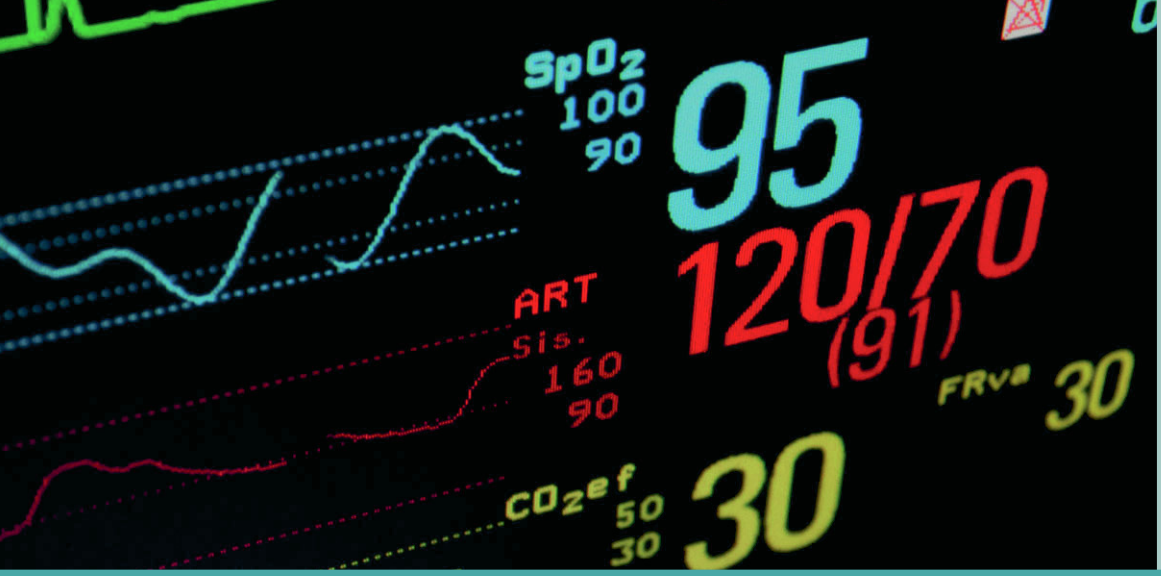

5.9 Competitive Advantage and Business Strategy

INTRODUCTION

As overwhelming as it may sound, figuring out an approach to intellectual property, R&D, quality, clinical trials, regulatory reimbursement, marketing, and sales is not enough. An innovator must also think about how all of these factors come together to create a compelling competitive advantage and, ultimately, a business strategy. Without an explicit point of view on how a company and its technology will be differentiated from the competition in the complex and dynamic medtech field, a product may never achieve or sustain its market potential.

OBJECTIVES

- Understand how to apply a fundamental framework for defining a competitive advantage.
- Appreciate how to develop business strategies designed to capitalize on that advantage.

Fundamentally, a company has a competitive advantage if its competitors cannot replicate its offering in some material way. The value of a competitive advantage is that it can prevent new competitors from entering a market based on the strength of the company's position and the barriers to entry that it has created through the development of key capabilities. It can also dilute efforts by established players to imitate what the company does well. Defining a competitive advantage is highly dependent on external factors within the market (e.g., intellectual property (IP), regulatory, customers, and competitive dynamics), as well as factors internal to the firm (e.g., strengths, weaknesses, and organizational issues). Once defined, the company's business strategy should be built around the optimization of its competitive advantage.

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COMPETITIVE ADVANTAGE AND BUSINESS STRATEGY FUNDAMENTALS

A company's competitive advantage is something special about the company that differentiates it from its competitors, creates **value** for its **stakeholders**, and prevents competitors from capturing the value it creates. By definition, a competitive advantage must be unique and/or difficult for others to replicate. No two companies will have exactly the same competitive advantage. In other words, there is no universal source of competitive

advantage, even for similar companies in the same industry.[1] A **value proposition** is a description of the improvements a customer will realize (at a defined cost) in terms that are meaningful to that customer (see 5.7 Marketing and Stakeholder Strategy). A competitive advantage, combined with an appropriate business strategy, can help a company to operationalize and deliver on its customer value propositions. There are two primary types of competitive advantages: positional and those based on capabilities.[2]

Positional advantages

Positional advantages come from a company's ability to strategically position itself relative to its competition and stakeholders. Positional advantages are, in general, quantifiable or measurable. A company enjoys a positional competitive advantage if it possesses an asset which is not easily obtainable, such as being first to market, obtaining key **patents**, or having the most widely recognized brand. For instance, companies that have direct access to the customer, through a strong direct sales forces or distributor network, achieve a positional competitive advantage by controlling key customer relationships (e.g., surgeons in the orthopedic market). A company that does not possess those relationships is at a distinct disadvantage when it tries to break into the market. Another way to achieve a positional advantage is to build a strong portfolio of products that offer comprehensive solutions that competitors cannot easily imitate due to technology limitations or other resource requirements. Broad IP portfolios can also be a source of positional competitive advantage. For example, J&J Interventional Systems achieved a strong positional advantage via its powerful Palmaz-Schatz patent portfolio surrounding its first coronary stent. Kyphon® achieved a similar advantage with its intravertebral balloon, as did ArthroCare with its coblation® technology.

Capability-based advantages

Capability-based advantages are built on a company's know-how, or competencies, as well as its ability to leverage its capabilities to become better than its competitors in key areas. Capability-based advantages sometimes are harder to quantify, and they usually reflect value that is embedded within teams or organizations. For example, a medical device company that develops an exceedingly capable IP team that is able to continually evolve and improve the company's patent portfolio enjoys a competitive advantage based on this capability. Another real-world example is SciMed Lifesystems, which established a capability-based advantage by becoming an expert in rapidly evolving processes to produce catheter and stent products with improved performance characteristics. US Surgical also established itself as a leader in minimally invasive surgical devices by developing a capability in advanced low-cost manufacturing techniques and rapid product iteration.

The interplay between positional and capability-based advantages

In general, positional competitive advantages are driven by a company's relationship to its *external* context. They are based on factors such as timing, size, location, specific assets, and access to important resources. These positional advantages are all relative to the other stakeholders in a field (customers, suppliers, or actual and potential competitors) and are continually changing. In order to understand the external landscape and establish a positional advantage, innovators must revisit the competitive analysis they conducted earlier in the biodesign innovation process (see 2.4 Market Analysis). It is a mistake to assume that the market situation remains static during the many years required to develop and introduce a new solution. Importantly, when performing competitive analysis at this stage of the process, innovators can get much more focused and specific in their assessment since they are now dealing with a **need** and a solution rather than just a need.

Once defined, positional advantages do not necessarily transfer effectively from one field to another. For example, Medtronic is the leader in cardiovascular solutions that utilize active implantable devices (e.g., pacemakers) and enjoys a strong positional advantage in terms of brand name and relationships in this field. However, the company has had a more difficult time creating a durable positional advantage in the field of catheter-based cardiovascular therapies.

In contrast, capability-based advantages are driven by factors *internal* to a company. They are based on a company's ability to do something better or less expensively than its competition and/or customers. These capabilities can be specific to a single process or generalizable across multiple processes. Capability-based advantages also may be transferable from one field to another. For instance, Pfizer's capability of effectively marketing and distributing drugs – frequently enabling the company to achieve the highest sales in a category within weeks or months of obtaining product approvals or acquiring those products – demonstrates how a capability can transfer from one medical field to another.

Sometimes the distinction between a positional advantage and capability-based advantage can be somewhat unclear. For instance, in the case of Pfizer, the company achieves a competitive advantage not only through its marketing capabilities, but also through the position it has achieved in terms of its relationships with physicians. Its broad product portfolio also makes it more appealing for physicians to spend time with Pfizer's sales representatives because they are able to address more products. Similarly, Medtronic has a positional advantage in implantable cardiovascular solutions, but has developed a unique capability for continuously developing complex, closed-loop systems that others cannot easily imitate. Innovators must recognize that multiple strengths often work in combination to create a company's advantage.

The link between competitive advantage and value propositions

Any number of strategies and competitive advantages can be combined to support a company's value proposition(s). For instance, if the value proposition of a company is to continually provide its customer with a constant flow of cutting-edge innovations, it might attempt not only to be first to market with any innovation (a **first mover** strategy), but also support that positional advantage with a strong, constantly evolving IP development capability. Another company seeking to provide its customers with the value proposition of an improved **user experience** might alternatively choose to follow quickly behind the market leader, allowing it to learn from the mistakes and usability issues encountered by the first mover. Alternatively, as a low-cost and low-price leader, a company may choose to offer a "best value" proposition which would de-emphasize market-expanding innovations in favor of a pricing advantage.

Value propositions must always be measured through the perspective of the customer. That is, they represent how a product, service, or company is viewed from the outside. The positional and capability-based advantages that are required to create and sustain a value proposition are what drives the creation of a business strategy for a company. For each value proposition a company defines for its stakeholders, it should carefully consider what strategies and potential advantages will enable it to successfully deliver on that vision and defend itself against imitation from its competitors.

Types of positional advantages in medtech

In the medical technology field, many innovators and young companies initially seek to develop core assets that give them a positional advantage. Another way to think about a positional advantage is as an initial barrier to entry. There are nine main sources of positional advantage.

1. *Intellectual property*

Establishing an initial patent portfolio (e.g., through a picket-fence strategy – see 5.1 IP Strategy) that is legally defensible can limit other companies' freedom to operate in a field and define a broad positional advantage for the company. J&J and Medtronic are well known for establishing broad, highly effective patent portfolios. Intuitive Surgical, Kyphon, and Acclarent also did this effectively during the early stages of building their companies.

2. *Key relationships*

The strength of relationships with important stakeholders, particularly physician key opinion leaders (**KOL**s) and powerful facility decision makers, can help a company more easily capture customers. For example, direct sales representatives in orthopedics and pacemakers wield substantial power on behalf of their companies due to the strong relationships they hold with these influential

stakeholders. As technologies continue to evolve in the **medtech** space, key relationships with patients (as consumers of some medical products and their related service offerings) can also be a source of positional advantage. Relationships with a wide variety of stakeholders can also be helpful in other aspects of the biodesign innovation process, such as efficiently gaining regulatory approval.

3. Reimbursement coverage

Companies who are first movers into a treatment area can sometimes gain a positional advantage by establishing **reimbursement codes** and **coverage** that favor their unique technologies if they operate in a geography where **payments** from **third-party payers** dominate the healthcare system. Of course, they often must invest significant time and resources into getting reimbursement set up. But once they achieve this goal, it is often difficult for other companies to leverage the same codes and/or justify the creation of additional codes in the same treatment area.

4. Strategic alliances

Partnerships with larger corporations and institutions can allow a new or smaller company to "borrow" reputation and keep other players from accessing the same limited resource (in the case of an exclusive alliance). Angiotech's relationship with Boston Scientific relating to drug-eluting stent technologies provides an excellent example of an effective medtech partnership. Recently, strategic alliances have become increasingly interesting as companies look for innovative ways to not only extend their capabilities but to share risks with other participants in the medtech value chain.

5. Geographic coverage/distribution channels

The ability to gain access to preferred suppliers for distributing products and/or providers for disseminating services to customers in key markets can lead to lower transaction costs and better terms than competitors can achieve. It can also be exceptionally difficult to replicate, as was the case for Stryker when it established strong, early distributor relationships outside the US, most of which continue to hold to this day.

6. Brand

Premium brands often achieve premium pricing. Branding can also increase product awareness, which in turn can lead to higher sales. Companies that establish strong brand awareness within their customer base are at a significant positional advantage with respect to incoming competition. For instance, surgeons are often reluctant to switch brands, especially when the products are life-saving and highly successful, such as the heart valves sold by Edwards Lifsciences or the hip and knee implants sold by Zimmer. As patients continue to amass more power in healthcare, innovators can expect issues of consumer brand awareness to become increasingly important. This is already happening in areas such as diabetes management, where consumers make brand-related choices about which blood glucose testing system to choose.

7. Financial access

Capital is a finite resource. Locking in top-tier venture capitalists, banks, and other funders can keep competitors from accessing the same capital resources, force them to deal with suboptimal terms, and/or leave them with less desirable alternatives. Companies such as Satiety, GI Dynamics, and Endogastric Solutions, which were early pioneers in the area of obesity, captured many of the desired medical device early-stage venture backers, making it much more difficult for later entrants to access capital.

8. Unique, exclusive, or low-cost access to a key resource

Key resources can include hard-to-find materials (such as nitinol, proprietary gene sequencing databases, or limited tissue samples) or exclusive relationships with technology providers in specific fields (such as slippery coatings for catheters, polymer drug-elution platforms, or silicone-polyethylene co-polymer blends). A company that can gain access to key resources exclusively, more easily, or at a lower cost has a positional advantage over its competition.

9. Information access

As healthcare delivery becomes more connected across the **cycle of care** and physicians, facilities, patients,

payers, and other stakeholders continue to expand their efforts to work together more closely and proactively, the company that has the best, most actionable information about key health-related interactions will create a strong positional advantage. Value can be generated by making this data available to health plans and providers to help them improve outcomes and reduce costs. It can also be generated by analyzing the information to understand customer behaviors and identify future customer needs. Medtronic, with its **acquisition** of Cardiocom, provides one example of a company seeking to build a competitive advantage based, in part, on access to information that can be used to optimize patients' experiences across the treatment continuum (see case example in 4.4 Business Models).

