

# Intellectual property as a foundation for funding

Putting in place a sound strategy for protecting and maximizing a company's intellectual property can boost its future value, say Steven Meltzer, Michelle Marks, and James McCormick.

Virtually every budding biotechnology entrepreneur asks the same question: what will make me fundable? Although part of the answer lies beyond the control of any individual seeking to enter a new market, there are ways in which you can improve the odds that a biotech investor will find your innovation worthy of funding.

One of the most important ways to create sustainable value in your business is to focus on your intellectual property (IP)—to determine what you own, how to protect it, and how to build on it. From the perspective of a potential investor looking at funding opportunities, to a large degree your IP rights *are* your business.

You may have developed the most exciting and versatile new platform technology in a decade, but unless you can deter competitors by making full use of the

government-sanctioned barriers to entry offered by IP law, you will have a hard time attracting the investment needed to turn your invention into a marketable product. A patent carves out the right to exclude others from making, using, or selling your invention for a specified period, keeping potential competitors out of your niche market while you reap the rewards of your innovation.

The key to retaining the exclusive legal right to use your innovations is to start early and think innovatively about build-

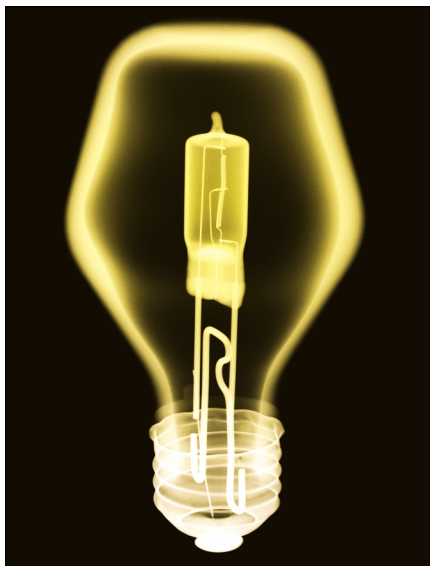
ing your IP foundation. All too often, bioentrepreneurs adopt either a crisis management or a scattershot approach to their IP rights. For example, some entrepreneurs wait until they are on the verge of negotiations with a prospective investor or strategic partner before they secure rights to their inventions. By adopting a last-minute approach, these inventors risk someone else beating them to the patent office. Other entrepreneurs eat into their financial resources through a lack of focus, submitting patent applications for developments that are of relatively little importance in the context of their business goals. As in other aspects of building a business, planning is the key to a solid IP foundation. A haphazardly built IP foundation has gaps that sophisticated investors will see through, and smart competitors will exploit.

This article suggests ten basic steps that you can take to build a solid IP foundation that will help attract funding from investors (see also "IP in a nutshell").

## Step 1: Identify your core technologies

The building blocks of your IP foundation are your company's core innovations and improvements that can be protected by law against competitors. To build a strong foundation, you first must identify what your essential technologies are, and understand how the law can protect them.

The first step is often tricky: for example, if you have developed a sophisticated technology platform, you must be able to distinguish between its core and non-core components—especially because investors expect you to be able to articulate your company's distinguishing innovation(s). What differentiates your platform from others in the field? How will you exploit



*Steven L. Meltzer is a partner, Michelle S. Marks is a special counsel, and James T. McCormick is an associate at the law firm Shaw Pittman LLP, Washington, DC (steven.meltzer@shawpittman.com; michelle.marks@shawpittman.com; james.mccormick@shawpittman.com).*



## IP in a nutshell

### Steps to protect ownership of IP

- Employee agreements: secure invention assignments
- Confidentiality agreements
- Records: keep proper laboratory documentation that supports your ownership and dates of invention
- Material transfer agreements: limit the ways in which your partners can use the biological samples you supply

### Technology audit: know what is yours

- Identify key developments, products, processes, know-how, and trade secrets
- Identify your core technologies that require protection
- Learn what can be protected and what cannot
- Identify the intellectual property you need that is, or may be, owned by others
- Recognize which aspects of your core technology are in the public domain

### Build and maintain a valuable IP portfolio

- Match your strategic goals with your proprietary rights
- Claim early, claim often, and update patent applications
- Go for quality over quantity when pursuing patent claims
- Remember that the scope of your rights equates with value
- Learn to recognize and avoid infringement of others' rights
- Conduct clearance searches, and survey the literature, published patents, and patent applications
- Identify and pursue revenue from licensing and partnering
- Do not overlook copyrights, trademarks, and trade secrets

it in ways that others cannot? Once you have sorted the core from the non-core innovations, you will be in a position to seek IP rights in the innovations that matter most to your business and to the investors funding it.

