Strategic Decision Support

Creating Strategic Manufacturing Flexibility - a Portfolio Approach to Managing Capacity Options

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> Securing manufacturing capacity is a critical issue for pharmaceutical and biotechnology companies. Utilizing a portfolio approach will ensure that your company identifies the optimal capacity options in order to maximize shareholder value and minimize risk.

As life sciences executives look to plan their capacity requirements, they must address a number of key questions:

1. How to secure the right amount of capacity to satisfy demand in an uncertain commercial and technical environment?
2. How to balance these requirements against a goal of maximizing ROI while minimizing the risk of having too little or too much?
3. How to create sufficiently flexible capacity options that meet above requirements in an environment of limited resources and capital?

This paper will explore how a portfolio management approach, used extensively to manage research and development projects, can be effectively used to plan (and manage) a company's manufacturing capacity needs.

A Challenging Planning Environment

Securing manufacturing capacity for a single product is a challenging exercise. Because product launch is years away, demand uncertainty is often significant. In addition, the technical uncertainties could result in the product never reaching the market, i.e. the product may fail clinical trials due to a poor safety and/or efficacy profile. The decision to secure manufacturing capacity must start relatively early in the process and a choice needs to made whether to build or buy. For example, building capacity for a biologic can take 4-6 years and up to $0.5 billion to implement, yet there is no guarantee that an outsourced solution will be available when needed or cost-effective and flexible enough to meet the needs of the company. Secure too little capacity and the company may loose substantial revenue opportunities. Build too much and the company will find itself scrambling to identify ways to recoup wasted investments that could have been better utilized elsewhere.

Now imagine extrapolating this situation to include additional pipeline products (at different stages of development) and demand uncertainty of products already on the market.

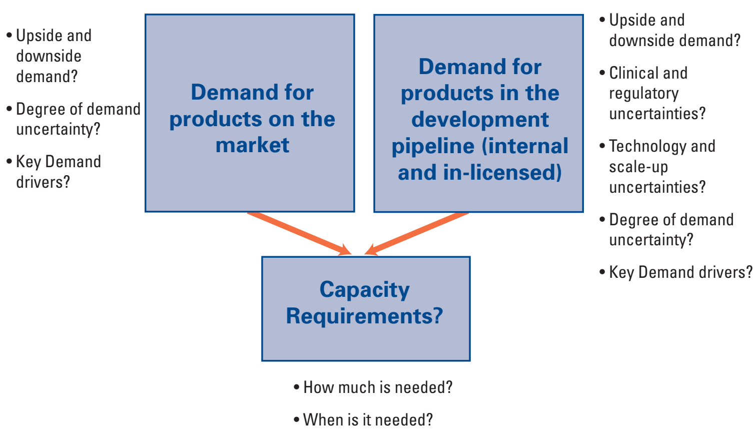

Figure 1: Uncertainty in demand makes for a challenging planning environment

As strategic planners review their capacity requirements over time, they have a number of alternatives to choose from:

1. Expand existing facilities and/or
2. Build new facilities (typically in areas with significant tax and other incentives) and/or
3. Free-up capacity within existing facilities through operational or process technology improvements and/or
4. Source capacity from third parties such as contract manufacturing organizations (CMOs) and/or other pharmaceutical/biotechnology companies with unused capacity as a primary or back-up source

Capacity Options		
Make (internal options)	**Make & Buy (hybrid options)**	**Buy (external options)**
• Build new facility • Expand existing facility • Improve capacity utilization in existing facility (free-up capacity)	• Lease with an option to buy • Joint venture	• Use contract manufacturer (CMO) or secondary (surge) capacity source • Other pharma/ biotechs with excess capacity

Each option involves unique investment requirements:

• Magnitude • Structure • Timing

Different implemenation lead-times

Figure 2: Many capacity options to choose from

Each of these alternatives has a unique set of attributes that must be considered. The timing of when capacity is needed will, to a large extent, dictate which options are feasible. Lead-times to bring capacity on-line will differ from a CMO with existing facilities and equipment versus building a new facility from the ground up. Each capacity option will also have different investment requirements, such as the timing, magnitude and structure of capital outlays, as well as different cost implications.

