



# WHITE PAPER

September 26, 2007

## GROWTH THROUGH VALUATION AND ACQUISITION OF INTELLECTUAL PROPERTY IN THE MEDICAL DEVICE INDUSTRY

### WRITTEN BY

Scott Lloyd  
Analyst

### In This White Paper

Introduction .....	2
General Patent Valuation Nuances in the Medical Device Industry.....	3
Challenges to Leveraging Medical Device Patents for Strong Returns.....	4
Bausch & Lomb's Acufocus Acquisition: a Case Study.....	5
Conclusion.....	9
About the Author.....	9
About Nerac .....	9



## INTRODUCTION

Private investment in the medical device industry has been rising steadily for the past few years. A lack of early stage government funding in most states and a high percentage of companies achieving liquidity are likely responsible for this trend. As Matt Megaro, the former CEO of Quill Medical, Inc., who successfully structured his company's \$200 million acquisition by Angiotech Pharmaceuticals, noted in a recent interview with the Council for Entrepreneurial Development, mergers or acquisitions are currently the favored exit strategy among medical device start-ups because they average an estimated five- to six-fold greater rate of return to investors than that achieved by development stage companies going public. The question for medical device startups then becomes, what are the most important valuation factors in considering an acquisition.

While acquisition valuations of medical device companies vary widely based on the internal criteria of acquiring companies, successful companies understand the importance of a strong intellectual property portfolio—particularly patents—to derive an accurate pre-acquisition valuation. This is important for the parties on both sides of the transaction. Ignoring for a moment any transactionally unique valuation factors, it is safe to say that all companies value patents based not only on the inherent strength of their claims, but also on their ability to translate into products that will make money despite any existing competition. Therefore, accurate valuation depends on accurate identification of the relevant product market, likely competitors, and the products that will be protected by the patent portfolio.

What follows is a general guideline to intellectual property portfolio valuation as it pertains to the medical device industry. We then take a look at how these principles apply in a case history format to the early 2007 Bausch & Lomb acquisition of Acufocus.

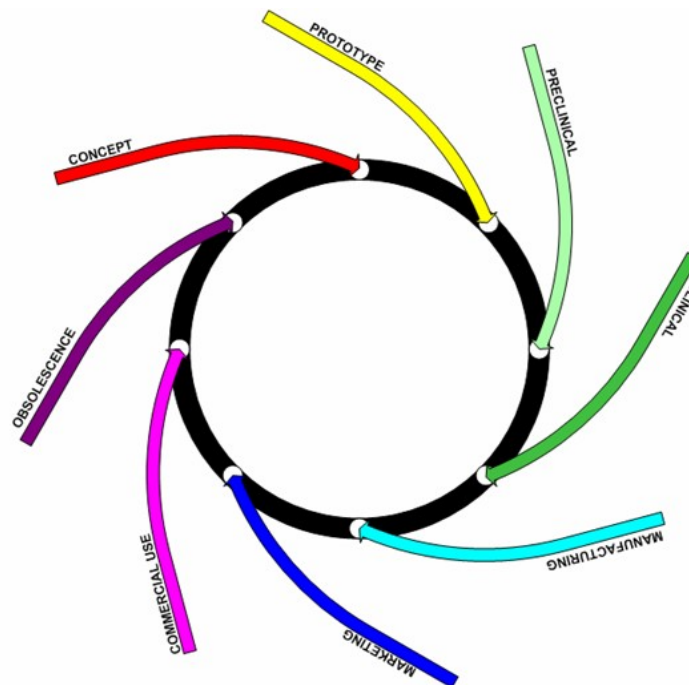
## GENERAL PATENT VALUATION NUANCES IN THE MEDICAL DEVICE INDUSTRY

Medical device IP typically takes the form of either trade secrets or patents. Trade secrets are assets that inure actual or potential economic benefits to their owners by not being known to the public. They usually require the owner to protect trade secrets through nondisclosure and non-competition agreements. Trade secrets are creatures of contract, and as such are only as strong as the contracts that protect them. Moreover, if trade secrets are discovered through independent external R&D or reverse engineering, their value as intellectual assets are depleted. Therefore, patents are generally considered much stronger intellectual assets.

