Combination Products and Intellectual Property

Realizing Value From Intellectual Assets Requires Preparation and Strategy

Michael R. Bielski,
ipCapital Group
and
Christine M. Ford,
Reed Exhibition

The convergence of medical devices, pharmaceuticals and biological agents in combination products such as drug-coated or advanced delivery systems is a large and growing trend. According to Navigant Consulting, the combination product market is set to grow 10% annually, reaching nearly $9.54 billion by 2009.

Combination products bring together the power of advanced therapeutics with the precision dosing made possible by sophisticated delivery technologies. Because of their hybrid nature, combination products frequently rely on innovations from a number of different sources and involve joint ventures, collaborations or licensing arrangements among partners. For this reason, it is crucial for all participants to understand the intellectual property (IP) issues related to combination product development and commercialization. To achieve success in the combination product marketplace, organizations should understand the essential elements of an IP strategy, know how to use IP to gain transaction leverage and keep abreast of industry and IP trends.

The Value of Developing an IP Strategy

Intellectual assets, a large portion of which are protected via IP, are replacing land, energy and raw materials as an organization's most valuable resource. In 2005, the *Economist* reported that as much as three quarters of the value of publicly traded companies in America come from intangible assets. However, a significant number of companies still do not have a strategy for IP development and management.

A carefully executed IP strategy facilitates the development of a valuable IP portfolio that companies can leverage when they enter into partnerships, licensing arrangements, mergers, acquisitions or other types of joint ventures. More often than not, a company with a strong IP position will receive better terms in a transaction, including acquisition, when compared to a company with a weak IP position.

This transaction leverage is critical for both large and small companies. Although large companies may have the resources to develop and manufacture combination products on their own, there may be a significant opportunity to reduce R&D expenditure by partnering with a smaller company. Alternatively, small companies may not have the in-house talent and capital needed to develop and manufacture combination products and, thus, will be forced to look for partnering or licensing opportunities. Such arrangements make it crucial for companies of all sizes to strategically create, document and develop their IP assets, ensuring that they can leverage their IP position to receive more favorable terms in future transactions.

For example, many of the new biologic therapeutic applications are not something that can easily be delivered in a pill but, instead, require targeted delivery systems. Biotech companies frequently need to seek device company partners to help develop the delivery portion of a combination product. By the same token, device companies may choose to actively seek biotech or pharmaceutical collaborators.

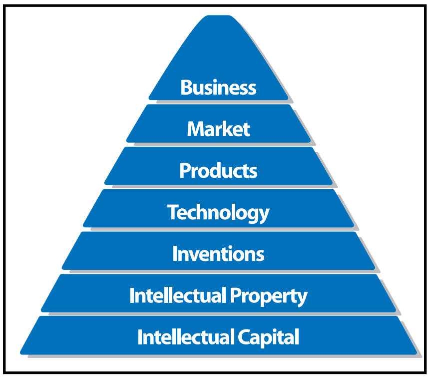
All players, of course, will want to protect their own IP and get maximum value for it in any business transactions or profit-sharing arrangements. A strong IP portfolio can serve as a bargaining chip in requests for shared royalties or as a trading card in negotiations among partners. To gain transaction leverage in such negotiations, it's critical to have IP documentation that discusses the combination product itself—its current and potential uses as well as how it might be used with other products. Quite simply, companies that have a stronger IP position—backed with well-founded documentation—are likely to get a better deal in the combination product marketplace than they would without it. An important way to increase transaction leverage is to develop an IP strategy.

What Is an IP Strategy?

By definition, an IP strategy is a plan or method to use IP to achieve business objectives. By linking IP processes and management to business objectives via an IP strategy, organizations can ensure that IP has a purpose, thereby reducing the competitive risks associated with ad-hoc IP development. The end result of a properly formulated and executed IP strategy is that the IP will "lead the business." In other words, the IP will be in place for use when the business needs it rather than requiring the IP to catch up.

For example, a large medical device company may realize that opportunities exist to integrate pharmaceuticals into a new device. However, the medical device company does not plan to develop this opportunity into a product. Instead, the company will develop an IP strategy to put patents in place that would provide leverage in future licensing transactions, joint ventures or litigation if third parties decide to enter this space.

In another example, a small medical device company developing combination products realizes its IP portfolio will be its most valuable asset and wants to strategically build the portfolio for the purpose of increasing the company's value during acquisition. The company obtains IP across the value chain, including compositions, methods of making the devices, the device itself, methods of using the device and integration into larger systems. Because of this effort, the company will be able to articulate and leverage the strength of its IP position across the value chain prior to acquisition as a means to increase the company's value.