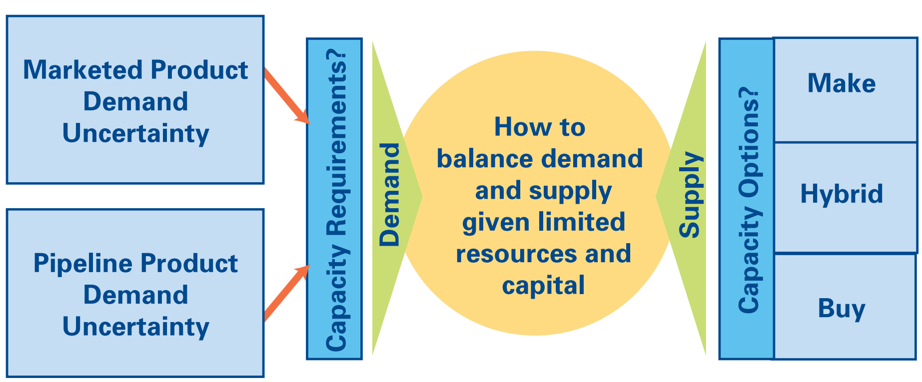

Figure 3: A planner's dilemma

Traditional Planning Approaches are Sub-Optimal

Typical approaches used for strategic capacity planning do not adequately address the challenge of securing capacity in a dynamic and uncertain environment. Companies often:

1. **Neglect to explicitly incorporate (and quantify) uncertainty and risk.** Often, planners rely on the discounted cash-flow (DCF) method to justify capacity decisions. Basic DCF uses single-point assumptions to generate demand and cash-flow forecasts. The underlying assumption when using single-point estimates is that the resulting projected cash flows are known with 100% certainty. Under these circumstances, planning capacity requirements is easy. The timing and magnitude of demand is not going to change over time and all products in the pipeline will successfully launch. This is obviously an unrealistic expectation. Demand can be highly uncertain – especially for products that are years away from launch. Products on the market can experience higher or lower demand than initially planned for, and pipeline products can fail to win FDA approval. Not only is demand uncertain, uncertainty grows with time, i.e. the further out the forecast, the greater the uncertainty.

2. **Optimize at the individual product level.** Many companies tackle the challenge of matching product demand with capacity as a series of discrete planning events. Capacity requirements are typically optimized at the individual product demand level rather than optimized across all products – those already on the market and those in the development pipeline. Alternative opportunities to create flexible capacity options across a network of manufacturing assets (owned and/or outsourced) are not explicitly identified or valued financially.

3. **Base decisions on static multi-year assumptions.** The discounted cash flow approach not only assumes 100% certainty in cash flow projections, it also assumes that all decisions to invest are pre-committed no matter what happens in the future, i.e. that decisions are all or nothing. In reality, decision-makers have the flexibility to stage their capacity decisions in a way that lets them re-evaluate their options at each critical decision point based on better information. So as new information becomes available over time they can make better capacity allocation decisions based on the best options available at their disposal within a changing constrained environment. For example, the capital budget may be significantly higher in a few years due to a new financing event.

As a result of this typical approach, it is not uncommon that strategic capacity decisions are based heavily on intuition with each stakeholder defining and pushing for their own set of priorities. For example:

- Sales and marketing is highly optimistic regarding demand and their ability to turn demand into sales – they typically advocate more capacity.
- Supply chain wants to ensure sufficient product availability – they would prefer additional capacity as back-up in case of a surge in demand.
- Manufacturing is concerned with asset and resource utilization in their facilities and would like to secure capacity as late as possible to ensure that capacity better addresses real demand.
- R&D is optimistic about their ability to push pipeline products to market – they would like capacity to be sourced early and internally in order to develop (and retain) the necessary process technology and to ensure sufficient supply of clinical material.

Each functional silo will have its own view of needed capacity and where this capacity should be sourced from. What is often lacking in the process is a data-driven and quantitative approach – an approach that does not replace intuition but supports an unbiased and transparent decision-making framework.