A patent is an agreement between the government—the United States for the purposes of this discussion—and the patent owner that allows the patent owner to exclude others from making, using, selling or importing patented subject matter for a specified period of time within the U.S. in exchange for full disclosure of the patented subject matter to the public. Remedies against patent infringers are also provided.

Figure 1

The Medical Device Life Cycle – Figure by National Instruments



The term remaining on a patent will always be a central factor in evaluating its worth in the marketplace. When valuing a medical device patent, it is important to consider the patent's useful life, defined as the amount of the patent term that is likely to remain after the FDA has approved the patented device or component. It is also important to consider the estimated time between marketing and obsolescence, or the product life cycle. In arenas where devices are frequently subject to recall, that fact also should be considered. These factors all play into the estimated

time the device will spend in the commercialization phase in the relevant market, and, assuming the patent is enforceable, the time the device will spend reaping returns on investment.

## CHALLENGES TO LEVERAGING MEDICAL DEVICE PATENTS FOR STRONG RETURNS

### 1. Accurate Market Identification

The first phase in considering any patent portfolio acquisition should be a clear, externally focused identification of the target market for the patented technology. Portfolio valuation will depend on the presence of actual or potential competitors in the target market. A product market share that is concentrated among few competitors is easier to size up, while defining returns in a market populated with multiple players may prove to be more challenging. Conversely, entering a market with high entry barriers and a limited number of players through acquisition is more likely to attract the attention of the Federal Trade Commission, which may require compliance with investigatory measures that could run up transaction costs, and reduce the deal's profitability.

### 2. Accurate Identification of Protected Products

Once the target market has been accurately defined, an acquiring company will then look to the potential strength of the portfolio in that market. The technology should provide a clear advantage over the existing IP that is likely to translate into revenue. If no obvious concerns are apparent, the opinion of patent counsel should be sought as to the scope and validity of the patent claims in relation to products on the market as well as latent patents that raise invalidity concerns. The scope of the incoming portfolio should capture the subject matter necessary for achieving the business objectives of the proposed acquisition, and the most important patent claims to be acquired must be valid and enforceable.

### 3. Sizing up the Competitive Landscape

Once an acquiring company is satisfied that the incoming portfolio covers the products of interest in the market identified, a combined internal-external analysis should be performed, especially if the acquiring company holds a major market share where further acquisition of patents is likely to eliminate competition. This is especially true when the transaction is in the nature of a horizontal merger such as a competitor buyout. The FTC measures market concentration using the conservative Hefindahl-Hirschman Index, which could result in transaction that takes the acquiring company from as low as a 25 percent market share up to a 30 percent market share being investigated. Such a result would be particularly problematic if the offending patents happen to drive the acquisition. Therefore, it is advisable to exercise care in properly defining target markets and measuring competition before acquiring patents that create enough market power to garner the FTC's attention.

Once a company determines that an acquisition is objectively desirable, focus should shift to other participants' market activity, as well as companies holding rights to IP or other business assets that could allow them to enter the market quickly. For example, if during a due diligence survey of related technologies patent counsel identifies a company with a strong patent portfolio that is not currently being used in the target market due to a lack of manufacturing capacity, that company should be considered a threat that drives down the value of the portfolio to be acquired. Portfolios belonging to or in-licensed by potential competitors should be evaluated, and the

prevalence of patent litigation and associated costs in the market should also be examined to the extent possible.

When considering an acquisition, all of the above steps should be conducted in view of the corporate business model. A company with little or no manufacturing or regulatory capabilities, for example, may consider acquisition for the purpose of out-licensing the acquired patents, or partnering with a company with the requisite infrastructure to fill in the gaps and bring the product to market. Indeed, some businesses simply acquire patent rights for the purpose of scavenging royalties from other competitors in the landscape after estimating how much competitors will pay to fend off the threat of litigation. Ultimately, the corporate business model dictates what should be acquired, and those assets should be analyzed accordingly.

