

# From Conception to Commercialization



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## Introduction

Thomas Edison is quoted as saying, “Anything that won't sell, I don't want to invent. Its sale is proof of utility, and utility is success.” Busy physicians often find themselves identifying a clinical need that could be satisfied with a new product or new technology. In fact, many of the best ideas are born on those difficult days when surgical cases present unique challenges.

Maybe it's a simple modification to a favorite implant or instrument; maybe it's a bit more – an exciting new product or even a breakthrough technology. Regardless, there are many questions to consider. Is it marketable? Would my colleagues benefit? Would they buy it? How do I protect it? And most importantly, how do I maximize the chances that the idea will even see the light of day? Partnering with the “right” medical device company may be the answer for many surgeon inventors, but how does one go about initiating the process?

## Documentation

Not surprisingly, the first step to take once an idea has hatched is to write it down. Draw sketches and date them. Describe the idea in words if it helps. Give some background information on the clinical problem that the idea helps to address. If available and deemed relevant, provide background marketing data to help justify the need for the idea.

Documentation is an absolute necessity. This cannot be overstated. The same meticulous record-keeping that is needed for patent protection should be applied throughout the development process. Although many napkin-sketch concepts have made it through the rigorous process to become commercially successful products, a little more work done upfront before seeking a corporate partner will pay dividends down the road. Often companies will place increasing value on an idea that has already made it to a detailed drawing stage, model or even working prototype.

However, be careful not to prematurely limit the idea in the interest of speed. A mediocre idea transformed into a prototype too quickly is not as valuable as a diamond in the rough. If possible, show the concept to a few close colleagues to get their opinions. Think through the idea by trying to consider every aspect and every angle – all possible combinations/configurations that will reach the same endpoint. When product designers at companies sit down to brainstorm concepts, one golden rule is that criticism is not allowed. The more ideas, the better. Often what happens as a result is that one idea builds on a previous one, and the outcome is stronger.

Coming up with multiple concepts has two important advantages. First, it gives the company's development team multiple avenues to follow in the event of obstacles along the pathway to commercialization. These obstacles could be related to design, materials, manufacturing, or a host of other reasons. Second, laying out multiple concepts allows a

patent attorney (should the idea be considered patentable and the company willing to pursue it) to write a broad application. Generally speaking, broad application claims lead to a stronger and more valuable patent position.

## Protecting the Idea

Points to consider for protecting an idea – whether through a patent, trademark or copyright – are outside the scope of this article. For more on this topic, reference the series of articles written in this publication by Mr. Perry Van Over. Suffice it to say that the farther an inventor goes to protect his idea, the more valuable the idea will be to a company. After all, companies love to show investors that they are adding to their patent portfolios.

In some cases, patents become very valuable strategic weapons. Perhaps nowhere has this been more apparent in recent memory than the court proceedings between Biomet and a number of spinal implant companies over their proprietary position on a polyaxial pedicle screw for the spine.

In addition to patents, there are other ways of protecting confidentiality. One simple way is to enlist the help of a lawyer to draft a confidentiality, or nondisclosure, agreement. Alternatively, potential company partners should have their own template agreements that can be used. This type of agreement binds the company from disclosing the idea for a pre-defined period of time, even if negotiations break down and the inventor takes the idea to a different company. Although not as strong as a patent, confidentiality agreements provide an important level of protection.

## Presenting the Idea

Great ideas can be lost in the hierarchy of corporate organizational structure if they enter at the wrong point. Companies have different points of contact. Sometimes the best person to speak to is a technical person – a Vice President of Engineering, for example. Sometimes it's a marketing person such as a Product Manager.

And sometimes, depending on the size of the organization, it's the Chief Executive Officer. Just try to make sure that the decision-makers have a chance to review the presentation. Next, consider the best method for presenting the idea to whomever you identify as the key contact. Some inventors prefer a simple faxed drawing with associated dimensions and notes while others prefer to put together elaborate PowerPoint presentations outlining the clinical need, market dynamics and design considerations.

