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Helping startups help themselves

"Anyone, I would imagine, who has tried to create a biotech company knows just how important patents are. You learn this when you're studying, and again at your first job, and if you haven't done so before, you realize it the first time you meet potential investors."

- Mads Øvlisen, Chariman of the Board of Directors, Novo Nordsik

Financing is typically the most pressing issue facing a new company during the startup period, regardless of the state of development of their technology. The principals of a biotechnology startup can rarely marshal enough initial capital early on and it can take many years before the company is self-supporting. Many startups must look outside for financing their innovation and this is normally done through venture capital investments. However, investing in a biotechnology startup is invariably risky and investors and principals must take steps to reduce the risks. One way to reduce the risks is through appropriate protection of the intellectual property of the venture.

When venture capitalists (VCs) are considering whether or not to invest, most try their best to mitigate some of the risk by doing their due diligence with regard to the science, team, business plan, and intellectual property (IP).

There is no doubt that VCs place a high value on a startup company's IP. So what can IP attorneys do (or not do) to better serve their startup company clients who wish to do business with venture capitalists? The following are a few strategies to consider.

Make sure the startup team knows not to disclose their technology to anyone. This may seem like a fundamental point. But the management team of a startup company has goals that can conflict with the necessity of keeping the company's innovation an absolute secret until patents are filed. VCs look for, among other things, a management team that can sell so that they can be reassured they will get a return on their investment. However, VCs also like extensive patent protection. Therefore, the management team must be made acutely aware that disclosing the startup's innovation before the patents are filed can bar them from obtaining patent rights. Everyone in the startup company should understand that absolute secrecy means no taking orders, no telling potential customers that the company will be coming out with a new product, no telling customers that a new product will provide a desired feature, and no promotional discussions. Additionally, all of the suppliers, vendors and team members should sign Non-disclosure agreements (NDAs) if they will have access to the startup's technology. The VCs should also sign NDAs. It doesn't hurt to have various NDAs and Non-competition agreements in place and this should be part of the normal course of business for startups.

A similar conflict can arise where a university professor is under pressure to publish results. However, even confidential disclosures for purposes such as peer review of a manuscript can be risky to the company if the results have not been properly protected in a filed patent application. There is no guarantee that the people reviewing the manuscript won't use the information to further develop similar technology on their own or even publicly disclose the information. Inventors should be reminded often to disclose any event they consider noteworthy to their IP counsel, so that it can be determined if protection is needed.

Assume there is no AIA (Leahy-Smith America Invents Act) grace period. Although AIA § 102(b)(1) references a grace period which allows for pre-filing disclosures of the invention, reliance on this section is extremely risky. This area of the law has not been litigated and the bottom line is that disclosure of the technology of a startup before the filing of a patent application can result in the forfeiture of patent rights.

Early disclosure can also complicate prosecution if the disclosure leads to a prior art publication of a variation of the invention before the startup files their patent application. In this case, it is not possible to rely on the one-year publication grace period to overcome the prior art variation because the one-year grace period does not apply to variations of the invention. Although the grace-period may seem like permission for an inventor to publish before they file, it is best to play it safe and only rely on the grace period provision if you are forced to pick up the pieces after a disclosure of the invention is made before filing.

Make sure the start-up company understands the importance of disclosing everything to their IP counsel. The flip side of the first strategy is that the startup team needs to understand the importance of disclosing everything to their IP counsel. Issues can arise where the startup company wants to keep aspects of their technology secret from their competitors and not include that information in a patent. This can have detrimental consequences. First, a provisional or non-provisional patent application based on the limited description may not be enabling and the startup's technology will not be protected because the patent application does not cover the desired technology or fails for lack of enablement or written description if legally challenged. Second, if the startup company markets their product without proper patent protection, the disclosure could bar them from filing a patent application in the U.S. and internationally. Sometimes startups are so determined to keep their invention secret from competitors, they will choose not to publish until their U.S. patent issues and forgo their opportunity to file internationally. Because VCs favor broad patent protection, this is generally not an advantageous strategy.