A Portfolio Management Approach Leads to Better Decisions

Portfolio management techniques are being used by leading pharmaceutical and biotechnology companies to make optimal decisions regarding R&D projects. The same approach can be used successfully to plan and manage strategic manufacturing capacity.

But what is portfolio management? Portfolio management is the ongoing process of managing a dynamic set of projects with the goal of maximizing value to the organization subject to resource constraints. In a manufacturing capacity context, the process can provide guidance on selecting the optimal portfolio of capacity options given existing constraints while highlighting the advantages of shifting these constraints to create a more valuable portfolio by increasing capital budgets; shifting resources; outsourcing versus keeping in-house, etc. The process can be used to communicate with others at the corporate strategic decision making level, the challenges and trade-offs that need to be made regarding capacity in a consistent, credible and transparent manner.

- Quantifies commercial and technical uncertainty rather than ignoring it
- Identifies key sensitivities, i.e., demand drivers — and what uncertainty needs to be resolved before a commitment can be made
- Enables dynamic management and prioritization of a portfolio of capacity options
- Values flexibility to adjust quickly to new opportunities while mitigating risks
- Makes capacity allocation decisions that maximize portfolio ROI while reducing risks (i.e. hedging strategies)
- Solves for key decisions: How much capacity to secure and when to commit investment dollars (shore/medium/long-term planning horizon)
- Includes constraints: resources, capital, lead-times, utilization, etc.

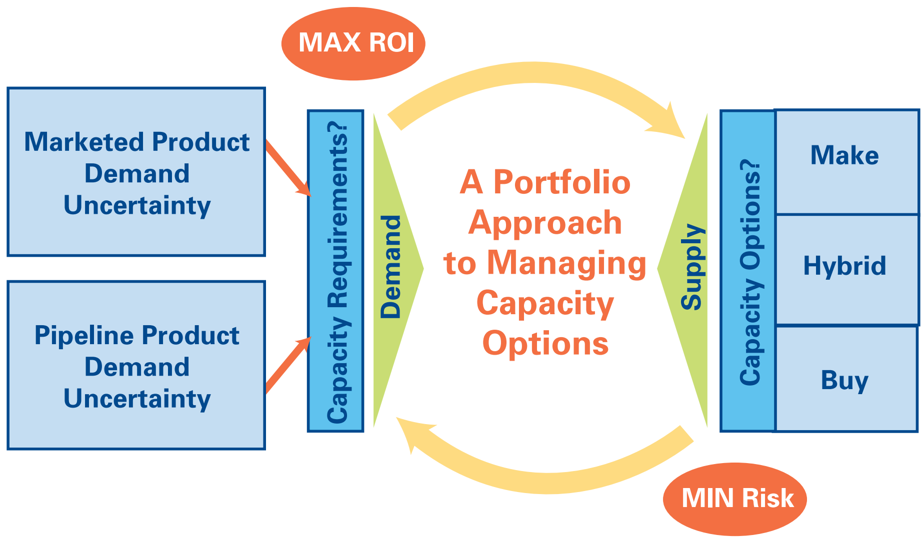

Figure 4: A portfolio approach to managing capacity options

For example, a mid-size biotech company has two products currently on the market: Product A and Product B, and a product candidate in late-stage development: Product C. Products A and B are currently produced in the company's existing manufacturing facility – each occupying 2 of 4 bioreactor suites. In addition, demand forecasts for each product exhibit varying degrees of uncertainty: Product A could run out of capacity in 3 to 5 years if upside projections materialize, while Product B would run out of capacity in 4 to 6 years. Product C is expected to launch in 3 to 4 years and requires at most one bioreactor suite for the first 5 years post launch. Given that Product C is starting phase III trials, there is still a 25% chance that it may not be approved.

The questions facing management in this simplified example is how much and when to secure capacity given uncertainty in demand forecasts? Where to secure this capacity from and how to secure the optimal mix of capacity options while maximizing return on investment and minimizing risks given alternative constraint scenarios (i.e. low/medium/high capital budget scenarios)?