Almost every successful medical technology company has, at least at some point in time, developed one or more positional advantages to fend off competition. For example, Fox Hollow, a company focused on the treatment of peripheral arterial disease (which was acquired by ev3), created an almost impenetrable barrier to competition by effectively developing strategic relationships with most, if not all, of the KOLs in the field. The use of key physician relationships has similarly been a fundamental basis for creating an advantage in the orthopedics industry (although this practice has fallen out of favor to some extent following concerns about the potential for these relationships to create conflicts of interest). Strategic corporate relationships offer another common approach towards achieving a positional advantage, such as J&J and Guidant's accord related to balloon catheters and Rapid Exchange (RX)™ technology, which permitted the two companies to cease several lawsuits and refocus efforts into more productive activities.

As noted, positional competitive advantages can be relatively perishable. Just as an army at the top of a hill enjoys a distinct positional advantage in attacking an opposing force in the valley below, that advantage deteriorates as soon as the troops charge down the hill and find themselves on a level playing field with the opposition. In the medical device field, companies that enter the market with an advantageous position must continually seek to improve and/or defend their position to sustain the advantage. For instance, a company that successfully establishes meaningful relationships with key opinion leaders must monitor and invest in those relationships on an ongoing basis or else a competitor may edge in and gradually appropriate them. Similarly, competitors will find ways to design around a company's initial IP position if the market is sufficiently compelling. And, with enough time and money, even new sales and distribution channels can be built to rival an established infrastructure.

Types of capability-based advantages in medtech

Innovators and young companies can also create a competitive advantage by developing a product or delivering a service that is better, cheaper, or more efficient than what is offered by the competition. While doing this creates a competitive advantage in its own right, capability-based advantages are often used to help sustain positional advantages. That is, a positional competitive advantage can be maintained by transforming it into a capability-based advantage and/or can be defended through the development of a strong capability in that area. In most cases, positional advantages can become capabilities if a company can learn to consistently perform better in the given area than the competition. The creation of specific systems and processes focused in the particular area can be the first step in developing a unique capability. Six valuable medtech capabilities are outlined below.

1. *Intellectual property management*

As noted, if a company seeks to recruit, develop, and retain a world-class IP team, it can transform a strong IP position into a best-in-class IP capability. This is accomplished through systems and processes designed to continually and aggressively monitor the IP landscape, anticipate competitive moves, and act more quickly than the competition to advance, strengthen, and defend the company's IP portfolio.

2. *Regulatory, quality, or reimbursement management*

Similarly, companies can build a capability-based advantage in regulatory, quality, or reimbursement

management by hiring and cultivating talent and building and managing world-class processes in these areas. With capabilities in these areas, companies can more efficiently satisfy essential requirements and more effectively anticipate and mitigate related risks.

3. Relationship management

To create a capability-based advantage focused on key relationships, it is not enough to manage and protect the company's position with established thought leaders. Systems and process must be created for (and resources must be dedicated to) identifying subsequent generations of potential opinion leaders and developing relationships with them before the competition.

4. Alliance management

A company can develop a unique capability when it comes to partnering if it has the right processes in place and resources on board to think about alliances in innovative new ways. Likewise, it can continually monitor the external landscape for mutually beneficial partnerships, and negotiate more exclusive (or otherwise more favorable) terms than the competition.

5. Human resource management

Human resources (HR) management refers to the creation of an optimal team of individuals with the essential competencies necessary to succeed in the market (e.g., technical, clinical, reimbursement). This is a capability-based advantage when it is achieved on an ongoing basis, despite the natural level of turnover inherent in any industry.

6. General management

Simply having good leadership and well-trained managers in key positions within a company could be a strong capability-based advantage. Installing management training and feedback programs can enhance and sustain this advantage.

Capability-based advantages can also be created in other areas where a company has unique process expertise, whether or not it is related to a positional advantage. For example, medtech companies may achieve capability-based advantages related to the following factors:

- **Time to market** – Having the people, processes, and systems in place to consistently get to market sooner than the competition.
- **R&D productivity** – Systematically generating more or better innovations than others in the field.
- **Low-cost manufacturing** – Achieving low-cost manufacturing through the acquisition of low-cost inputs is a positional advantage while achieving it through more efficient processes is a capability-based advantage.
- **Accessing and developing global markets** – Having the talent and experience within an organization to establish and manage global R&D, manufacturing, and/or sales and distribution is becoming an increasingly valuable capability.

Innovators should remember that even the most impressive capabilities are not a source of competitive advantage if one or more competing companies can match them. Capabilities can only become a source of sustainable competitive advantage if they are hard to imitate or the company can continuously improve upon them before others can catch up. When a competitive advantage resists competition, it is said to be sustainable.[3]

Often, capability-based competitive advantages are widely understood in an industry, but still difficult to replicate because no one is certain what causes them. Complex routines, structures, and individual attributes within an organization, combined with a high level of tacit knowledge, can make them difficult for competitors to imitate.[4] For example, Ethicon was widely considered to be the worldwide leader in surgical closure technology and, in particular, suture technology. However, in the 1970s, US Surgical began making inroads into Ethicon's markets with the introduction of its surgical staple technology as a substitute for traditional sutures in minimally invasive laparoscopic procedures. Buoyed by its success, US Surgical decided to enter the suture market and directly compete with Ethicon in its core market by introducing its own line of sutures in 1991. However, US Surgical dramatically

underestimated the strength of Ethicon's suture manufacturing capabilities. The company did not realize how challenging it was to produce a high-quality suture that did not break, stayed attached to the suture needle, and performed consistently, package after package. In the end, the product released by the company failed to meet physician quality expectations and, as a result, never claimed the market share that US Surgical expected. Ethicon's proprietary know-how (i.e., trade secrets) in suture manufacturing proved to be a formidable competitive advantage that US Surgical could not overcome, even with its vast resources.

Fundamental business strategies

After a company has identified its potential sources of competitive advantage, it can effectively evaluate the best fundamental business strategies to pursue in order to optimize them. No single strategy can be expected to work for a company indefinitely; instead, innovators should think about choosing the combination of strategies that will enable the company to achieve long-term success.

While some of the strategies described below lend themselves more readily to positional rather than capability-based advantages, they can still be used in combination and/or in sequence to enable both types of competitive differentiation.

First mover

A first mover strategy refers to being the first company to offer a product or service in a market. Being first to market has significant advantages, including the ability to establish key IP that can serve as a barrier to entry, form relationships with important early customers and other resources, and define the most important product attributes and regulatory and reimbursement strategies that future competitors will have to consider. In some cases, a first mover can also create high **switching costs** for customers in order to keep future entrants from selling to the same customer base. This often happens with capital equipment, such as MRI and CT machines, that require a large upfront investment by the hospital that purchases them.

However, first movers incur certain costs for the positional advantages this strategy typically affords them. These costs include the need to define the regulatory and reimbursement pathways, educate customers to drive adoption of a new product category, and train **users** on new techniques. These pathways can then be used by other companies to more quickly and less expensively create follow-on products. Typically, reimbursement and regulatory pathways paved by first movers are exploited by those that follow. But sometimes the first mover creates barriers by developing those pathways – they set the hurdles higher for those that wish to enter. For example, early developers of certain cardiac implants set a 10-year testing cycle standard that has required all that followed to abide by those criteria.

Importantly, a first mover advantage is only sustainable if the company in the lead continues to find creative ways of exploiting its first mover position. Otherwise, it will fall quickly into the ranks of the competition when other companies arrive in the market, forfeiting any benefits associated with being the first mover.

Another example of a successful first mover is Kyphon. Kyphon focused on treating vertebral compression fractures, a previously overlooked and under-treated market, by creating a new, minimally invasive procedure it called kyphoplasty. By setting up a dominant IP portfolio, the company deterred many competitors from entering the market and remained the leader until it was acquired by the competitor that posed its greatest threat. Guidant, on the other hand, was unable to sustain its first mover advantage in the field of interventional cardiology after several years of being the market leader. Instead, it fell into more of a follower position due to the company's early reluctance to explore new products, such as the area of coronary stents.

Fast follower

Instead of blazing the path to the market, **fast followers** often leverage other advantages to quickly capture market share from the first mover. Large companies in the fast follower position can often leverage their established distribution channels and customer relationships to this end. Both large and small companies may be able to introduce new features that create subtle differences between their technology and the first mover's product.

This can allow the company to overcome barriers to entry created by the first mover's IP position (in that different IP can be pursued). New features can also be used to address known shortcomings of the first mover's technology, further eroding the strength of its position. Fast followers also benefit from the reimbursement, regulatory, and awareness/education campaigns that have already been conducted by the first mover.

Boston Scientific's drug-eluting stents (DES) provides a good example of a successful fast follower strategy. Johnson & Johnson (J&J) created a dominant first mover position in the DES market with its Cypher® stent, holding a monopoly position in the US for nearly a year. During this time, however, J&J ignited tensions with many doctors by pricing its technology at levels that many considered to be unreasonable. The company also experienced significant supply problems, which further angered physicians when they could not obtain an adequate supply of the product to satisfy the patients on their waiting lists. When Boston Scientific launched its Taxus® stent, physicians already understood the benefits of a drug-eluting device and were receptive to the new technology. The company intentionally took advantage of the relationships that had been damaged by J&J's supply and pricing issues by ensuring that it had plenty of supply on hand, and was working with hospitals to develop mutually beneficial pricing strategies. Furthermore, Boston Scientific promoted the product features of its DES that made it more flexible and easier to work with in direct response to criticisms of the Cypher stent, which was perceived as stiffer and more difficult to place. As a result, Boston Scientific captured nearly 70 percent of the DES market from J&J in its first seven weeks on the market.[5]

Me-too

Unlike the products of fast followers, **me-too** products are relatively undifferentiated from the products that are already on the market. Typically, me-too products seek to benefit from the technical and market development of earlier players by creating a product that is cheaper to develop or manufacture and, thus, may be offered at a lower cost or with some very modest improvements. By watching earlier competitors, purveyors of me-too products often manage to avoid costly mistakes and sometimes can go through less arduous regulatory steps. Since me-too companies have lower development costs to recoup than the first movers and fast followers, they often compete based on price.

A prime example of a me-too product is found in SciMed's initial entry into the angioplasty catheter market. The company's first product was not tremendously differentiated from other competitors in the marketplace at the time. Interestingly, as noted previously, SciMed ultimately developed a powerful iteration and rapid development capability that moved it away from this me-too strategy into a first mover strategy.

Another example of a me-too product strategy is seen with generic versions of drugs. Generic drugs can save significant time in getting to market and can incur lower development expenses by using separate regulatory pathways from those used in new drug approvals. Once a generic enters the market, the original product must leverage its brand to retain some advantage. However, a positional brand advantage can be eroded quickly because the less expensive alternatives are favored by price-sensitive payers. This me-too strategy applies not only to generic drugs, but to any follower joining the market on the heels of another company's pioneering product, particularly once that product category has been well established. While fast followers often enter with differentiated products that they believe to be patentably distinct, generic followers enter only once key patents have begun to expire. In both cases, the followers have the distinct advantage of having watched the pioneer in the market make mistakes and adjust its strategies. If they can use these learnings to help them navigate whatever competitive barriers have been erected by the predecessor, they have the opportunity to gain market share much more rapidly.

Niche strategy

Rather than attempting to own a product category, **niche strategies** focus on owning the customer relationships in a specific, focused area of medicine. Companies often pursue a niche strategy when a group of physicians, typically in a smaller subspecialty, remains underserved by the market. To meet the needs of a niche market,

a company may tailor a selection of its products to the unique needs of the physician/customer group. The overarching goal is to gain a positional advantage through strong customer relationships as a method for blocking competitors. Another niche strategy is to target a particular geography (or demographic) that may not be compelling to the dominant, established players in the field, and then use this as a springboard into other areas as the company builds momentum. Start-up companies in low-resource environments such as India are using this approach when they believe their products have the potential to be attractive in both developing and more developed settings.

American Medical Systems (AMS) executed a niche play to win the urologist market. While other companies called on urologists with the same sales representative that called on general surgeons, AMS positioned itself narrowly as a urological disorders business with products to treat conditions such as erectile dysfunction, incontinence, and prostate disease. By focusing exclusively on serving urologists and the diseases that urologists treat, the company sought to position itself "not only to benefit from growth in the urology market, but to drive it,"[6] as compared to some of its more broad-based competitors that participated in multiple market segments. This strategy was extremely effective, allowing AMS to build strong relationships with customers that others had trouble accessing.

Another variation on a niche strategy is to pursue "orphaned" drugs and diseases – rare conditions with relatively small populations that previously have been overlooked by medical technology and pharmaceutical companies (e.g., renal cell carcinoma, glioma, and acute myeloid leukemia).[7] One definition of orphaned diseases is that they are diseases where the manufacturer of the vaccine or treatment cannot expect to make a profit (many tropical diseases are also considered orphans because the tens of millions of patients suffering from them are too poor to pay for medical interventions).[8] However, some analysts perceive an opportunity for orphaned diseases to become more interesting to drug and device manufacturers. As medicine becomes more personalized and the discovery of "blockbuster" products gets less and less common, companies in geographies around the world may increasingly take advantage of the special incentives offered by governments in the regulatory process (e.g., **FDA's Humanitarian Device Exemption** – see 4.2 Regulatory Basics) to try profitably serving these markets[9] and/or using them as a springboard into related treatment areas.

