

The Startup Manual

A Guide for Biotech Ventures

Basics for launching your
new venture from the
attorneys of
Gardere Wynne Sewell LLP

THE STARTUP MANUAL

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**Provided by:
Gardere Wynne Sewell LLP**

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CORPORATE ISSUES

TEN IMPORTANT BUSINESS QUESTIONS NEW BIOTECH VENTURES SHOULD ASK:

1. What type of business entity should I form?

A new business may take many different forms, including sole proprietorships, partnerships, limited liability companies, and corporations. The corporate form is most likely the best structure for a new company, although there are a few exceptions. There are two types of corporations: "C" corporations and "S" corporations. The most significant distinction between a C corporation and an S Corporation is that a C corporation's profits are taxed both at the corporate level and when the profits are distributed to its stockholders, while S corporations are not taxed separately from their stockholders. C corporations are also probably the best form to start with because setting up a C corporation is simpler (cheaper) than setting up an S corporation. The tax benefit of an S corporation is probably irrelevant to a new company since most new companies lose money in their early years while they are looking for investors and, subject to certain restrictions, can accrue these losses to offset future profits. Additionally, there are restrictions on the number and type of stockholders an S corporation may have which limit the company's ability to raise money. Also, institutional investors (e.g., venture capitalists) prefer to invest in corporations for tax reasons. Last, the C corporation form is the simplest structure in which equity incentives (i.e., options and restricted stock) may be granted, thereby easing the difficulty of finding and retaining good employees.

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Although the corporate form is most likely the best option if you expect to seek investment or need to grant equity incentives to employees or consultants, other business entity forms might be a better choice depending on your circumstances.

2. *What is a board of directors, and who should sit on my company's board?*

Corporate law provides that corporations are managed by their board of directors. Although a corporation's stockholders have the right to elect directors and approve certain significant transactions or events in the corporation's life, the board of directors holds ultimate management control of the corporation. The board of directors then hires management (president, chief financial officer, etc.) for the day-to-day operations of the company.

The board of directors of a company will often initially consist of the founders of the company (i.e., the people who created the product or service and the people that invested money to get started). As the company grows, having directors from outside the company becomes important because they provide an objective sounding board for ideas and strategy and contribute valuable advice to the company's management. Additionally, any significant or professional investors in the company will probably want some voice in how the company is managed and will demand a representative on the board to invest in the company.

Although investors will dictate who will be their representative(s) on the board, you may also influence who sits on the board. When considering whom to add to your board, remember that outside directors of the company are ideally individuals with experience managing new and growing companies and who can

introduce the company to potential investors and strategic opportunities. Your board should ultimately consist of both management and outside directors with the experience and knowledge to help your company grow. Ask your legal and accounting team for advice in identifying board prospects.

3. *Who should I look to for help to run the company?*

Hiring management for your new company is often a difficult step for start-ups to take because it requires the people who founded the business to give up some amount of control over the business to strangers. However, by sacrificing control, you can ideally gain people with skills that make up for your deficiencies. Think about what parts of running your business you are you are most qualified. Research and development? Marketing? Administration? Your search for a management team should focus on filling the positions for which you are least suited. Be realistic about your own strengths and weaknesses, and be prepared to sacrifice control of one area of your business if your skills are weaker in that area. It is likely that your attorneys and accountants can recommend candidates for your management team.

4. *What outside professional help do I need?*

In order to start out on the right foot, your company should retain legal counsel and accountants almost immediately. Legal counsel will help you make sure that your company starts out by avoiding any legal traps that are expensive and time-consuming to fix later. Accountants can provide tax and accounting advice and invaluable financial expertise.

When a company is new and doesn't have very much money, management may neglect to hire outside

professionals or might hire the cheapest professionals that the company can find. However, as the business grows, the problems and opportunities that face the company become more complicated. Often, any savings that are achieved by hiring “cheap” lawyers and accountants are quickly lost because other professionals are required to spend substantial time cleaning up the mess or getting up to speed on the business to manage the complicated audit or tax issues, transactions or litigation that the initial professional firm couldn’t handle. If you hire top-shelf legal counsel and accountants, although the initial cost may be higher, you will probably save your company money in the long run. Last, as you read this list of questions and answers, you will note that good professional help will not only provide you with legal and accounting services, but also have contacts and experience that will help your company grow. Good professional help can provide not only competent legal and accounting advice, but also many other invaluable intangibles.

5. *What are securities laws, and what do I need to know about them?*

Put simply, securities laws govern when and how your company can issue or sell its stock or other ownership interest in the company. When you initially form your company and issue stock to yourself, that will be a securities transaction that is subject to federal and state regulation! Securities laws cover more than just stock, however. Securities laws also address stock options. Each time you raise money for the company through stock or equity, the securities laws govern the transaction. Securities laws will govern what people can invest in your company and even who you can issue stock to. In short, the securities laws are very complex and the easiest rule of thumb to follow is to always contact your legal counsel when you are considering selling or issuing stock.

6. *What kind of insurance should I get?*

All new businesses need to consider whether or not to purchase workers' compensation insurance. Although not required in many states, including Texas, the law limits the amount of liability an employer will incur should an employee be injured at work if that employer has purchased workers' compensation insurance. Failure to purchase workers' compensation results in unlimited liability to the employer and the loss of certain defenses should the employee sue the employer for his injury. Failure to purchase workers' compensation liability insurance requires the employer to make certain disclosures and notices to its employees, and therefore an attorney familiar with this process should be consulted prior to making the determination of whether or not to purchase workers' compensation insurance.

New businesses should also consider general liability insurance. Liability insurance covers any claims (except for employees' claims) for bodily injury or property damage that could be levied against the company. Depending upon whether vehicles are owned by the company, commercial automobile insurance should also be considered. In new businesses, one large liability claim could bankrupt the enterprise so careful consideration should be given to whether these purchases should be made.

A new company should also purchase property insurance. Property insurance protects the new company's investment in its assets and property in the event of fire, tornado, or other catastrophic events.

