, MN Pharmaceuticals, a maker of injectable generics for sale in its home country and the surrounding region [3].

Many pharmaceutical companies have relied on M&A deals rather than organic growth to gain market share in the generic sector. An M&A strategy allows them to effectively secure high-quality active pharmaceutical ingredients (API), diversify product portfolios, achieve economies of scale and, most importantly, expand their presence in emerging markets where growth is predominately driven by generic drugs.

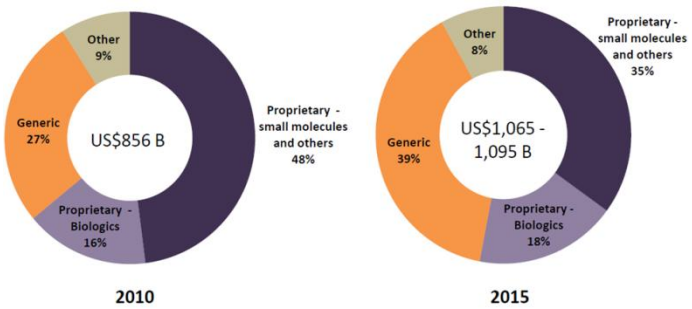

Figure 1 - Global spending on medicine by proprietary and generic products, 2010 and 2015. Source: IMS [1]

Dissecting Pharmaceutical Manufacturing

Production of APIs is an integral part of the drug manufacturing process. Based on synthesis methods, the global API market can be broadly divided into two categories; namely small molecules and biopharmaceuticals. At present, the market is dominated by small molecules. However, biopharmaceuticals are rapidly gaining market share.

Small Molecules

The global API market was valued at US$109 B in 2011 and is expected to grow steadily at 7.9% CAGR in the next five years [4]. Of the total global API production in 2011, 62.4% was done in-house by pharmaceutical companies. The remaining 37.6% was outsourced to Contract Manufacturing Organizations (CMOs) [5]. To date, API revenues from CMOs are almost evenly split between APIs supplied to the generic drug market and the proprietary drug market (Figure 2). The CMO revenue from generic APIs is projected to

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increase at 7.3% CAGR to US$27 B by 2015, whereas the CMO revenue from proprietary API production is forecasted to grow at 2.8% CAGR to US$23 B in the same period. The differential growth rates will strengthen generic APIs as the mainstay in the CMO business.

The shift of industrial power to the East

Pharmaceutical spending is expected to nearly double in emerging countries, which is led by China, Brazil, India and Russia, adding US$150 B by 2015 [1]. However, only 20% of the total increased spending from emerging markets is expected to originate from proprietary products. While Western CMOs manage the current market volatility by balancing their portfolios with generic as well as custom manufacturing for innovator pharmaceutical companies, Chinese and Indian CMOs collectively share more than half of the global generic API outsourced market (Figure 2) [5]. With its significant low cost advantage the CMO business in China and India is supported by rising domestic demand in two of the fast growing emerging markets. Labour cost of fine chemical production in China and India is at a staggering ten-fold lower level as compared to US and Western European countries [6].

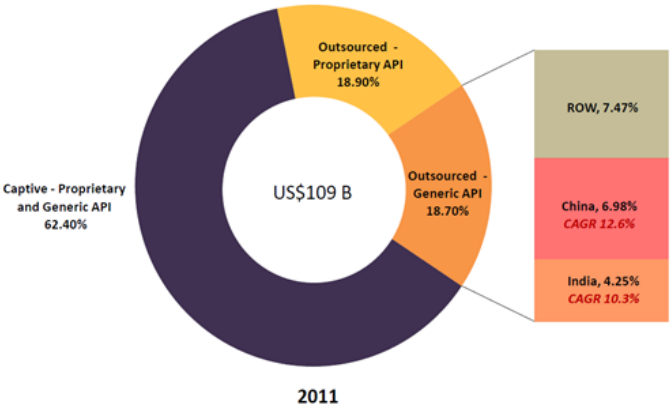

Figure 2 - Outsourced manufacturing in the generic market is further segmented by geography, where China and India are forecast to see double-digit growth through 2016. *Source: Chemical Pharmaceutical Generic Association [5]*

Notwithstanding lower labour productivity in Chinese and Indian fine chemical manufacturing industry, typical conversion costs from raw materials are US$50/kg in the West, US$23/kg in India and US$18/kg in China, respectively. Furthermore, low investment costs in modern multi-purpose cGMP plants in the East also boost domestic CMO business and attract Western pharmaceutical companies to establish local manufacturing facilities.