Low-cost provider

An approach that often works well in combination with another strategy, such as pursuing orphaned diseases, is the **low-cost provider** strategy. With this approach, companies must find and sustain creative ways to drive innovation at a significantly lower cost than its competitors so it can pass along lower prices to customers. In mature healthcare markets, innovation has traditionally been stimulated by the desires of advanced health systems to build their infrastructures and expand their capabilities. But some analysts expect this model to become all but outdated as more and more innovations emerge from geographies and other environments faced with severe resource-constraints and infrastructure limitations.[10] Moreover, the incremental approach to making product improvements that traditionally has dominated medtech is becoming obsolete, with the benefits from making incremental improvements to existing devices dwarfed in comparison to the cost of realizing those improvements.[11] Innovations at significantly lower price points are already emerging from companies using a low-cost provider strategy in places like China, India, and Brazil. Companies in established markets such as the US may be at a disadvantage in pursuing a low-cost innovation strategy if they are entrenched in a more traditional mindset. However, over time, government and competitive pressures to lower healthcare costs are likely to make different ways of thinking and acting an imperative for all medtech companies.

Often, companies with a low-cost provider strategy choose to emphasize the "de-featuring" of products over radical innovation. GE's MAC line of electrocardiogram (ECG) machines, which offer basic functionality at a cost of $500–$800 instead of $2,000–$10,000 for conventional ECGs, provides one well-known example.[12] Yet, some companies are able to offer both affordability *and* high-quality innovation, as the Mindray story illustrates.[13]

FROM THE FIELD MINDRAY MEDICAL

Realizing competitive advantage with a low-cost provider strategy

Mindray Medical International Limited was China's largest medical device company in 2014.[14] Founder Xu Hang originally started the company to serve Chinese hospitals, mostly in rural areas, that could not afford basic medical equipment. The company's initial focus was on providing low-cost in vitro diagnostics and patient monitoring systems of acceptable quality at the lowest possible price. However, over time, Mindray's ambitions expanded. To compete on a larger scale against global medical device manufacturers, the company sought to augment its low-cost provider strategy by making its products more innovative and improving their overall quality.[15] To do so, it would optimize its business around improving what the company calls its "performance-to-price ratio."[16]

In orchestrating this transition, Mindray focused on paying close attention to the needs of mid-tier hospital that traditionally had been ignored by large multinational companies. It then directed its innovation efforts on improving the functionality of its devices based directly on these needs.[17] The company also reported devoting 10 percent of its revenues[18] and 30 percent of its staff[19] to research and development each year. With this investment, Mindray has developed an R&D capability that enables it to launch as many as 13 new products a year.[20]

To hold down costs as it increased innovation and quality, Mindray built a vertically integrated production model that allows it to design, develop, and manufacture its devices in-house. The cost of labor in China is one factor that supports the company's low-cost approach. But other strategies, such as using common resources and modular components within and across product lines,[21] help it maintain a cost advantage. Mindray typically offers its equipment at price points as much as 40 percent lower than its multinational competitors.[22]

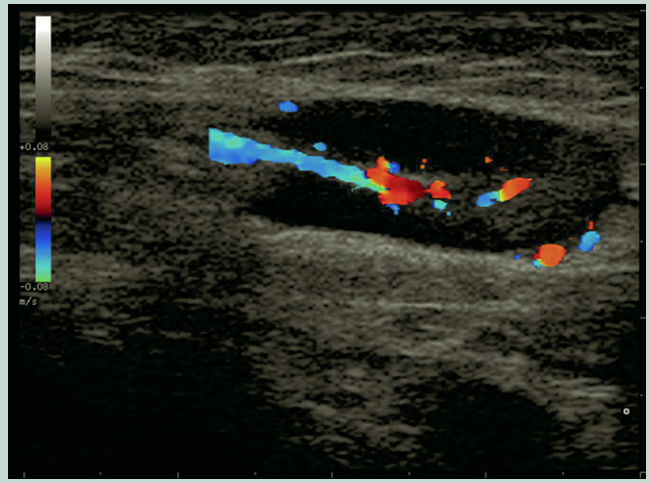

FIGURE 5.9.1
A color ultrasound image of the lymph nodes (by Nevit Dilmen via Wikimedia Commons).

One of the company's first domestically developed, innovative devices was a digital color ultrasound imaging machine which, when it was launched in China, caught the attention of Mindray's international rivals (see Figure 5.9.1).[23] From there, Mindray has expanded its product portfolio to more than 60 products sold in 140 countries around the world,[24] including Asia, Africa, Europe, and the United States. Roughly half of its revenue is from sales outside of China.[25] In these international markets, Mindray continues to focus on smaller and mid-tier hospitals, as well as private clinics with the intent of expanding from this beachhead.[26]

Relative to its domestic competitors, Mindray garners a 20 percent premium due to its brand name and reputation for quality.[27] However, it is still working to convince some customers in markets

like the US that a low-cost provider can deliver high-quality products. Lee Weng, General Manager of Mindray's first overseas R&D center in Seattle, Washington, once referred to the aversion of some international buyers to Chinese medical devices as a "prevailing prejudice."[28] To combat this perception and strengthen its strategy, Mindray remains focused on developing affordable, innovative products that meet the requirements of regulators in the European Union and US.[29]

Distribution strategy

Distribution strategies focus on product breadth and channel relationships rather than on product superiority. By meeting the needs of customers through diverse product offerings, more flexible payment arrangements, or strategies to bundle products and/or services, a business may keep more focused entrants out of the market.

Stryker, a leading manufacturer of orthopedics products, offers a broad product portfolio and thus can be a single solution for all of a hospital's orthopedic technology needs. Theoretically, it would be possible for Stryker to bundle the purchasing of hip and knee implants together and, thus, keep a new knee implant company out of an account. While the bundling of products is regulated by antitrust regulations like the Sherman Act,[30] a company that offers a one-stop solution may win in the market – especially in commodity markets. Baxter and J&J are good examples of companies that use a distribution strategy to maintain an advantage in hospital supplies (e.g., I.V. bags, gloves, bandages) and other lower-cost/commodity markets.

Disease management

A more advanced strategy related to the bundling of products and services that is emerging in the medtech sector is sometimes referred to as a disease management strategy or "**owning the disease**."[31] With this approach, technology companies are:

> *migrating from an episodic or intervention-focused business model to a convergent care model that enables them to provide solutions along the continuum of care. The integrated solutions inherent in this approach . . . combine drug, device, diagnostic, and consumer-centric solutions to establish creative platforms in which a company can dominate the diagnosis and treatment of a disease or condition.*[32]

In simple terms, some companies that once acted as hardware providers, focused on selling medical devices designed for a distinct intervention, are now interested in becoming problem solvers that provide end-to-end solutions for their customers. This strategy is consistent with the anticipated shift from traditional volume-based, fee-for-service health systems to a more cost-conscious, value-driven, and outcomes-focused orientation.

Larger organizations have a certain advantage when it comes to owning a disease due to the scale of their operations, the relationships and resources at their disposal, and the ability to take the time needed to assemble all of the parts of the solution.[33] However, it can be difficult for established organizations to undertake the radical change necessary to dismantle their old strategies and embrace new ones (see the Merck Serono case example). For this reason, start-ups and small companies can sometimes realize greater success in assembling an end-to-end solution. For instance, WellDoc has created a multi-faceted solution to own type II diabetes that engages prescribing physicians, the company's own trainers and healthcare providers, telecommunications companies, payers, and patients through its BlueStar™ offering.[34] This system, which is FDA-cleared and approved for reimbursement, is sufficiently further along and more disruptive than the offerings of the larger companies with an interest in diabetes management.[35]

FROM THE FIELD MERCK SERONO

Realizing results through a disease management strategy

To effectively employ a disease management strategy in a large, established organization, Don Cowling, Merck Serono's former Senior Vice President and Managing Director for Western Europe, acknowledged that, "You have to first blow up the current model."[36] His organization did just that in seeking to dominate the market for human growth hormone therapy for endocrine and metabolic disorders. When its drug Saizen® (somatropin) was on the cusp of becoming generic, the company adopted a strategy to transform its UK team from "a power-driven sales organization to a knowledge-driven outcomes organization."[37] The strategy centered on "adding value to the products you already have," said Cowling.[38] As one article described, he and his team determined that growth for drugs (and the devices that support them) is in adherence rather than finding new patients since half of all prescriptions are never filled, and half of those are never taken.[39] Yet, they recognized that stakeholders – including patients, physicians, facilities, and payers – do not want to pay for compliance. "They buy pharmacoeconomic outcomes."[40]

After extensive research and a significant rethinking of its approach, Merck Serono designed the easypod™ injector, a wireless-enabled, electro-mechanical device that resembles an early mobile phone (see Figure 5.9.2). A cartridge of medication is inserted into the side of the device, with a single-use needle attached to the end. The healthcare provider programs easypod with the dose, treatment plan, injection depth, and other specifications. When deployed by the patient, the device records the date and time of the injection, along with other relevant data. A sensor detects the angle of each injection (which is important for preventing unpleasant side effects) and a dose confirmation feature notifies patients when they have properly administered treatment. This information is stored in the device and uploaded to the Serono delivery team, which monitors it for missed doses or other warning signs and then makes outbound contact with patients or their clinics when intervention is needed.

FIGURE 5.9.2
The easypod injector (courtesy of EMD Serono, Inc.).

Once the team obtained regulatory clearance for the device, Serono began to gather evidence that demonstrated how the accurate, consistent use of its drugs was linked to desired therapeutic outcomes. It also gleaned insights about patient behavior patterns that allowed it to begin selling its drugs differently to providers and payers. The company was able to document value propositions tailored to customers' particular concerns. If a payer was concerned about the cost of non-compliance and prescriptions that were filled but never used, Serono could tap into patient data, analyze behavior patterns, and then offer per-injection pricing that would enable the insurer to pay only for

administered treatment. Alternatively, if a provider was more concerned about how to manage cost overruns, Serono could use its data to devise a capped payment agreement, essentially insuring the hospital or clinic against unanticipated spending.

When Cowling left the company in 2012, after 10 years of building and optimizing the model for Saizen, as well as several other products, he had roughly tripled his division's revenue while dramatically reducing total staff. Few financial results were publicly available, but one report claimed Serono had achieved a 38 percent compound annual growth rate in the mature growth hormone market through this patient-centric, outcomes-based approach to owning a disease state.

Information aggregator

Another emerging strategy in medtech is to become an **information aggregator**. As medical technologies become more and more connected, the value of new devices is no longer solely in the products themselves,[41] but in the information they generate, as well as the insights and solutions that the data enables. However, effectively capitalizing on this information is no easy feat. Issues of connectivity, bandwidth, integration, and security are daunting challenges, not to mention the analytics needed to understand and utilize the data. Companies are needed that can help healthcare stakeholders effectively manage the promise of connected (or mobile) health and mitigate its perils.

In response to this opportunity, companies outside health – mostly technology and telecommunications companies – have been expanding into the sector. For example, Verizon launched its Converged Health Management solution, which is an FDA-cleared remote health monitoring service. This offering provides physicians and patients with real-time access to data from connected biometric devices to enable anywhere, anytime monitoring.[42] Qualcomm is another company that entered the healthcare field through its Qualcomm Life division, as highlighted in the following case example.

FROM THE FIELD QUALCOMM LIFE

New opportunities in healthcare connectivity and informatics

Mobile health (**mHealth**) and health information technology (HIT) solutions are proliferating at a rapid rate, all with the goal of more effectively facilitating the flow of information among patients, providers, and other healthcare stakeholders to optimize patient wellness, diagnosis, and treatment. Wireless remote monitoring devices for tracking patient blood pressure, blood glucose levels, activity, and other important health indicators provide an example of one growing class of products. The success of this relatively new healthcare sector relies not only on the devices being developed in the space, but on the ability to make the data they gather accessible and actionable.

To help shape the intersection of connectivity, communications, and healthcare data management, telecommunications company Qualcomm launched Qualcomm Life, Inc. This wholly owned subsidiary has three core initiatives: the Qualcomm Life Fund, a $100 million investment fund managed by Qualcomm Ventures that is focused on start-up wireless healthcare companies; a strategic ecosystem group that collaborates with universities, trade and policy groups, and research institutes to provide resources to developers who want to apply wireless technology in the healthcare field; and a business arm that sells

cloud-based communications platforms (specifically, the 2net™ and HealthyCircles™ Platforms) optimized for healthcare customers.

Qualcomm Life's first offering is the 2net Platform, which enables the wireless transfer, storage, and display of medical device data. The platform is designed to be "technology agnostic," meaning that it seamlessly provides wireless connectivity and interoperability between different medical devices and applications from disparate manufacturers that patients and providers use across the continuum of care.[43] Data from these devices and apps reach the 2net Platform through one of four gateways. The first is the 2net Hub, an FDA-listed Class I Medical Device Data Systems (MDDS), stand-alone connectivity device that is roughly the size and shape of a nightlight. As Don Jones, VP of Global Strategy and Market Development for Qualcomm Life, explained, "2net works the way you wish your Wi-Fi actually worked. You open the box, plug it into the wall, and it recognizes any medical devices in the room that have a cloud-based relationship with our platform." The other gateways include medical data from mobile phones, devices with an embedded cellular component, and server-to-server interfaces between Qualcomm Life and other service platforms.[44] As Jones elaborated, "The 2net Platform gathers the data from these gateways and securely delivers it to healthcare providers [and other stakeholders] in a 'mash-up' format, meaning that it enables the capture of multiple data streams to make one big picture" (see Figure 5.9.3).