Depending upon the company's products or services, product liability insurance should likely also be considered. If the company distributes or manufactures

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a product it could be liable for several different claims, including claims for a defective product, mislabeling of the product, and failure to warn of possible harm that could occur from use of the product. Any resulting harm would likely be covered by the product liability insurance. An analysis should be made as to the degree of harm likely to occur and the costs of purchasing the insurance.

Many companies purchase medical insurance for their employees and families, or at least offer the product for the employees to purchase. Since employees typically need health insurance, providing health insurance eases the difficulty in hiring and retaining quality employees.

Other insurance that the company might consider as it grows would be umbrella coverage for catastrophic incidents, directors and officers coverage for acts of the board, and/or officers and fidelity insurance for theft. An experienced insurance broker should be consulted to discuss each individual company's specific needs, as some insurance is peculiar to an industry and not all companies need the same coverages, either in types or limits.

7. *What is a business plan, and how do I prepare one?*

A business plan is a written document that communicates the company's story to prospective investors or other providers of capital (such as a bank lender). Your business plan should not be more than 30 pages and should include an introductory (or "executive") summary that succinctly addresses such things as:

- a description of the company and its history;
- a description of the company's products or services;

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- the company's historical financial performance, including balance sheets and income statements;
- projections of financial activity assuming receipt of the capital, including critical assumptions;
- an analysis of the company's industry, including the company's perceived place in the industry and a review of the company's competition;
- biographies of the management team; and
- how much money the company seeks, and how it plans to use that money.

The remainder of the business plan should address each of these points in substantially more detail. The company should identify its significant customers or target customers. It should discuss the market that the company competes in, identifying growth opportunities and discussing why the company is uniquely suited to compete in that market. Although the business plan is intended to whet investors' appetites for giving money to your company, it is important to remember that the business plan must identify not only your company's strengths, but also its weaknesses and how the company intends to correct them.

A business plan is helpful for at least two reasons. First, it helps you establish your goals and develop a plan to reach them. Second, it allows potential investors to review your goals, get to know your business, understand how you expect to achieve your goals, and how their money will be used.

Since the business plan will be used as an "advertisement" for investors, it is important that the company obtain legal counsel to help prepare and review the business plan to ensure compliance with federal and state securities laws.

8. *Where do I get the money to get started?*

Most entrepreneurs and companies begin with funds that they receive from private investors. Private investors include friends and family, as well as professional individual investors (often called “angel investors”). Although raising money through friends and family and angel investors is easier than obtaining financing through venture capitalists, private investors might not bring as much management experience or as much money as institutional investors or lenders.

9. *What is a venture capitalist?*

Venture capitalists are professional investors that have raised large pools of cash (capital) and invest that capital in growing businesses. Venture capitalists raise their money from private investors as well as institutional investors, such as pension or retirement funds or corporations. Typically however, venture capitalists are not interested in investing in brand new companies but rather prefer to invest in young companies that have an established financial history and are attractive to the marketplace. Venture capitalists can usually provide invaluable advice and contacts to a relatively young and growing business. Venture capitalists can be helpful in formulating a business strategy, filling management vacancies, shepherding companies through their growth and introducing the company to other investors. The tradeoff that comes with venture capital investment and the accompanying advice is the loss of more control of the company. Venture capitalists will demand some amount of control of the company both in management (through appointing one or more board seats) and in ownership (through stock in the company).

10. *How does an investor decide how much to invest in my company?*

The amount of money that an investor will invest in your company is based on a combination of factors, including the value of your company and the amount of the company that the investor is purchasing.

Determining the value of a company is significantly more of an art than a science. Theoretically, valuations are largely determined by first calculating the projected value of the company at some future date and then discounting that amount to obtain a present value. The present value is further discounted by such things as the risk of the market and the size of the company. Realistically, however, the value of a company has a great deal to do with the enthusiasm and ability of management, the quality of the product, and the “one-of-a-kind” features of the business that are difficult if not impossible to quantitatively determine.

Other factors are also considered, such as when the investors will want to get out of your company (e.g., at an IPO or in a few years), and the amount of control you are willing to sell to the investor. It is important to remember that, since you are sacrificing some control over your company in exchange for the money, the best investor might not be the investor that wants to invest the most money. Instead, the best investor for your company might be the investor who shares your vision for the company, even though the investor might not invest as much as another investor.

COMPARISON OF BUSINESS ENTITIES

	General Partnerships	Limited Partnerships	Corporations	Limited Liability Companies
Investors required to form	Two or more. No restrictions on type of investors.	Two or more with one or more limited partners and one or more general partners. No restrictions on types of investors.	One or more (if S Corp, cannot exceed 35). No restrictions on types of investors unless S Corp, then no corps, nonresidents, aliens, partnerships, certain trusts, pension plans or charities.	Two or more.
Name given to Investors	Partners	Partners	Shareholders	Members
Formation and filing	Formed by filing an express or implied agreement to enter into business as co-owners. No filing required.	Enter LP agreement and all general partners must file certificate of LP with Sect. of State	Select corp. name, file articles of incorporation with Sect. of State; capitalize corp. through sale of stock; hold organizational meeting of directors; adopt bylaws governing corp.	File articles of organization with Sect. of State; members must adopt regulations to govern operations of the LLC.

Corporate Issues

	General Partnerships	Limited Partnerships	Corporations	Limited Liability Companies
Liability	Each partner has fiduciary duty to partnership and has joint and several liability for obligations of the partnership and partners' malpractice	<u>General Partners:</u> Same liability as partners in GP <u>Limited Partners:</u> limited liability (unless limited partner participates in control of business)	Shareholders shielded from personal liability beyond assets of the corporation (an their investment), but "piecing the corporate veil" considerations are necessary.	Resembles corporate liability: limited to extent of members' investment. Member and LLC are liable for member's E&O, but other members are not liable.
Ownership	Tenant in partnership. Each partner has equal right to property for partnership purposes only	Tenant in partnership	May own and use property in its own name. Shares in corp. are freely transferable subject to state and federal securities laws, TBCA restrictions, and corp. restrictions	Similar to corporation rules.
Management	Each partner has equal rights to participate in management (unless otherwise agreed)	Centralized in general partners; limited partners are generally unauthorized to take part in management to avoid liability as GP.	Generally controlled by the holders of majority of shares who elect the board of directors; managerial duties may be delegated to officers and agents	Members may manage LLC or select managers.

