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Pitfalls to avoid when starting a biotechnology company in the USA

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Abstract This paper presents an overview of some of the principal legal issues associated with establishing a biotechnology venture in the USA. We address the basic rules surrounding the establishment of a corporation and identify policies that should be followed by every company in order to prepare it for its next stage of growth.

Keywords: incorporation, founders, capitalisation, trade secrets, stock options, employee compensation

Introduction

How does a scientist, academician or inventor turn a great idea with commercial potential into a business? To start a biotechnology business in the USA the entrepreneur would need to bring together technology, a solid business plan, capital and a capable and experienced management team. This paper addresses a critical yet often overlooked element in forming a new company: the legal framework.

The purpose of this paper is to address the basic rules that an entrepreneur needs to know and practise to build a successful biotechnology company in the USA. The paper presents an overview of some legal issues but is not meant to address all issues that might arise. It is important to discuss specific circumstances and requirements with legal counsel. We highlight a number of issues that can cause significant problems if they are not addressed early in the process. Fortunately, all of these issues can be cost-effectively addressed in the early stages of a company's life by using proper documentation and implementing and following simple policies. Doing so is not

just to follow good form: no matter how great the idea, no one is likely to invest in a company that does not control its intellectual property or where there is a dispute over the ownership of the company.

From idea to entity

A scientist who has an idea he or she would like to commercialise must be sure they own the idea before proceeding to form a new business around that idea. One should first ask if other people were involved in developing the idea. If so, they may have legal rights to the idea. Even if the idea came entirely from a scientist's individual efforts, the former or current employer of the scientist may own the idea or have the ability to prevent anyone other than the employer from commercialising it.

Employers in the USA often try to ensure they have rights to their employees' ideas if they were conceived during business hours, or using company funds or equipment, or are related to the employer's business. All agreements between the scientist and his or her former or current employers that address the concept of an idea or an

invention, or that include confidentiality, non-disclosure or non-competition provisions should be reviewed with legal counsel to ascertain whether the employer has any right to the idea or to prevent the scientist from pursuing it. Even if there is not a specific agreement between the parties where the scientist agrees to assign inventions to the employer, if the idea was conceived during the course of his or her employment or using the company's assets, the company may have certain rights to that idea, especially in situations where the company's trade secrets or other confidential information are involved. For example, the common law 'corporate opportunity doctrine' in the USA generally provides that a director, officer or controlling shareholder of a company may not appropriate an opportunity belonging to the corporation. The determination of whether the opportunity belongs to the company is 'fact specific', and may depend in part on circumstances such as company's line of business and whether corporate funds were expended in pursuit of the idea.

The mere fact that another person or entity may have rights to the idea does not mean that the scientist should abandon the venture before it has even begun. Often the other party will either (i) agree that they do not have any rights in the idea or (ii) be willing to license or assign their rights to the scientist or the new entity. Academic institutions and medical centres generally have specific guidelines regarding the terms on which they will license technology to organisations that are affiliated with members of their staff or that arise out of research they funded. It is important to identify and address any issues surrounding the ownership of the idea early in the process because these issues become more expensive, and sometimes impossible, to resolve as a company begins to bring value to the idea.

The corporate structure

Once someone with an idea has made the decision to start a new business, one of the first choices they need to make is to select

the type of legal entity to use for the business. Choosing a form of business entity depends to a large extent on the nature of the business and its strategic plan as well as the objectives of the founders. There are a number of types of entities available, including limited liability companies, partnerships and corporations, each of which have different tax and other attributes. Some of these entities are appropriate only for small and closely held businesses. A founder who intends to build a business that will attract venture capital and other institutional investors has really only one choice, a corporation. (A limited liability company, which is treated as a 'pass-through' entity for tax purposes, is often useful where individual investors (including so-called 'angel' investors) can benefit from being allocated a proportionate share of the company's tax-deductible expenses. Venture capital investors are generally reluctant to invest in limited liability companies.)

