Innovative Sourcing Strategies

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The efficient allocation of capital, particularly in the "make or buy" decision, has the power to increase earnings and shareholder value. The state of the pharmaceutical industry makes strategic sourcing decisions more important and more urgent than ever. What are the benefits and possible problems inherent in sourcing, and what are the best ways to innovate and implement a sourcing strategy?

The choices that leaders of pharmaceutical companies make in the allocation and management of capital have the power to increase shareholder value, improve profitability, provide the resources to fund strategic investments internally, and shorten response time and customer service.

Potential performance improvements like these are welcome at a time when pharmaceuticals are struggling to maintain profit and growth scenarios, greater market competition, and increased pressure from both society and government on their R&D pipelines, and to deliver healthcare solutions at lower costs.

Strategic sourcing and supply management offers wise managers one of the powerful opportunities to extract cash from the value chain and set the stage for continued product and service innovation and growth. The key to unlocking the value in sourcing rests with an understanding of efficient capital management. Capital drives everything. When the major players in the pharmaceutical industry were generating strong positive cash flows, capital was not an issue. Now, however, to maintain acceptable margins, these companies must run at a leaner pitch. This imperative for leaner operations added to escalating cost pressures and the emergence of capable new manufacturing sources demands that pharmaceutical companies now re-evaluate their in-house manufacturing operations.

Even if companies continue to do all, or just part of their manufacturing in-house-for proprietary, quality, competitive, or even 'insurance' reasons, the potent combination of market forces has already begun to change the rules of the game.

Typically, companies are willing to pay what amounts to a premium for in-house manufacturing, particularly in the critical launch phase of a new product. However, as the product matures, the market may very well accept these premiums.

The entrepreneurial biotechnology companies, for reasons of necessity, have already adopted progressive sourcing strategies, and their example is serving as a wake-up call to companies with traditional in-house manufacturing operations.

Capital and other cost pressures

After more than a decade of mergers, acquisitions, restructuring, and fundamental changes in the basis of competition, our experience suggests that in-house pharmaceutical manufacturing operations are often under-used, and burdened with overhead cost—less efficient than external alternatives. Some drug makers are starting to see their in-house operations as non-core contributors to their overall business performance.

Underlying the wake up call is the experience of the 1970s, during which the FDA and European Regulatory agencies understandably added essential requirements and controls. Pharmaceutical companies responded with capital-laden facilities together with over-designed and over-demanding business processes and policies relative to audit, assurance, regulatory and manufacturing functions.

Some of the companies proudly established policies and control procedures exceeding regulatory agencies' requirements, winning the hearts of the medical community. A deeply rooted culture of delivering higher standards through bureaucratic operating procedures has grown and it is difficult to change as these policies and procedures are perceived as threshold requirements in the face of growing capital, cost and other competitive challenges.

During the high-growth, high-return days of the 1980s and early 1990s, these basic business flaws were easily absorbed in most companies' bottom lines. Today, however, the changing power structure in managed care, the regulatory environment, global access to information and markets, and the ever-increasing pressure for new compounds put continuous pressure on pharmaceutical manufacturers.

Healthcare companies are working harder to maintain the same profit margins they saw in the 1980s. This has led many companies to look beyond traditional boundaries for ways of creating new value.

Escalating cost pressures, directly influenced by managed care, integrated health systems and employers, have been accompanied by demands for more services and value, such as supply chain integration with disease management programs. The result squeezes profits. Meanwhile, as market competition allows every player the ability to 'choose the best at the best price', management will continue to concentrate on R&D, sales, and marketing, the drivers for increasing shareholder value. Add to this scenario the increased financial pressures from more complex development cycles, requiring greater capital investment for development launch and production, and the subsequently reduced patent protection time. This makes it more difficult to recover capital investment. This is the essence of the problem. The demand at one end of the value chain for increased investment in R&D and at the other end for marketing to stay competitive draws capital away from the manufacturing process itself.

In the face of these competing demands for scarce financial resources, companies have launched rationalization initiatives. In some cases, excess manufacturing capacity has led companies to generate spin-off facilities and business units, thus fueling the nascent contract manufacturing market.

Until recently, this contract manufacturing market was fragmented and without clear leaders. Some players have developed specialized skills, such as complex tableting or effervescents. BASF is an example. But the market has been characterized by a large number of small suppliers, each with limited capabilities and limited, if any, global coverage. There have also been problems of poor compliance by some companies, and certain suppliers, spin-offs, and buy-outs from mergers were often inflexible— tailored to a limited number of products and technologies.