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	General Partnerships	Limited Partnerships	Corporations	Limited Liability Companies
Tax Considerations	<p>1. Pass through entities; partners allocate their share of partnership income, losses, and tax attributes (but to a certain extent, these amounts can be allocated differently among partners by agreement)</p> <p>2. Not subject to Texas franchise tax</p>	<p>1. Pass through entities; partners liable for their share of partnership income, losses and tax attributes (but these can be allocated among partners by agreement)</p> <p>2. Not subject to Texas franchise tax</p>	<p>1. Double taxation on distributions, but some corporations can elect S status, which generally eliminated tax at the corporate level</p> <p>2. Subject to Texas franchise tax</p>	<p>1. Allowed to choose partnership or corporate taxation.</p> <p>2. Subject to Texas franchise tax</p>
Tax Return (Federal)	<p><u>Partnership</u> IRS Form 1065</p> <p><u>Partners</u> IRS Form 1065 Schedule K-1</p>	<p><u>Partnership</u> IRS Form 1065</p> <p><u>Partners</u> IRS Form 1065 Schedule K-1</p>	<p><u>C Corp</u> IRS Form 1120</p> <p><u>S Corp</u> IRS Form 1120S</p> <p><u>S Corp Shareholder</u> IRS Form 1120S, Schedule K-1</p>	<p>Elect: Partnership Taxation <u>Member</u> IRS Form 1065 Schedule K-1</p> <p>Elect Corporation Taxation <u>C Corp</u> IRS Form 1120 <u>S Corp</u> IRS Form 1120S</p>

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	General Partnerships	Limited Partnerships	Corporations	Limited Liability Companies
Advantages	<p>Maximum flexibility</p> <p>No double taxation</p>	<p>Liability protection to limited partners</p> <p>No double taxation</p>	<p>Liability limited to extent of shareholders' investment</p>	<p>May have unlimited number of members and still receive favorable tax treatment</p> <p>Enjoys limited liability of corporation while qualifying as a partnership for tax purposes.</p>
Disadvantages	<p>Joint and several liability</p>	<p>General Partners have joint and several liability</p>	<p>Possible securities offering requirements</p> <p>Subject to Texas franchise tax</p>	<p>Subject to Texas franchise tax</p>

EMPLOYMENT ISSUES

When a company is in its infancy and all of those involved share a common passion to develop the business, it is difficult to foresee the necessity of dealing with employment related matters. It is, however, essential that start-up companies are aware of employee/employer issues that can dramatically affect the success of the venture.

The following checklists provide some useful information that should be considered when conducting interviews, preparing employment agreements, and conducting internal investigations. A listing of the various state and federal statutes that require some form of record keeping are also included.

JOB APPLICATIONS AND THE INTERVIEWING PROCESS

- I. *Seek job-related information*
 - Education
 - Work experience
 - Qualifications
 - References
 - Is applicant subject to a non-compete agreement?
 - Professional goals

- II. *Avoid questions regarding:*
 - Marital status (Are you married?)
 - Pregnancy or children (Do you plan to have children?)
 - Health, disabilities, or worker's compensation history (Are you taking medication?)
 - Age or date of birth (When did you graduate from high school?)
 - Religion (What church do you attend?)
 - Birth place, national origin, or citizenship
 - Race
 - Whether applicant has filed for bankruptcy

- III. *Pre-employment medical screening*
 - Physical examinations are not necessary for most employers
 - An employer may condition a good faith offer of employment on the results of a medical examination or screening if:
 - All applicants for the same job classification are required to undergo the same process
 - The results are kept in a confidential file separate from the personnel file
 - The results are not used for any purpose prohibited by the Americans With Disabilities Act

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- Under EEOC guidelines, the following factors are considered to determine whether a procedure is a medical examination:
 - Is it administered by a healthcare professional or someone trained by a healthcare professional?
 - Are the results interpreted by a healthcare professional or someone trained by a healthcare professional?
 - Is the employer trying to determine the applicant's physical or mental health or simply identifying impairments?
 - Is it invasive?
 - Is it normally given in a medical setting (for example, a healthcare professional's office)?
 - Is medical equipment used?

CHECKLIST FOR EMPLOYMENT AGREEMENT

- ❑ Term of Employment or At-Will Employment
- ❑ Expiration of Contract
 - Automatic rollover provision
 - Continuation as at-will employee
 - Termination of relationship
- ❑ Duties of employee
- ❑ Full time and attention to company's business
- ❑ Compensation
 - Amount
 - Bonus
 - Discretionary or guaranteed
 - Eligibility factors
 - Profit sharing
 - Commissions
- ❑ Fringe benefits
 - Health insurance
 - Life insurance
 - Disability insurance
 - 401(k) plan
 - Pension plan
 - Vacation
 - Continuing education
 - Holidays
- ❑ Business Expenses
 - Reimbursement for marketing activities
 - Reimbursement for travel
- ❑ Termination
 - Termination for cause
 - Employee's death
 - Disability
 - Criminal conduct

Employment Issues

- Inadequate attendance
 - Failure to follow directives
 - Terminations for other than cause
 - Notice requirement
 - Severance provision
 - Voluntary termination by employee
 - Change of control
- Confidential Information
- Non-Competition Agreement
 - Ancillary agreement
 - Duration
 - Geographical limitation
 - By geographic area
 - By particular client
 - Scope of activity
- Arbitration

CONDUCTING AN INTERNAL INVESTIGATION REGARDING DISCRIMINATION

- I. Gather all relevant documents
 - Company policies
 - Personnel files
 - Organizational charts

- II. Select an investigator
 - Human Resources Department
 - In-house counsel
 - Outside counsel

- III. Interview the complainant
 - Meet in a private, comfortable setting
 - Reassure the complainant that they will not be subject to retaliation for filing a complaint
 - Reassure the complainant that the investigation will be kept as confidential as possible
 - Emphasize that it is important for the complainant to disclose all information
 - Advise the complainant that the investigation will be completed as soon as possible
 - Topics to be covered
 - Names of all witnesses
 - Dates and times where conduct occurred
 - Location of conduct
 - How did the complainant react to the conduct?
 - Confirm that the company has all relevant documents
 - Inquire as to how the complainant would like to have the issue resolved

- IV. Interview the accused
- V. Interview all witnesses
 - Obtain written statements from all individuals who are interviewed
 - Take excellent notes

Employment Issues

VI. Results

- Evaluate the evidence
- After evaluating all documents and witness interviews, draft a final report that describes how the investigation was conducted.