Qualcomm Life's second offering, the HealthyCircles Platform, is a hosted enterprise software-as-a-service platform solution that provides a secure communications and record-sharing infrastructure for care team coordination, post-discharge transitional care, and complex condition management.[45] Together, these offerings aggregate device and app data, medication history, labs, care team data entry, and patient

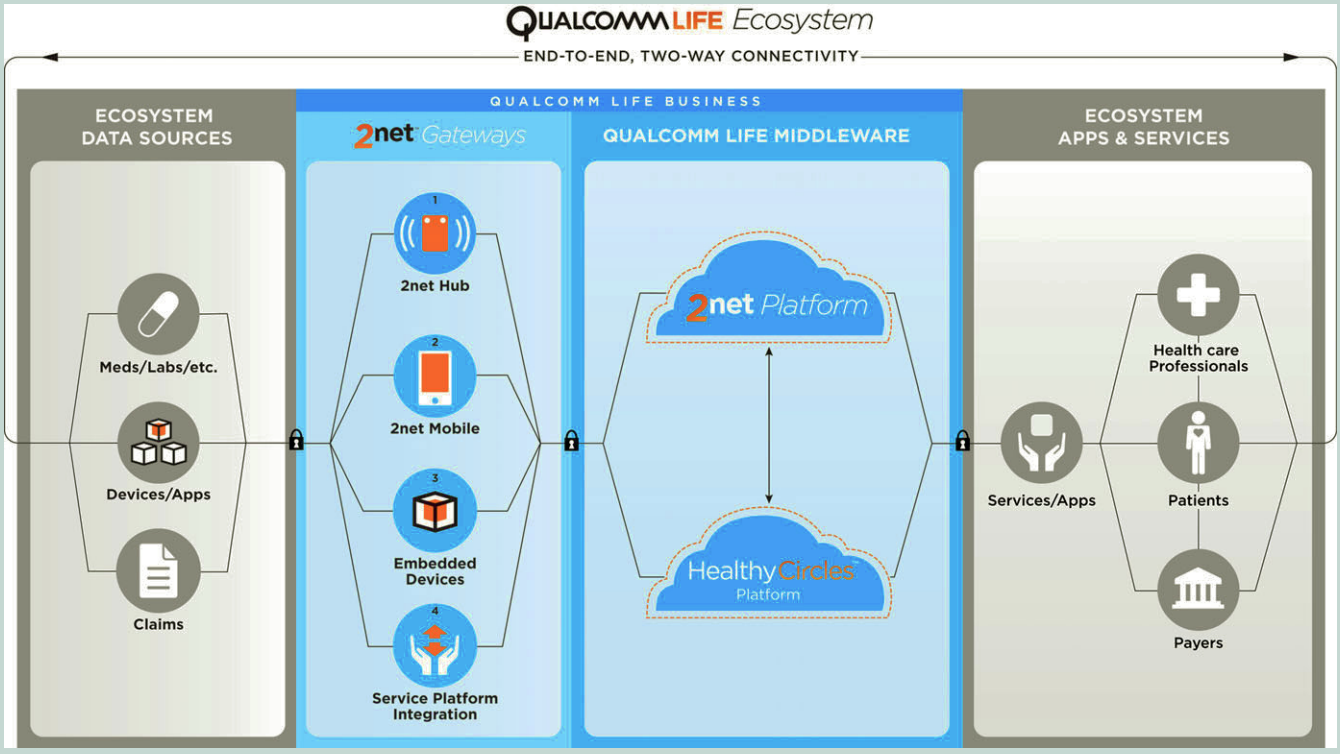

FIGURE 5.9.3
A visual representation of the Qualcomm Life 2net Ecosystem (courtesy of Qualcomm Life).

symptomatic self-assessment to create robust datasets for Qualcomm Life's customers.

According to Jones, Qualcomm's decision to enter the healthcare space was fueled by recognition of a growing unmet need. "Literally hundreds of companies had come to us for advice on how to use wireless, connectivity, and network architecture to create solutions in healthcare," he recalled. "And many of them were trying to reinvent the same wheel." Qualcomm realized that if it took on the challenge of building an enabling platform and connectivity infrastructure, "We could not only do it better and more efficiently, but we could take a lot of cost out of these healthcare solutions and support an ecosystem of companies," Jones stated.

Qualcomm found the healthcare opportunity attractive because it possessed key capabilities that gave it a significant competitive advantage. Specifically, the company's deep expertise in radio and communication protocols, as well as wireless network infrastructure made it possible to cost-effectively develop a robust platform that meets the needs of the multiple user groups involved in mobile health. Additionally, the company had positional assets that enabled it to quickly build a business with a substantial global footprint. "Qualcomm does business in nearly every country in the world and has a broad network of operating centers," Jones said. Further, he noted that Qualcomm is the "hidden name" inside the architecture of almost every 3G and 4G device built worldwide. "We are responsible for either the base system, chips, security, or IP systems that make those devices work." This reach gave Qualcomm Life a head-start on establishing a distribution infrastructure and customer base for the new offering. The company's competitive advantages also enabled it to design a communications platform that met the security, privacy, and regulatory requirements of 43 different countries. "We were in the unique position of understanding how, in an inexpensive way, to design an efficient network architecture that provided the most robust solution, working within the particular requirements of healthcare," Jones said.

From a strategy perspective, Qualcomm Life was leading innovation in the space as both a first mover and an information aggregator. To maintain its edge, the company's plan is to keep a sharp focus on expanding the business. "The ecosystem we're putting into place increases in value as there are more users and more companies plugged into it," Jones explained. "Patients and providers don't want go to individual portals to get health data from different devices. They want access to it all in one place," he said. "So we're building a scenario in which users don't have to be tied to one manufacturer's bathroom scale or blood pressure cuff or cardiac monitor. As the network grows, we hope they will be able to choose from hundreds of different devices from different manufacturers, because the data these devices generate will be available through a single Qualcomm cloud interface."

Initially, Qualcomm Life will generate revenue primarily by helping stakeholders connect and share data. Using the 2net Platform as an example, Jones said, "2net has as many as six different business models in terms of who pays – from the consumer to a health insurance plan or healthcare provider, to a device manufacturer. However, most customers either pay a one-time fee for access for a defined period of time, or they pay a monthly fee." But, over time, he envisions the company extracting more value from its offering as an information aggregator. "Ultimately, there will be a shift to informatics," he said. "This is the first time in history this kind of health data has been digitized," Jones stated. He perceived that Qualcomm Life would have significant opportunities related to data management and analytics. "Qualcomm is not a healthcare company," he emphasized. "But, most likely, we will build tools that help our customers effectively use this data, anonymized or with appropriate permissions, to develop predictive models that support better clinical decision making."

Original equipment manufacturer/licensing

Using an original equipment manufacturer (**OEM**) strategy, a company provides technology and/or components to another company that then assembles and sells the finished product. This strategy is commonplace in the computer industry where components, such as hard drives, processors, and video cards for a single computer, may all come from different manufacturers. Early-stage medical device start-ups looking to reduce their upfront capital commitments may contract with an OEM (e.g., for the manufacturing of machined or molded components). Or, they may become OEMs themselves by selling their physical products or **licensing** their technologies for use by another company. Some examples of OEM relationships include Gyrus' relationship with Ethicon (involving endosurgery equipment) or Surmodics' relationship with J&J (providing the polymer coating for the Cypher stent).

The contracts involved in becoming an OEM and/or entering into a licensing agreement can range from simple to complex. One of the most strategically important terms is whether the contract is exclusive or non-exclusive. Exclusive agreements can limit the company with the technology from sharing it with any other firms (thereby giving the licensor a strong positional advantage). In turn, the licensor may or may not agree to use only this one technology and not seek alternative suppliers. In non-exclusive arrangements, both parties are free to make deals with other companies.

For example, Wilson Greatbatch is a large company whose primary strategy is to be the OEM of certain battery and electrical component technologies. Specifically, it brands itself as a leader in the development, design, and manufacture of components critical to implantable medical devices.[46] A typical arrangement for Wilson Greatbatch is to supply batteries and electrical components (technologies that are complicated and protected by strong IP positions) for the pacemakers produced by all the large implantable pacemaker manufacturers. As shown by this example, if a company owns a component or service that is considered rare but potentially can be widely used, an OEM strategy is a good way to capitalize on this competitive advantage. Other examples of products/services well suited to OEM strategies include high-volume, five-axis machining used to create orthopedic implants, which is almost completely controlled by the major orthopedic manufacturers, or guidewire technology, which is dominated by Lake Region Corporation.

Partnering

Sometimes two companies become partners so that each one can leverage the competitive advantage of the other (more information is included in 6.4 Alternate Pathways). Typically, two companies form an exclusive, contractual agreement in order to shepherd a product into the marketplace. The most common **partnering strategies** occur in the pharma-biotech field and the pharma-drug delivery space. Usually the smaller entity makes a new technology available and the large pharmaceutical entity brings capital, expertise, and distribution to the partnership. Partnerships are often structured so that the large entity covers portions of the development costs and makes **royalty** payments. In return, the larger entity gains marketing and distribution rights for the product. An example of this arrangement was the partnership between Nektar Therapeutics, a smaller biotech company, and Pfizer, a large pharmaceutical company, to develop and bring inhalable insulin to the market (Exubera).

In the medical device field, partnering between small and large companies is often centered on a distribution, investment, or technology relationship, although more variations are being explored as companies consider disease management strategies. While obtaining a partner may result in fewer strategic options for a company, it also can reduce strategic options for competitors. Consequently, partnering can sometimes be a prudent step, especially when the useful strategic options generated from these relationships are considered relatively scarce. For example, consolidation has resulted in few acquirers of businesses or technologies in some markets. As a result, a key partnership could solidify one of those rare relationships and limit exit options for the competition. Such a scenario can be found in the interventional cardiology field where there are now just four primary

players – Boston Scientific, J&J, Abbott Vascular, and Medtronic. If a small start-up is competing against a vast number of companies with similar products or services, a partnering relationship with one of these major players could provide it with a significant advantage against its peers, especially if only three others would potentially be capable of solidifying a similar relationship with the remaining major players. If one of the four major players has a more dominant position than the others, then a relationship with that leader could provide an even more powerful advantage.

Using competitive advantage to define the basis for competition

Beyond choosing the appropriate business strategy(ies) to capitalize on their competitive advantages, innovators and companies should seek to create a basis for competition in its field that plays to their own strengths and attacks the weaknesses of key competitors. The basis of competition refers to the features, benefits, or qualities that become central to the way businesses compete with each other. Price, quality, brand perception, customer support, training, or certain technological features can all serve as bases for competition. If a company is a first mover or early entrant to a relatively new field, it is usually able to exercise more control in this regard and essentially define the "playing field." One example is the way J&J, upon being the first entrant into the stent market, used "stent strut strength" as a basis of competition in the early days of coronary stenting. This forced all subsequent competitors to test their devices to a standard that was difficult to beat while addressing other customer needs. While this basis of competition was later eroded by competitors, it served as a significant barrier in the early days of stent development.

If a company is a later entrant to a well-established field, then it must try to change the basis of competition by developing capabilities and positional advantages in areas where leaders do not have them. For instance, if a small company intends to compete in a medical device market against Medtronic or J&J, it would be impractical to try to challenge these firms on the strength of their distribution positions and capabilities. However, by interacting with key stakeholders to understand these companies' areas of weakness, the smaller firm may be able to gain a foothold. If physicians are frustrated by the ease of use of an established device, for example, the company might target innovation in this area. Or, if J&J or Medtronic has neglected customer service, a competitor might seek to develop deep capabilities in this area in an effort to win over customers.

In the field of active implantable devices, a completely new basis of competition has evolved to include web-based disease management systems (such as Medtronic's CareLink®) used by doctors and hosted by the companies that provide the implants to ensure improved patient care. The Innerpulse case in 2.3 Stakeholder Analysis provides another example of how a new entrant can seek to differentiate its offerings and redefine the competitive playing field. By choosing to focus on primary prevention of sudden cardiac death, Innerpulse attempted to avoid head-to-head competition with the large, established ICD manufacturers that historically targeted and successfully captured the secondary prevention market.

Importantly, choosing where to invest and what advantages to develop is essential. Otherwise, a company runs the risk of becoming a "jack of all trades, master of none," which can make it difficult to defend any competitive advantage that it may have. It is not realistic to expect that any company can develop all of the sources of competitive advantage discussed in this chapter. Often, as companies are getting started, they first identify gaps in the product offerings of their potential competitors. Then, they seek to determine which advantages to build in the near term and which ones to invest in or develop at subsequent stages of their strategic evolution in order to exploit these gaps. As with any strategy, decisions regarding competitive advantage should be reviewed frequently, based on changes in the external and internal environments, to ensure they remain valid and attainable.

The ev3 story demonstrates how one company explicitly defined and managed its competitive advantage.

FROM THE FIELD EV3

Building a company on capabilities and business strategy

The formation of ev3, a company focused on delivering products for coronary, peripheral, and neurovascular applications, was somewhat unique in that Warburg Pincus, the private equity investors that backed the venture, funded a capability-based competitive advantage and a supporting business strategy rather than a traditional product. Jim Corbett, ev3's former CEO, described the advantage upon which the company was built. "We had assembled a team of executives experienced in the market who we thought could identify the right technology segments and then acquire or develop products to create a company," he said.

