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Outsourcing Strategies – Future Trends?

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Abstract. Outsourcing production of bulk active ingredient manufacture has recently been a growing trend amongst many pharmaceutical companies. To consider how the trend might develop, one needs to consider the factors that have driven outsourcing and the critical role of the custom synthesis industry in delivering expectations.

Introduction

If the level of interest in a business topic can be measured by the number of management seminars held, the pitches made by management consultants and the articles written in trade publications, then outsourcing of bulk pharmaceutical manufacturing has undoubtedly been a hot issue over the past couple of years. Perhaps the heat has now started to cool a little, in favour of new areas of focus? If so, I do not believe this reflects diminishing interest, simply that with issues better understood, companies are now developing and implementing specific outsourcing strategies that meet their business needs. For many, the 'thinking about it' phase has been passed.

Before considering some of the specific drivers behind outsourcing, it is worth spending a little time looking at the changes in the pharmaceutical industry which have led to the step change in outsourcing activity.

The rapidly changing business environment within the pharmaceutical industry has been well documented. In many areas of the world, price pressures have continued to intensify. Product development costs are increasing as is cost of goods, driven by greater product complexity and the ever more demanding requirements of the regulators. Add to this the economic consequences of marketing more diverse product portfolios, and you arrive at a margin squeeze of unprecedented severity.

The most visible response to these intensifying business pressures has been the number of mergers and acquisitions witnessed over the past four years. Whilst other forms of synergy have driven these deals to varying degrees, cost efficiencies have been a major factor in each of them.

When seeking cost efficiencies, manufacturing and supply is always on the agenda. Merger situations lead to strategic reviews because step change opportunities are often available. By comparison in a routine business situation of organic growth, the opportunities tend to be more incremental where a combination of long lead times, high-switching costs and an inherent conservatism has led pharmaceutical companies to carefully build on their existing manufacturing platforms.

So, mergers and acquisitions have provided a stronger focus on the structure and ownership of supply chains. It is evident that a move to greater outsourcing has not been a universally adopted strategy, but where it has, site closures or sales have been a common implementation vehicle. Selling a site with an ongoing supply agreement is a convenient and quick route to outsourcing because many of the regulatory change lead-time issues are overcome, and operational disruptions in the short term are minimal. The flip side to the operational convenience is that the underlying economics are slower to change. The financial benefits are only captured over an extended period. These can come from several sources, but in the end, boil down to a combination of better overall resource utilisation and the cost of providing these resources. Obviously, a facility sale does release capital. Like all business decisions, some will work out better than others, but in any event, more pharmaceutical companies have now looked at outsourcing at a strategic rather than tactical level, and many of the previously established norms have been challenged and shifted.

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Some of the Drivers Behind Outsourcing

In the introduction, I suggested mergers and acquisition in the pharmaceutical industry have been a key driver for outsourcing, albeit supported by a simplistic analysis. To consider how outsourcing trends might develop, it is important to think about why outsourcing can be attractive to pharmaceutical companies. It is a complex picture with cost being only one of many factors and not always, if ever, the most important.

A quick review of the role of manufacturing and supply is a good place to start. You can justifiably spend a lot of time and money deciding whether or not bulk active manufacturing is a core activity for a pharmaceutical company. I think most companies start with the key recognition that supply of product is absolutely critical for success, and, therefore, if internal manufacture is seen as the best option for delivering supply in certain technologies or for certain products, then those aspects of manufacture are indeed core activities for the company.

Most pharmaceutical companies have taken a fairly traditional and simple view of the role of manufacturing and supply. Product quality, security of supply and cost have been the key areas of focus, with cost being the main variable.

In today's more competitive business environment, other factors have become increasingly important. Time-to-market is an obvious one, but access to novel production technology that can provide sustainable advantage is another. More dynamic markets lead to greater demand volatility, so responsiveness, without resorting to excessive inventories, has also grown in significance. Product portfolios are broadening as are the technologies used in manufacture. Managing complexity is now critical to success. Finally, we can no longer apply the same supply philosophy across the business. Supply chains have to be differentiated to recognise the specific business drivers of markets, products and their position in the life cycle.

So why are some pharmaceutical companies outsourcing more of their bulk active manufacturing? For each company, specific circumstances and needs will drive

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decisions, but there are probably some common threads running through the strategies.

