Five IP tips to spread your business wings

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Intellectual property (IP) is a critical asset at most life science start-up companies. Savvy organizational management of IP strategies and assets is essential in optimizing IP value as a sustainable business is built.

As a scientist turned entrepreneur at an early-stage biotech company, it is critical that you understand how to efficiently and effectively implement and manage your new enterprise's IP strategy and assets. Even though you may feel you have an adequate understanding of what a patent, license or trademark is, you should not make the mistake of having little to no appreciation for basic aspects of organizational IP management—a process that is essential to leveraging optimal value from your IP assets.

For my purposes here, 'IP assets' broadly encompasses a company's worldwide patent, trademark and copyright portfolios (pending, issued and registered); its trade secrets; its valuable know-how/show-how pertaining to its products, processes and technology; its worldwide in- and out-licensing portfolio and technology and product alliances; and its collaborative partnership portfolio. Also, when I refer to 'IP strategy,' I mean a company's strategic plan for protecting and leveraging its IP assets in a manner consistent with its overall strategic business plan and in a manner that returns value from investment in those assets.

Failing to implement an effective IP strategy or keep it aligned with other activities in the company are among the most common errors of inexperienced entrepreneurs. In the following article, I provide a few valuable tips on how to get the most out of your new venture's IP activities and assets and how to manage them effectively.

Tip 1: think synergistically

Within the business organization, corporate vision drives specific objectives, also known as corporate missions, and those missions in turn define departmental business goals, which go on to determine business development, sales and marketing, IP and R&D strategies. Because these distinct strategies necessarily interface with, depend on and synergize with each other, IP strategy can only be as effective as the other strategies to which it relates. For example, spending time and money on securing patent protection for inventions that do not fit within the business development strategy and/or executing an R&D strategy that does not support the intended IP strategy is inefficient, wasteful and will lead to poor execution of the intended strategies. In fact, failing to think synergistically can bring about all sorts of problems (**Box 1**).

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Box 1 Failing to think synergistically

Company A (real name withheld) was a profitable early-stage research reagent developer with rising worldwide sales. Its primary business was catalog reagent sales, most of which were based on nonproprietary protein targets, with a fairly small number of products based on in-licensed patented targets and an even smaller number based on new targets identified and patented in-house. In addition to its R&D programs for catalog reagents, the company had a fairly substantial internal basic research program aimed at discovering previously unknown molecular targets and biomarkers in cancer. Executive management dedicated financial, equipment and staffing resources (including staff time required to prepare research abstracts and publications in top journals or at prominent conferences) to the program. Some of the biomarker and drug-target discoveries were provocative, so management decided to file patent applications on those inventions. After the applications were prepared and filed by internal patent attorneys, the company had patent committee meetings to discuss the inventions and their potential future commercial value. The committee included the chief patent counsel, the director of the research group in which the inventions were made, several members of executive management and several independent internal scientists.

The initial patent filings were made with the intention of providing additional time for invention and commercialization development. But company management never actually implemented any commercialization strategy or plans for the patented technologies, nor did it seek to monetize them by out-licensing to interested third parties or by forming joint ventures with partners, though there were several internal champions pushing for a joint venture opportunity with an interested third party. This failure to derive return on investment from intellectual property assets resulted from the lack of an integrated plan, start to finish, for moving inventions from the discovery phase to the market. The company's research project, although scientifically interesting, was not driven by or aligned with its business model. With no clear, well-developed postfiling commercialization development plan, the filing became a moot point commercially. This scenario could have been avoided by synergistic thinking about the main discovery goals of the company, how the goals did or did not fit with its long-term strategic and commercialization plans and then collectively deciding whether acquiring the intellectual property would serve those interests.