When looking at available options, capacity for each product demand can be accommodated in a number of different ways:

1. **Products A and B**

   a. Invest in facility expansion or build new facility in a different location

   b. Use contract manufacturer or other third party facility

   c. Free up sufficient capacity to meet upside demand in existing manufacturing suites through process technology improvements or operational improvements.

2. **Product C**

   a. Continue with existing contract manufacturer that is currently manufacturing clinical trial material for phase III

   b. Build new facility or expand existing facility to accommodate Product C demand

   c. Use freed-up capacity in existing facility. Assumes that a significant improvement in expression yields will be successfully achieved. Initial feasibility studies show that a 2X improvement is possible for Products A and B. That said, the investments and risks associated with these significant process technology improvements vary between the two products. Manufacturing scale trials are still necessary. Additionally, significant investments are required to reconfigure and validate existing facility for use with Product C as well as additional purification capacity.

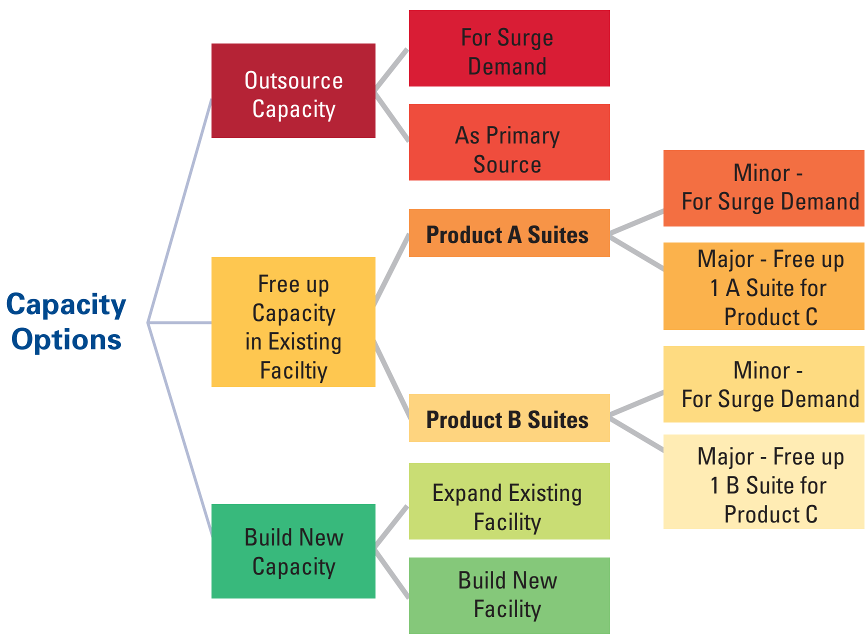

Figure 5: A decision tree for capacity options

Capital is assumed to be the only limiting constraint (aside for implementation lead times). Demand for each of the existing marketed products is uncertain but to varying degrees: Product B's demand uncertainty is greater than A's. On the other hand, upside demand may not materialize. Demand uncertainty for Product C is even greater than for Products A or B. In addition, Product C may fail to get FDA approval.

When considering the many uncertainties in demand, strategic planners must evaluate different alternatives that could potentially meet their capacity needs. Each alternative will have a different set of attributes such as unique investment requirements (magnitude, structure and timing); risks; the degree of flexibility to manage uncertainties (mitigate risk of too little or too much capacity); etc. For example, product demand can be supplied through the following alternative portfolios of capacity options:

Alternative Capacity Portfolios

	1	2	3	4	5	Etc.
Product A	Contract with CMO for surge capacity and pay reservation price to hold capacity until needed	Contract with CMO for surge capacity and pay reservation price to hold capacity until needed	Option to complete 2X improvements if Product C successful Product A can now be mtg in 1 suite[1]	Investment in incremental yield improvements (less than 2X) for surge capacity needs	Investment in incremental yield improvements (less than 2X) for surge capacity needs	
Product B	Contract with CMO for surge capacity and pay reservation price to hold capacity until needed	Option to complete 2X improvements if Product C successful Product B can now be mtg in 1 suite[1]	Contract with CMO for surge capacity and pay reservation price to hold capacity until needed	Investment in incremental yield improvements (less than 2X) for surge capacity needs	Investment in incremental yield improvements (less than 2X) for surge capacity needs	
Product C	Contract with CMO for post-launch support	Move product into freed-up Product B suite	Move product into freed-up Product A suite	Expand existing facility with 1 new bioreactor suite and additional downstream capacity	Build new facility that can accomodate Product C for the long-term (5+ years) and other products in the pipeline[2]	

1 Assumes that for very little effort, incremental yeild improvements can be made to the process to accomodate surge capacity needs within Suite 1

2 Assumes that new facility will be built in a location with advantageous tax credits and other incentives

Figure 6: Possible capacity portfolios

For each portfolio of capacity options, an expected net present value (eNPV) is calculated. The eNPV of each portfolio is based on the sum of the individual capacity projects required to accommodate demand for each product. The eNPV of each portfolio is then plotted as described in Figure 6, for different levels of capital investments (other attributes can also be used, for example, eNPV vs. risk, capital versus capacity utilization, etc.) As a result, an efficient frontier is established, in other words, for different levels of capital, a planner can construct an optimal portfolio of capacity options (Figure 7, yellow diamonds). In our example, if a company is constrained to a low-level capital budget, than the optimal choice is portfolio 1. For medium levels of capital, portfolios 2 and 3 are optimal. If capital is not constrained, than portfolio 2 yields the highest value of all alternatives. The portfolios that fall underneath the efficient frontier (Figure 7, blue diamonds) are suboptimal choices.

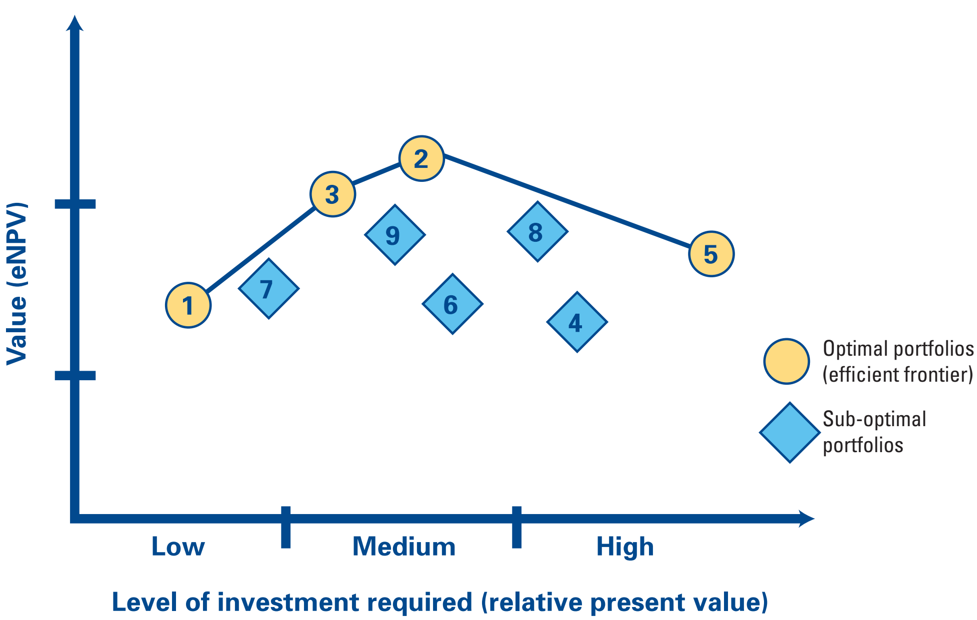

Figure 7: Optimal capacity portfolios given alternative capital allocation scenarios

eNPV in our example, is the statistical mean of a range of NPV scenarios and factors the uncertainty inherent in demand forecasts and other commercial uncertainties as well as the value of being able to make better managerial decisions as some of this uncertainty resolves itself over time. The Monte Carlo statistical method is used to simulate uncertainty, while the Real Options approach is used to calculate the financial value of managerial flexibility (a brief description of both techniques is given at the end of the article.)

