bioentrepreneur
Brought to you by nature biotechnology

IP/Technology Transfer

Published online: 24 April 2006, doi:10.1038/bioent907

# Trendspotting: a shift in intellectual property focus

**Marcia H Anderegg[1], Joshua M Thayer[1] & Kathleen M Williams[1]**
Marcia H. Anderegg, Joshua M. Thayer and Kathleen M. Williams are at Edwards Angell Palmer & Dodge, 111 Huntington Avenue, Boston, Massachusetts 02199, USA. e-mail: kwilliams@eapdlaw.com

**An analysis of recent trends in intellectual property that affect early- to mid-stage life sciences companies and their investors.**

Throughout 2005 and into 2006, we have observed several trends affecting early- to mid-stage life sciences companies in the areas of intellectual property, financing and licensing and collaborations. Many of these trends appear to be related to each other, or the natural consequences of larger trends. For example, the reemergence of early-stage corporate collaborations appears as the natural consequence of the flurry of activity in later-stage collaborations over the past several years. In addition, the traditional emphasis on intellectual property in early-stage life sciences companies has shifted from protection to freedom to operate, due in part to recent court decisions involving licensed third-party patents.

In this, the first of a two-part series, we focus on recent developments in intellectual property and their effect on the life science industry. We spoke to numerous individuals at operating companies and venture firms for their take on the trends. We also relied on our own experience and expertise to address the diverse legal issues in financings, licensing and collaboration transactions, and the intellectual property protection and strategies that life science companies and investors face.

## Build carefully and move nimbly

Intellectual property always has been considered a cornerstone to early-stage deal-making in life science. Historically, a prerequisite to create a life sciences company has been to own or have exclusive rights to a key patent or patent application by which the company can exclude its chief competitors from the marketplace. Often, the historical prerequisite was a family of patent applications and/or patents to form a basis and platform for the startup. Now, although this trend continues in a kind of ideal world scenario (that is, who wouldn't want a good set of patents to rely upon to control competitor growth?), the emphasis on protecting the startup's science and technology has shifted. It is notably now less emphatic on protection (the exclusion of competitors), with more substantial emphasis on being free of third-party patents, or patents not owned or licensed to the company.

Although it is attractive for a drug discovery startup to own or have rights to patent protection of its science, this is now recognized as not required to form a company and move forward because the science may shift rapidly, rendering the exclusionary intellectual property less valuable as the company shifts its course. Those companies who are comfortable not owning intellectual property at the outset perceive their value to be in their future discoveries. Witness the focus of Cambridge, Massachusetts-based Sirtris Pharmaceuticals on screening targets for anti-aging effects (a commercial interest spurred in part by the so-called anti-aging component of red wine), where present value could be in having the freedom to operate to screen different targets but not yet in patenting compounds.

When a drug discovery company has a unique platform that can be easily copied, it most often chooses to wall-off or picket-fence the platform science with exclusionary intellectual property protection (see Box 1). Certainly, whether an early-stage company is a drug discovery or a therapeutic drug company, if it possesses intellectual property, it has the obligation to protect that intellectual property. How does an early-stage company decide what action to take in protecting its intellectual property against competitors who are infringing (see Box 2)?

Investment analyses now place a strong emphasis on ensuring that the startup is not precluded from operating commercially rather than on excluding the competition. Commercial operation for a biotech startup legally includes a number of activities—making, using, selling and/or

importing its science and technology in the marketplace. Being free of third-party patents is known as freedom to operate (FTO). If a startup has FTO, then this is a significant advantage that permits the company to move forward quickly and use less money on patent licenses in the process. However, if a startup does not have FTO, and thus is subject to one or more third-party patents, then the question becomes how to get access to third-party intellectual property without incurring upfront fees or reducing profit by paying royalty percentages—hence, the preference for collaboration and other sharing arrangements, where access to expensive third-party intellectual property is part of the deal.

FTO was at the heart of last year's US Supreme Court decision in *Merck KGaA v. Integra LifeSciences*[1]. The Court held that the use of patented compounds in preclinical studies is not an act of infringement as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to an FDA submission (even when the patented compounds do not themselves become the subject of an FDA submission). Although clearly expanding the noninfringement safe harbor under patent law, the Supreme Court left many questions unanswered and remanded the case to the lower court. Until the dust settles, potential licensees of research tools may be less willing to pay significant amounts for tools, particularly royalties on sales of products discovered through the use of the tool.

Certain types of life science startup collaborations bring a package of essential intellectual property that the startup needs to operate commercially, and may have the added advantage of bringing into the deal competitor exclusionary patents. Witness specialty pharma endeavors, where a product has already been sold for one therapeutic use, is patent protected for a time and has FTO by virtue of its being on the market for that use. A new and special use will involve investigating FTO for that new use, and also may involve creating and/or acquiring patents around the new use. An example of this includes S. San Francisco, California-based Cerimon Pharmaceuticals' in-licensing of Simulect, an antibody currently being marketed by Novartis for the prevention of acute organ rejection in patients receiving renal transplantation, and which Cerimon is now developing for the treatment of certain autoimmune diseases.