The market ev3 would go after was the endovascular field. "The endovascular market had become very large over the preceding 10 or 15 years, and it had consolidated," Corbett explained. "That consolidation created some rather large global companies – Cordis/J&J, Boston Scientific, Medtronic, and Abbott Vascular. Those companies, in their success, had developed mega-product categories that they were defending. So, if you're in CRM [cardiac rhythm management] or if you're in drug-eluting coronary stents, you really cannot afford to lose your beachhead because there are billions of dollars of earnings at stake. The consequence of that was that the rate of innovation in the endovascular markets had dramatically decreased, because the big R&D centers were all focused on the defense or preservation of their market position rather than on creating new **concepts**, or new devices, or new market segments." ev3, with its experienced management capability, developed an explicit business strategy to target opportunities that existed within this "innovation gap."

The company's name refers to the three primary types of opportunities it would target in the profitable endovascular market: coronary, peripheral, and neurovascular devices and interventions. To establish its preliminary product position, ev3 rapidly acquired nine companies and/or technologies that its management team believed could be commercialized in a competitive time frame for a reasonable cost. Because physicians, particularly those in peripheral and neuro, had been relatively underserved by the major medical device players, ev3's strategy was somewhat of a niche play. For example, according to Corbett, the market leader in peripheral stent technology had not introduced an innovation for roughly eight years. In neurovascular, the market leader had been offering the same base product for nearly 10 years. "So there were real opportunities for us to find the chinks in our competitors' armor, so to speak, and create platform technology, and innovate, and bring something new to market," he said.

ev3's idea was to use a niche strategy to establish a foothold and then expand its position. For instance, to become a dominant player in the neurovascular market, which was stronger in Europe than in the US, ev3 added a geographic element to its niche approach, which it reinforced through the development of new positional and capability-based competitive advantages. "Two-thirds of the global market for neurovascular products was outside the United States, which was very atypical for most medical devices," explained Corbett. At that time, "Usually the US market is dominant, or is the largest segment between the two. We made it part of our early strategy to have direct selling operations in Europe. So we put a lot of effort into global distribution which, again, was an uncommon choice for an early-stage medical device company. In fact, a lot of companies these days choose not to do it at all, and rely on improving their product in the United States because they actually plan for consolidation. But that was a very important distribution choice on our part and it paid a lot of dividends." Within a relatively short period of time, a sizable portion of ev3's sales were made outside the

US and it was the fastest-growing segment of the business.

Over time, ev3 recognized the need to further focus its business strategy and its approach to the market. The larger, established companies continued to enjoy a competitive advantage in the coronary field, where Corbett estimated they spent as much as $1.5 billion per year on R&D for DES alone. Staying true to the company's desire to innovate around its major competitors, ev3 decided to drop the coronary market as a focus area. Looking back, Corbett said it was an easy decision to focus on the two fields with the greatest opportunity for innovation. At that time, many peripheral and neurovascular devices were nothing more than repurposed or scaled-down coronary devices, which left ev3 with plenty of room for entirely new devices and intervention innovations. In addition, development of these products was potentially much faster than coronary products and so offered a lower investment risk to ev3.

Another explicit decision made by the company was to invest in developing a strong capability in internal development and innovation. One of the primary reasons for doing so was to help give the company a more sustainable competitive advantage. "Product innovation is the core basis of competition in our industry," said Corbett. By developing a deep capability-based advantage in this area, ev3 would be able to "create a footprint of a company, not just a product line," he added, also noting proudly that, "In 2005 and 2006, we introduced more new products into the market than the four biggest endovascular competitors combined. And that was all internal development." One of the new products the company was most excited about was the EverFlex® peripheral stent (see Figure 5.9.4). Fractures in peripheral stents, which occur in as many as 25 percent of all cases, cause restenosis, surgery, and amputations. ev3's EverFlex stent had been shown to have a fracture rate four to five times lower than the leading product in the category.

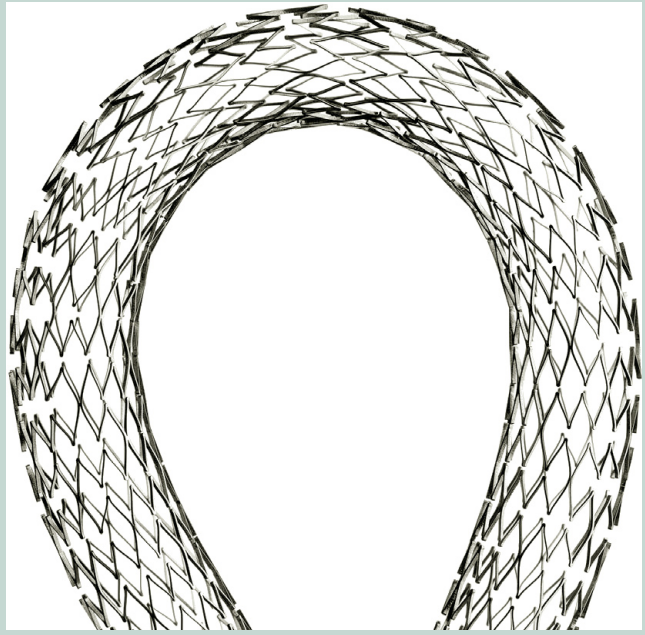

FIGURE 5.9.4
The EverFlex peripheral stent (courtesy of ev3).

When thinking about developing a competitive advantage, Corbett had this advice to entrepreneurs: "Resist *not* focusing. Both at the beginning and along the way, there is such an opportunity to take on new tasks. But it will take away from your ability to execute on your core strategy. Focus is the path to success, without question." He also underscored the importance of moving swiftly. "Speed is key. Obviously speed has to be conducted with excellence, and you should never do speed if it compromises quality, or ethics, or any of those types of matters. But the time you spend getting to market burns cash, and you need that cash. There is often a tinkering mentality that emerges in young businesses, especially when they're privately held. But speed is a core capability that you should try to develop from the start."

Ev3 was acquired by Covidien in 2010 for approximately $2.6 billion.[47]

Developing a statement of competitive advantage

When innovators or companies are working on defining their sources of competitive advantage and the business strategies needed to support them, they should consider articulating them in a statement of competitive advantage. In developing such a statement, look at those created by other companies for ideas about how to effectively capture the key ideas (other recommended steps can be found in the Getting Started section).

Unfortunately, detailed information is not always available regarding other companies' statements of competitive advantage because they are often considered proprietary. However, even in the absence of inside insights, innovators can frequently discern the focus of a company's competitive advantage from the information it makes publicly available. For example, when a private company goes public:

- Evaluate its prospectus carefully. Usually there is a section entitled "Our Strategy" or "Business Strategy" that contains relevant information.
- Identify the aspects of this text that are indicative of the company's core assets and chosen fundamental business strategy.
- Use professional judgment and knowledge of the field to translate this information into a statement of competitive advantage.

Information gathered from public sources can be used to reconstruct a statement of competitive advantage, as shown in the Working Example on Kyphon.

Working Example

Kyphon, Inc.: Discerning a competitive advantage from public information

The following information was drawn from a Kyphon prospectus that was released prior to the company's initial public offering.[48] Within this public description of the company's strategy, the elements that correspond to Kyphon's core assets are shown in italics. Kyphon specializes in devices that enable the minimally invasive treatment of spinal fractures caused by osteoporosis or cancer

Business strategy

Our goal is to establish treatments using our proprietary balloon technology as the **standard of care** in orthopedic applications. We are initially focusing our efforts on vertebral body compression fractures. The key elements of our strategy are to:

Penetrate the spinal market using a direct sales force

We believe that a *direct sales force* will allow us to most effectively educate and train physicians in the use of our products. Our products are sold directly to physicians by our experienced sales team, comprising 20 sales representatives, three managers and a vice president of sales. By leveraging their *extensive spinal market experience*, our sales people are able to identify key physicians and provide effective case support to accelerate market adoption of our procedure. Our sales team is supported by two in-house coordinators and four field-based associates.

Educate referring physicians and patients

Patients with vertebral body compression fractures often are not referred to spine surgeons for treatment. Our objective is to *establish referrals from physicians who initially diagnose* vertebral body compression fractures to spine-focused surgeons who perform Kyphoplasty. As a result, we have implemented an *awareness marketing campaign* to educate internists, family physicians, gerontologists, and other primary care physicians about Kyphoplasty and its potential to be an effective therapy. As part of this campaign we provide educational materials to treating physicians, referring physicians and patients, and organize regional market seminars where surgeons trained in performing Kyphoplasty educate referring physicians.

Expand clinical support of the Kyphoplasty procedure

We are conducting *outcome studies* to increase awareness of the procedure within the medical community, to develop additional marketing claims and to support third-party reimbursement. Through our own outcome studies and those of surgeons currently performing the Kyphoplasty procedure, we are gathering data for ***peer-reviewed*** *journal articles* in support of reimbursement efforts.

Work with opinion leaders

We have obtained the advice and *support of nationally recognized spine surgeons* who are helping us to further develop our products and the procedure, to demonstrate the benefits of Kyphoplasty, and to obtain third-party reimbursement. Because these leading physicians help *set medical policy* in their respective areas of expertise and are experienced in outcome assessments, we believe they will help create patient referrals and advance third-party reimbursement. The reputations of these physicians and their leadership in professional societies help bring recognition and credibility to our products.

Expand surgeon adoption of Kyphoplasty through training

We have implemented specialized training programs and are *rapidly expanding the number of physicians trained in Kyphoplasty*. As of August 31, 2000, we had trained approximately 300 physicians in the United States and Europe and we plan to have trained more than 400 by the end of 2000. We support these physicians through professional development programs, which include funding local seminars, funding travel to national medical conferences and assisting in the preparation of scientific papers for publication.

Expand into Additional Orthopedic Markets

We intend to leverage our *proprietary balloon technology platform* for other applications, including compression fractures of the wrist, knee and hip. These new applications involve refinements of our current products, and we intend to conduct outcome studies in these applications to support market adoption. We believe our *intellectual property position* and our *position within the orthopedic marketplace* will allow us to become the leading provider of minimally invasive medical devices for the treatment of compression fractures.

From this overview, one can infer that Kyphon is developing a competitive advantage that depends on the core assets of:

Intellectual property – To protect its innovative technology in the area of spinal orthopedics, Kyphon defined its initial market narrowly and built a strong and extensive IP barrier to protect its desired position in the market. Through its IP strategy, the company also positioned itself for expansion into other markets.

Owning key relationships – To create additional barriers to entry for competitors, Kyphon has invested heavily in locking up the specialist market (including key opinion leaders in the field) through training and other professional development activities. The company also has gone after generalists (who diagnose the target condition and refer patients for treatment) to increase the strength of its relationships further and make it more difficult for competitors to gain a clinical customer base. To keep the clinical community engaged and convinced of its product's value, Kyphon is also performing ongoing outcome studies to be published in peer-reviewed journals.

Establishing core channels – To support the development and nurturing of its key physician relationships and further strengthen its barriers to entry, Kyphon developed a strong direct sales force. Given the specialized nature of the Kyphon product, this type of channel makes the most sense for sales and distribution. By investing in a team of highly educated sales representatives that can assist in training physicians, the company is positioning itself for easier, more rapid user adoption while also making it more difficult (and costly) for competitors to replicate its sales/distribution capability.

Based on the core assets indicated by the company and a basic knowledge of the industry, one might next infer that Kyphon is pursuing a niche strategy. Rather than initially going after the general orthopedics market, it targeted a small subspecialty and has invested heavily in achieving a leadership position in this area. Kyphon also benefited from a first mover advantage which enabled it to leverage its core assets effectively (i.e., in locking up opinion leaders and creating an impenetrable IP barrier).

Given this positioning, the company's statement of competitive advantage might read something like this:

Kyphon will establish a leadership position in the minimally invasive treatment of spinal fractures caused by osteoporosis or cancer through a strong IP position (from which it can expand beyond this niche), deep relationships with specialists and key opinion leaders in the field developed and maintained by a highly educated, top-tier direct sales force, and widespread general awareness of the efficacy of Kyphoplasty among referring physicians.

Online Resources

Visit www.ebiodesign.org/5.9 for more content, including:

- Activities and links for "Getting Started"
  - Understand the competitive advantages of competitors
  - Identify the company's competitive advantage(s)
  - Create a statement of competitive advantage
  - Set a strategy
- Videos on competitive advantage and business strategy

CREDITS

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NOTES

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STAGE 5: STRATEGY DEVELOPMENT

As the team began thinking about its next stage of work, it was time to find a name for the venture. After considering a series of different possibilities, they agreed on Acclar*ent*. The decision to embed ENT within the new company name was intentional, as the group began to grow increasingly excited about the many opportunities to address unmet needs in the field.

Their next efforts were focused on transforming the *Balloon Sinuplasty*™ concept into a product and building a business capable of bringing that technology to market.

5.1 IP Strategy

As described earlier, the team recognized intellectual property as an important element of its work early in the life of the company. At this point, it was decided that a full IP search would be conducted to evaluate the complete landscape of patents and study the prior art. While several relevant prior art references were found and added to the information disclosure statement made to the patent office, nothing was discovered that the team believed would stand in the way of proceeding with the chosen technology into commercialization. "At this point we were inventing at a very fast pace and we tried to capture as much as we could in our notebooks," Makower said.[1] "It seemed that wherever we looked we saw more and more opportunities to expand the technology of Balloon Sinuplasty more broadly, along with other product extensions and other ENT needs that still required innovation."