Avoid "cover sheet provisional" patent applications. The term "cover sheet provisional" is generally used to describe a provisional patent application that consists only of the Patent & Trademark Office's transmittal cover sheet and presentation materials or a manuscript or other documents. These documents are usually about to be publically disclosed and cause a patentability bar. This can be a common scenario when the startup company is founded by university professors who are also under the gun to publish and present their research publically or when a company wants to cut costs (many startups say that patent filings are the biggest line item in their budgets). However, problems can arise when it comes time to convert the cover sheet provisional into a non-provisional application. First, the provisional will be useless as a basis for priority without a complete description that fully enables the technology claimed in the non-provisional. Second, there may be a valuable embodiment that should be included in the non-provisional but was not described adequately in the slides or manuscript used to form the coversheet provisional. Without a thorough review of the documents used to create the provisional patent application by an IP attorney, these valuable embodiments can go undiscovered and unprotected. Consequently, cover sheet provisionals create a risk that the desired claims won't get the benefit of priority from the provisional filing date. Third, if the startup discloses technology that is not contained in the materials which make up the cover sheet provisional, they could be barred from filing patents in the U.S. and more likely will be barred from filing internationally.

File applications at every technological milestone. VCs like to see substantial patent protection. A strategy for ensuring that the rapidly developing technology of a startup company is protected throughout its life cycle is to file a patent application (or a comprehensive provisional application) every time a milestone is reached. For example, applications can be filed (1) at the time of discovery, (2) when the prototype has been developed, (3) when results have been obtained and (4) when more efficient designs are developed. This strategy can establish good habits of disclosing information to the startup's IP counsel. This strategy is also in line with the first to file provisions of the AIA.

Startup companies can further protect themselves and also win the favor of VCs by filing patent applications on variations of the invention that may not be of primary interest to the startup at present but that could be used by the startup's competitors. These patent applications may describe inferior products or processes that the startup has no intention of bringing to market but may limit competition by creating prior art for the competitor. Filing these patent applications also leaves the door open for the startup to change its mind about seeking protection on such variations.

Let the venture capitalists prepare their own freedom to operate opinions. In order to mitigate risk, venture capitalists will often want to know whether there is a chance the startup company could be held liable for patent infringement for a particular process or product. Lawsuits by larger companies can exhaust the R & D capital of the startup and these lawsuits are sometimes initiated to accomplish this result. A freedom to operate opinion (not to be confused with a patentability search) is prepared by identifying patents covering similar technology held by others and analyzing these patents for infringement liability, claim by claim. These opinions are appealing to VCs, however, insisting that the VC have their IP attorney or an outside IP attorney prepare the opinion may be a smart strategy.

First, FTO opinions can cost more than $10,000 (and depending on the case, $20,000-$30,000). Second, preparing an FTO opinion can carry a risk of malpractice for the attorney and liability for the startup company. This is because in a FTO opinion, you are saying that the startup company's product or process will or will not likely infringe.

Under ABA Model Rule 4.1, attorneys have an ethical obligation to avoid knowingly making a false statement of material fact or law to a third person, or to assist a client in a fraudulent act. In some cases, it was found that the third party use of a legal opinion can create a basis for liability for malpractice from the opinion's author to the third party. In other words, if the VC bases a business decision on the startup's FTO opinion and the opinion can be shown to have been misleading, the VC may be able to sue the startup company. Third, under 37 C.F.R. § 1.56, the attorney, and anyone else that is involved in the prosecution of the startup's IP, is obligated to disclose any information, material to IP prosecution, to the USPTO. This includes information that is discovered while preparing a FTO opinion. The duty to disclose material information to the Patent Office may also conflict with confidentiality agreements. Although, this can be avoided by including a clause in the confidentiality agreement that expressly permits submission of pertinent documents to the Patent Office. Therefore, to keep costs down, avoid liability and limit the required USPTO disclosures, the attorney for the startup company should insist that the VCs prepare their own FTO opinion.

Have the startup and VC meet to discuss and develop a realistic IP strategy that is in line with the business plan and VC's expectations. Developing a business plan is the first step in establishing a startup company. Often, the VCs will evaluate the startup company's product potential, the product's market potential and the management team before they even decide to perform IP due diligence. Therefore, one of the goals of IP due diligence, beyond determining the value of the IP portfolio, is to help the VC assess how the startup's IP will help with the execution of the business plan. For example, this could mean only pursuing the patents that have commercial utility (i.e. a market for the invention and an invention that can be manufactured at a cost sufficient to fulfill market demand) or pursuing IP protection in other forms such as trademarks or trade secrets. It is therefore vital that the startup and VC have an open dialog so that the startup and VC are working toward the same goals and time and money are not wasted.

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