Looking at the extreme cases, the difference in investment cost per total reactor volume (in m^3) of a mid-sized fine chemical manufacturing plant between a low end facility in China (Hovione, Hisyn, China; US$30 K/$m^3$) and a high end facility in the US (Roche, South Carolina, USA; US$12 M/$m^3$) is around 400-fold. The economic advantages of China and India have led major global pharmaceutical companies to increasingly shift manufacturing facilities to the East with the intention of reducing production costs and boosting local market penetration. Earlier in 2009, Novartis announced a US$250 M investment to construct a new global pharmaceutical development facility for API manufacturing in Changshu, China [7]. More recently, AstraZeneca, the top pharmaceutical company in China by domestic prescription drug market last year [8], announced a US$200 M investment in a new manufacturing facility in Jiangsu, China [9]. The new multi-purpose plant represents AstraZeneca's largest ever investment in a single manufacturing site globally, and will produce both intravenous and oral solid medicines to reinforce the company's leading position in China. The increased production capacity is also expected to capture more of the estimated 900 million patients in urban and rural communities who current have no access to affordable high quality medicine.

Consolidation in fine chemical manufacturing industry

As the pharmaceutical industry continues to make a shift from proprietary drugs to generics, large pharmaceutical companies are downsizing manufacturing plants and divesting excess capacity. This has fuelled the adoption of more outsourced manufacturing. The CMOs have responded by rapidly evolving their business model to suit the changing demands of medicine supply. The API manufacturing industry is currently highly fragmented with the presence of several hundred companies that produce APIs for both innovator medicines and generics. There is a high degree of redundancy because a vast number of service providers have very limited differences between their technology platform and manufacturing capabilities. In particular, generic API manufacturing is a large-volume low-value commoditized activity that requires scale and concentration to drive profitability. As a result, an opportunity for consolidation exists for manufacturers in the generics sector where significant efficiency gains by combining production volume of certain APIs to improve profit margins.

The generics sector has witnessed a wave of M&A deals in recent years, with the US$5.6 B acquisition of Actavis Group by Watson Pharmaceuticals Inc being the latest announcement in April 2012 [10]. The acquisition makes Watson the world's third largest generics company, thus positioning it as a significant competitor to leading rivals, such as Teva Pharmaceutical Industries and Sandoz. Despite the fragmented nature of the API manufacturing landscape, it is still dominated by large companies that cater to top pharmaceutical industry clients and provide high-volume drugs due to their high capacity and greater economies of scale. Medium and small-sized API vendors are facing certain operational challenges, including limited capacities and reduced access to capital for expansion. As a

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result, these vendors tend to focus on low-volume, customized manufacturing services that provide a high-return.

High-Potency API

API vendors are increasingly focused on capability expansion to differentiate themselves from the competition and high-potency API (HPAPI) manufacturing is one of the niche segments driving this differentiation. Advances in drug development allow new chemical entities (NCEs) to achieve higher potency. These NCEs are more complex to synthesize and are administered in smaller doses. Hence, high-potency small molecules have lower volume capacity in term of manufacturing and require highly sophisticated facilities and specialized technical capabilities. Although HPAPI manufacturing has a high barrier to entry due to costs and resources required for achieving the higher standards for regulatory, health, safety and environmental approvals, this niche segment is expected to provide significant returns in the long run.