5.2 R&D Strategy

After the meetings with Sillers and Bolger, Chang, who would become the company's vice president of engineering, remembered thinking, "Okay, we need to add to the team. I can't do all of this by myself." His first move was to bring in an experienced engineer with a broad background. "I needed someone who was a jack-of-all trades, executes well, and who I worked well with under pressure and stress." To fill this role, Chang recruited a former colleague, Julia Vrany, with whom he knew he could partner to do everything from "clinical protocol writing, cadaver testing, development, working with vendors, quality, sterilization, validation and verification testing, and packaging – the full gamut of product development to get to first-in-human testing." Chang's next hire was a young engineer, John Morris, who was early in his career. "He was a Stanford grad – smart and hungry for experience," Chang said. As development progressed, Chang recognized the need for more balloon expertise so he identified an OEM vendor that was a specialist in this area. "So we had our super-broad generalist who was great at project management, our worker-bee engineer, and a great OEM partner who really knew balloons," he said. Together with Chang, these three pieces formed the team that would develop the working product used in the company's first-in-human study. "It's a balancing act," he added. "You need enough resources to get you there, but not so many that you sink the ship" (see Figure C5.1).

At this point, they began working on the key technical challenges associated with the "family" of devices necessary to perform a balloon dilation procedure in the paranasal sinuses, which included not just the balloons but the guides, inflation devices, and other key elements of the system. However, not surprisingly, many of the greatest issues to overcome had to do with the balloons. Chang elaborated:

> *We needed something that was non-compliant, meaning it would keep its shape. We were fracturing bone, so we had to figure out what sort of pressures were required. And then, probably most*

FIGURE C5.1
Member of the early team, from left to right: Chang, Makower, and Vrany (courtesy of ExploraMed).

significantly, we saw that we were puncturing balloons. We realized that we were placing more stress on the balloon than typically seen in a coronary or peripheral vascular procedure. The targeted bone was not only strong, but typically sharp. And since we recognized that doctors would likely be inclined to use the same balloon in multiple sinuses, the balloon would need to survive multiple cycles of placement, dilation, and removal.

This durability issue meant that the team could not use available balloon technology – Chang and his engineers agreed they would have to develop something unique. "It turned out that helping with development is exactly what our vendor did very well," he said. The next step was to move into a collaborative development loop, with Acclarent using input from its expert physicians (such as Sillers and Bolger) to refine the requirements it fed to the supplier. According to Chang, "Working with our physicians, we were really able to tune the catheter length, balloon dimensions, pressure requirements, and burst requirements – we quickly iterated a number of times between the doctors and the lab [where the testing occurred] and the balloon manufacturer. It was a great partnership."

Of course, noted Chang, "We were in super-stealth mode at the time. So we didn't really tell the supplier what we were doing, even though we had an NDA. After we had made several iterations and significant progress, they more frequently asked what we were doing. I'd say, 'Look, you've just got to understand that we're not going to tell you what we're doing. But I can tell you what the spec on the balloon needs to be.' It became a running joke. We would have a call about the next iteration and they would close with, 'And you're going to use this on . . .?' And I would just answer 'Somewhere near, in, or around a body that may or may not be human.'"

Acclarent entered into an exclusive supply agreement with this vendor for balloons in the ENT field. "Our approach as a start-up company was that we didn't need to own every solution or every capability. There are a lot of people who know how to make balloons. Our goal was to find the one that would satisfy our needs. Once we identified the right supplier, we promptly transitioned from a project-based OEM relationship to more of a long-term partnership that we could scale with," Chang explained.

To get a working product, the team used a similar approach for developing the other devices it needed. Basic development, robust testing, and the detailed

refinement of all specifications was performed in-house, but then external suppliers were entrusted to produce the actual devices. Under Facteau's leadership, prior to the commercial launch, Acclarent would make the decision to bring all development and manufacturing in-house. But, until then, this model served the company well.

Chang described the engineering environment at the time as requiring "all hands on deck." Everyone on the team was expected to contribute at full capacity. In terms of the philosophy, he said:

> *Sometimes people fall into the trap of wanting a perfect solution, the perfect prototype. We weren't at all afraid of trying something a little crude and fast – in fact, the faster the better, because you can't replace time. You don't have to be perfect because you're going to learn so much from each prototype. Failure teaches you a ton, right? So just go, go, go, iterate as much as you can. We literally had labs two days apart where we'd go in and test the product to its limits. If something didn't work well, we'd go back, try to fix it, get another cadaver, and try again. It was all about speed. Otherwise, you could spend a month, or two, or three, or more trying to make the perfect prototype. And that just didn't make sense from our perspective.*

Before long, the team got to the point where it had a system of devices that allowed physicians to get access to a sinus, demonstrate that they were truly inside it, put a balloon across, dilate the ostium, and show that they had enlarged it via fluoroscopy and endoscopy (see Figure C5.2).

At this point, Chang said, "We felt ready to prove it clinically – to demonstrate proof of concept, safety, and feasibility."

5.3 Clinical Strategy

To prepare for first-in-human studies, Acclarent took a careful approach, working closely with its expert physicians to plan an appropriate course of action. When the team asked the physicians about the risks associated with performing the procedure in humans, they referenced skull-base fractures that could create serious complications. "We needed to determine if a high-pressure balloon dilation would cause a fracture to propagate in an uncontrolled manner or cause a 'tectonic plate' shift of bone and ultimately lead to a skull base fracture and cerebral spinal fluid leak, or worse," remarked Chang. If the company could demonstrate that this risk was minimal, Bolger, Sillers, and others advised, it would be ready to move into a first-in-human safety and feasibility trial.

To clear this hurdle, they brainstormed with the physicians to come up with a study that would demonstrate that Balloon Sinuplasty devices did not create these adverse events. In the end, they designed a cadaver study that would require a CT scan before and after the ostia were accessed and dilated. In order to test the "worst case scenario," the study would use the largest balloon Acclarent had developed and it would be inflated to its maximum pressure. A comparison of the CT scans would allow the team to assess any adverse events. Concerned about microfractures that might be missed in a CT scan, however, one physician suggested that a complete dissection might then be used to examine the results of the procedure. According to Chang:

> *So that's what we did. We took six cadaver heads, scanned them, put them in a cooler, jumped in the car to take them to the cadaver lab, dilated them, took them back and scanned them again, and then brought them back again to the lab where we cut them in half. The physician who was there [Bolger] spent three days with us. He flew out and dissected every single cadaver head and said, "Okay, looks good. No fractures." Every single one. We put the results together and the work resulted in a paper and the foundation for our argument to move into live humans.[2] This was the last key piece we needed to get the ethics committee comfortable with the idea that the technology was safe for human use.*

Consistent with its stealth strategy, Acclarent decided to perform its first-in-human trial in Australia. This approach would allow the company to keep the study quiet while still generating results that would have a relatively high likelihood of being accepted in the US by the FDA. In addition to having a population that enjoyed reasonably high standards of living and healthcare, Australia had a well-established regulatory agency, the

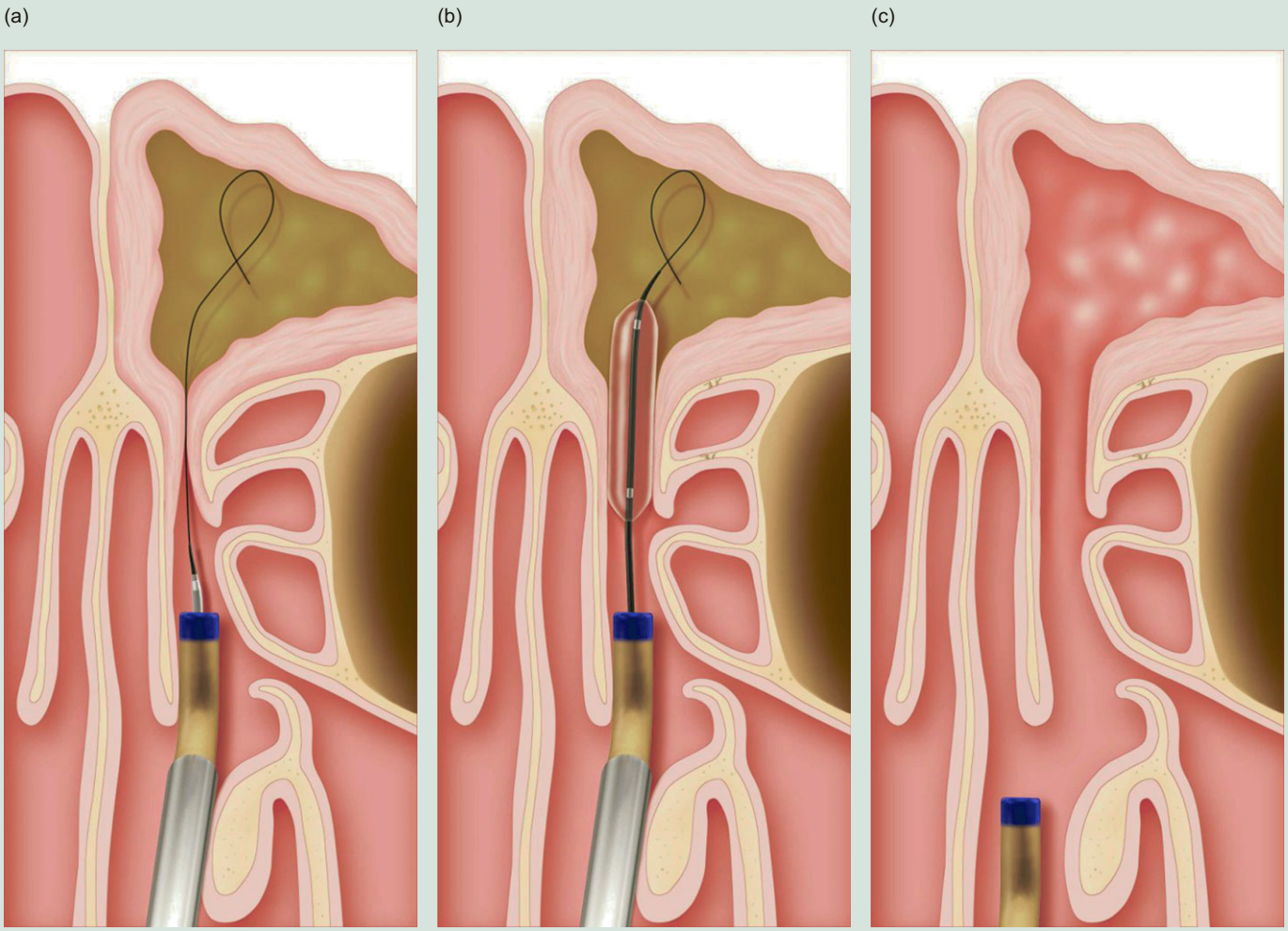


FIGURE C5.2

There are three primary stages of using the Balloon Sinuplasty technology. First, a flexible atraumatic guidewire gains full access to the sinus cavity (a). Second, a balloon catheter smoothly tracks over the wire. Balloon dilation opens the blocked ostia (b). Third, the devices are withdrawn, leaving open ostia with minimal tissue disruption (c) (provided by Acclarent).

Therapeutics Goods Agency (TGA). "You can never be positive how your data will be received, but we were hopeful that it would be received favorably in the US," said Chang. Another advantage of performing the study abroad was to help Acclarent further delay any competitive threat and strengthen its IP position based on the results of the study before word of its approach got out in the domestic market.

In Australia, clinical trials were regulated by the TGA and required ethics committee approval prior to being launched. The process of gaining ethics committee approval was similar to being granted institutional review board (IRB) approval in the US by the hospital or other facility where the procedures would be performed. The first step was to find an investigator willing to work with the company to perform the study. Fortunately, the expert physicians in the team's network were able to help them identify and secure the participation of an appropriate surgeon, Dr. Chris Brown in Melbourne, Australia. Acclarent then put together a package of information that included all the necessary background information, cadaver test data, and other relevant materials for an ethics committee review. "The ethics committee had a couple of questions for us, which we answered to their satisfaction," recalled Chang. "So they gave us a green light for doing the cases in Australia. But they

FIGURE C5.3
From left: Chang, Bolger, Makower, Brown, and Vrany after completing the first clinical trial cases using Balloon Sinuplasty technology (courtesy of ExploraMed).

limited us. They said, 'You can only do 10 patients, and you can only treat two sinuses in each patient.' We said, 'Okay, that's good enough.'"

In total, it took the company about two months to get approval to conduct the study. Then, with everything queued up in advance, it took another month or so to enroll the patients, ship all required materials and supplies to Australia, and execute the trial (see Figure C5.3).

Chang described the outcome (see Figure C5.4): "We went in and had unbelievable results – 10 out of 10 patients were successfully treated. It was beyond our wildest dreams. You just don't dare predict or hope for something that good. We were very fortunate."

While an important clinical milestone had been achieved, Acclarent viewed this as just the beginning of its clinical strategy. The company's plan was to begin lining up its next human trials, which it would initiate in the US shortly after receiving FDA clearance for its devices (the next study would become known as the CLEAR study). "We knew we needed more clinical experience and more data that we could share with people," said Chang. "So we started to line up investigators in the US very carefully. The early physicians helped us identify more investigators and called ahead to make introductions. They would tell their colleagues, 'You're going to get a phone call from somebody. Talk to them. They're not going to tell you a whole lot until you sign an NDA.' This process was in anticipation of the need to increase our volume and get data from a mix of academic and private institutions."