This contract market is now changing. Large pharmaceutical companies, having recognized the problem are starting to cooperate to drive improvements in the supplier market. A number of suppliers have recognized the opportunity and are trying to acquire critical mass in terms of competence and volume. Specialty chemicals companies, for example, have come to see that a large proportion of their products are commodities, with low margins and high sensitivity to the overall business cycles.

With this new knowledge and vision, the chemical companies have begun to see themselves as life science companies supplying active ingredients used by the large pharmaceuticals, and these are companies with critical mass and global reach. The generic drug companies are another factor. For them, partnerships with large pharmaceuticals may be an excellent fit in terms of core competence for particular manufacturing operations.

Benefits and advantages

As we noted earlier, the biotechnology companies have been among the earliest to adopt focused sourcing strategies, not so much for strategic reasons, but rather because they have lacked the necessary resources. The potential benefits they have seen could be realized by the large pharmaceutical companies.

Cost potential

Current typical capacity utilization in pharmaceutical companies is no more than about 50 to 60 percent on a two-shift basis. This is in contrast to US industry as a whole, which averages more than 80 percent. Suppliers can have higher capacity utilization, achieve volumes of scale, and consider manufacturing as their core competency. This generally produces greater capability and lower costs. Shareholders of these companies do not expect the same profit margins that the large pharmaceutical companies achieve.

As periods of patent exclusivity shrink and competing therapies with comparable indications come on line, pharmaceutical companies must increase R&D and their various marketing investments—in advertising, brand management, and direct consumer marketing—while honing the effectiveness of their product development and launch pipelines. Hence, capital effectiveness is now critical. Compared with other industries, pharmaceuticals are relatively inefficient in terms of return on capital employed (ROCE). On average, the big pharmaceuticals have been hovering below 20 percent over the last decade. Because each percentage point of ROCE contributes so significantly to performance, other leading industries have moved to improve capital efficiency and are currently achieving over 22 percent ROCE. The conclusion is clear: pharmaceutical companies should not tie up capital resources in manufacturing the associated inventories—at least, not without an explicit competitive justification.

Properly focused and executed sourcing can assure rapid time-to-market for new products and time-to-customer for in-line offerings, both of which are increasingly important success factors. Healthcare products and solutions sourced from the most competitive providers, whether internal or external, will help ensure success.

Management attention

Decisions on core competencies, based on the company's business strategy, guide the roles of manufacturing and sourcing. In essence, contract manufacturing companies devote full management attention to the problems and goals of manufacturing. This is not always the case among major pharmaceutical companies in dealing with in-house manufacturing operations.

Capital and assets

Capital effectiveness is now crucial and should not be tied up in manufacturing without a clear competitive justification.

Operational advantages provided by third-party partners are just what you would expect: flexibility, increased capacity, and specialized expertise and technologies. Given the same standard of quality compliance, the most compelling argument for outsourcing, however, is the capital advantage arising from improvements on both the balance sheet and the income and expense statement.

The range of choices is straightforward: maintain (or establish) fully integrated manufacturing competencies in-house; move to a virtual company model, similar to what American Home Products has done successfully; or pursue a hybrid of sourced manufacturing and in-house operations, retaining control of highly proprietary technology.

During R&D and through launch, the critical factors are protection of proprietary technology (versus access to a third party's superior technology); the ability to gain process improvements critical to later-stage production efficiencies; launch security; and strategic issues, such as 'first-to-market'.

During the 'proprietary' stage, sourcing decisions will reflect a continuation of choices made earlier in the life-cycle, with, most likely, a still-limited motivation to switch to outsourcing.

At each milestone in a product's life cycle, the options and factors become clearer, and a progressive sourcing strategy provides a framework for making explicit decisions.

The predictability of product demand and production needs evolves over a product's life cycle, and the factors influencing sourcing choices change.

The significance of technology as a sourcing consideration cannot be underestimated. Growing product complexity and more complex manufacturing processes drive up the costs and the capital investment required for R&D, product launch, and manufacturing.

At the same time, pricing pressures, growing competition from comparable therapies, and reduced periods of exclusivity make it more difficult to recover these investments. This is where advanced technology can be a major consideration, as the biotechnology companies, such as those developing drugs based on recombinant methods of synthesis, are well aware.