- If misconduct occurred, appropriate courses of action include, but are not limited, to the following:
 - Written warning
 - Counseling
 - Transfer
 - Demotion
 - Suspension
 - Termination

- If it is not clear what conduct occurred:
 - Have all parties acknowledge in writing the company's policies
 - Remind the accused that retaliation is unlawful
 - Remind the complainant to immediately report any further conduct
 - Maintain confidentiality

EMPLOYEE RECORDS

Federal Record Keeping

- The Fair Labor Standards Act
- The Equal Pay Act
- The Immigration Reform and Control Act
- The Occupational Safety and Health Act
- Title VII of the Civil Rights Act of 1964
- The Age Discrimination in Employment Act
- The Americans with Disabilities Act
- The Family and Medical Leave Act
- Uniformed Services Employment and Re-employment Rights Act
- Executive Order 11246 (federal government contractors)
- Employee Polygraph Protection Act

Texas Record Keeping

- The Texas Unemployment Compensation Act
- The Texas Worker's Compensation Act
- The Texas Commission on Human Rights Act

Intellectual Property Issues

The traditional cornerstones of intellectual property have been patents, trade secrets, copyrights and trademarks. In the United States, copyright and patent protection have their source in the U.S. Constitution and implementing congressional legislation, and secure exclusive rights for a limited time to authors and inventors for their respective "writings" and "discoveries." On the other hand, trademark and trade secret protections historically evolved from common law principles of commercial fair dealing and are of potentially unlimited duration. From these traditional cornerstones, the intellectual property field has expanded to include a wide range of "personal" rights, including moral rights protecting creative attribution and integrity, "neighboring" rights assuring performers, record producers and broadcasters control over the exploitation of their works, and publicity rights preventing unauthorized use of name, likeness, or other personality characteristics. Moreover, intellectual property rights have either been crafted or extended to meet the challenge of protecting an ever-expanding technology. Thus, Congress has created hybrid protection utilizing principles of both copyright and patent law for protection of semiconductor chip designs, while the principles of copyright law have been expanded to cover computer software. Patent concepts designed to protect the cotton gin and the first steam engine have been molded to accommodate space travel and biotechnology advances.

OVERVIEW OF INTELLECTUAL PROPERTY PROTECTION

Patents

Patents are generally considered to afford the greatest degree of intellectual property protection. There are three classes of patents in the United States - utility patents, design patents and plant patents. Patent rights and their scope are derived and defined solely by the federal law, specifically Title 35 of the United States Code. Characteristics common to each class of patent include a nonrenewable term of limited duration, a stringent level of creativity (novelty and nonobviousness) as a prerequisite to protection, and no requirement that an infringer have prior knowledge of the patent as a prerequisite to infringement liability.

Utility Patents

Utility patents are obtainable for products, processes, machines or compositions of matter. Briefly stated, a utility patent protects technological innovations and advancements and is arguably the most important class of patent. Examples of inventions protected by utility patents are pharmaceuticals, methods for diagnosis or assay and oligonucleotide synthesizers. Utility patents do not protect nonfunctional works of authorship or artistry like books or paintings (protectable by copyright), nor commercial symbols (protectable as trademarks), nor mere ideas or concepts (potentially protectable as trade secrets).

The scope of protection of a utility patent is defined by precisely crafted numbered paragraphs at the end of the patent known as "patent claims." The breadth of these claims is ultimately determined as a result of the examination by a patent examiner as to whether the claimed invention is a sufficient departure from the prior art, i.e., from what is already known. The patent owner may then exclude

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others from making, using, selling or offering to sell products incorporating the patented invention, or from carrying out other specifically defined activities in or with respect to the United States, for the life of the patent. The expiration of the life or term of a utility patent is now twenty years from the filing of the application for a patent, with previously issued, unexpired patents having the greater of the twenty years or seventeen years from date of issuance.

It is imperative to understand that the ownership of a patent does not insulate a business enterprise from claims of patent infringement. Thus, while the patent holder may prevent others from making, using or selling its patented invention of, for example, a new and improved laser scanning device, the patent does not provide an unqualified right to the patent holder to make use, and sell the patented compositions if such activities would infringe an unexpired dominant patent of another covering generally.

Design Patents

Design patents are obtainable for ornamental designs for articles of manufacture. Design patents therefore protect the non-functional aesthetic characteristics (configuration, shape or surface ornamentation) of a product. An example of an invention protected by a design patent is the aesthetic shape of a modernistic looking chair. The term of protection of a design patent is fourteen years from the date of grant.

Plant Patents

Plant patents are obtainable for new and distinct varieties of asexually reproduced plants. This class of patents excludes others from asexually reproducing the patented plant or selling or using the plant so reproduced.

Other Patents

Additional and different types of patents exist in countries foreign to the United States and must therefore be considered when dealing with transactions having international ramifications. For example, many countries have patents of addition for protection of improvements or alterations of an invention made by the owner to its existing patented invention. Here, the prerequisite for patentability is less and the patent normally expires with the parent patent. In many South American countries, patents of importation provide protection corresponding to the home country patent. Utility models or petty patents in other countries protect the specific shape or configuration of an article when such configuration serves a utilitarian purpose; and design registrations having protection similar to design patents in the United States protect the external non-utilitarian appearance of an article.