There were also important lessons from the Australian study that required the company to change its clinical approach. For example, said Chang, "The outcome measure questionnaire that we used in Australia was much too complicated. People didn't understand it; they couldn't fill it out by themselves. We recognized that and switched to a simpler outcome measure instrument."

The results of the first-in-human trial also affected device development. Chang shared another example: "Based on our experience in Australia, we completely changed the design of our guides. We made significant modifications to get them ready for prime time. We spent a lot of time working on these types of changes before we went commercial."

5.4 Regulatory Strategy

Acclarent needed a regulatory strategy for its entire family of devices. According to Chang, "There were three different balloon sizes, five different guides, an inflation device – just a ton of different things." The team had previously assessed which components of the system would likely fall into each FDA class, as part of its decision to pursue a 510(k) regulatory pathway. The next step was to identify appropriate predicates for each one. For simple components, such as tubing, guidewires, and needles, Acclarent readily found predicates. However, identifying devices upon which it could demonstrate substantial equivalence for the balloons took a little more searching. "From a balloon perspective, we looked hard

Title: Safety and Feasibility of Balloon Catheter Dilation of Paranasal Sinus Ostia: A Preliminary Investigation

Authors: Christopher L. Brown, MD, William E. Bolger, MD

Objectives: Endoscopic sinus surgery (ESS) is an effective option for managing patients in whom medical therapy for rhinosinusitis fails. However, ESS is not always successful, and serious complications can occur. New techniques and instrumentation that improve outcomes and reduce complications would be seriously welcomed. Innovative catheter-based technology has improved treatment of several conditions such as coronary artery disease, peripheral vascular disease, and stroke. Recently, catheter devices have been developed for the paranasal sinuses. Cadaver studies confirm the potential use of these devices in rhinosinusitis. The objective of this investigation was to ascertain the feasibility and safety of these newly developed devices in performing catheter-based dilation of sinus ostia and recesses in patients with rhinosinusitis.

Methods: A nonrandomized prospective cohort of 10 ESS candidates was offered treatment with a new technique of balloon catheter dilation of targeted sinus ostia. The frontal, maxillary, and sphenoid sinuses were considered appropriate for this innovative catheter-based technology. The primary study end points were intraoperative procedural success and absence of adverse events.

Results: A total of 18 sinus ostial regions were successfully catheterized and dilated, including 10 maxillary, 5 sphenoid, and 3 frontal recesses. No adverse events occurred. Mucosal trauma and bleeding appeared to be less with catheter dilation than is typically observed with ESS techniques.

Conclusions: Dilation of sinus ostial regions via balloon catheter-based technology appears to be relatively safe and feasible. Larger multicenter clinical trials are now warranted to further establish safety and to determine the role of this new technique.

FIGURE C5.4
An overview of the results of Acclarent's first-in-human clinical trial, as summarized in the abstract to the clinical journal article in which the results were eventually published (from *The Annals of Otology, Rhinology, and Laryngology*, April 2006).

for predicates in ENT," said Chang. "We actually found something in the eye, a lacrimal duct catheter, that was pretty close." This balloon device was developed for dilating constricted lacrimal ducts which connect the eye to the nasal cavity; thus, the location was similar to Acclarent's intended use. The company would make submissions, with good predicate devices, on all aspects of its system with the intent of having the FDA either exempt or clear them for commercial use.

A strategic decision would need to be made regarding the submission for the balloons. Acclarent had to determine whether or not to submit the data from its Australian study along with its 510(k) application for this device. It was unclear if the data would be required by the FDA as no other device in this category needed clinical data to receive clearance by the agency. For this reason, the decision was made to submit the 510(k) without clinical data, but to be prepared to provide it if the FDA made a direct request.

When Acclarent made its submissions for its class I devices, the FDA responded within 10 days, indicating that all of them were exempt from premarket notification requirements. One week after the first submission, the company filed its 510(k) application for the balloons. Two months later, the FDA responded with a series of questions, including a request for clinical data to demonstrate that there would be no adverse events. "I think they probably expected us to file for an IDE," said Chang, "but we already had the study results in our back pocket." Within a week, the team had prepared a comprehensive response to the FDA's inquiry. "We scrambled that whole week to answer their questions in the most thorough and complete way we could. It was a true team effort. Within a week, we had a thorough and carefully reviewed clinical package with data submitted for the FDA's review. After a few additional phone calls and questions, we were able to provide the appropriate information that eventually led to our 510(k) clearance. The company was now one-step closer to its planned clinical trial in the US, which it intended to launch immediately after clearance.

5.5 Quality Management

In parallel with its clinical and regulatory efforts, the Acclarent team began thinking about quality system and the need to bring some structure to the way the company managed important processes. According to Chang:

> *When we started getting some traction and realized that we were marching toward a major clinical*

experience, we recognized that we needed to have a quality system and certain controls in place. Because we were running lean, we had a consultant come in and we worked with him to develop a fledgling, flexible quality system. We knew we needed design controls, processes for supplier audits, and other standard operating procedures so we could prepare for a commercial launch of the products.

The idea was to build a quality system that would initially allow the company to cover the FDA's requirements, but that had the capacity to effectively and efficiently scale with the company as it grew and faced the need for more structure and formality in its approach. "We started with standard operating procedures [SOPs] that were flexible and adaptable," said Chang. "We recognized as we grew, we could then tailor these SOPs and make them more specific. And that's really what has happened over the last four years."

With the plan in place, the team began executing it. Because Acclarent would be using contract manufacturers to produce its first family of products, Chang had particularly vivid memories of performing several supplier audits. "We went out to vendors and audited them with our check list. We examined their quality manual, how they received and inspected materials, as well as their manufacturing processes and methods of keeping lot history records, etc." Based on the outcome of these inspections, the team chose certain vendors to work with, ranging in size from large, established contract manufacturers to smaller "mom and pop" shops with specialized expertise in a certain area. "What we learned over time," said Chang, "was that some vendors were not as good at helping us develop processes, with appropriate quality systems, as others." Gradually, as Acclarent moved closer and closer to launch, it had to replace those suppliers with others that could better support the company's growing needs.

5.6 Reimbursement Strategy

As part of its preliminary reimbursement analysis, Acclarent received two favorable opinions that it would be able to use the existing FESS codes to obtain reimbursement for its Balloon Sinuplasty devices. However, as Lam Wang pointed out, "It's much more political than that." The company believed that it would be important to get the leading professional society in the field – the American Academy of Otolaryngology (AAO) – to endorse the position that the new balloon technology could be used with these codes. Lam Wang elaborated:

In the end it's the third-party payers who have to pay for the technology. In general, when the volume of claims being submitted by surgeons adopting a new procedure is low, the claims can go under the radar. It's when the volume of claims starts to get kind of high that the insurance companies start looking for reasons to not pay. When you hit this critical mass, they start questioning it. And it's really good if you have a professional society to support you, saying, "We agree." The third-party insurance companies don't pretend to practice medicine – they defer to the physicians. If the physicians say, "We used these new products to perform the FESS procedure because of medical necessity and we agree that they should be covered by these codes," they're more likely to agree.

To solicit AAO support, Acclarent's reimbursement consultant recommended that the company seek a letter from the society indicating that it agreed with the use of FESS codes to cover the Balloon Sinuplasty devices. Acclarent could then take such a letter to the American Medical Association (AMA) and work with that organization to make this recommendation part of the current addendum to its coding policy. Ideally, this letter would be created and provided by physicians familiar and experienced with the technology. Thus, the selection of investigators was an important step in developing this strategy. The good news was that it seemed clear from the feedback that the device's use fell squarely under the existing codes.

5.7 Marketing and Stakeholder Strategy

The company's efforts to secure reimbursement were closely coupled with its marketing and stakeholder strategy. While reimbursement looked at how physicians would be paid for performing the procedure with Acclarent's products, the larger marketing and stakeholder strategy sought to understand the other ways in which Balloon Sinuplasty devices would affect their practices so

that Acclarent could promote the benefits and mitigate any downsides. Lam Wang described the in-depth interviews she conducted with a handful of physicians (who were all under NDAs): "My approach was to understand who they are and how their practices work. Fundamentally, I wanted to understand the product positioning of Balloon Sinuplasty within the physician's practice and within the treatment of this patient population."

According to Lam Wang, the responses she received varied significantly. Some physicians viewed the balloon as just another "club in their golf bag" that they would use when it made sense, or in hybrid procedures that used both traditional FESS and Balloon Sinuplasty tools. "One doctor took it on a sinus-by-sinus approach," she recalled. "He said, 'The maxillary sinuses are so fast and easy that I wouldn't bother to use the balloon. But, for the frontal sinuses, this is definitely an awesome solution.'" Other physicians viewed the balloons as a more fundamental leap in technology. "They saw it as a potential paradigm shift in how they would treat patients – no more sharp instruments, no more picking at tissue, but balloons, catheters, and wires." While tools could have utility in most of the sinuses, it was not clear at the time how the technology would apply to the sinus called the ethmoid sinus since it did not have one simple drainage pathway like the others. Some physicians cited this limitation as a reason why the device might have less utility. Comments such as these gave Acclarent a strong understanding of how Balloon Sinuplasty technology would potentially fit into these physicians' practices, how it would be used, and, by extension, how it would affect them financially.

Lam Wang did some additional research into the effect on facilities – primarily hospital outpatient facilities and ambulatory surgical centers. "I also looked at the ramifications of bringing endoscopic sinus interventions back into the office, but it was clear this was not going to be as easy." As the launch approached, Acclarent began revisiting the needs of patients and evaluating the interests of referring physicians (e.g., general practitioners who would refer patients to the sinus specialists).

When it was time to define clear value propositions for each of these stakeholder groups, Lam Wang sought to put these messages in context:

> *I felt it was important to have a story. I believe that's the backbone of any marketing program, especially for a new company with a new technology. So I spent some time putting together the story for Acclarent. It's not enough to say "new product, unmet need, done deal." You really have to tell a story for why this technology makes sense. The value it provides is the core component of the messages you give out to all of your stakeholders, whether it's patients, surgeons, or facilities.*

Once these value propositions were defined and embedded within the context of a story for each stakeholder group (see Figure C5.5), Lam Wang turned her attention to the development of a plan to support promotion and advocacy. "Our next focus was all about getting ready for the commercial launch," she said. The team hired an ad agency to help it establish a brand, as well as a look and feel for the product. This brand was used as the foundation of all marketing communications, including brochures and a website (note that the company's publication strategy was managed separately; see the Sales and Distribution Strategy section for information about professional training and education). Significant effort was also put into planning a major product launch at the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) conference, which would occur in September 2005. This was the meeting at which Acclarent planned to transition out of stealth mode and announce its technology to the world. The launch plan for this event included a booth, where Acclarent staff would show the technology and answer questions throughout the conference, as well as a symposium at the show with presentations by thought leaders in the field (e.g., Bolger and Sillers) and a video demonstrating on a real patient how the procedure worked.

Pricing

Acclarent also needed to decide on a price for its products, an exercise that was closely linked to the company's business model, funding requirements, and its overall viability. "We had to figure out the average price we could sustain per procedure," said Lam Wang. She explained her approach:

Key Messages to ENT Surgeons

- There are over 600,000 chronic sinusitis or recurrent acute patients per year in the U.S. who have unmet clinical need. These patients are underserved by medical therapy; they are surgical candidates, but they are not getting FESS.
- The goals of sinus surgery are to restore ventilation and normal sinus function by opening up blocked ostia while maintaining as much normal anatomy and mucosa as possible.
- However, there are shortcomings associated with today's surgical instruments that make achieving those goals challenging. Straight, rigid tools are used in the tortuous sinus anatomy for a delicate, targeted procedure. As a result:
  - More tissue removal than necessary often required just to gain access (e.g., ethmoidectomy to access sphenoid or frontal areas, uncinate regularly removed during maxillary antrostomy.
  - Procedure hard to tolerate for patients – bloody, packing, general anesthesia, long recovery. Many patients hesitate to undergo surgery.
  - Potential complications can be serious – penetration of eye or brain cavity with these straight, rigid steel instruments. FESS most common reason for litigation against ENT surgeons in the U.S.
  - Frontal procedures are challenging and prone to iatrogenic scarring and stenosis – unrefined instruments make it easy to cut, tear or strip mucosal lining from the recess during ethmoid surgery.
- Improvements to the field have been made – but still same basic problem of using straight, rigid tools.
  - Microdebrider – powered instrument shaves away diseased tissue while sparing normal tissue.
  - Image Guided Surgery – allows surgeon to see instrument location relative to historical CT landmarks.
- There is a need for a new way to accomplish sinus surgery:
  - Devices that conform to the tortuous sinus anatomy.
  - Devices that stretch sinus tissue rather than tear or cut.
- Now, there is a new, less invasive procedure alternative.
- Balloon Sinuplasty uses soft, flexible balloon catheters to gently open up blocked ostia, allowing drainage and return to normal sinus function.
  - Innovative platform change in technology from straight, rigid instruments to soft, flexible catheter-based devices.
  - Devices conform to the tortuous sinus anatomy.
    - Less need to remove sinus tissue in order to gain access.
    - Allow improved access to more remote areas.
    - Less likely to penetrate into the orbit or brain.
  - Balloon catheters stretch sinus tissue rather than tear or cut.
    - Less bleeding during and following surgery.
    - Less likely to stimulate scar tissue.
    - Lower potential of revision surgery.
  - Adheres to physiologic principles and goals of sinus surgery.
  - Safe, low rate of complications.
- FDA cleared.
- Balloon Sinuplasty works.
  - Clinical data to date.
  - Case studies.
- We have thought leader support.