If a company's business strategy calls for bringing innovative drugs to the market faster than the competition, then the sourcing strategy must support this. Sourcing strategies must provide a global reach to match business strategy and tax benefits. They must accommodate local regulatory and delivery requirements.

These strategies should be made only with players whose levels of quality, service, flexibility, and cost are world-class. Strategic sourcing should help companies become more focused on core competencies, generally by out-sourcing everything that is not core. Instead of viewing these relationship as adversarial, the old arms-length buyer-seller paradigm, wise managers should view the relationships as strategic alliances. In relationships like these, value can be created for all the parties. Finding supply chain partners requires attention to a short list of commonsensical considerations. Not heeding one or more can mean the difference between a business combination that succeeds with the hoped-for synergy and one that limps along at less than its full power to realize anticipated benefits. Here are ten ways to ensure that your alliance stays healthy and thrives:

1. *Balance the benefits among the* parties—Each party must believe that the benefits of the relationship are mutual and equitable a win-win situation. Benefits must be clearly communicated and evident to both parties.

2. *Align strategic* goals—If the long-term strategic goals of the parties to a relationship aren't explicitly aligned at the outset, the result can be failure to capture all the benefits of the combination.

3. *Clarify objectives, and be specific about expectations*—In today's health care markets, alliances are sometimes forged because other manufacturers, health plans, suppliers, or distributors, seem to be aligning. Parties to a new arrangement fear they may be left out unless a partnership is created. The parties may have good intentions but neither side is specific about its expectations.

4. *Create a prenuptial agreement; don't go in without a way back out*—Defining how each party can get out of an agreement is as important as identifying why to get into it at the start. A strategic sourcing partnership should exist for three to five years to make it worthwhile for each party to invest and develop it. Changes in the competitive frame, changes in health policy, and new technological advances can undo the best laid plans. For legitimates reasons, either party may need to end the relationship before the end of the contract period.

5. *Define processes and specify the ways the parties will work together; include performance measures and follow-through*—Building new sourcing relationships demands that companies take the time to create detailed definitions of how the parties will work together, and take the time to understand how the parties *should* work together to obtain the maximum value from the relationship.

6. *Commit enough people to do the job, and commit the right* kinds *of* people—Strategic sourcing alliances are among the most challenging sorts of partnerships to make succeed. They require dedicated talent to provide content knowledge about the science and technology, businesses, customers, and operations, and to provide leadership competencies. Alliances that succeed fully must recognize these needs, and assign staff at every level and at all levels of performance to execute the alliance. Executives managing the alliance must not underestimate the time and breadth of functional skill needed to make a relationship work. A strategic business case must be made to attract capable people to the integration team. Characteristics of team members from all the parties to the alliance must include the ability to work effectively across functional and enterprise boundaries, to lead and direct teams with little supervision, to engage multiple stakeholders, to listen actively and communicate constantly, and to persevere in the face of short-term adversity,

7. *Communicate, communicate, communicate; develop a communications program and ensure that information systems are compatible and equal to the communications* expectations—Among the most commonly overlooked requirements of alliances, and of corporate change programs generally, is effective, tireless communication—top down, bottom up, and across functions and enterprises. Effective communications initiatives must establish the context for the alliance in terms that staff at every level can understand—aligning corporate objectives down through team and individual objectives. Communications initiatives must be frequent and consistent. They must enable two-way dialogue and provide a logical cascade of tangible information and clarity, always answering stakeholders' most fundamental question, "What's in it for me?" Communications programs must have a business as well as a cultural imperative. Early in the partnership, both

parties must work through the tedious effort of defining the basis of measurement of critical metrics, how performance against those metrics will be reported and tracked by complementary information systems, and how information will be shared across systems and communicated as a stream of indicators of progress and growth.

8. Get top leadership to commit, visibly and early—A clear, open, and explicit mandate from the top of both alliance partners is absolutely essential. The business case must be described in terms consistent with the strategies and priorities of each party, and must be reinforced frequently.