Trade Secrets

Trade secrets is that area of intellectual property protection in which business enterprises' proprietary technology and commercially sensitive business information are protected from misappropriation. Trade secrets derive their protection from state statutes (both civil and criminal) and from the common law. The potential reach of trade secret protection is very broad in that it includes not only a business enterprise's proprietary technology (e.g.: computer program algorithms, product formulas, manufacturing know-how) but its confidential business and financial information (e.g.: customer/supplier lists, cost data, pricing structure) as well. While requirements may vary from state to state, the qualifications for trade secret protection are generally that the information asserted to be a trade secret not be publicly available nor readily ascertainable, that a competitive advantage accrue to the enterprise due to the information and its secret status, and that the business enterprise has exercised

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reasonable efforts to keep the information secret. The focus is not on the level of creativity of the information; it is instead on its value and status of secrecy. Once qualified as a trade secret, the law protects the secret from direct appropriation by improper means, such as industrial espionage, unauthorized employee or former employee disclosure, or breaches of express or implied obligations of confidentiality imposed upon individuals privy to the trade secret.

Trade secret protection is broader than patent protection in the sense that ideas and concepts may be protectable as trade secrets, while they are not protectable under patent law, and trade secret protection is of potentially unlimited duration, while patents have a limited life. On the other hand, the protection for trade secrets is narrower than patent protection in that, unlike patent protection, there is no right to prohibit another's use of a trade secret which has been independently developed, reverse engineered, or derived from independently available sources. Thus, the law of trade secrets does not protect the ideas themselves, but protects them from misappropriation.

Copyrights

Copyright protects the particular creative expression of authorship or artistry that has been recorded in a tangible medium. Moreover, a copyright does not protect the underlying idea, principle or theme embodied in the recorded expression, only the form of the expression. Thus, the author of a poem that describes the beauty of the setting sun cannot prevent another who has access to the poem from also describing this phenomenon, only from describing it in the same or substantially similar manner as that of the author.

Copyright protection attaches to the particular work at the moment that it is created and recorded without any further formalities. In that regard, the only criteria that must be met in order to obtain copyright protection are

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(1) the work must be of the type that is protectable, (2) the work must be original in that it is the author's own product and not a copy or trivial variation of an existing work, and (3) the work must be fixed in some form of tangible medium (printed page, record, film, computer disk, etc.).

In the United States, the spectrum of the works afforded copyright protection and the scope of that protection are derived exclusively from federal law, specifically the Copyright Act, Title 17 of the United States Code. Among the classes of works protected under the United States statutory copyright law are literary works (which include computer programs), musical works, dramatic works, pictorial, graphic and sculptural works, motion pictures and other audiovisual works, sound recordings and architectural works. The duration of protection of a copyright in the United States depends upon the class of author (corporate, individual or anonymous) and may range from fifty to over 100 years from creation of the work.

Under federal law, the copyright owner is given the exclusive right to reproduce, distribute, publish, publicly display and perform, and prepare derivative works of, the created work. Neither affixation of the familiar copyright notice nor registration of the copyright with the Copyright Office is a prerequisite to securing copyright protection. Nevertheless, carrying out these formalities is strongly advised, as their absence will preclude the copyright owner from obtaining the full range of monetary remedies available for copyright infringement.

Unlike patents, there is no requirement that a work embody a significant degree of novelty or ingenuity, only that it be original. Also unlike patents, proof of access and actual copying of the copyrighted work is a prerequisite to liability. An independently created work can never constitute copyright infringement even if it is identical to the copyrighted work. In addition, it is not a

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copyright infringement to copy a work that is in the public domain. However, it is important that it is the actual public domain item that is copied and not a more current rendition of it. Thus, while a particular sculpture may be in the public domain, a photograph of that sculpture may still be subject to derivative copyright protection.

Issues of ownership require particular scrutiny in the case of copyrights and due diligence investigations regarding same. For example, while a work prepared by an employee within the scope of his or her employment would vest copyright ownership in the employer as a "work made for hire," independent artists, authors or photographers retained to prepare illustrations, create text or photograph events normally retain ownership of the copyright to their respective creations, in the absence of an express written agreement to the contrary.

Trademarks

A trademark is a commercial symbol that is used by a business enterprise to identify its products and/or services, and to distinguish them from the products and services of others. Once a trademark is adopted, and used, the trademark owner can prevent another's use of a same or deceptively similar mark in connection with such goods or services that would likely cause consumer confusion. Practically anything that effectively acts as an indicator of origin and aids consumers in identifying and distinguishing the products and services of competitors from one another can be protectable as a trademark. Thus, trademarks include names (such as "Kodak," for photographic products), logos or designs (such as McDonald's "golden arches," for hamburgers), slogans (like "The Greatest Show on Earth," for circus services), sounds (like the NBC chimes, for radio and television services), colors/color combinations (like yellow with red or black, for film), fragrances (like that of plumeria blossoms, for thread and yarn) and product

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container shapes (like the Coca-Cola bottle). The concept of trademark law has also been extended to protect distinctive packaging for goods and services and is referred to as trade dress.

The source of protection of trademarks in the United States is the common law, with those rights having been expanded by federal statutory law to provide nationwide registration protection and relief from infringing activity occurring in interstate and foreign commerce. While the theory of trademark protection is based upon concepts of unfair competition and preventing consumer confusion the burgeoning area of trademark licensing has resulted in the tendency by the courts to treat trademarks as property, precluding their use even when consumer confusion may not be evident. This treatment has been enhanced by the passage of federal and state statutes prohibiting "dilution" and "tarnishment" of recognized trademarks, irrespective of consumer confusion.

Trademarks also include collective marks used by members of a collective group, like a trade association, for indicating membership therein, and certification marks used to certify the regional origin, material, mode of manufacture, quality, accuracy or other characteristic of goods or services. Trade names of business enterprises that do not function as trademarks are generally not protectable in the United States except under circumstances such as intentional palming off.