The HPAPI market is valued at US$8.9 B in 2011 and is forecasted to grow at 8.3% CAGR till 2016 [4]. The growth is predominately driven by an increasing demand for oncology therapeutics worldwide (e.g. cytotoxics), as well as for prostaglandins and certain types of hormones. In the last couple of years, several CMOs have been adding HPAPI capacity in anticipation of future demand. SAFC Pharma has made a US$75 M investment to expand its HPAPI manufacturing plants in the USA and to build a new plant in Israel for large-scale bacterial and fungal fermentation-derived HPAPIs [11]. France-based Novasep built a US$12.7 M HPAPI plant in Le Mans, France, to increase its HPAPI production capacity by 50% [12]. Finally, Switzerland-based Carbogen Amcis (a subsidiary of India's Dishman Group) invested US$20 M to build a manufacturing plant in Gujarat, India [13].

Biopharmaceuticals

At present, new biological entities (NBE) represent a smaller market than their small molecule counterparts. The NBE market is forecast to grow by 6-9% CAGR until 2015 [1]. Global spending on biopharmaceuticals was US$150 B in 2011, predominately driven by sales in the US, Japan and European markets from successful launches of recombinant insulins, human growth hormones, monoclonal antibodies (mAbs) and erythropoietins (EPOs) [1,14]. Globally, over 75% of installed biopharmaceutical manufacturing capacity is currently controlled by ten companies (Figure 3) [15] and more than half of the capacity is concentrated in the US. As more opportunities arise in the Asian market, manufacturers are actively expanding their capacities locally to meet demand. It is forecast that 16% of the globally-installed biopharma manufacturing capacity will be in Asia by 2016 [15].

Biopharma outsourcing

The biopharmaceutical sector is experiencing an upsurge in outsourced manufacturing in recent years as biopharma CMOs are expanding their capabilities with novel technologies. Last year, an industry-wide survey on 352 global biopharmaceutical companies from BioPlan Associates [16] showed that secondary manufacturing (e.g. fill/finish operations), API biologics manufacturing and cell line development are some of the key activities being outsourced today. Several cell-based manufacturing platforms are utilized to produce biopharmaceuticals, namely mammalian cell culture, microbial fermentation, plant cells and insect cells. While roughly half of the global biomanufacturers retained all of their production in-house, the outsourcing trend is rapidly growing across all platforms as shown in Figure 4.

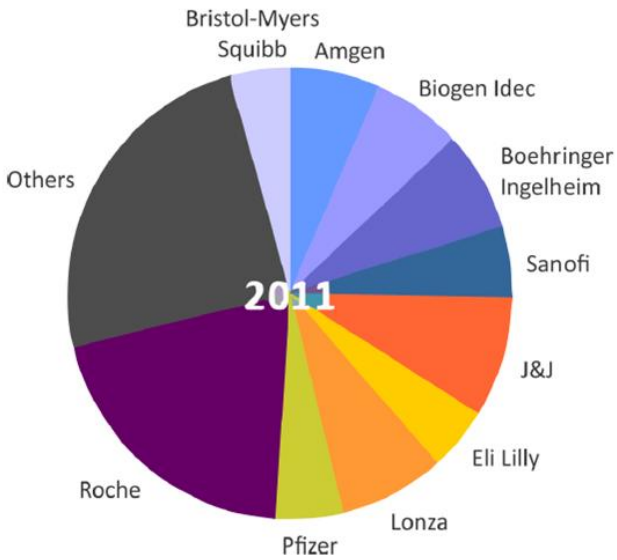

Figure 3 - Over 75% of global installed biopharmaceutical manufacturing capacity is controlled by ten companies, 2011. *Source: BioProcess Technology Consultants, Inc. [15]*

Currently, plant cell and insect cell platforms are not commonly used for commercial manufacture. Interestingly, the annual outsourced production of biopharmaceuticals utilizing these two platforms nearly doubled in 2011, indicating research organizations are also turning to biopharma CMOs to fulfil their manufacturing needs for preclinical and perhaps some early clinical supplies. Furthermore, the number of industry participants who outsource API biologics manufacturing activities increased by over 150% last year and the trend is expected to continue in the next couple of years. Secondary manufacturing operations, including prefilled syringes, cartridge systems and multi-use adjustable syringes, account for almost two-thirds of outsourced activities in biomanufacturing today.