Box 2 Leveraging beyond patents

Company B (real name withheld) was a start-up medical device company with pre-sales activities. Its main in-development product was a noninvasive patient-controllable medical device that offered improvements over the standard-of-care device in performance, tolerance and patient satisfaction. The product had two distinct components, and worldwide patent coverage was pending that provided broad protection. The firm had initiated a strategic plan to globally partner and out-license the assembly, marketing and sale of the product but still directly and exclusively control the manufacture of one of the components at its own domestic plant. This particular component of the device was not straightforward to manufacture, and the company had developed and identified some important trade-secreted aspects of the manufacturing process that they did not desire to out-license to any other party. By identifying, protecting and smartly exploiting such trade secrets, the company leveraged its IP portfolio to its fullest benefit, beyond simply licensing its patent portfolio to key partners. The trade secrets provided a second proprietary fence around certain key aspects of their technology should the core patents be held invalid, unenforceable or not infringed. The decision to exclusively retain the trade-secreted manufacturing improvements and exploit them at their own domestic facility also provided an extra element of control over their core technology and allowed extra leverage in negotiating deals with overseas manufacturing and marketing partners. Finally, the identification, protection and exclusive possession of their trade-secreted improvements stood as an important IP asset on their corporate books, therefore increasing their valuation and attractiveness to potential investors, including venture capitalists.

Although this may seem obvious, it is a classic problem within many, if not most, start-up companies in which organizational management may not be optimal and heads of different departments may not communicate and collaborate sufficiently to execute their respective strategies. Alternatively, in a start-up lacking distinct departments and in which the founding executives are acting as the *de facto* implementers of respective corporate strategies, it is common to overfocus on R&D activities and underfocus on integrating the IP, business development and sales and marketing strategies that will move R&D results to market. As a new executive, avoid this pitfall by always thinking synergistically, keeping in mind the various departmental objectives and activities. You must consider IP strategy within the context of other corporate strategies, rather than individually and in a false vacuum. When reviewing organizational activities for synergy, take an 'outsider's eye' approach to consider things freshly, without bias, and ask obvious but challenging questions: is the business development team (or the executive acting as the *de facto* business development lead) initiating and executing the types of deals that have been mandated by executive management to achieve the corporate vision? Is the R&D department engaged only in projects that serve and advance the bottom line, or are satellite or pet projects draining resources and diverting focus? Is the sales and marketing team (or the executive acting as the *de facto* sales and marketing lead) properly interfacing with the legal department to ensure that any eventual worldwide distributorship and/or product partnership arrangements are not undermining the IP strategy and/or business development strategy? Ask these questions often to keep your organization running well and running synergistically. If the answers are not what they should be, act promptly to correct deficiencies.

Tip 2: involve counsel early and often

Scientists turned bioentrepreneurs commonly make the costly mistake of failing to involve their IP counsel early and frequently enough in various corporate activities. Often, this failure stems from either a general fear of attorneys (a 'we don't need the lawyers' type of thinking) or a lack of appreciation for the critical role that IP counsel, whether internal or external, should play in strategic planning and business development.

Keep in mind that IP counsel is trained and experienced not only in the legal acquisition of IP but also in how to optimally leverage it as a corporate asset for value. Your IP counsel brings valuable perspective and input on such matters as the optimal types of deal structures, partners and negotiations that will help the company best leverage its IP assets and achieve its long-term goals. Accordingly, IP counsel should not be thought of as a final set of eyes in a multistep process but rather as a critical consult at every stage of the process from inception to implementation. Failing to involve IP counsel early or often enough usually results in a host of negatives, ranging from misaligned departmental activities, such as business development pursuing deal structures that don't fit the corporate strategy, to inefficient or fatal deal negotiations because counsel couldn't steer the firm clear of bad terms and deals. Avoid this mistake by involving and seeking the perspectives of your IP counsel regularly.

Tip 3: leverage beyond patents

Bioentrepreneurs often understand the value and importance of having patent applications filed on their cornerstone technology, but they frequently have little or no appreciation of the importance of other key corporate IP assets, including trade secrets, know-how/show-how, trademarks, reputation and goodwill. Similarly, they might fail to appreciate important in-licensed technology and rights or future IP rights (gained through collaborative, joint-development or alliance relationships) as part of their corporate IP asset portfolio. Failing to see this importance is a mistake, as such rights are often critical to the value proposition needed to close deals and define a corporation's competitive IP fence line. Indeed, nonpatent rights, such as trade-secreted improvements to core technology and associated know-how/show-how in practicing such technology, is often just as important, if not more so, than the core patent rights in securing key partners and closing deals. Avoid the patent myopia trap by remembering that patents are but one tool in your corporate IP asset toolbox and appreciating that other tools, like trade secrets and trademarks, may be equally important in moving your enterprise toward its ultimate goals. Often, manufacturing trade secrets can provide value, too (**Box 2**).