Trademarks are protectable under the common law and under federal law even absent their registration, although their protection is limited to the particular geographical areas in which they have become known or naturally expect to expand. Nevertheless, registration of trademarks is preferred since such registration provides constructive notice, cuts off common-law rights not already established, and provides remedies not available under the common law or state statutes. In countries foreign to the United States, particularly those

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whose laws are not based upon the common law, the registration of a trademark becomes more of an imperative since it often is the only source of protection. Though trademark protection is potentially of infinite duration so long as the trademark owner continues to use its mark, the registration statutes of the United States and other countries require periodic renewal of the registrations.

Special Areas

(a) Semiconductor Chip Protection. A special form of intellectual property protection for the three dimensional layout or topography of semiconductor chips has been created in the United States and in a growing number of foreign countries. First introduced in the United States in 1984 in the form of federal legislation known as the Semiconductor Chip Protection Act, the legal protection is provided by a hybrid of copyright and patent principles. The protection is based upon the registration of the three-dimensional pattern or "mask work" for producing the particular semiconductor chip. The requirement for registration is that the mask work be original and not comprised of a design that is staple, commonplace or familiar in the semiconductor industry.

In the United States, the mask work registration must be filed in the Copyright Office within two years from its first commercial exploitation. Protection then extends for ten years from such registration or from first commercial exploitation, whichever is earlier, and entitles its owner to prevent the reproduction of the mask work as well as the importation or distribution of semiconductor chip products incorporating the same or substantially similar chip topography. The failure to register the mask work within the two-year period injects the topography into the public domain.

(b) Right of Publicity. The intellectual property right of publicity precludes others from commercially exploiting one's identity without consent. Aspects of identity that

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are typically protected are a person's name, nickname, appearance, voice, performing style or personality. In the United States the right of publicity has its source in state statutory and common law, and in some states may still apply and extend to the heirs after the death of the celebrity. Although it is not a requirement that a person be famous to be entitled to right of publicity protection, claims involving the right of publicity typically arise when a photo or improperly obtained likeness of a celebrity, or a celebrity look-alike or sound-alike, is used in commercial advertising without authorization. Claims may also arise from the unauthorized use of nicknames or personality-identified phrases (e.g., "Goodnight Gracie").

(c) Moral Rights/Neighboring Rights. Many countries foreign to the United States have long recognized the rights of an author of a creative work to subsequently exercise control over its use and exploitation. For example, "moral rights" enable authors and artists to restrict modifications or exploitations of their works when such changes are inconsistent with their professional honor and reputation. Also, "neighboring rights" provide protection for performers, record producers, and broadcasters to control the commercial exploitation of their intellectual creations. When dealing with transactions having international scope, one must therefore be cognizant of these foreign rights.

While not adopting the same breadth of protection as may exist elsewhere, the United States has provided through its federal copyright laws protection of selective aspects of moral and neighboring rights. Specifically, the right of attribution (right to claim or disclaim responsibility for offering or creating a particular work) and the right of integrity (right to prevent unauthorized distortion, mutilation, modification or destruction of one's work) are now provided to the creators of certain limited works of "visual art" (graphic, sculptural and photographic works) as a consequence of the Visual Artist Rights Act of 1990 supplementation to the

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Copyright Act. Moreover, changes to the Copyright Act have been effected in order to provide both civil and criminal protection for performers, record producers and broadcasters.

(d) Synergy of Protection. Effective protection of the intellectual property of a business enterprise often results from the synergistic application of multiple components of protection. Protection of a company's computer software may involve the application of the patent, copyright and trade secret laws. A uniquely configured product may be protected by the use of a design patent, by copyright procedures, and, to the extent that such design has become distinctive of one's product, by trademark. Establishing a business enterprise's right to commercially use a photograph of a sports or movie celebrity requires securing the copyright from the photographer and may also require a waiver of the right of publicity from the celebrity who is the subject of the photo. Establishing freedom from intellectual property violations of a target enterprise which produces and sells semiconductor products now requires the investigation of not only subsisting patent rights in the countries in which the products are made or sold, but also an investigation as to whether and to what extent the target enterprise may have misappropriated a registered mask design and/or improperly obtained information from an ex-employee of the mask's proprietor.

TRADEMARKS

Selecting Trademarks

Issues to Review in Attempting to Reduce Risks in Trademark Selection

It is important to consider factors that affect the ultimate value of a mark to its owner. Some of these are as follows:

Availability

One should determine, through your IP professional, whether there are other parties with superior rights in the same or a substantially similar mark. If any such rights exist, your rights may not only be limited but may infringe on the prior owner's rights. If a prior owner's rights are not discovered until after you have developed goodwill in the mark, all such goodwill may be lost.

Registrability

All applications to register marks are subject to an examination to determine whether the mark is (a) likely to be confused with another pending or registered mark, (b) merely generic, or (c) descriptive of the goods or services the mark represents. Generally, the more arbitrary or capricious a mark, the more likely it is to obtain registration. The more descriptive the terms in a mark, the less likely the mark is to be approved for registration. The flip side of that issue is, however, the fact that more descriptive terms often have greater marketing appeal. Thus, there are times when a company may forego registration in order to use descriptive terms in a mark, or may link descriptive terms with a distinctive term and seek to obtain registration for the mark as a whole.

Protectability

This is often the least considered and, from a cost/benefit standpoint, the most important issue when selecting a mark. One should consider whether the mark is sufficiently distinctive from other marks, trade names, etc., that it will generate recognition by the relevant purchasing public of the source of the goods or services represented by the mark. A mark owner should consider whether its customer base will develop clear recognition that the mark identifies the owner, rather than another party, as the source of the goods or services at issue. The value of a mark ultimately depends on the level of such recognition. It is also important to assess the possible need and costs of defending claims that the mark infringes on another's rights and of prosecuting infringements of the mark by others, and to weigh those risks against the desired amount of investment in the mark.