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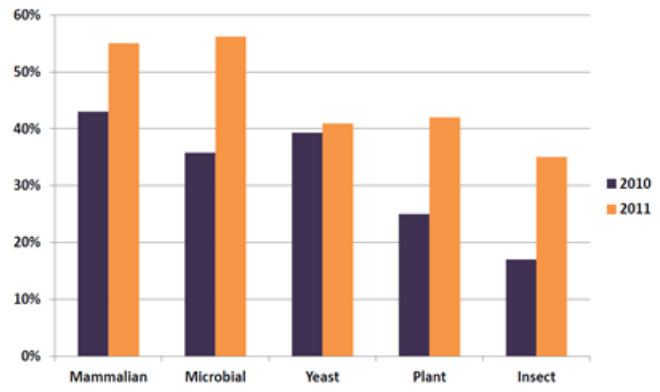

Figure 4 - Outsourcing trends in biopharmaceutical production across all cell-based platforms, 2010 and 2011 (Responses from 325 global biopharmaceutical companies expressed as percentage of parties that outsourced part of their biopharmaceutical production in 2010 and 2011). *Source: BioPlan Associates, Inc. [16]*

Single-use bioreactors

New technologies, such as single-use bioreactors, are becoming increasingly favourable in the production of biologics API as they provide flexibility and cost-effective manufacturing strategy for niche markets. Orphan drugs, which account for a third of the innovative biologics approved by the FDA in 2011 [17], require a much smaller manufacturing scale compared to small molecule blockbusters. Shire has recently set up a biologics manufacturing plant in Massachusetts, USA, catering for orphan drug production by exploiting 2000L single-use bioreactors [18]. By eliminating cleaning and engineering costs, it has been estimated that disposable bioreactors reduce production time and lower labour costs by about 30%. Single-use systems also allow biopharma CMOs to combine multi-product flexibility, faster set up times and reduction in the cost of manufacturing infrastructure to provide R&D and clinical supplies manufacturing worldwide.

Development of biosimilars

Lonza and Boehringer Ingelheim are the leading manufacturers in mammalian and microbial systems. However, the industry is getting progressively more competitive with the global expansion of biopharma CMOs and biosimilar* manufacturers. Only 58 biopharmaceuticals gained approval within the EU and the US during 2006 – 2010, of which merely 40% (25) were NBE [19]. The rest are biosimilars or reformulated versions of previously approved products. Several blockbuster biologics, such as Enbrel® (Pfizer), Avonex® (Biogen Idec), Lantus® (Sanofi), Neulasta® (Amgen) and Humira® (Abbott), are facing patent expiry over the next five years [23] and reveal new opportunities for biosimilars players. Biosimilars are follow-on biologics that closely resemble the originator drugs with no significant clinical differences in safety, purity and potency between the products. The penetration for biosimilars is minimal at present with global spending of US$378 M for the year to the first half of 2011 [14]. Currently, there are variations in approval guidelines for biosimilars across the continents and a clear successful launching strategy has not yet been defined. Furthermore, the development of biosimilars is associated with significant barriers to entry, such as the cost of running clinical trials compared to that for small molecules generics, the highly technical process involved in manufacturing, as well as marketing support to raise the awareness of patients and clinicians to new biosimilar products. Manufacturing of biopharmaceuticals is a capital-intensive, complex and highly technical process in comparison to that of small molecules. The average development cost for biosimilars, estimated between US$100-250 M (inclusive of manufacturing plant development), is considerably higher than the typical development cost of US$1-5 M for small-molecule generic drugs [14, 20].