## Step 2: Audit your technology, understand your rights

A technology audit is one way to bring your core innovations into focus—and to

and the types of IP protection available to you, you should determine the probability that you can obtain IP protection for each. Although you cannot be certain of your rights until a patent has been issued (and even then, others may seek to invalidate your patent or narrow its claims), you should be able to rate the odds of receiving protection for each of your core technologies as being “likely,” “unlikely,” or “uncertain.”

A competitive intelligence review

and tools. Do not overlook computer source codes, or trade names, domain names, and service marks for which you might want to seek copyright or trademark protection. Your trade secrets—information not known outside your company that gives you a competitive advantage over others—also merit legal protection. An IP lawyer helps you to determine how to protect your key innovations and works with you through the process of obtaining patent, copyright, and trademark rights.

## Step 3: Gauge your chances of IP protection

Once you have identified your key distinguishing technologies

management. How will you respond if your competitor files a patent application covering your core technology shortly before or after your application? How will a business objective succeed or change if you are ultimately denied ownership of, or access to, essential patents? Once you have answered these questions, you should have a clear idea of the IP needed to protect your core technology and the rights you have—or need to obtain—to make, use, license, and sell the technology while excluding others from doing the same.

## Step 4: Get employees to assign inventions to the company

Suppose your senior scientist departs the company, taking with him or her an in-depth knowledge of an embryonic but promising technology that you *thought* was yours. If the scientist has not signed an “invention assignment” agreement at the start of his or her employment, then the burden may fall on you to prove that you have rights in the technology, which could be an expensive and uncertain endeavor. Under an invention assignment agreement, an employee agrees to assign to your company any inventions he or she develops in the course of employment. As a condition of employment, everyone you hire should sign one of these agreements before beginning work—otherwise you may find that your IP is as mobile as your employees. Be aware that a recruited scientist may be under a pre-existing obligation(s) to assign or grant rights to his or her inventions to a university, government agency, or former employer that funded his or her previous research.

With an invention assignment agreement in place, neither you nor your employees will be in any doubt that your company is entitled to the rights in the IP developed during the course of their employment, including the IP developed during working hours or while using company facilities. To encourage employees to report their discoveries, consider offering an invention disclosure incentive program that rewards employees for their creativity.

## Step 5: Implement non-competition and confidentiality agreements

A comprehensive confidentiality, non-competition, and non-solicitation agreement will require your employees to keep secret any non-public information they learn about your business and IP while working for you. In some jurisdictions,

**A technology audit is one way to bring your core innovations into focus—and to reduce the risk that you will overlook developments that may be worthy of protection.**

reduce the risk that you will overlook developments that may be worthy of protection. The purpose of a technology audit is twofold: first, to identify the key innovations that you plan to use in your business; second, to determine whether legal protection is available for each. As a biotechnology entrepreneur, you are most likely to be concerned with patentable property—new, useful, and unobvious products, processes,

screens for patents, published patent applications, and scientific literature closest to your core technology. This review is an essential part of understanding what property you can protect, what you may need to license from others, and what may already be in the public domain (see “Competitive intelligence review”).

Armed with the knowledge gained from these searches, you can consider IP risk-

such an agreement can also be used to prevent them from working for a competitor or poaching your customers, employees, and business partners for a reasonable time period after they stop working for you. (Note that employee non-competition agreements may be unenforceable in some jurisdictions, notably California.) Do not forget to enter into confidentiality agreements with your independent contractors and any prospective business partners to whom you disclose your business or technical information.

### Step 6: Establish procedures to protect your IP rights

Your company's internal practices and procedures can also help you to prove the "who, what, when, where, and how" of the developments that you claim to own. For example, your claim to a disputed invention is greatly strengthened if you can produce proper laboratory documentation, including bound notebooks with numbered pages that were witnessed and signed daily. Documentation can be used to prove the dates that an invention was conceived, made, used, tested, and demonstrated to work.

When forming partnerships with other businesses, make it a practice to limit your partners' rights to use your technology. For example, if you lend your biological materials to others, whether for a fee or not, enter into a material transfer agreement that limits the recipient's right to use the materials to specific applications only, and that clearly identifies both the ownership rights related to the materials and the downstream innovations they make possible.

### Step 7: Use patent applications offensively and defensively

IP strategies should include a patent procurement program that is both offensive and defensive. An early-stage company should focus on procuring patents that can be used offensively—to create exclusivities for the inventions that are essential to your company's success. The defensive purpose of a patent filing is to block competitors from patenting and practicing your invention. Whenever you review or help draft patent claims, ask yourself: "Is this the broadest set of claims that my invention supports?" In other words, "What activities or products would require a license under one or more of these claims?" A patent claim that only defines examples of the invention can keep others from replicating the demonstrated examples, but will not protect you if others

substantially change your claimed invention. Instead, file a patent specification and pursue patent claims that describe and define the full scope of your invention, which can

rights. Investors assess risk as well as value. They look at whether you may be sued or need to sue others. You should keep track of your competitors' rights by monitoring

## Be paranoid! Preserving the value of your IP requires vigilance against infringement, including the infringement of your rights by others and your infringement of others' rights.

protect the foreseeable ways in which you—or your competitors—might alter it.