Cost will always be important and it certainly has a strong influence on outsourcing decisions, in a number of ways. There is a growing reluctance within pharmaceutical companies to invest heavily in production capacity. In the past, investments were justified against new products when in truth they were being made against older products that could alternatively be outsourced to make room for the new products coming through. So, the first step is to use internal capacity principally for new and growing products. Successful companies have strong product pipelines which need to be supported with supply capability. Investment decisions for bulk active manufacture have to be made well before launch, and to provide internal manufacturing capability for the upside volumes across all potential products would be expensive and very risky because evidence shows that not every product candidate will be a runaway success! The contract manufacturing industry can spread the risk of demand uncertainty across a number of customers and help to ensure that industry capacity remains closer to total demand than would otherwise be the case.

There is also an often quoted argument that capital not spent on production can be invested to better effect elsewhere in the business. This is appealing but does not survive logical challenge because major pharmaceutical companies are not generally capital-constrained. If internal investment provides the best financial situation, all factors considered, that should be the decision.

There are many other assumptions made about the comparative costs of internal manufacture *vs.* outsourcing, usually that the custom synthesis contractor will be cheaper due to a lower cost base. This may be true, but when costs are compared, it is essential to fully understand the real reasons for any differences. If the lower cost is achieved only through an unacceptable deficiency in operations, there is no real saving. Conversely, if the cost of internal manufacturing is impacted by unnecessary support costs and overspecified assets, this has to be taken into account in the analysis.

This leads into another driver for outsourcing, the ability to construct differentiated and appropriate supply chains. In simplistic terms, the business drivers for new products are about speed, technical and regulatory support, responsiveness and no cost-related entry barriers. For mature products, the focus shifts much more towards cost efficiencies in what is usually a more stable or predictable situation, the post patent expiry period excepted. It is hard for any single organisation to meet all the varied business needs at the same time, especially when diverse market needs are taken into account. Outsourcing does give pharmaceutical companies an opportunity to develop a network of focused specialists either directly or *via* a smaller number of 'strategic partners'.

Outsourcing can support the speed to market requirement of new product introduction in several ways – I have already mentioned the access to manufacturing assets and similar arguments apply to other resources. Outsourcing further along the added value chain requires a different approach to process development and regulatory support. Custom synthesis is more than simply renting plant. Assuming one gets the partner selection right, never a trivial decision, potential synergies go beyond efficient use of people as the specialist knowledge of suppliers can be leveraged. Ownership of valuable know-how and intellectual property can be an issue, but should not be a barrier if a genuine cooperation mentality exists.

Customers have always outsourced where proprietary technology, know-how or specific plant capability made this a necessity. Perhaps a shift in thinking has taken place, so that now pharmaceutical companies positively seek out opportunities to achieve synergies from their supplier's skills and knowledge. The not invented here syndrome is no longer applied by default.

This is by no mean an exhaustive list of the factors that companies will consider. I have not mentioned quality and supply security because these are 'givens' which simply have to be met, whether manufacturing internally or outsourcing. Many companies will have special technologies or capabilities that they believe provide advantage in the market place and as such argue against outsourcing in these areas.

Perhaps the strongest influence is a company's starting point together with its management's attitude to risk, and specifically control.

Supply-Industry Response

There is absolutely no doubt that the contract manufacturing or custom synthesis industry is changing, both in response to increased outsourcing from pharmaceutical companies and in readiness to influence future trends.

Some of the changes are significant and need to be understood. I do not know if it is fair to classify the traditional contract manufacturing industry as a 'cottage industry'? It was certainly fragmented, and many of the players had relatively narrow and stable product ranges. Some facilities were showing their age, especially those supplying only raw materials. Of course, those companies already supplying pharmaceutical companies (which had always outsourced bulk active manufacture) were in a stronger position.

As well as the increased outsourcing activity from pharmaceutical companies other forces have influenced changes in the supply industry. Greater competition from competitors in developing economies has forced companies to review their target market segments in favour of higher added value work, principally registered stages. The increased infrastructure and support costs associated with this segment combined with the higher investment needed to upgrade facilities has made scale economies much more important to success and indeed survival. Any contractor that wants to compete in the new products segment must be able to offer a broad range of capabilities from a diverse asset base. This inevitably leads to overheads that require a base business of adequate size. Hence, the concentration seen in the industry over recent years and which continues with considerable momentum.

The switching costs and lead times associated with changing sources for registered production stages drive customer and contractor towards a long-term and close relationship. If a contractor does not have a relationship with a target customer, it can take many years and a measure of opportunism to build one. A quicker route is to buy a foothold by acquiring a company that does have a relationship with the target customer, and I am sure this has been a significant factor in some of the recent deals. It seems we are heading towards an industry structure where there will be a number of major players that can offer a wide range of services and access to several key technology areas. However, whilst 'Big' might now be beautiful, there will still be room for niche players with genuine specialisation in technology or capability.

