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Strategic Sourcing for the Orthopaedic Industry



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**Bradford L. Goldense**  
 Founder and Chief Executive Officer  
*Goldense Group, Inc.*



## Evolving IP Management Practices in The Orthopaedic Industry

While the importance of intellectual property (IP) – its value and protection—has grown dramatically in the past twenty years, many companies neither adequately protect their assets nor do they have a system to manage IP decision-making. These are the findings of a recent study conducted by the Goldense Group, Inc. (GGI).

In its 2004 Product Development Metrics Survey, GGI interviewed 202 research and development firms, primarily in North America, and collected data on their IP management processes, systems and tools. While the research was not focused exclusively on orthopaedics, the following health care sectors were represented in the survey: medical products (7.0%), biotechnology (1.0%), health services (0.5%) and pharmaceuticals (1%).

Results show that while most respondents recognize the value of their IP, some companies do not protect their intellectual property at all. The study also notes that in many cases, IP management processes are largely undocumented.

GGI's research found that while 75 percent of firms legally protect their IP frequently or almost always, six percent never protect it. (Protection includes the use of patents, trademarks, copyrights and the like.) It is encouraging, however, that 60 percent of companies are registering their IP in the early stages of the product development process, i.e. before a product idea is selected for full development. This indicates that many firms are protecting their ideas early, whether or not these ideas actually reach the market. But as much as 50 percent of the processes to manage IP are undocumented and informal.

Fortunately, the processes and systems for IP management are evolving as its importance grows. GGI's research found that nearly half (49 percent) of respondents have a central organization or steering committee that makes IP decisions. Most companies rely on external counsel to support their internal organization; 47 percent have internal law departments aided by external counsel, and 22 percent have part-time legal staff supported by external counsel. The importance of proper IP management is clearly illustrated in a quick review of the \$1.35 billion settlement between Medtronic and Dr. Gary Michelson in 2005. Dr. Michelson is known for his inventions including spine implants, surgical tools and surgical techniques. In the 1990s, he licensed these inventions to the orthopaedic giant Sofamor Danek, which was later acquired by Medtronic.

In 2001, Medtronic sued Michelson, claiming that he was marketing some of his inventions to competitors. Michelson counter-sued, stating that Medtronic failed to develop the inventions in question, thus depriving him of royalties. In the Fall of 2004, a federal jury ruled in favor of Michelson, ordering Medtronic to pay over \$500 million in compensatory and punitive damages. Dr. Michelson appealed the court's decision, seeking up to \$1.7 billion from Medtronic. By April of 2006, the parties came to a \$1.35 billion agreement, the largest one-time intellectual property award in U.S. history.

The growing importance of IP, especially in the valuation of companies, underlines the importance of determining which intellectual assets to select for legal protection. Processes, systems and tools do exist to support decision-making for IP, although these are now in the early stages of maturity. IP decisions, when considered early in the product development process, can affect the selection of products for full development and launch to the marketplace. The IP management process, used in conjunction with well-established product development processes, will lead companies to better decisions to protect their valuable assets.

For detailed results from the 2004 Product Development Metrics Survey, please contact GGI.

*Bradford L. Goldense is Founder and CEO of Goldense Group, Inc., a consulting and education firm concentrating in advanced business and technology management practices for line management functions. Mr. Goldense has consulted to over 150 of the Fortune 1000 and has worked on productivity improvement and automation projects in over 400 manufacturing locations on four continents. Further, he has authored or been quoted in over 150 articles on competitive product development and manufacturing. He can be reached at [blg@goldensegroupinc.com](mailto:blg@goldensegroupinc.com).*

Goldense Group, Inc.  
 1346 South Street  
 Needham, Massachusetts 02492  
 781-444-5400 (phone)  
 781-444-5475 (fax)  
[www.goldensegroupinc.com](http://www.goldensegroupinc.com)