FIGURE C5.5
Acclarent developed a story that included its core value propositions for each key stakeholder group. The example shows some of the messages targeted at ENT surgeons (provided by Acclarent).

For the first pass, I revisited the average payment for FESS per sinus treated, and then by procedure. I understood after this analysis that, in a given FESS procedure, physicians could bill up to nine codes, and that the codes would stack, meaning that they would get paid the full amount for the first procedure done on a certain sinus and then receive 50 percent of each code after that. Next, I did this super in-depth analysis to determine what a typical case looked like at the time. That's when I went back to talk to our physician advisors. And I learned that there was a combination of sinuses that was typical. After that, I looked at an average case from a break-even perspective. If I was going to add cost to the system [by charging for reusable devices], I then had to figure out where I could take cost out of the system.

"I looked at it from a long-term perspective to make an economic justification for this new technology," said Lam Wang. Ultimately, the sum total per case benefit of what a physician or facility would gain from increasing patient flow and decreasing procedure time, taking into account what third-party insurance companies would pay, represented the high end of what Acclarent could charge. She continued, "I completed a 12-page analysis and came up with a range – it was something like $1,200–$2,000 per case. So not per balloon, not per device, not per sinus, but just per patient."

With this range in mind, the Acclarent team again approached its advisors to discuss pricing. For the purposes of conversation, the company used a figure of approximately $1,200 per procedure. Facteau explained what happened next:

When we talked with some of our physician advisors about this, we got some initial push back. At that point, we decided to share some confidential information to help them gain an appreciation for what it really takes to build a medical device company from scratch. We explained to them how and why we came to our decision on price, we shared with them our P&L and cash flow assumptions, and pointed out that in our first year we would lose $16 million. We mentioned that we could do things a lot less expensively, however, we believed the right thing to do to build a great company is to invest in clinical research, physician training (which included a cadaveric experience), and innovative products. Couple those investments with a direct sales organization and we anticipated the need to raise $75–100 million before we would break even. Therefore, at that point, $1,200 of disposables per procedure really didn't seem to be as big of an issue for them, and they became supportive of the pricing strategy.

5.8 Sales and Distribution Strategy

In terms of sales and distribution, Facteau had a clear vision from the outset regarding the model he wanted to adopt:

I had a strong bias that we should go direct, and that we needed to hire an experienced, clinically savvy sales organization that could execute on our vision. We needed to train physicians really well to preserve the safety of the device and the procedure, and to protect the Balloon Sinuplasty reputation as a safe tool. We thought about how we could leverage distributors, but the direct model made more sense. I was a strong proponent of this. When no one gave me any real resistance, internally or with our investors, we agreed to create a direct sales organization in the US.

Lam Wang underscored the key advantage of this approach. While a direct sales force was more expensive and time-consuming to build, she said, "It allows you to maintain more control."

Deciding on the type of sales representatives that would be best suited to represent Acclarent's technology turned out to be something of a challenge. "We asked ourselves, of all the people in our sales careers that we had interviewed, how many had come from ENT?" recalled Facteau. "And we couldn't point to one." For this reason, the company decided not to target sales people with ENT experience. Instead, they decided to look for people who had worked in interventional cardiology and had experience selling balloons, catheters, guidewires, and other equipment similar to the components of the Balloon Sinuplasty system. "That's where we started," Facteau said, "but that turned out not to be the right model for us."

Ultimately, Facteau and team discovered that, while cardiology sales people understood the technology, most had not actually developed the skills to introduce a paradigm shifting technology into the operating room.

Ultimately, Acclarent determined that it needed sales people with deep experience training physicians and who had spent time in the operating room. According to Facteau, representatives who had been in a start-up before also tended to work out well, as did people who had helped develop new markets in the past. "Market development is a lot different than taking share in an established market," he noted. "And I think a lot of people don't really appreciate that. If you have a better mousetrap and there is an established market for it, that's a much easier, predictable sale than if you have to go out and create a whole new market from scratch."

Training

Through its direct sales force, Acclarent intended to invest substantially in the training it delivered to physicians on its technology. "Even though it had never been done before in ENT, we knew that's what we needed to do," said Facteau. The company believed firmly that Balloon Sinuplasty products would lead to improved results if they were used consistently by surgeons – the key was to get each one to use the products and perform the procedure in the same way to achieve comparable results to those achieved in the company's studies. "We had to standardize," Facteau recalled. "What was missing in sinus surgery was standardization. You could go to 10 different hospitals and watch sinus surgery and you'd see 10 different ways to do it." For this reason, the team worked diligently to define best practice processes and protocols that would be taught consistently to physicians and could easily be replicated post-training. Facteau elaborated:

> *I started my career at US Surgical, and I am of the opinion that they were the first to crack the code on physician training. They spent a significant amount of resources to ensure proper education for new medical procedures. One of the guiding principles to successful patient outcomes and adoption was centered on standardization. No matter what OR you were in, general surgeons placed trocars in the same location, they held the instruments the same way, and utilized the same retraction techniques to gain better visibility. This ultimately led to better outcomes. We set out to accomplish the same with Balloon Sinuplasty technology. "If you do it this way, we believe you're going to get good results because we know the proper techniques resulted in good outcomes in our clinical studies."*

Led by experienced physicians and Acclarent's sales representatives, physicians would be trained on this standardized approach. For those surgeons open to the idea of training, the team was confident that this approach would protect patients and the reputation of the company while enabling desired results. However, as Facteau explained, "We had some concern that this level of standardization – our commitment to standardization – might not necessarily be well received, especially early on because it had never been done before in ENT by a manufacturer. Despite this potential resistance, the company believed strongly that this was an appropriate (and necessary) approach to take when introducing novel technology to a market that had not seen a great deal of innovation in decades (see Figure C5.6).

As far as building the sales organization, Facteau took a somewhat measured approach. For instance, he decided that Acclarent would not begin hiring any sales representatives until the company had received clearance from the FDA on its balloon technology. Other critical milestones were put into place to keep the rate at which the sales organization expanded in alignment with the commercial viability and adoption of the technology. While this made some members of the team a little nervous as the launch date rapidly approached with no sales force in place, "We felt like it was fiscally responsible – and the right thing to do," said Facteau.

5.9 Competitive Advantage and Business Strategy

When the company began thinking about creating a competitive advantage, the Acclarent team relatively quickly

FIGURE C5.6
Surgeons being trained to use Balloon Sinuplasty products in Baltimore, Maryland (courtesy of Acclarent).

FIGURE C5.7
Facteau lays out his vision for Acclarent at a staff meeting (courtesy of Acclarent).

focused on two core capabilities: developing a world-class direct sales force/training organization and establishing a pipeline of innovation. Facteau explained (see Figure C5.7):

The first was around the commercialization. We wanted to build the best ENT commercial organization in the world. There have been some good examples of companies in other specialties that have done that, but no one had tackled it in ENT. We benchmarked companies like Kyphon, Fox Hollow, and Perclose. We performed case studies in an attempt to understand what they did well and to try to learn from their mistakes. In doing this, one of the things we realized was that none of these companies developed a true pipeline of innovation that could drive organic growth for a long time. We decided that we wanted to be great at both, which is no easy feat.

Developing a strong internal R&D capability was also consistent with Acclarent's business model and the company's desire to get ENT physicians "addicted to innovation." Lam Wang added, "Bill's vision was not just to focus on 'N,' but 'E' and 'T,' too. We want

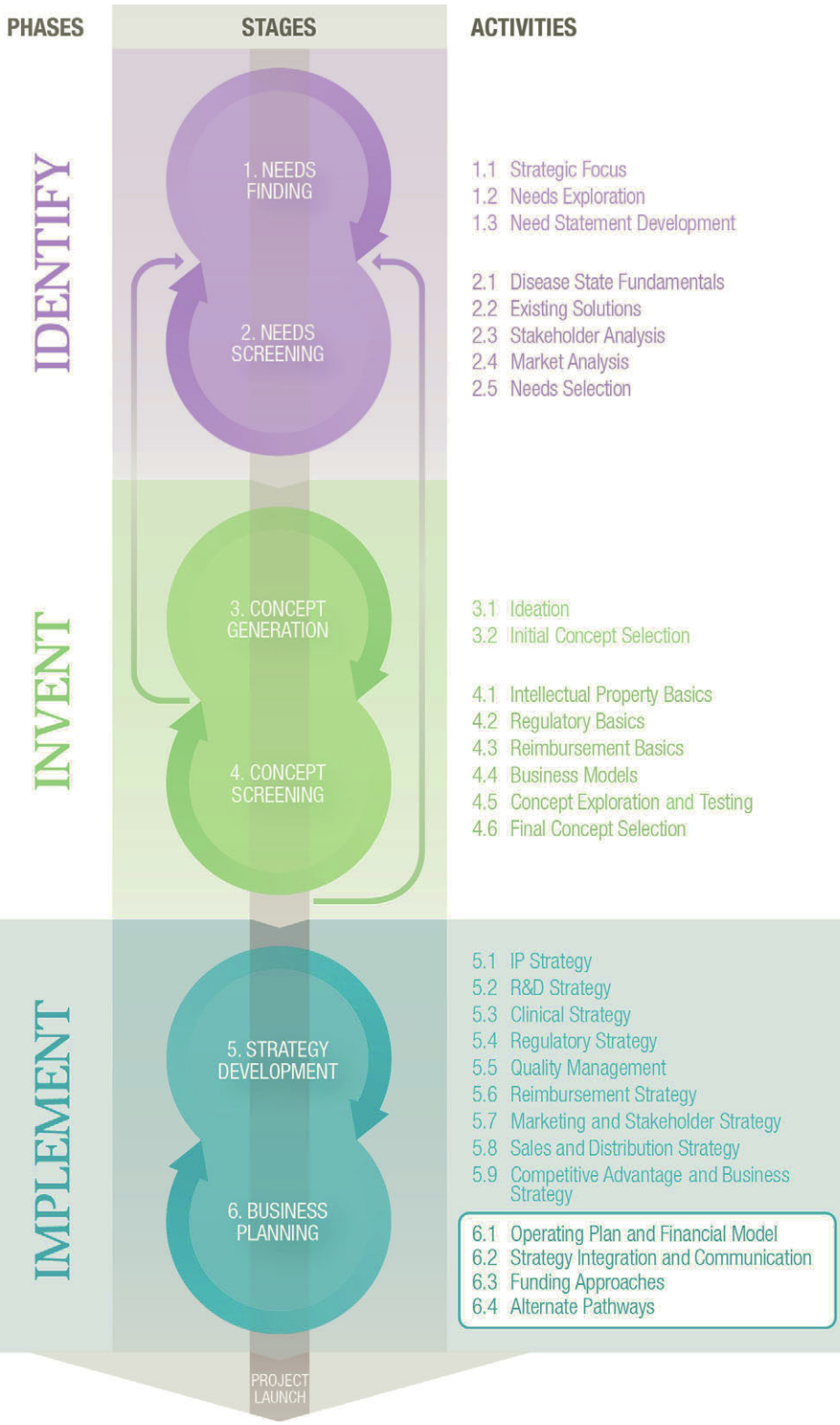
to be everything for the ENT surgeon." Sensing that untapped opportunities existed across the ENT field gave Acclarent a source of ideas that it could develop into an ongoing pipeline of innovative products. The decision to focus on developing this capability dovetailed with Acclarent's decision to begin the process of bringing all R&D and manufacturing in-house.

NOTES

1 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

2 William E. Bolger and Winston C. Vaughan, "Catheter-Based Dilation of the Sinus Ostia: Initial Safety and Feasibility Analysis in a Cadaver Model," *American Journal of Rhinology*, May/June 2006, pp. 290–4.

IMPLEMENT Business Planning



Knowing what to do is not enough. One of our main recommendations is to engage more frequently in thoughtful action.

Jeffrey Pfeffer and R. Sutton[1]

Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning.

Winston Churchill[2]

6. BUSINESS PLANNING

IMPLEMENT

While this is the final stage of the biodesign innovation process, it is in fact the beginning – the beginning of your sustained effort to implement a product or business around the need you've identified and your invention or innovation. Business planning supports the integration and direct execution of all of the strategies plans you've developed in Stage 5.

A very specific focus of this stage, and indeed this book, is around the start-up process. Building and managing a small business, generating the business model, developing a cohesive pitch, and navigating the complicated waters of fundraising are all essential components and are explored in depth. Remember, once outside sources are involved, the enterprise no longer belongs solely to the innovators.

The final chapter looks at alternate approaches to starting a business – that is, the options of partnerships, licenses, or the outright sale of an idea, transferring control to the new owner. If you have a great idea, but there is an existing company with better resources to develop it, one of these pathways can provide a wonderful route to get a solution into practice.

Regardless of how you approach it, the journey should be fun. That's not to say that many lessons won't be learned the hard way, but the optimism and, indeed, idealism of the innovators can profoundly catalyze transformation in healthcare. Good luck.

NOTES

1 Jeffrey Pfeffer and Robert I. Sutton, *The Knowing-Doing Gap: How Smart Companies Turn Knowledge into Action* (Perseus Distribution Services, 1999).
2 According to the Churchill Centre, this statement was made at the Lord Mayor's Luncheon, Mansion House, London, following the victory at El Alamein in North Africa, November 10, 1942.