Tip 4: do the right deals

Early-stage enterprises invariably have cash-flow challenges, and executives at such start-ups are therefore often tempted to 'grab the low-hanging fruit' and do modest cash-up-front deals, even when the structure of those deals might not best serve the longer-term corporate goals. Remember that more cash up front usually means fewer IP rights and/or monetary share in the downstream successes, as larger up-front cash payments usually mean the partner will retain the lion's share of value down the line. Although there are often good business reasons to forgo stronger downstream rights, such as joint ownership and desirable field-of-use licenses for IP resulting from the relationship, there are often equally good business reasons to

avoid such deals. These include the creation of a negative industry precedent that sets an expectation with future partners to sign the same kind of deal.

The critically important task for new bioentrepreneurs is appreciating when to accept the quick cash up front and when to hold fast and fight hard for more important long-term rights. This can, of course, be hard to swallow for executive managers at a cash-starved, early-stage enterprise, but resolve and commitment to long-term corporate goals are frequently just as important to corporate success as chasing the carrot of up-front dollars, even if it means walking away from the wrong deal. Avoid this trap by having a clear picture of your long-term goals and a deal strategy for getting there, ensuring your entire senior management team understands the mandate and is vested in it, negotiating hard for the right deals and terms and knowing when to walk away from the tempting modest up-front cash deals.

Tip 5: align the efforts

Executive managers of corporations are often likened to conductors of symphonies: they are not themselves virtuosos of any corporate activity *per se* but instead know how to bring together those virtuosos to create harmonious effort and resulting magic. Think of your senior management team as your symphonic virtuosos, who are all looking to you, the conducting executive, for direction on harmonization with other players. In start-up or early-stage companies, particularly those in which newfound executives lack significant organizational management training or skills, there is often a lack of integration between independently acting departments and their directors, resulting in corporate cacophony instead of harmonious and aligned activity and effort. Avoid this common organizational pitfall by being a strong leader, staying apprised and on top of the week-to-week (or month-to-month) activities of each department reporting to you and ensuring that you keep those departments and their leaders working toward the same overarching corporate goals. Regular senior management meetings should feature briefings by each departmental head. Ask challenging questions and require departmental heads to make a case justifying particular actions based on a pro-versus-con analysis. Also, encourage open exchange of ideas, perspectives, doubts and brainstorming among those departmental leaders—all of this will help keep things aligned in your new organization. Specific senior managers that should be included in this process include, at a minimum, chief operating officer, chief counsel, chief scientific officer, director of business development, director of marketing and sales and director of licensing (if any). If independent departmental heads do not yet exist, the founding executives acting as the *de facto* heads should similarly conduct such meetings or discussions to keep things organizationally aligned.

Conclusion

In summary, savvy organizational management of IP strategies and assets is essential for bioentrepreneurs at early-stage companies seeking to optimize the value and return on investment of the IP assets (patents, trademarks, copyrights, license rights and trade secrets) owned by the company. Executives and entrepreneurs at such companies can get a big leg up in smartly managing their IP strategies and assets by remembering these five simple tips: think synergistically, involve counsel early and often, leverage beyond patents, do the right deals and align the efforts. At every stage of corporate development, from start-up to maturation and possible exit (by sale or initial public offering), IP strategy should be viewed in the context of, and kept aligned with, sales and marketing, business development and R&D strategies, as well as with a complete toolbox of IP assets. That means not only patents but also related trade secrets, trademarks, know-how and other license rights should be synergistically leveraged when possible to optimize return on investment on such IP assets.

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