## Picking the Right Partner

When the idea has been reasonably documented and protected, it's time to think about taking the product idea to a company that represents a good match. Now the hard work begins. Picking the right partner is crit-

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ical to both the success of the commercialization effort and the overall expectations of the inventor. When negotiating with companies interested in the idea, be careful what you wish for, as the old saying goes. The dominant players in the industry with “instant on” potential may be particularly enticing for their broad distribution network, hefty marketing budgets and name recognition.

But sometimes a good product can get lost in the mix, since it will essentially compete for sales time with all other products in the company's portfolio. Conversely, a smaller company may promise to make the new product their flagship, but may not have the financial wherewithal for adequate promotion.

The key is to understand the culture of the target companies. Insist on working with only companies who will listen and allow you to be a driving force throughout the process. The right partner will recognize the inventor's passion for the subject area, creative energy and certainly clinical expertise. They will put it to good use from the very earliest design work all the way through the launch of the product.

Surgeon inventors should ask about provisions for handling new unplanned projects. If corporate marketing and development plans have already been established, reviewed, approved and budgeted for the fiscal year, it may be an uphill battle trying to get funding and personnel allocated to a new project. Some companies will have well established idea submission processes that tightly integrate with their quality management system, while others may want to handle a new idea on an informal custom basis before proceeding to a formal project plan. Understanding how a company operates and what steps are involved in the design control process is extremely helpful.

Figure 1 shows the major steps of Altiva Corporation's product development process. Very simply, the process can be depicted as a chain where each link of the chain is a separate stage through which a project must pass.



## Types of Agreements

When it comes to structuring a deal with a company, there are several options to consider. Depending on the needs and standard business practices of the company, one may be preferred over the others.

Consulting agreements, common to the orthopaedic industry, are not covered since they are not restricted to developing a product or technology and often assume a prior working relationship between a physician and a company.

1. **Development Agreement.** In exchange for ownership of the idea and any resulting products and patents, a company will offer royalty payments based on sales, milestone payments, stock options or other incentives to the physician. Often the physician will be expected to assist the company in product development activities and training for sales representatives as well as customers. Development agreements offer the physician the opportunity to work with a company on multiple projects and can lead to a long term working relationship if executed properly.
2. **Acquisition.** Of both the invention and related assets should they exist (e.g. intellectual property, regulatory approvals, inventory, etc.) by the company in exchange for royalty payments on the sale of resulting

products. An upfront fee and milestone payments may also be part of the deal. The company benefits through an acquisition by gaining a relatively low cost platform upon which to build a commercially successful system and the physician benefits by sharing in the long term success of the product on someone else's nickel. Royalties are paid as a percentage of sales, traditionally in the 2% to 6% range depending on a number of factors.

3. **License Agreement.** A license may be given on an exclusive or non-exclusive basis for a specified period of time and allows the physician to retain ultimate control over the invention. This becomes especially important if the physician desires to keep his or her options open for a different type of agreement down the road. License agreements can take a number of different forms and payment terms will vary. Generally speaking, payments to the inventor will be lower for a license than for an acquisition because ownership has not transferred. For the company, there is a business risk in committing to a product idea that is not owned.

Whatever the structure, it is a good idea to include in any agreement a “best efforts” clause. This will help ensure that the company does not bury the idea or technology effectively stifling competition instead of developing it. In addition, it bears repeating that companies will place a higher valuation (and hence pay higher royalties) on an idea that has been reduced to practice.

Value rises as a product makes its way through the development stages because a portion of the overall project cost has already been incurred and a portion of the overall design and business risk has been mitigated.

## Conclusion

In summary, bringing new ideas to market can be both a professionally and financially rewarding experience for the physician and the company. Ultimately, and most importantly, patients benefit as well if these new products improve quality of care by making life easier for the surgeon – especially during those complicated surgical cases. Once a new idea is born and you are ready to take the next step, establishing a game plan that includes key elements of documentation, protection and presentation is critical.

Knowing a little bit about the target company and its culture helps further by reducing the risk that the relationship will sour along the way. When both parties understand and seek to align their expectations, great things can happen. Creating a win-win scenario between the physician and the company establishes a positive working relationship which continues to foster new ideas for years to come.

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