Biosimilars in the EU

Germany, France and other European countries currently account for over 80% of the biosimilar market by value because the EU had taken the initiative to establish a regulatory framework for biosimilar products in 2006. There are 14 approved biosimilar products in the EU with reference to three originator biologics, namely filgrastim, epoetin and somatropin [21]. Recently, the European Medicines Agency (EMA) received the first regulatory application for a biosimilar mAb from Korea-based Celltrion with reference to Johnson & Johnson's blockbuster Remicade® [22]. There are 16 approved indications for Remicade (whose earliest EU patent expires in 2014) with worldwide sales forecast to be US$4.3 B in 2012 [23]. Celltrion is also preparing to register their mAb biosimilar products in emerging markets, such as Asia and Central/South America, where Remicade is not under patent protection.

Biosimilars in the US

The US biologics market fosters a significant incubation hub for biosimilars adoption once the FDA has finalized its guidance on biosimilar products development and approval process as part of the implementation of the Patient Protection and Affordable Care Act of 2010. Following the publication of draft guidance relating to the development of biosimilars, the US FDA received nine IND applications for biosimilars as well as 35 requests for pre-Investigational New Drug (IND) meetings for proposed biosimilars with reference to 11 originator biopharmaceuticals [21]. Nevertheless, the imminent market for biosimilars in the US is likely to be established slowly due to stringent clinical requirements and the manufacturing process involved. Behind every patent for biologics filed under the FDA's Biologics License Application (BLA) [24], there are potential lines of defence for originator companies, including process patents, which may impede the entry of biosimilars when new markets open.

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Biosimilars in Asia

Leading countries in the pharma-emerging markets, including China, India, Brazil and Mexico, have developed their own regulatory framework for the approval of biosimilars. These approval guidelines are less stringent and have already prompted local biopharmaceutical manufacturers to launch their biosimilar products in the mAb and EPO segments in emerging markets. For instance, India-based Dr. Reddy's and Biocon, China-based Shanghai CPGJ and Mexico-based Probiomed have marketed several lines of biosimilar products in emerging markets. Some of the biosimilar products sold in emerging markets include blockbuster biologics that are still under patent protection in developed markets, such as Roche's Rituxan® and Enbrel.

Furthermore, the Chinese government and the South Korean government have taken initiatives to boost the bio-pharma industry by implementing capital support. The Chinese government has pledged to invest US$3.1 B in the next five years in the biotechnology sector, to focus solely on innovative medicines and development of biopharmaceuticals [25], which has led China-focused biotech companies to expand their manufacturing businesses. For instance, AutekBio has secured US$100 M in venture capital from private and government sources to build a large scale biologics CMO facility in Beijing, China, conforming to US FDA and EU EMA cGMP standards for global biopharmaceutical requirements [26].

Similarly, the South Korean government has announced financial and institutional support with the aim of taking 22% share of the global biosimilars market by 2020 [27]. In response to this vigorous proposal, Korean electronics giant, Samsung, has committed to invest US$2 B through to 2020 in its pharmaceutical business [28]. The company has already invested US$266 M to build a biologics manufacturing plant in Seoul, South Korea. In partnership with the CRO Quintiles, the plant is expected to be in operation by 2013 and offer the production of biopharmaceuticals on a contract basis initially, followed by biosimilar versions of Rituxan - the world's best-selling biologics blockbuster - Enbrel, Humira and Remicade by 2016 [29]. Samsung has also signed a US$300 M joint venture with US-based biotech company Biogen Idec to develop, manufacture and market biosimilar products [14].

Globally, the biosimilars market is projected to reach up to US$2.6 B by 2015 [1, 14]. More companies are forming strategic alliances to capture the market potential, especially in emerging economies where the lower manufacturing costs and less stringent regulatory approval process provide first-mover and cost advantages to bring in biosimilar products at competitive prices. In 2010, the Indian generic company Cipla invested US$65 M in India-based biotech MabPharm and China-based biotech BioMab to build its biologic capabilities needed to enter the biosimilar market [30]. Last year, Merck signed a partnership with Parexel (CRO) to develop biosimilars [31], as well as a deal worth up to US$720 M with South Korea-based Hanwha Chemical Corporation to develop and commercialize biosimilar version of Enbrel [32]. Recently, biotech giant Amgen and Watson Pharmaceuticals have entered a US$400 M agreement to develop, manufacture and market undisclosed biosimilar products [33].