Implementing a successful portfolio management process for capacity decisions requires a number of key elements:

1. Alignment with corporate vision and strategic objectives
2. Coordination and alignment with critical stakeholder groups such as R&D portfolio management, regulatory affairs, marketing, finance and supply chain
3. A set of guiding principals that define the key parameters that can form the basis for strategic alternatives, for example, products with proprietary process IP will manufactured in-house; capacity utilization will be limited to 80%; etc.
4. Defined short/medium/long-term planning horizons dictated by demand requirements and lead-times to bring capacity on-line
5. A consistent and transparent portfolio management process for dynamically valuing alternative portfolio scenarios
6. Commitment to action – implementing capacity allocation decisions in an optimal manner

In addition, an appropriate set of tools and techniques can facilitate the process. These techniques allow planners to efficiently and effectively value different strategies/alternatives to achieve desired capacity objectives:

- Monte Carlo Simulation – a statistical tool used to measure the range of possible outcomes of a given output variable (i.e. NPV, IRR, year x cash flow, etc.) given a series of uncertain input variables such as demand, price, market share, etc. Monte Carlo Simulation can help answer the following questions:
  - How wide is the cone of uncertainty?
  - Which demand drivers have the biggest impact on demand uncertainty?
  - What is the expected value of the resulting output variable?
  - What is at risk? What is the probability of breaking even? What is my confidence in the results?
- Real Options – an approach based on financial options theory. Real options values managerial flexibility, that is, a manager's ability to make optimal strategic investment decisions by choosing the best available option that maximizes value when some level of uncertainty is resolved over time. Typical options include:
  - Abandon a project or follow-on investments due to negative business conditions
  - Wait for results of market research/pilot program before moving forward
  - Switch to lower cost manufacturing alternative
  - Expand into new market
  - Accelerate development efforts
- Stochastic Optimization – considers uncertainty while optimizing an objective function such as NPV, IRR, etc., given a set of constraints such as capital, resources, capacity utilization, etc. For example, optimization can help decision-makers choose the capacity options that maximize value in an environment of demand and technical uncertainty but subject to budgetary constraints and capacity utilization thresholds.

For a more detailed discussion of these financial and decision analysis techniques, see "Investing in Biotech Manufacturing Capacity – Valuing Strategic Flexibility" by Uriel Kusiatin, *Pharmaceutical Manufacturing*, May 2006.

Summary

At first glance, strategic flexibility sounds like an oxymoron. Strategy is about commitment to markets, technology, customer segments and manufacturing philosophies. Strategic capacity planning is often implemented as a rigid commitment for a set number of years. Flexibility, on the other hand, is about the ability to stay nimble i.e., exploiting new opportunities and mitigating risks. A portfolio management approach to strategic capacity planning is all about creating strategic flexibility in the face of an uncertain and dynamic business environment. The benefits of a portfolio approach include:

- Higher return on investments in manufacturing capacity
- More effective mitigation of risk
- More efficient allocation of resources and capital

Companies that successfully adopt a portfolio approach to capacity planning are able to identify value maximizing options that create the flexibility necessary to mitigate the risks of over-capacity and/or to capture upside demand opportunities.

About the Author

Todd Applebaum leads the Strategy/Operations practice at Maxiom Consulting Group, a life science focused business and IT solutions consulting firm. The Strategic Decision Support practice works with executives to substantially increase their decision-making confidence when facing significant commercial and technical uncertainty. Our solutions are focused on key business decisions such as major investments in manufacturing and supply chain infrastructure; R&D portfolio management; and partnering and collaboration strategy and deal structuring.

Mr Applebaum has a distinguished track record in business strategy, manufacturing, and supply chain management, having led strategic and operational initiatives at large industrial clients across the biopharmaceutical, electronics, and automotive sectors. He holds a MBA from Carnegie Mellon University and BS in Industrial Engineering from General Motors Institute.

About Maxiom Group

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