## BAUSCH & LOMB'S ACUFOCUS ACQUISITION: A CASE STUDY

Bausch & Lomb's investment in Acufocus, Inc. earlier this year provides an interesting backdrop to illustrate how this all works. Acufocus is a U.S. corporation founded on the development of corneal inlay surgery for presbyopic patients that provides a convenient alternative to reading glasses. Acufocus independently garnered over \$37 million in venture capital before B&L's investment, which was announced in January 2007. While the author has no inside knowledge of the thinking behind the acquisition, here is how the transaction reflects the approach suggested above.

### 1. Market Identification

A B&L press release dated Jan. 15, 2007 said that the U.S. market for Acufocus's proposed products comprised about 50 million patients suffering from presbyopia, a natural degeneration of eyesight that a majority of people over 40 experience and that results in the need for reading glasses. Presbyopia is typically fixed either by corrective lenses—reading glasses, bifocals, contact lenses—or refractive surgery that has enjoyed limited success. Market identification by B&L as potentially all presbyopic patients suggests a belief that the Acufocus surgery is convenient enough to build consumer preference over the non-surgical alternatives of contacts and glasses, and more effective than existing surgical methods. Furthermore, by building a record of identifying the relevant market as all presbyopic patients, B&L is working to define its market broadly so as to capture numerous competitors and ward off FTC scrutiny of the transaction.

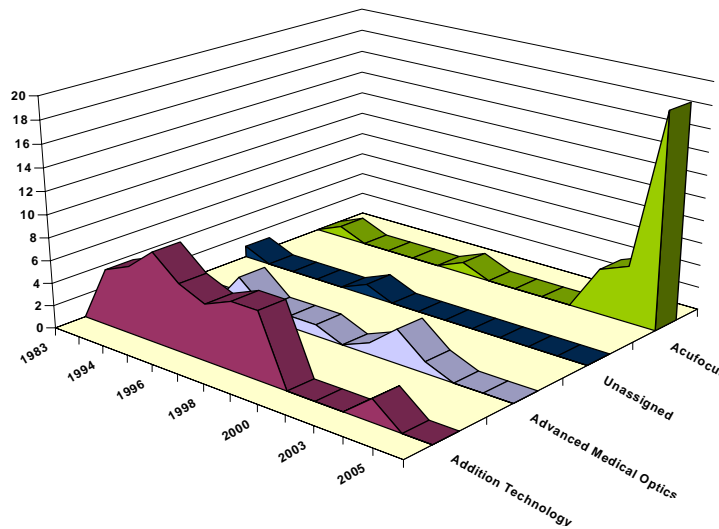
### 2. Protected Products

Key technologies in the Acufocus portfolio included surgical methods and corneal implants that scientists affiliated with Acufocus invented. These technologies offer distinct new methods of treating presbyopia. The convenience of implants over glasses or contacts is obvious. However, Acufocus distinguishes its technology over two competing surgical alternatives, intraocular lenses and sclera expansion bands, and describes its superiority to those alternatives. During due diligence, B&L undoubtedly investigated these claims from consumer, regulatory, and patent claim perspectives. In essence, results of clinical trials were deemed favorable, and assurance of patent claim coverage was adequate.

In addition to evaluating claim scope, however, other factors are important in patent valuation as well. Not only must the claimed subject matter protect the competitive advantage sought, but the rights must be secured, and the claims must stand up to challenge. In some cases, start-ups may have several applications in their portfolios, but no procured patents. This was the case with Acufocus. Thus it may have been useful for B&L to compare the Acufocus filing trends to those of related companies, as depicted in Figure 2 below.