Overcapacity in Manufacturing Operations

With diminishing R&D pipelines and the patent cliff, pharmaceutical and biotechnology companies are restructuring their operations significantly to cut costs and to maximize productivity. Industry participants have resorted to consolidation in the form of mergers, acquisitions and strategic alliances. Some of the largest M&A deals occurred over the past few years include Pfizer-Wyeth, Merck-Schering Plough, Roche-Genentech, and, most recently, Sanofi-Aventis and Genzyme. Consolidation in the pharmaceutical industry has resulted in redundant manufacturing facilities and created an industry-wide challenge, with most participants holding manufacturing capacities that exceed demand by approximately 40% [34].

Furthermore, many leading pharmaceutical companies have inflexible manufacturing facilities that cater to the production of high-margin, high-volume, patent-protected small molecule APIs. These facilities become surplus to requirements when branded drugs lose patent exclusivity and are subjected to competition from generics. Many leading pharmaceutical companies offer their idle manufacturing capacity as CMO business to improve margins, such as Pfizer's CentreSource, Sanofi's CEPiA as well as Merck's and GSK's contract manufacturing units.

Another key driver of overcapacity in manufacturing operations is today's sluggish R&D pipelines, which make traditional stainless steel facilities too inflexible, slow and costly for managing capacity uncertainty. Downsizing of manufacturing operations by reducing plant network has become another strategic approach to liberate prohibitive installed capital cost and to eliminate limited long-term asset utilization. The nature of the API manufacturing business favours Asian industry participants who have inherent low costs advantages. In response, many pharmaceutical companies have begun to shut down API manufacturing plants or divest manufacturing assets in the US and Europe since 2007.

PharmaVentures has helped a number of leading global pharmaceutical companies to divest their small molecule and biologic manufacturing facilities over the past few years. Most of the sites we have encountered to date had capacity utilization rates of 11-50% which meant that these facilities carried substantial operating costs when the facilities were idle. In particular, total salary cost as a percentage of total costs for the manufacturing facilities in Western Europe and

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the US was about 36%, which was significantly higher than that in Eastern European countries (22%) and India (11%).

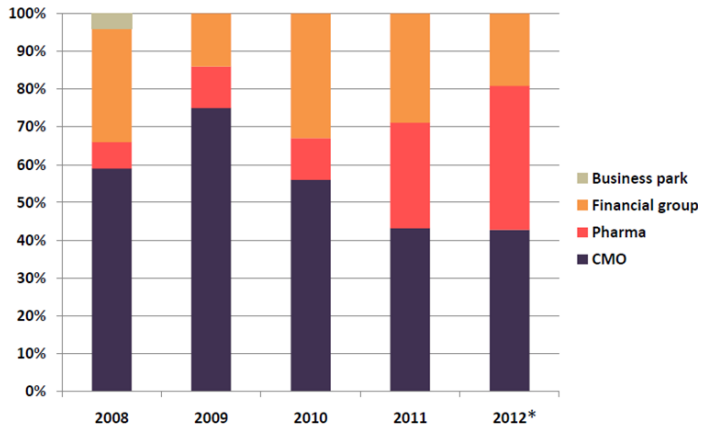

Figure 5. Relative interest shown by buyer groups expressed as a percentage of parties having executed CDAs in out API manufacturing divestments. 2008 – May 2012.

A common divestment strategy of big pharma is to sell their manufacturing assets to a third party with whom they would also enter into a supply contract to manufacture the drugs being made in those facilities. Long term supply contracts (5 years or more) are vital inducements for buyers as it provides the financial buffer for the buyer until they are able to increase profitability by bringing in additional manufacturing contracts.