When intellectual property (IP) development is linked to business objectives via an IP strategy, the IP protects the company's core technology and ensures that IP resources are used.

In both cases, the IP would be used not only to defensively protect the company's core technology, but also to proactively advance each organization's business objectives. Furthermore, the IP was filed ahead of the pressing business need—a direct result of implementing an IP strategy. It already was in place for the large company when third parties entered an emerging technology space, and it maximized value of the small company at the time of the acquisition.

How to Develop an IP Strategy

The most important aspect of developing an IP strategy is the communication between business, legal, technical and marketing departments within an organization. Without this communication, it is difficult to align the development of the IP portfolio with corporate business objectives of the organization, creating the risk of ad-hoc IP development.

Once communication is established across these departments, there are five critical steps to developing and implementing an IP strategy for combination products:

1. Identify Business Objectives With Respect to Combination Products. Before IP can be used to achieve business objectives, these goals must be identified—preferably derived from C-level executives. Business objectives can vary greatly by organization. Examples may include:

- Support the current development of a combination product. This company will require a thorough understanding of the business, enabling the organization to extract, document and obtain IP across the value chain.
- Protect a future opportunity. This company, having already identified a combination product application of its core technology, may want to put IP in place even though there are no current plans to fully develop the product. By doing this, the organization can leverage the IP in future licensing transactions, joint ventures, litigation and/or future product development.
- Address competitors that are developing combination products. This company may want to formalize creative brainstorming sessions, in conjunction with patent counsel, that result in enabled combination product opportunities using the company's core technology.

2. Evaluate the Organization's Current IP That Maps to Combination Products. Once the organization understands its business objectives pertaining to combination products, the organization's

Case Study

Situation

A medical device company was interested in developing a product around an emerging technology. The company wanted to develop a secure IP position around this opportunity to improve its competitive advantage in the marketplace and increase shareholder value.

Action Steps

In order to develop the most valuable IP portfolio it could, the company developed a graphical representation of the technology space, in essence, a "landscape" of how this new business would work. This landscape included the raw materials of the device, how the device would be made, the device itself, how the device could be incorporated into larger systems, and how the invention as a whole would be used by physicians.

The company then mapped competitive patents to this landscape, identifying where competitors were patenting, the trends, and the strengths/weaknesses of these existing IP portfolios.

The company developed an IP strategy that attacked all areas of the landscape, specifically focusing areas of greatest opportunity—the device itself and in integrating the device into larger systems. Creative brainstorming sessions were held by the company to develop IP in areas where current invention levels were low.

Value Added

After implementing the IP strategy, the company had the most comprehensive IP position of any organization in the technology space. This IP position secured the organizations current and future revenue drivers and was used to increase the valuation of the company during acquisition negotiations.

current IP should be mapped to this opportunity. This mapping should occur throughout the value chain and may include raw materials, methods of making the device, the device itself, methods of using the device and integration of the device into larger systems. This process allows organizations to understand the strengths and weaknesses of its IP position and grasp where the opportunities for IP exist in this combination product opportunity.

3. Review the Competitive IP Position Relevant to Combination Products. Now that the organization understands its own position with respect to a combination product opportunity, it is critical to evaluate the competitive IP in the relevant technology space. Questions to address include:

- Are there many patents filed or issued in this technology space?
- Where do they map on the value chain? (In other words, where are they patenting?)
- Are they large companies or small companies?
- Are device companies integrating pharmaceuticals? Are pharmaceutical companies obtaining IP on devices?
- What are the trends? What are the opportunities?

Understanding the competitive IP will help guide the IP strategy, helping to avoid roadblocks as well as identifying opportunities for IP leverage.

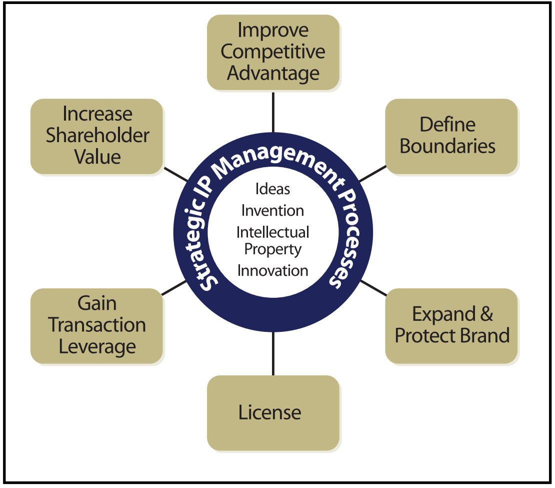
4. Use This Information to Develop an IP Strategy That Aligns With Business Objectives. Once the business objectives, current IP position and competitive IP position are understood, an informed, proactive IP strategy can be developed to achieve the identified business objectives of the organization. By design, the IP that results from the implementation of this IP strategy now will be aligned with corporate business objectives with respect to combination products. This will eliminate the competitive risks and wasted resources associated with adhoc IP development. The IP strategy may include the elements of:

- ***Creative Brainstorming.*** Implementation requires representatives from all departments—engineering and design as well as technical, legal, business and marketing personnel—to hold formal brainstorming sessions that accelerate the development of innovation in a specified technology area. This often is used when inventions are needed to fill gaps in an IP portfolio and strengthen market position. Best-in-class organizations should hold brainstorming sessions that result in enabled invention disclosures regularly to address industry trends for combination products.
- ***Defensive Publication.*** This is a low-cost way of preventing competitors from obtaining IP in a technology space, implemented by publishing invention documents as prior art. This tactic often is used when resources prevent patenting of incremental innovations or multiple applications of core technology, and there is a risk of competitors obtaining this IP that would adversely affect the company's business.
- ***Invent-around.*** Inventing around IP involves identifying other ways to functionally achieve the objects of an identified invention. Best-in-class organizations invent around important IP and publish and/or patent these invent-arounds before their competitors do. This may be done on both their own and competitive IP. This is a way to both strengthen the company's current IP portfolio as well as avoid any potential competitive IP roadblocks.

• ***Invent-on-top of.*** This process determines how a core technology may be used down the value chain—for example, how a combination product may be developed using a known medical device. Alternatively, this process may be used to determine how a combination product may be incorporated into a wireless medical system. Similar to invent-arounds, inventing-on-top of relevant IP and patenting/publishing these inventions before competitors do is a best practice.

There are many other tactics that an IP strategy may employ, depending on the business objectives of the organization. Development of the IP strategy should take into consideration these many different tactics, carefully implementing those most likely to achieve business objectives within budgetary and other resource constraints.

5. Implement and Execute the IP Strategy. Developing an IP strategy without execution is meaningless. It is critical to develop an IP strategy that not only is executable with the resources available to the organization, but that also has execution items that are assigned to designated parties with deadlines. One way to facilitate the execution of an IP strategy is to ensure that there is alignment between the execution items of the IP strategy and the company's current IP management practices. For example, are the firm's invention disclosure processes, invention review processes, brainstorming processes and competitive IP analysis processes, etc. functioning at a level such that the IP strategy can be successfully implemented? If not, it may be time to review and improve core IP management practices.



An IP strategy connects your core portfolio of ideas, invention, IP, and innovation to IP management processes that create value and reduce costs. To fully maximize ROI from innovation, an IP strategy also outlines tactics that will produce returns relevant to your business objectives.

Even the most well conceived IP strategy is doomed to fail if C-level executives do not buy into it. Therefore, it is critical to ensure that both the business objectives and IP strategy are developed with C-level executive input.

Finally, IP strategies should proactively be updated on a routine basis. There may be new competitive information or a change in business objectives that should redirect the efforts of the IP strategy.

Keeping Abreast of IP Trends

Medical and pharmaceutical technology increasingly is based on combinations of individual technologies. The rise of these combination products is likely to fuel greater collaboration as well as competition, as formerly separate players become partners or competitors.

There always will be "disruptive technologies" that carve out their own space in the market, and the best creative minds are likely to strive toward these kinds of inventions. Most of the time, though, innovation occurs incrementally and cumulatively—with collaborators working together to build on what has come before. Given this reality, it's crucial for companies developing combination products to understand and protect their intellectual assets; doing so is just as important an exercise as developing the expertise and systems needed to successfully bring products to the market.

To stay abreast of all the factors that affect IP strategy, it is critical that combination product developers take advantage of new opportunities to learn and network in this burgeoning industry. ❖

Michael R. Bielski is a senior associate at ipCapital Group. Since 1998, ipCG has maximized financial results for companies that seek to develop and execute intellectual property (IP) strategies; strengthen and monetize IP portfolios; and establish and implement Intellectual Asset Management practices. Michael's practice focuses on the development and implementation of IP strategies for companies of all sizes, with particular attention to how medical technology companies can increase valuation using IP. He can be reached at (802) 872-3200 x255 or mbielski@ipcg.com.

Christine M. Ford is event director of PharmaMedDevice. Since joining Reed Exhibitions in 1991, Ford has been involved in a variety of conference and event management positions within a range of event portfolios including technology, life sciences and manufacturing. Since 2004, she has focused the majority of her business development work within the life sciences and healthcare industries, including the PharmaMedDevice launch. She can be reached at (203) 840-5391 or cford@reedexpo.com.