A corporation is created under state law and is a legal entity existing separate and apart from its owners (called stockholders or shareholders). The laws of the state of incorporation will govern the corporation's structure. For a local business that will operate in only one state, there may be advantages to incorporating under the laws of that state. Delaware has the largest body of corporate case law and one of the nation's most sophisticated and flexible corporation statutes from the standpoint of management. In Massachusetts, for example, in order for the stockholders to act without a meeting, all holders must execute a written consent.¹ Delaware law, in contrast, requires only the written consent of the holders of the minimum number of shares required to authorise a given action,² and accordingly offers more flexibility for a start-up company that expects to have several rounds of venture capital financing, each of which is likely to require stockholder approval. Institutional investors investing in Delaware corporations know what rights they will have as a matter of corporate law. It requires less due diligence for them to invest in a Delaware corporation

than to invest in a corporation where they are not familiar with the particular state's law. Without a compelling tax or other reason to incorporate elsewhere, new biotechnology companies should generally incorporate in Delaware.

An entity is incorporated under its corporate name. Before selecting a name, founders are well advised to look into availability and potential conflicts in three areas: state corporate names, federal trademarks and Internet domains. At the state level, founders should check with the Secretary of State's office (in the proposed state of incorporation and each state in which they plan to have a physical presence) to see if the corporate name is available. If there is an entity operating in the state under a name, the state will not let another entity use that name without permission. States will generally allow a name to be reserved upon written request to the Secretary of State. It is advisable to do a trademark search of a corporate name if the company contemplates doing business on a national scale. Another reason to do a trademark search is to ensure that the name is not infringing on someone else's trademark. Many companies seek to protect their corporate name by seeking a trademark registration of the name. Although not required, many companies also check the availability of the Internet domain name before they select a name.

Corporations are required to have a Board of Directors. The Board is elected by the stockholders and has the responsibility as the representative of the stockholders to oversee the operations of the corporation. The Board elects the officers of the corporation, who are responsible for the day-to-day management of the corporation.

The corporation should observe basic corporate formalities by keeping good corporate records (including records of all stock issuances) and by holding regular Board meetings. All stock and option issuances and major contracts must be approved by the Board. A clear record of the company's equity ownership is a prerequisite for a venture financing or public offering.

A Delaware corporation can have as few as one director.³ There is no upper limit on the number of directors a corporation can have. Typically, the founders are the initial members of the Board. Often it is not until an outside investor, like a venture capital fund, insists on having a Board seat that the founders seek to expand the Board. Founders may want to consider expanding the Board earlier to bring on directors with relevant industry experience, general business or financing experience, strategic contacts or other attributes that complement the strength of the founders. However, a company should exercise care with respect to its Board composition since the Board exercises ultimate power over and has ultimate responsibility for the company. Companies sometimes establish scientific or medical advisory boards that do not have corporate oversight responsibilities but that provide the means for involving valuable experts without putting them on the Board of Directors.

The goal in establishing the initial capital structure of the corporation should be to provide maximum flexibility relating to the company's future financing requirements while minimising filing fees and franchise taxes. Generally a corporation will want to authorise the maximum number of shares that are available for the minimum state filing fee so that the corporation has enough shares authorised to cover initial issuances to the founders and key employees and the first round of outside funding. It should be noted that Delaware allows corporations to calculate their annual franchise tax using an alternative asset-based method, which allows corporations with a large number of authorised shares but modest total assets to pay a relatively low franchise tax.⁴ The authorised number of shares can be changed after incorporation by vote of the Board and the stockholders. Because stock must be issued at a price that is at least equal to its par value, it is preferable to have a nominal par value.

Start-up companies may want to authorise a class of preferred stock in addition to common stock. A company's charter can authorise the Board to designate the rights and preferences of the series of preferred

stock in the future. This will give the company flexibility to issue preferred stock at a later date to investors without needing a stockholder vote. Investors often require preferred stock for the investment because it can be senior in liquidation and can have other economic and governance rights that are superior to those of the common stock. Early-stage companies may desire to issue preferred stock to the investors since by issuing a class of stock to the investors that is senior to the common stock issued to the founders and employees, the company has a basis to set fair value of the common stock below the price paid for preferred stock. This will allow the company to grant stock options and issue shares of common stock to employees in the future at a price that is less than the price per share of the preferred stock issued to investors without adverse accounting consequences.