Looking at interested parties executing confidential disclosure agreement (CDA) to progress through our sale processes, potential buyer groups can be categorized into CMO, pharmaceutical and private equity (PE) firms. CMO is the biggest group looking to buy manufacturing assets, while pharmaceutical companies and PE firms are becoming more prominent seekers of such assets since 2010 (Figure 5). CMO and pharmaceutical groups are looking for assets that align with their strategic needs, such as differentiation through acquiring proprietary technologies or more sophisticated API production or formulation capabilities. Some may also be looking to bring in-house low cost manufacturing through Asian acquisitions. PE firms tend to look for underperforming businesses with notable annual sales and the potential for high growth following additional capital injection. Typically, they are looking to exit from their investment after four to five years.

In terms of geographic location, US firms show significant interest in European assets, whereas European firms do not show similar interest in assets in the US or rest of world. Indian firms are increasingly looking to buy Western assets. We found that Asian buyers are keen to gain access to the leading Western markets through acquisition of products, technologies and premises approved by USA FDA and EMA. They are looking to expand their technology base globally with the intention of moving up the value chain in drug manufacturing.

In order to withstand the highly competitive market space, many CMOs are differentiating their capabilities beyond API production by providing fully-integrated services. This includes a range of services, such as formulation development, packaging as well as distribution. We have observed an increased demand in sterile liquid manufacturing capabilities, especially in sterile filling and lyophilization of biopharmaceuticals and controlled drugs. Fully-integrated facilities have the potential to minimize contamination risks and reduce total product costs. Newer formulation technologies, such as immediate release, controlled-release or extended release also play a significant role in driving up the value of pharmaceutical drugs. Niche segments, such as manufacturing of controlled drugs, provide good examples of innovations in formulation technologies. The FDA's strategies to control abuse and misuse of opioid products [35] have spurred a number of manufacturers, biotech and pharmaceutical companies such as Acura Pharmaceuticals, Purdue Pharma, Pain Therapeutics, Elite Pharmaceuticals and King Pharmaceuticals (acquired by Pfizer for US$3.6 B in 2010) to work diligently to develop novel abuse-resist formulations.

Conclusion

Notwithstanding the rise of generics and erosion of drug pricing, the pharmaceutical drug manufacturing industry is facing huge competition from Asian players who offer high-quality products and increasing technical expertise at competitive prices. Overcapacity in pharmaceutical manufacturing in developed countries has resulted in many assets becoming available to purchase. Akin to increased outsourcing trends of API production by pharmaceutical companies, many underutilized manufacturing assets are divested to CMOs across the globe. More API manufacturers are expanding their technology base to drive competitiveness by providing value added services or venturing into HPAPI and biosimilar markets.

Pharmaceutical companies are putting an emphasis on maximizing the use of existing internal resources, while outsourcing certain activities outside their core competencies to drive efficiency and to direct cost savings; presenting a great opportunity for CMOs because they offer new technologies and expertise in manufacturing operations that pharmaceutical companies might not have in-house, especially in the production of biopharmaceuticals where the market is still underdeveloped. The added efficiency helps accelerate the time to bring products to market, which translates into notable revenue enhancement and provides a faster turnaround when opportunities cease. Moreover, CMOs offer distinct value to smaller biotech companies by providing access to capacity as well as flexibility without investing heavily in manufacturing assets. Finally, the provision of value-added services, such as advanced formulations and packaging are expected to consolidate vendor-customer relationships making the overall drug manufacturing outsourcing process a strategic decision.

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About PharmaVentures

PharmaVentures (www.pharmaventures.com) is a leading results driven consultancy that assists pharmaceutical/biotechnology and private equity/venture capital clients across the world in all aspects of deal making. The Company's core business is the provision of bespoke consulting and transaction advisory services to the Life Sciences industry in the area of Strategy, Valuation, M&A, Licensing and Expert Testimony. The company has an established track record in generating outstanding value for clients, and over the past 20 years has assisted in more than 500 strategic and financial reviews and transactions of Life Sciences companies and assets.

If you would like to speak to one of our advisors to see how we could help your company with its deal making strategies, please contact:
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