Steps to Reduce Risk

By considering the factors discussed above and by taking the following steps, a prospective mark owner can reduce the risks associated with selecting, registering, and maintaining rights in a mark. The greater the value of one's mark due to goodwill and name recognition, and the greater the potential damage to the business due to having to dispute the use of the mark (or losing the right to use the mark), the more valuable and cost-effective these considerations become.

Step 1

Conducting a computer-screening search is a very cost-effective way to identify most of the other marks in commerce that could be potential problems. This is the type of search that IP professionals often conduct in their offices, and it is relatively fast and convenient.

Step 2

Developing several prospective marks each time one mark is needed and conducting searches on all prospective marks at one time has several advantages. One benefit is that it forces the prospective mark owner to focus on more than one option as a potential mark. There is always a tendency to shut down the consideration process after one hears or sees “the right mark.” After one becomes convinced that a certain mark is ideal, it is much more difficult to make the necessary risk trade-offs. For instance, a search of five to ten alternatives will generally result in two or three that appear free of obvious conflicts and that the company may wish to pursue further. In addition, it is generally less expensive to search and analyze several prospective marks at the same time, rather than repeating the entire process for each potential mark.

Step 3

By filing several intent-to-use applications (for several different proposed marks, provided one has a bona fide intention to use such marks) as far in the future as possible, one may be able essentially to “reserve” the marks that appear to be free of obvious conflicts. A subsequent search several months later may reveal some further potential conflicts that did not appear on the initial search due to the lag time between the time applications are filed and the time that references to such applications are added to the data bases, and will help one to assess which marks are most likely to attain registration.

Step 4

By conducting further searches to uncover additional similar marks and common law users that may have similar marks, one can further assess in advance many of the potential risks associated with a particular mark. More comprehensive search services are available to conduct these expanded searches. Search firms that specialize in such services will search trade periodicals, telephone books and numerous other sources of

information in an attempt to uncover common law users. It is often very cost-effective to conduct such a comprehensive search prior to investing a substantial sum of money in developing a mark and promoting the product or service that bears the mark, and we highly recommend that such searches be conducted on mark that appear relatively free of conflicts on the initial computer searches.

Scope of Protection to Be Sought and/or Claimed

There is a significant—and from the mark owner’s standpoint critical—distinction between marks that one can use with reduced risk of infringement, and marks that one can prevent others from using. It is vitally important to at least conduct an initial screening search of all marks to avoid infringement risk when possible. If it appears that a mark can be used without infringing on the rights of another, then registration, when available, generally provides the broadest scope of protection of one’s mark.

“Intent-To-Use” Applications

If an applicant has not yet begun using a mark that it desires to register, an application can be filed based on an “intention to use the mark.” In the U.S., the application will need to be later amended to show actual use of the mark before registration certificate will issue. So-called “Intent-to-Use” or “ITU” applications, as they are referred to in the U.S., are often valuable tools to essentially “reserve” a mark that one has a bona fide intention to use in the future.

PATENT LAW ISSUES OF INTEREST

Provisional Patent Application

This application, which is limited to applications for utility patents, makes your invention of record in the United States Patent and Trademark Office, thereby allowing you to mark your products as "patent pending." This application will never be examined and cannot become a patent by itself. In order for the application to be examined and become a patent, a non-provisional utility patent application must be filed within one year of the filing date of the provisional patent application.

Those situations in which provisional patent applications are normally filed are: (1) when in the developmental stages of an invention; (2) when it is necessary to disclose the invention to a third party and there is insufficient time to file non-provisional application; and (3) those who want to preserve foreign patent rights prior to any sales or public disclosure of the invention. While there may be some situations where provisional applications are warranted, it is generally more advisable to file a complete conventional non-provisional application on a timely basis.

Protection While the Application is on File

Although infringement of an invention may develop before the patent issues, non-dilatory prosecution of the application is usually in the client's best interest.

With the exception of very limited rights afforded through a recently enacted publication procedure, the U.S. law affords no protection during the interim period in which the patent application is pending. But the law does permit a patent applicant who finds that infringement has developed to "make the application

special," thereby accelerating the date of issue. Care should be exercised in using this expedited process because it may result in the only thing being made "special" is the rejection of the invention.

Deadline for Application Filing

In the United States, there is a one-year "grace" period between the first public use of an invention and the filing of a patent application. This public use can be in a printed publication, through an offer for sale or actual sale, or other commercial use. In general, experimentation to perfect an invention is not considered a commercial use, although market experimentation type testing does not qualify. Most foreign countries do not have this one-year grace period. If foreign patent protection is desired, therefore, a patent application must be filed before the first use of the invention.

If there has been a disclosure in a publication, a sale of the subject device, or a public or commercial use of the invention, the complete circumstances must be disclosed to your patent professional.

Evidence of Conception

Occasionally, controversies arise requiring proof of an inventor's conception and the date of first disclosure to others. Evidence of this conception may be a written description of the invention, preferably on a form like the one attached, which should then be witnessed by one, and preferably two, persons who are capable of understanding the invention. Your patent professional, by law, will qualify. This procedure is also a useful way in communicating your invention to your patent professional.

INVENTION DISCLOSURE FORM

(If you already have created a written spec, notebook, drawings, documents etc. describing the invention please send a copy with the printed and signed Invention Disclosure Form to the patent coordinator. Please print and sign this form, all inventors must sign it, and send it to the patent coordinator. If you have already submitted an unsigned electronic copy of this form, please print it, sign it, and submit it, indicating it is a signed copy of a previously submitted disclosure.)

1. Please suggest a title for the invention:
2. What business strategies does this support? Select all that apply:
 - a. Manufacturing
 - b. Testing
 - c. Marketing
 - d. Design
 - e. Computer Tools
 - f. Product Area: _____
 - g. Packaging
 - h. Other : _____
3. What is the problem that is solved by the invention?
(Attach a description, or write one, here)
4. What is your solution to the problem?
(Attach written description, or, write one here)
5. When was your solution to the problem first conceptually complete? ___/___/____
6. What is the first written or recorded evidence of the completion?
 - a. Dated : ___/___/_____
7. What is different about your solution to the problem, compared with other approaches to the problem?