It is critical for early-stage companies to pay particular attention to complying with US federal and state securities laws and seek the advice of experienced legal counsel in doing so. The sale of stock to investors is subject to complex and burdensome registration requirements unless an exemption can be found. Most start-up companies rely on Regulation D under the Securities Act of 1933 which allows an offering to 'accredited' investors to be exempt from registration. Accredited investors include a director or executive officer of the company or an individual with a net worth of US\$1m or income during each of the past two years of US\$200,000 for individuals and US\$300,000 for families. As a practical matter, issuing stock only to accredited investors will save a company substantial effort and expense and will make it easier to satisfy the 'due diligence' review by venture capital investors who come in after the early 'seed' capital is raised.

Protecting key assets: Intellectual property and employees

Intellectual property considerations

Developing and implementing an intellectual property (IP) strategy is one of

the most important aspects of establishing a successful biotechnology company.

Depending on the nature of the technology and the ideas, a company may have the option of protecting its IP using trademarks, copyrights or patents or under a trade secret protection programme. Trademarks protect names or symbols used in commerce.

Copyrights protect an author's rights in his or her creative expression. For example, copyrights prevent illegal copying, modification or distribution of manuals, works of art or computer programs. Patents protect new and useful inventions. A trade secret is confidential business information that has economic value because of its limited availability and that its owner has taken reasonable precautions to keep secret. Because much has been written on trademarks, copyrights and patents, and most companies that are considering them are consulting with a lawyer, this paper will not discuss them in any detail.

Regardless of the IP protection strategy a company chooses to employ, it should require all employees and consultants to sign an assignment of inventions agreement which obligates the employee or consultant to assign all rights to inventions developed during the course of their work or using company resources. Many start-up companies are surprised to learn that under the patent law doctrine of employee invention, the patent rights to an invention could belong to the employee, and not the company, even if the invention was conceived and developed by the employee during the course of his or her employment using company materials. Similarly, under copyright law, the title to a work created by an independent contractor initially belongs to the individual author, not to the company who engages the author to perform the work. The 'work-for-hire' doctrine in the US Copyright Act of 1976, however, deems the employer the author if the work is prepared by the employee during his or her employment, and may deem the company the author in other limited circumstances.

Nearly all companies have trade secrets. They can be as complex as a data model for a software program or as simple as a list of

customer contacts. The range of items that may be trade secrets under applicable state law includes patterns, compilations, programs, methods, processes and techniques.

Early-stage biotechnology companies often err by not taking the necessary precautions to turn their proprietary information into protectable trade secrets. In determining whether a company's proprietary information is a trade secret that will be able to receive the legal protection afforded by law, courts consider both the nature of the information (ie whether it is valuable because it is confidential or secret) and the precautions taken by the company to maintain its secrecy.

Biotechnology companies must be proactive in maintaining the secrecy of their proprietary information. The steps that serve as real-world protections against loss are the same as those that a court will consider in evaluating whether to provide legal protection to the information. Management should consider the following precautionary steps:

- **Execute confidentiality agreements.** It is imperative to any company that all employees and any third parties, such as consultants, subcontractors, vendors, customers and licensees of the company's technology with access to the information, execute appropriate confidentiality agreements protecting the company's trade secrets. Confidentiality agreements serve to put the recipient on notice that the disclosed information is considered a trade secret as well as to evidence the trade secret owner's expectation that the recipient will keep it confidential. Every company should have a good form of confidentiality agreement and should take steps to ensure it is widely used.
- **Inform employees of their obligations.** In addition to requiring confidentiality and assignment of inventions agreements from all employees, a company should include in its employee handbook a statement about the importance of preserving the secrecy of trade secrets. From time to time, the company should

remind employees of their confidentiality obligations and the value of the company's proprietary information to the company. In exit interviews, the company should remind employees leaving the company of their duties to return all physical and electronic forms of trade secrets in their possession and to keep all intangible confidential information secret. A company may wish to require employees to confirm in writing that they understand these obligations.