Turning to the product lifecycle, contractors focused on the new products arena are aware that key success factors will change over time. To keep business through the life cycle, they will have to change the conditions of supply. Effectively they face the same challenges as the internal chem-

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ical manufacturing division of the pharmaceutical companies they serve. A number of responses can be observed. Some contractors accept that eventually business will transfer to lower cost sources, especially beyond patent expiry when generic manufacture becomes well established. Other companies see benefit in managing the transfer on behalf of the customer by forging alliances with developing economy sources or by acquiring such companies. The anxiety to keep the business cradle to grave may be driven by revenue and profit considerations. Perhaps a more important objective is to reduce the opportunity for developing economy sources to move up the product life cycle into their core business segments by trying to limit direct relationships between their pharmaceutical company customers and the low-cost suppliers?

So, there is much evidence that the custom synthesis industry has responded to an emerging opportunity and it will be interesting to see where the restructuring stops. I suspect that the major contractors will be constrained in their growth aspiration by the reluctance of their major customers to be too dependent on any single company. Major pharmaceutical companies might also be concerned about being overdependent on a supplier that forms a key part of the supply chain of a competitor? Backward integration still happens! The supply security issue will always be a critical factor, and every eventuality needs to be considered.

Continuing concentration and restructuring in the contracting industry will make pharmaceutical companies somewhat nervous, because it highlights the fact that whilst one can create an entirely acceptable external supply structure over a period of years, the whole strategy can be undone overnight *via* a merger or acquisition. If you try to tie the whole situation up in contractual knots you might as well own the assets yourself!

I think it is appropriate to make a few points about relationships. Evidence suggests that as usual there is no single solution, but there are common themes. It costs a lot of money to introduce a source of supply and even more to change one. In such an environment, long-term relationships are the norm and mutual trust is absolutely essential. A 'surprise' or deception can set a relationship back years and in some cases send it into terminal decline. I would be misleading you to suggest that this was a 100% balanced situation. Customers can probably get away with more than contractors. However, we never forget that when difficult times arrive, it is the strength of a relationship that usually resolves the problem.

Some companies prefer to maintain a high level of control over their contractors taking a strong contractual position and hands-on approach. Others take a less intrusive stance, relying on the professionalism of the contractor in a cooperative environment. Some pharmaceutical companies favour the depth of relationships that can be developed with a few strategic alliances. An alternative approach is to develop a portfolio of important contractors which can help to spread risk and dependency and at the same time allow direct access to developing technologies and capabilities.

The message for contractors is that they do need to be flexible in their approach to relationships and also to recognise that some customers might have a preferred style that they find unworkable? Just as it is impractical for a customer to have too many contractors, it is equally impractical for a contractor to serve too many customers.

The Future: More, Less or The Same?

The answer is really quite simple!

A shake-up in the pharmaceutical industry has fed through to a shift in thinking amongst those pharmaceutical companies that have traditionally manufactured the registered production stages for their bulk actives. This has opened up a new opportunity for the contract manufacturing industry which has been recognised and responded to.

Many pharmaceutical companies have made, or are making, positive moves in the direction of greater outsourcing. I think the pace of this change, where it ends and the avoidance of a reverse gear kicking in depends largely on the performance of the contractors themselves! If promises are kept, supply reliability is up to the high standards achieved with in-house manufacture, and if financial benefits are realised, the incentive to go back to a previous model will be weak.

There are also signs that readily usable contract capacity is becoming scarce. If contractors insist on capacity expansion projects being fully underwritten financially by their customers either directly or *via* fixed supply contract terms, then the risk-sharing benefits of outsourcing will be largely undermined, and the case for building in-house will be strengthened. Again, the increasing size of the major contractor is in part a response to this challenge.

Eventually, supply security will rule the day. There have been several recent examples of supply-chain failure leading to marketing problems for pharmaceutical companies. Outsourcing 'failure' has been a factor in some of these, and it is not only the affected companies that take note. Any company seeking significant involvement in a pharmaceutical supply chain has to recognise that responsibilities go beyond the mere financial consequences of failure.

As some companies progress with outsourcing plans, others who have been there are moving in the opposite direction. I can think of at least one major pharmaceutical company that has recently purchased a chemical plant to take full control of the supply chain for important new products. Other pharmaceutical companies have chosen to enter the contract manufacturing industry rather than divest what they see as key competencies for their business.

Clearly there is no 'right' answer, and pharmaceutical companies will continue with their chosen strategies, but at the same time maintain barometers in the industry to ensure that it remains the best option.

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