Figure 2

Recent Patent Application Filings Among Related Companies



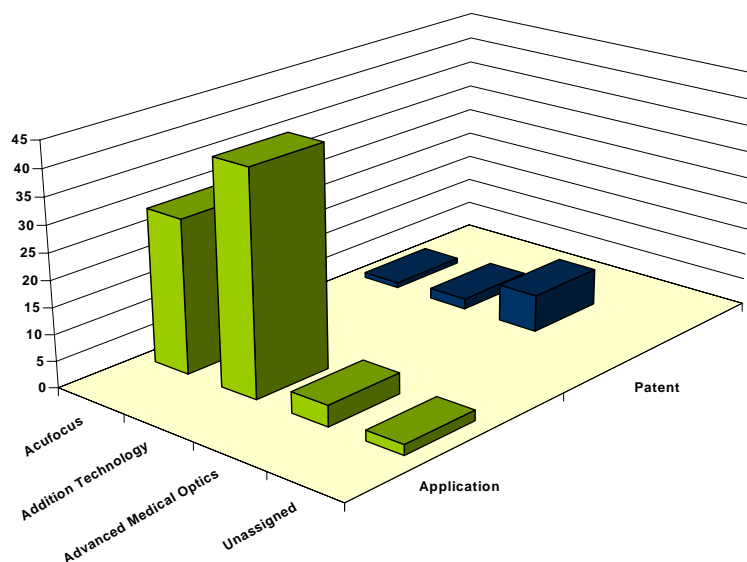
Notice that patent filings covering the most closely related technologies owned primarily by Addition Technologies or Advanced Medical Optics are either older or fewer. This visualization shows Acufocus emerging as a leader in the space in the most recent years, and the absence of litigation would lend itself to the credibility of the Acufocus inventors and their technology. Also, because the documents are primarily in the application stage, the remaining term of the overall portfolio is likely to be relatively long and cover the useful lives of the covered corneal implants.

### 3. Competing Products and Companies

Figure 3 illustrates competitive concerns as well as information related to patent valuation. Specifically, potential competitors Addition Technologies and Advanced Medical Optics are revealed. B&L, recognizing these companies as potential competitors for the target market, would likely have evaluated them based on their activity in the market and the focus of their research to determine the nature of any threat. Interestingly, key inventors Thomas Silvestrini and Carl Knopp were affiliated with all three companies, an observation that reduces the likelihood that the companies were competing. (See Figure 4.) To be sure, many entrepreneurial scientists often find themselves directing and consulting with more than one small company to hedge their bets on which technology will take off.

Figure 3

Distribution of Patents and Applications Among Related Companies



These observations are important in terms of alleviating concerns that the companies in possession of the most closely related technologies to those of the Acufocus portfolio are likely to compete for a share of the presbyopic patient market. Commonality of inventorship and the presence of ongoing relationships between key inventors and multiple companies suggest different business directions among the companies.

Figure 4

Inventor Distribution Among Patents and Applications Owned by Acufocus and its Closest Potential Competitors

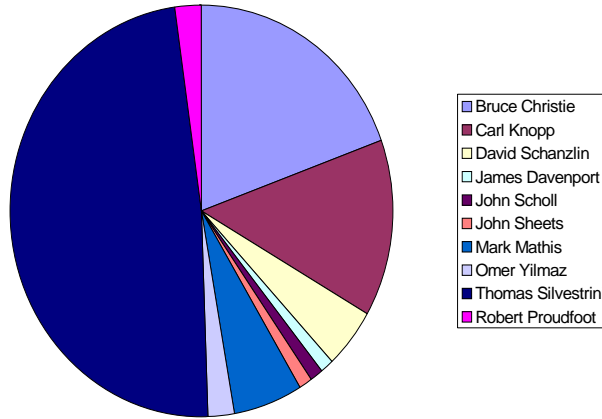
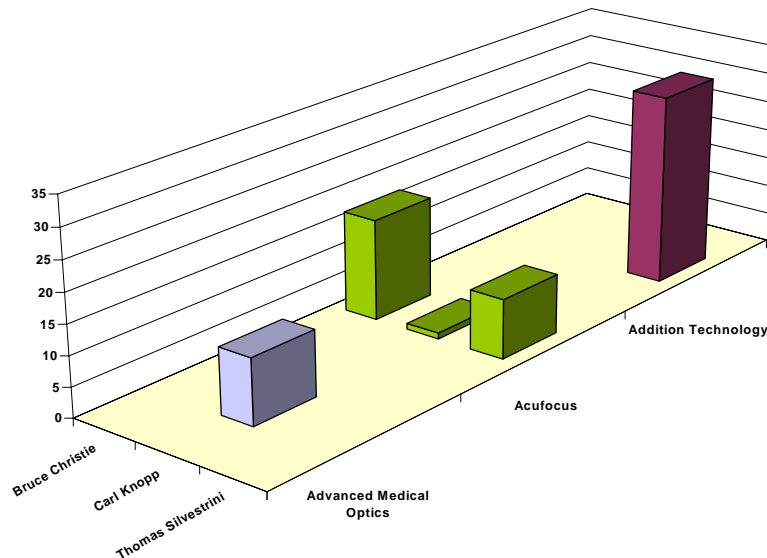