9. *Make rules for governance and decision-making, and align written and unwritten* rules—No strategic alliance can exist without issues emerging that must be resolved in real-time. To deal with issues, the alliance partners must create a clear governance structure independent of the actual strategic alliance agreement. Senior leaders from both sides must take part.. The formality and definition of responsibilities in this governance structure should be negotiated during the due diligence. Each party has its own, independent governance structure created without contemplation of any particular alliance. Even when one of the parties has an ownership interest in one of the others, governance can become an issue. These 'rules of engagement' must take into account—and align—each partner's own rules, both written and unwritten. These are a company's formal policies and procedures, and the informal, tacitly understood ways the company works. Staff members must understand both to succeed. Common breakdowns in alliances arise from mismatched or misunderstood rules. If the alliance fails to get the respective cultures and governance tools in synch, the men and women designated to carry the alliance forward, will very likely torpedo the effort along the way.

10. Tend to the cultural issues constantly—Culture is defined as "The way things really are around here." It is important because it can literally make or break a strategic sourcing alliance. Most executives pay too little attention to corporate cultures. First, they focus on getting a relationship, then on producing desired business results. When creating a sourcing alliance, good cultural due diligence can identify similarities and differences in cultures that should influence whether the alliance is worth doing at all and, if so, what cultural issues must be addressed to make the alliance succeed. After the deal is done, effectively addressing the culture issues can accelerate performance and improve the chances of producing desired results. Cultural issues underpin virtually all of the recommendations on this list. Organizational alignment, strategic alignment, post-alliance integration, and all the associated process adjustments are deeply dependent on communication and at the most fundamental level, cultural issues. Unfortunately, cultural differences have impeded the success of many strategic alliances.

In today's fast-changing healthcare marketplace, the context of strategy, including the formation of alliances, is risk and uncertainty. The word "risk" derives from an early Italian word, *risicare*, which means "to dare." In this sense, as Peter Bernstein in his 1996 book, *Against the Gods—the Remarkable Story of Risk*, points out, "risk is a choice, not a fate." The freedom to make strategic sourcing decisions should involve enough risk to justify the rewards and to ensure that something is learned. If you are making the choice of entering into an alliance or merger, learn from this checklist to improve the likelihood of your success.

Finally, a successful sourcing strategy will emphasize simplicity. The objectives of truly effective sourcing strategies are fewer suppliers, simple logistics, fewer interfaces and hand-overs, and clearly defined, widely understood performance standards among internal sourcing managers and external partners.

As always, the first thing senior managers must do is develop a solid business case to sell a new supply management strategy. Naturally, this business case will derive from, and have a solid foundation in, the company's overall business strategy.

Establish a commitment to the new strategy from the top down, and reinforce this commitment with measurable performance objectives. This will ensure that the plan works from the top down and the bottom up, with key responsibilities closely aligned with functional managers.

The top-down element will ensure that the new sourcing and supply management strategy is closely linked to the overall business strategy. And the bottom-up accountability will ensure that the right players take charge of the right processes and procedures. At the same time, cross-functional 'bridges' must be built so that the plan covers the entire company where appropriate.

Build relationships with suppliers capable of meeting your plan's requirements. Sometimes this will require disengaging from current contracts and current suppliers.

Monitor, measure and react to the strategies' performance.

Overcoming internal obstacles may be the most difficult part of putting together a winning sourcing strategy. Not only will some companies have to disengage from some current contracts, but a compelling business case will have to be made to convince internal manufacturing leadership that there are distinct advantages to the new strategy.

Inertia, conservatism, turf protection, and a tendency to hide behind regulatory issues all will have to be dealt with. Also, fear of risks to quality and security of the supply system will have to be assuaged.

Some managers might argue that under-utilized capacity is a reason for keeping more of the manufacturing in-house. Such arguments will have to be won by demonstrating the full range of benefits—higher flexibility, freed-up capital, faster time-to-market from sourcing-versus high overhead, and non-core status of in-house operations. Key to this argument is making sure that the relevant stakeholders fully understand the cost of capital and the role and value of operations in competitive positioning and are actively engaged in choosing the path forward.

The role of managing third-party manufacturers/partners is very different from the traditional procurement and manufacturing roles.

Finally, companies must ensure that the right people make the sourcing decisions. Leadership insight, and skill are critical for shaping and managing the complexities of any business process, but especially sourcing strategies — both internally *and* with sourcing partners. Leaders must manage sourcing, make the critical decisions (with a full understanding of the overall business strategy), and set the direction to prevent or eliminate 'over insurance', that is, excess resources locked up in sourcing. This is the most significant determinant (and potential constraint) in developing lasting improvements in the operating performance of the pharmaceutical companies.

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