### Step 8: Focus on the scope of your claims

By all means file and update patent applications early and often, but concentrate more on the quality and scope of the claims than on the number of patents. After all, the scope of the rights that are exclusively yours defines the value of your IP. Skilled analysts look beyond the number of patents issued and applications filed to determine the breadth and quality of your exclusive rights. Broad, carefully crafted patent claims protecting your core technologies create strong barriers to entry into your niche market—and boost your company's value in the eyes of potential investors.

### Step 9: Keep informed of your competitors' rights

Be paranoid! Preserving the value of your IP requires vigilance against infringement, including the infringement of your rights by others and your infringement of others'

published patent applications, such as Patent Cooperation Treaty applications, which are published 18 months after the priority application is filed. You can identify these applications through various databases (see "Competitive intelligence review"). Keep in mind that no patent database is comprehensive and up-to-date because of the 18-month window between an application's filing and its publication. Also, not all applications are published, and many innovations are protected by trade secret alone, with no patent application filings to be found. Any search, therefore, provides only a partial picture of the IP currently being pursued within your field. The likelihood of infringement is reduced if your employees, major investors, and IP counsel are kept informed. Make sure that your board of directors and major investors understand what you are doing so that they, too, can be watching for competitive applications and products.

Regular surveillance of industry literature and published patent applications may cause you to revise your business

## Competitive intelligence review

Companies must continually screen databases for the closest patents, published patent applications, and scientific literature relevant to their own IP:

- Search scientific literature and published nucleotide and protein sequences in the National Library of Medicine's PubMed database (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>) and commercially available databases
- Search issued US patents and published US patent applications in the US Patent and Trademark Office's databases (<http://www.uspto.gov>)
- Search published Patent Cooperation Treaty (PCT) applications in the electronic PCT Gazette (<http://pctgazette.wipo.int>)
- More comprehensive sources of information on worldwide patents and published patent applications are available from commercial databases, such as Derwent's GENESQ and FASTAlert (<http://www.derwent.com/worldpatentsindex/index.html>, <http://www.derwent.com/geneseq/index.html> and <http://www.derwent.com/fastalert/index.html>)
- Other comprehensive sequence databases and bioinformatics tools require licenses for access, such as those developed by Incyte and Celera (<http://www.incyte.com/sequence/index.shtml>, <http://www.celera.com/genomics/commercial/home.cfm>, respectively)

goals, patent strategies, and the drafting of future patent applications and claims. For example, a claim to a new DNA or protein sequence cannot cover sequences already disclosed by others. Although many partial sequences have been placed in the public domain, a combination of skillful patent claim drafting and knowledge of the commercial, technological, and IP landscape can be successful in procuring protections for your commercially important products and processes, despite the fact that they build on public information. By keeping track of the patent rights being pursued and obtained in your market and technology niche, you can police your own patents and pipeline innovations. Vigilance also teaches you to sense when you are getting close to making or using the patented technology of others, reducing the chance that you will find yourself on the wrong side of an infringement suit.

### Step 10: Seek low-cost revenue opportunities

So what is the potential payoff for all this work? Not only might you create a profitable

exclusive market that is in high demand, the rewards also may include low-cost revenue generation through licensing. Licensing out your technology can be as much a part of your IP strategy as the filing of patents, competitive surveillance, and the establishment of ownership. In addition to acquiring patent or other rights to exploit the inventions that you and your employees develop, you will be on the lookout for potential partnering opportunities and strategic alliances with the owners of IP that complements your own.

Because virtually every emerging technology uses and builds upon prior patented innovations, one revenue-generating model that may prove popular in the commerce of today's interdependent technology platforms is patent pooling. Patent pooling is a joint agreement among patent owners to make their patents, which are essential within a particular technology, available to all parties on fair, reasonable, nondiscriminatory terms under a single license. Through patent pooling, an entire set of tools essential to the practice of that technology may be easily acquired. In the United States, antitrust authorities have

permitted the creation of pools of patents covering MPEG-2 and DVD technology. Patent pooling seems increasingly applicable to interdependent technology platforms as the number of blocking patents and infringement lawsuits grows, requiring downstream developers to obtain licenses from multiple IP owners.

A word of caution: when negotiating a strategic alliance or a cross-licensing arrangement, be wary of discussing prices, because antitrust regulators closely scrutinize any transaction that suggests price-fixing, which is a criminal offense.

### In summary

IP is one of the key components in attracting financing, and it is an element over which you can exercise a great deal of control. By concentrating early on building a solid foundation of broad rights in your core technologies, and pursuing a well-thought-out IP strategy, your company will be in a position to exploit the market exclusivities that the law grants innovators—and you can be sure that potential investors will take note.