- **Impose access controls.** A company needs to consider who should have access to the company's trade secrets and impose the proper physical and electronic barriers to prevent unauthorised access. For some, this may be as simple as locking the doors at night and making sure access to computer code is password protected.
- **Be careful disseminating business plans.** Anyone outside the company, including potential investors, should be subject to a confidentiality agreement before reviewing information on technology, business strategy and other important matters. There may be situations when a company should not share a trade secret even if the other party is willing to sign a confidentiality agreement, such as when a potential investor or strategic partner is also a potential competitor.
- **Enforce the company's rights.** If a company's trade secrets are improperly used or disclosed, the company should take appropriate legal action, if necessary, to enforce its rights and prevent further disclosure.

Whatever the company's proprietary information is, if it is valuable because others do not know it, the company should take steps to preserve its secrecy in order to protect the company's legal rights and future.

Employee matters

Attracting and retaining key employees are often as critical to a start-up biotechnology company's success as protecting IP. In his or her enthusiasm to assemble a high-quality

management and scientific team, a founder may unwittingly commit the company to more than it can deliver, such as, for example, by making promises of continued employment. By engaging in due diligence in the hiring process, using well-crafted offer letters and being judicious in the use of stock incentives, a company can avoid many costly hiring mistakes.

It may seem obvious that a company needs to be careful whom it hires. Even if a person is hired on an 'at will' basis (meaning that the company or the employee can terminate the employment relationship at any time, with or without notice or cause), a person is afforded extra protections by the nature of being an employee. For example, US federal and state laws contain detailed protections for employees on such matters as health and safety, wage payments and discrimination. The anti-discrimination laws protect job applicants and employees from discrimination on account of race, national origin, sex, age, religion, disability and certain other protected characteristics. Companies need to be mindful of these laws and take steps to ensure that all employment decisions (from hiring through termination) are made in a fair and non-discriminatory manner.

In addition, too often a company hires someone as an employee when in fact they only need their services for a short time and would be better off engaging the person as a consultant (as long as they get the person to sign an assignment of invention and confidentiality agreement), provided that the individual meets the legal test for 'consultant' rather than an 'employee'. In certain circumstances, a company can be liable for an action by its employee even if the company did not direct the employee to take the action, so an employment relationship is not one to be entered into lightly.

Companies must use care to ensure that by the mere act of hiring someone they are not exposing themselves to a threat or suit from the employee's prior employer. Before hiring someone who has worked in the same industry, a company should find out if

the prospective employee has any non-solicitation, non-competition or confidentiality obligations to his or her prior employer. A non-solicitation covenant restricts the ability of an employee to solicit business from an employer's customers and/or to recruit or hire the employer's other employees. A non-competition covenant restricts the ability of an employee to work for a competitor for a specified period of time. A confidentiality covenant restricts an employee from disclosing or improperly using the company's proprietary information. State law varies on the degree to which each of these covenants is enforceable. For example, many employment-related non-competition agreements are not enforceable in California. However, in general, if the restriction is reasonable to protect a legitimate business interest of the employer it may be enforced.

Although there is no legal requirement to set out the terms of employment in writing, using a well-designed form of offer letter that is provided by a lawyer is a cost-effective and time-saving action that every company should take. Offer letters are good vehicles for setting out the basic terms of the employee's employment and help avoid later confusion about such matters as compensation, benefits and job duties. In addition, offer letters are generally preferable to employment agreements since employment agreements include many future commitments of the company. In addition to setting forth the basic terms of employment, an offer letter should state that the employment relationship is 'at will' and that either the employer or the employee can terminate the employment relationship with or without cause or notice. It should provide notice to the employee of confidentiality and assignment of inventions agreements, as well as any non-solicitation and non-competition agreements, that must be signed as a condition of employment. The employee will also be required to provide proof of eligibility to work in the USA. An offer letter should also include a representation by the prospective employee that his or her employment by the company

will not violate any agreements that the prospective employee may have with a former employer or other party. An offer letter should avoid promises and predictions, particularly in the areas of continued future employment and equity compensation. It should never promise the employee a percentage interest in the company. Rather it should speak in absolute numbers about stock (based on the company's actual capitalisation at the time of the letter) if that is to be an element of compensation.