## Increased due diligence

In addition to spending time and money on traditional intellectual property due diligence[2, 3], including an investigation of the issuer's patent portfolio and freedom to operate, venture capitalists, we find, are focusing heightened scrutiny on the terms of a potential portfolio company's core license agreements. In our experience, venture capitalists are now frequently hiring licensing attorneys, along with corporate and patent attorneys, to analyze such agreements, and are not hesitating to compel the renegotiation of the licenses as a condition to closing, at a time when the company's leverage over its licensors is presumably strongest.

An investor we spoke to described the phenomenon as being necessitated by what he sees as increasingly aggressive university and hospital licensors, who he believes are more willing than ever to demand rich terms from the scientific founders of prefunded biotech companies. The agreements tend to be more complex and negotiation times have increased, particularly with respect to the licensee's ability to sublicense the right to a third party, which is critical to an early-stage company. Perhaps in response to historical criticism that they are not business savvy, some nonprofits have even begun to engage venture capitalists as advisors to serve on review committees or provide advice on licensing negotiations.

Next month, we will analyze recent trends in the world of financing, such as the growing size of early-stage venture financing transactions, and the increase in convergent technology licensing deals between biotech and device companies. We also answer the important question, "Who is Getting Financed?" Stay tuned.

**Box 1: Patent myths debunked**

1. **If I have a great idea, I can patent it.** Patents are not granted on mere ideas; the idea must be reduced to practice.
2. **A patent will allow me to practice the claimed invention.** You might not be free to practice your patented invention at all. Your patent doesn't tell you what you can do, it tells others what they cannot do.
3. **My patent application should always, from the outset, claim the invention as broadly as possible.** For strategic reasons, you might want to claim the invention more narrowly to obtain quickly a patent that covers your commercial embodiment; pursue broader claims in a continuation application.
4. **I don't have to worry about prior art that is very old, out of date, or that was published in an obscure, little-read publication.** Once something is prior art (with very few exceptions) it is always prior art; the US Patent and Trademark Office (USPTO) has even used the Bible as a prior art reference.
5. **I can keep the best way of practicing my invention as a trade secret.** The law does not permit one to patent an invention and to keep it as a trade secret. The two are mutually exclusive. The patent statute requires that you disclose the best mode of practicing the claimed invention; the patent office is granting you a limited monopoly on the claimed invention and, in exchange, you must fully disclose the best way to make and use the invention.
6. **I can protect multiple inventions in a single patent application.** The USPTO only permits one invention per application. For example, an inventor discovers 100 genes, the overexpression of which is a useful marker for development of colon cancer; the inventor will be required to select one single gene to pursue per application. To protect all 100 genes would require 100 separate patent applications.
7. **Once my US application is filed, the major costs are over.** Filing the application is just the beginning. US prosecution costs can be an additional $5,000 or more after the application is filed; foreign patents can cost tens of thousands more, depending on how many countries you pursue and the need for translations.
8. **You can reliably predict when and with what scope your patent will issue.** Timing in the USPTO is unbelievably unpredictable. It depends upon a given technology and art unit not being overburdened, and numerous other procedural, human resource and workflow factors. There is risk in relying on your ability to get very broad claims. The extraordinarily broad claims that it seems you should be able to get based on a detailed analysis of the invention and the prior art may be difficult to obtain. Consider a strategy that protects your key technology first, and then pursues the broader claims as the icing on the cake.
9. **I can enforce my US patent overseas.** A US patent only allows the patentee to exclude others from making, using or selling the invention in the US or importing the invention into the US. The patentee must obtain a patent in each foreign country in which they want to enforce their rights.

**Box 2: Enforcement checklist: when to sue and when to license**

The decision of whether or not to bring suit is based on consideration of several factors.

- Litigation is expensive (potentially millions of dollars in the first few years).
- The outcome of litigation is uncertain—there is always a risk that your patent may be held invalid and/or unenforceable.
- However, if the patent goes unenforced against infringers, there is a period of time (differs between jurisdictions, but generally 5–8 years) after which the patentee cannot bring suit for infringement (referred to as laches).
- An unenforced patent has little or no value.

Other considerations:

- Do you have the resources?
- The patentee will need both financial and human resources to support a lawsuit. Patent litigation, particularly discovery, is very time-consuming, and may take key personnel away from valuable functions, such as research and further innovation.
- What do you gain by bringing suit?
- A consideration should be made as to whether the alleged infringer is a direct competitor. If the alleged infringer is not practicing your primary commercial embodiment, the risk-benefit calculus may shift to favor negotiating a license.
- Consider whether the alleged infringer may be an opportunity to expand your freedom to operate through cross-licensing.
- How strong is your patent?
- Composition claims are generally more straightforward to enforce than method/process claims.
- Consider the risk that your patent may be held invalid and/or unenforceable.
- How easy would it be to design around your claims?

## References


- *Merck KGaA v. Integra LifeSciences I, Ltd.*, 125 S. Ct. 2372, 162 L. Ed. 2d 160 (June 13, 2005).
- Gogoris, A.C. & Clarke, P.J. *Nat. Biotechnol.* **19**, 175–177 (2001). http://www.nature.com/nbt/journal/v19/n2/full/nbt0201_175.html
- Gogoris, A.C. & Clarke, P.J. *Nat. Biotechnol.* **19**, 279–281 (2001). http://www.nature.com/nbt/journal/v19/n3/full/nbt0301_279.html