Figure 5 speaks to this point, indicating that while Bruce Christie appears to be the most prolific Acufocus inventor, both Silvestrini and Knopp are affiliated as well, and hold some key interest in the other companies. It would be against inventor business objectives to make these kinds of assignments without justification, and if the companies viewed each other as competitors they would likely have fashioned non-competition agreements for these inventors to sign to prevent this type of activity. Figure 5 below shows the inventors' cross-company activity, and all inventors appear primarily affiliated with Acufocus.

Figure 5

Corporate Affiliations of Key Inventors



## CONCLUSION

The B&L/Acufocus case study raises an interesting question in terms of how the presbyopic patient market is defined. It should be obvious that B&L is a leading producer of eyeglasses and contact lenses, products that would compete against the Acufocus technology for market share. Yet B&L still apparently found Acufocus a worthwhile investment. It could be that B&L wanted to position itself as a leader in the presbyopic treatment market as the market shifts from glasses and contacts to one-shot surgical methods. If these technologies compete for the same customers, would acquisition of Acufocus by B&L raise concerns that the transaction would create too much market power for B&L? B&L presumably thinks not. Alternatively, could B&L simply have made the investment to scavenge royalties from companies with competing surgical technologies? Many business objectives could have driven the transaction, and this case study was designed to illustrate some of the possibilities. In the end, of course, the public knows only that an equity investment with option to purchase was made. The precise drivers for the transaction will remain largely speculative until it impacts the marketplace.

## ABOUT THE AUTHOR

Analyst Scott Lloyd works collaboratively with clients to identify intellectual property requirements and provide competitive analysis to help them to make key business decisions. He works across multiple disciplines in developing strategies for patents, licenses, and acquisitions. He identifies white space for innovation in various patent landscapes, providing grounds for patent validity challenges and invalidity defenses to infringement suits. He also provides clients with due diligence research for patent portfolio valuations and freedom to operate assessments, and assisting clients with patentability determinations for emerging technologies in the biosciences. Mr. Lloyd has 10 years of combined academic and industry experience in biotechnology and pharmaceuticals. He earned his law degree at the University of Maryland School of Law, holds a master's degree in tumor biology from Georgetown University, and has a bachelor's degree in biology from Loyola College in Maryland. He is a member of the American Intellectual Property Law Association and the American Bar Association. Mr. Lloyd is a USPTO registered agent. He has several peer-reviewed publications to his credit and has presented at multi-national scientific meetings. Mr. Lloyd also served as notes and comments editor for the *Journal of Business and Technology Law* from 2006-2007.

## ABOUT NERAC

Nerac is a research and advisory firm for companies developing innovative products and technologies. Our Analysts deliver custom assessments of product and technology development opportunities, competitor intelligence, Intellectual Property strategies, and compliance requirements through a proven threefold approach to custom analysis: review of technical knowledge, investigation of intellectual property, and appraisal of business impacts. Nerac deploys analysts in diverse disciplines to help clients discover new applications, serving as a catalyst for new thinking and creative approaches to business problems or identifying strategic growth opportunities.

The information contained in this report has been obtained from one or more copyrighted sources. No reproduction or further dissemination of the report in whole or part may be made without the express written consent of Nerac, Inc.

This report is provided on as-is basis and does not constitute a recommendation to make or not make an investment. This report provides information that the recipient must independently analyze and verify in its evaluation process. The recipient of this report can accept or reject its findings at its sole discretion. The terms of any investment decision, including the merits and risks involved, must be solely and independently analyzed by the client.

Nerac specifically disclaims any and all warranties, including without limitation, warranties of merchantability and fitness for a particular purpose. This Report is given on and as of the date hereof only, and it does not contemplate, and no opinion is given or intended with respect to, future events or subsequent changes or developments in science, law or fact, and Nerac has no obligation to update this report with respect thereto.

Nerac shall not be liable for any loss, injury, claim, liability, or damage of any kind resulting in any way from any use of this report.