The issuance of equity compensation can provide a powerful incentive to employees and minimise the company's cash outlay but is prone to both legal and accounting pitfalls. The most common devices used are restricted stock and stock options. Before issuing any equity compensation a company should understand the associated tax and accounting consequences.

Restricted stock is stock that is actually issued but 'vests' over time. It is typically granted to the employee at a nominal price and at the outset of employment. The terms require the stock to be subject to repurchase by the company for the price paid upon termination of employment. This repurchase right lapses at a specified rate over a period of time (such as 25 per cent per year over four years). Restricted stock generally is not taxable to the person receiving the award until the restrictions lapse. At that time the income recognised is the fair market value of the stock when the restrictions lapse less the price paid. However, a person can elect to recognise the income currently as though the restrictions do not exist by filing an election with the Internal Revenue Service (called a Section 83(b) election) within 30 days of receiving the stock. A company that issues restricted stock should remind the recipient of the need to timely file a Section 83(b) election. For early stage companies, where the common stock has a low value, restricted stock can offer the best tax benefits for founders and early employees, depending on the spread between the tax rates on capital gains and ordinary income.

A stock option gives the recipient the

right to buy shares of the company's stock at a specified price. Like restricted stock, this right generally vests over time. Incentive stock options (ISOs) that meet certain requirements specified in Sections 421 and 422 of the Internal Revenue Code, can provide a way for both the company and the employee to obtain favourable tax treatment. These requirements include that ISOs can only be granted to employees of the company and with an exercise price that is equal to the fair market value of the underlying stock at the time of the grant. To preserve advantageous tax treatment, the stock purchased upon exercise of an ISO must not be disposed of prior to the second anniversary of grant and the first anniversary of exercise. A company that wishes to take advantage of this treatment must ensure that the ISOs are granted under a written plan that was approved by the company stockholders and that satisfies the requirements of the Internal Revenue Code. All other stock options are called non-qualified or non-statutory stock options (NSOs). For most companies, the tax results for NSOs are generally less favourable to the employee and can be more favourable to the company than ISOs. A company that seeks to adopt an equity compensation plan should consult with an accountant or tax attorney who can review the company's specific situation. This is especially important since tax and accounting consequences change over time.

Regardless of the form of equity incentive a company chooses to offer, it should consider the vesting provisions that will be associated with the equity. The best vesting policy is one that applies to everyone, including the founders, with variations, if any, only in unusual circumstances. A company needs to decide on the duration of the vesting (ie how long will it take for the restricted stock or option to be fully vested) and the frequency of the vesting (ie annual, quarterly, etc.). Any provisions relating to acceleration of vesting upon the occurrence of a change in control must be carefully drafted so they work in the way they were intended.

In employment, as in other areas, a

company can avoid expensive and disruptive mistakes by adopting policies in key areas such as non-discrimination and harassment and by making sure that it is complying with immigration, wage and labour laws. Most US employers have detailed personnel manuals that set out these basic policies (some of which, like the non-discrimination and harassment policy, are critically important) and procedures that give guidance as to the company's expectations and requirements. Government agencies, trade organisations and many law firms provide samples of forms companies can use for different employment situations.

Conclusion

To succeed, a biotechnology company must be able to raise capital, commercialise its trade secrets and other intellectual assets

and attract and motivate management talent. How a biotechnology company deals with legal issues in the early stage of its development may have a significant influence on its ability to accomplish those goals. This paper addressed simple steps an entrepreneur can take to position their company to be attractive to outside investors, protect its intellectual property and provide appropriate equity and other incentives to key employees. In doing so, a start-up biotechnology company can prepare itself for its next stage of growth.

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