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8. What are the advantages of using your solution to the problem, over other approaches?
9. What products, methods, processes, or operations currently in use, use your invention?
10. What is the date of the first implementation of your invention? __/__/_____.
11. What written record exists of this date?
12. Is there any future use or implementation of your invention planned? (NOTE: Patent protection does not require that an invention be built or completed, so long as it can be described in writing. It is important to file for patent protection before a product, method, or offer for sale is made using the invention, so we need the information to know the critical dates for filing for the patent in those cases.)
 - a. Is so, when? __/__/_____.
13. Has the invention been disclosed to anyone outside the company, published, shown, described in a press release, marketing brochure, customer pitch, or otherwise?
 - a. When? __/__/_____.
 - b. If the invention has been disclosed, was the disclosure covered by a non-disclosure agreement or NDA with the other party? Who has that document?
14. Has a product, which incorporates the invention, been announced, released, shipped, or quoted to a customer?
 - a. When? __/__/_____.

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15. Was the invention conceived, developed, or implemented in the performance of a contract for a government agency (such as DARPA)?

a. If so, do you have the contract number?

I acknowledge that the invention described in this invention disclosure is being submitted pursuant to my existing employment agreement to assign inventions and that the invention is the property of

_____.

Inventor 1:

Printed Name _____
Home Address _____
City, State, ZIP _____
Country _____

I am a citizen of _____.

Signed _____ Date _____

Inventor 2:

Printed Name _____
Home Address _____
City, State, ZIP _____
Country _____

I am a citizen of _____.

Signed _____ Date _____

Inventor 3:

Printed Name _____
Home Address _____
City, State, ZIP _____
Country _____

I am a citizen of _____.

Signed _____ Date _____

POTENTIAL INTELLECTUAL PROPERTY PITFALLS IN THE FDA APPROVAL PROCESS

Obtaining approval from the FDA to market a new drug or medical device can be a time consuming and expensive proposition. For this reason, the FDA has developed streamlined procedures that allow companies to greatly reduce the time and cost of obtaining approval for their new products. But these procedures, unless caution is exercised, can conflict with the ability of a company to obtain enforceable patent protection for the approved drugs or devices.

The streamlined approval processes depend upon the FDA applicant emphasizing the similarity of the new compounds or devices with those that have previously been developed and approved. The enforceability of a patent, on the other hand, depends upon proof of the non-similarity with what has gone before. This is because the patent law requires patentable inventions to be new and non-obvious. Thus, there is a conflict between the respective premises of FDA approval and enforceable patent protection. Companies seeking to avail themselves of the streamlined FDA processes therefore need to avoid making careless statements that can lead to loss of patent assets.

Drugs

New drugs may be approved for use through either the Investigational New Drug (IND) process or the New Drug Application (NDA) process. Both require extensive testing to establish that the new compounds are safe and effective.

Generic drugs, on the other hand, can be approved under the Abbreviated New Drug Application (ANDA) that allows the applicant to rely on the testing previously done for the original drug. This greatly reduces the time from application to approval; however, in practice, this

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process can be problematic unless caution is exercised in what statements are made during the process.

An ANDA can also be used for drugs that are not identical to previously developed compounds; these drugs are sometimes referred to as Branded Generics. Here, the FDA applicant is required to establish the bioequivalency of the new compound with the previously approved drug. In doing so, the FDA applicant must be careful to avoid statements which would represent that the new drug is "just like the old one" if it desires to also obtain patent protection on the new compound. Intellectual property counsel must therefore work in close cooperation with the company's FDA counsel so that statements damaging to the patent process can be avoided while at the same time providing the requisite showing of similarity to the prior drug.

As another issue that arises with ANDA approval, and one which can be problematic, the applicant is required to certify that it is not infringing any patent covering the original drug. This certification has routinely led to a patent holder disagreeing with the applicant's certification and filing a patent infringement suit against the FDA applicant. Even if the claim of infringement is unfounded, the expense of defending against it and the time lost in selling the new drug can be substantial. Therefore, your intellectual property counselor should carefully scrutinize the language of the certification.

Another streamlined approval process is the so-called 505(b)(2) application. This approval process allows for a simplified application process for variants of previously approved drugs where the new product is not eligible for approval as a generic under the ANDA procedure. The 505(b)(2) process can be thought of as a "negotiated NDA." The applicant is allowed to rely on testing done by third parties that established the safety and efficacy of a previously approved product. In some cases the FDA may require additional clinical data, but the process

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is usually shorter and less expensive than a regular NDA.

Again, unless carefully controlled, the 505(b)(2) process can expose the FDA applicant to needless litigation. If statements are made to the effect that the "new drug is just like the old drug", then the applicant may be sued by the patent holder for the "old drug", and the FDA applicant will find its own statements offered to the jury as proof of infringement.

Medical Devices

Similar perils exist for the developers of new medical devices. While the procedures have different names, the processes are analogous. A new medical device can be submitted for approval by the FDA under a Premarket Approval Application. Just as with a new drug, this process requires extensive testing to demonstrate that the device is safe and effective.

An alternative process, called a 510(k) application, allows the maker of a new device to demonstrate that it is the "substantial equivalent" of a device that has already received FDA approval. Unless statements are carefully scrutinized, it can often be the case the FDA applicant will wind up hearing its own statements to the FDA used to support "obviousness" allegations by an infringer, thus leading to invalidation of the FDA applicant's patent rights. The challenge is having a description that meets the FDA requirements while at the same time having that statement preserve the uniqueness of the device to sustain its patentable merit.

Conclusion

When FDA approval of a new drug or medical device is sought, it is essential that all of the ramifications of the chosen method for obtaining the approval be considered. The advantages of getting to market more quickly must be weighed against the potential of losing

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patent rights. However, with experienced counseling, and cooperation between the company's FDA counsel and patent counsel, a company can have "the best of both worlds."

General Information

Contact Information

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