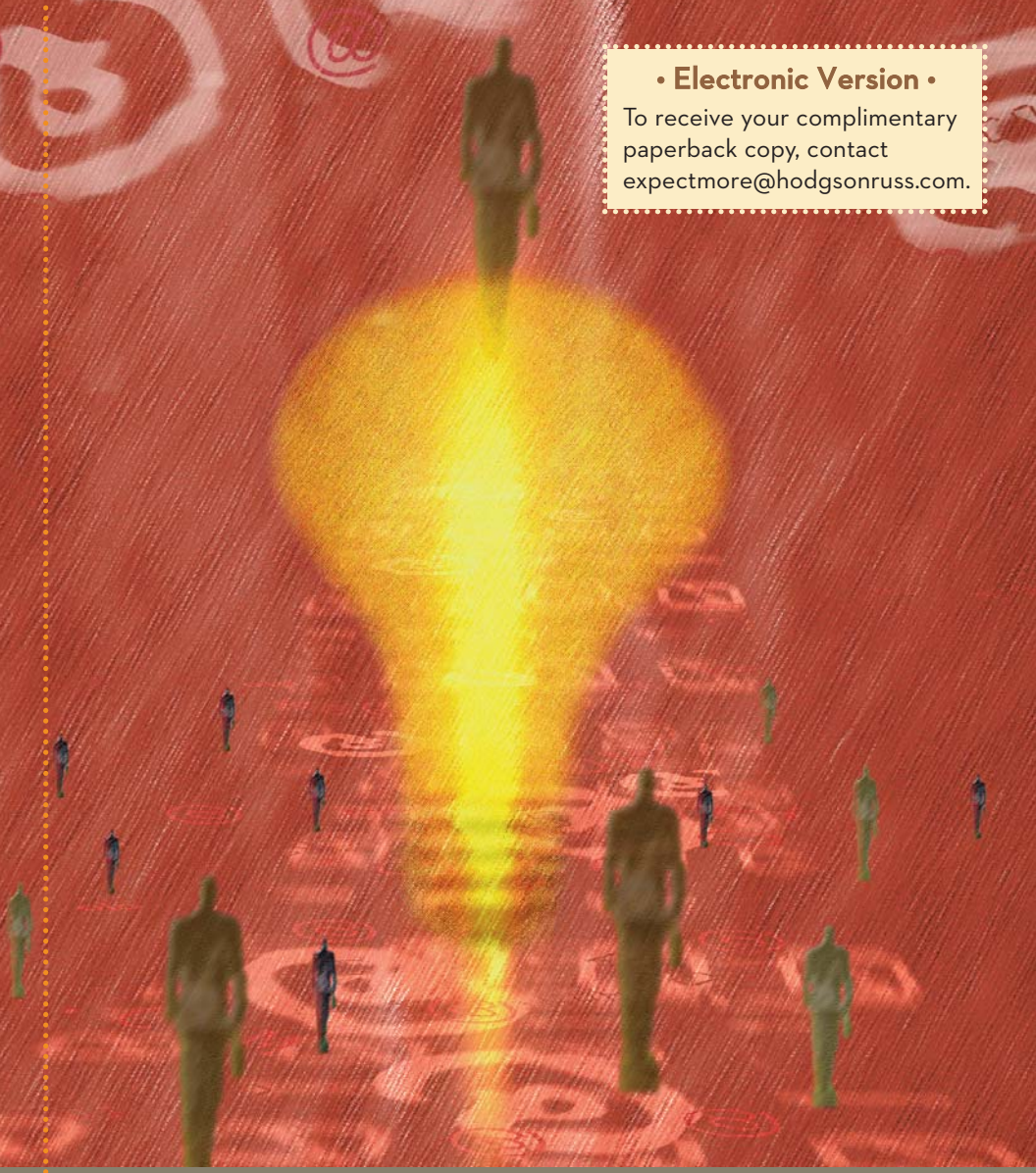

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Entering the Market:

A Legal Primer for Emerging Companies

Hodgson Russ LLP
ATTORNEYS

We help innovators who mean business.

Entering the Market:
A Legal Primer for Emerging Companies

Third Edition

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Introduction

Your ideas are fresh and innovative. You see great potential for your company as your vision starts to become reality. But do you have the right legal strategies in place to help you achieve your objectives and avoid the pitfalls that commonly hinder emerging businesses like yours?

As a new company about to enter the U.S. marketplace, your enterprise will emerge into what is arguably the most challenging legal and business environment ever to face the business world. Each business has its own set of legal issues, some common but some unique to what it does. All emerging companies must consider the advantages and legal ramifications of particular business structures, financing options, and employee benefits plans. But, there are also issues specific to your own business. For example, do you have intellectual property, and how do you protect it from infringement by competitors? And what steps can you take to reduce risk and comply with the specific regulations governing your particular industry?

Entering the Market: A Legal Primer for Emerging Companies provides an overview of these and many other basic legal considerations that could be critical for your company as you launch your enterprise. Written by attorneys at Hodgson Russ LLP, it is based on our extensive experience advising emerging businesses in many industries. As one of the nation's oldest law firms, we have a long history of advising companies during their initial launch and through all stages of growth.

With offices strategically located in Buffalo, New York; Toronto, Ontario; and New York City, Hodgson Russ has developed a strong international/cross-border practice. Our experience shows that many mid-sized foreign companies wishing to enter the U.S. market face similar challenges to U.S.-based emerging companies, so we have included a chapter addressing the specific needs of foreign emerging companies.

This handbook is by no means an exhaustive guide, but we hope it will help you better understand the challenges you face and prove a handy resource as you develop your company's strategy and business

plan. We have included a section outlining our special Jumpstart Plan to help your company get off the ground, along with information about our firm and contacts who can answer questions about how specific areas of law may affect your business. We are happy to answer any questions you may have regarding this book's contents or other legal and business concerns.

We wish you and your business partners all the best as you embark on your new venture.

Chapter 1:
Getting Started: Establishing Your Company

Choice of Entity

When beginning a business, one of the first decisions to be made is the selection of an appropriate business entity. In making the selection, it is important to consider what type of business entity best suits a business's short- and long-term goals. The different business entities vary in many significant ways, including their ease of formation, statutory governance, tax status, and – perhaps most importantly – the liability of their owners.

Below is a summary of some of the common forms of business entities available in the United States. Please be aware that this is only a brief overview. Before forming any business entity, we recommend you consult with an attorney who has knowledge of corporate, tax, and other laws associated with starting and operating a business.

Corporation

A corporation is a business entity that is a separate and distinct legal entity from the individuals who own and manage it. A corporation can act in its own name in that it can enter into contracts, own property, and be sued. There is no limit on the number of owners of a corporation, and the owners are generally not liable for the debts and obligations of the corporation. Corporations must abide by state-specific statutory rules that provide for the creation, operation, capitalization, and termination of a corporation. If the goal is to take the company public at a later date, then a corporation is the ideal form of business entity. The stock of a corporation is generally very liquid and easily transferrable.

The drawback to a corporation is that it is subject to double taxation. The corporation is first taxed at income it receives at the corporate level. If any earnings of the corporation are then distributed to its shareholders, the shareholders are also taxed on those earnings.

"S" Corporation

An S corporation is a corporation that has elected to be taxed under Subchapter S of the Internal Revenue Code, which means the corporation's income is generally not taxed at the corporate level, and profits and losses pass directly to the shareholders, who take their shares of the income into account for income tax purposes. However, an S corporation must meet certain requirements in order to receive this beneficial tax status, including a limitation on the number of shareholders, all of whom must be U.S. individuals (including citizens and permanent residents holding green cards), estates, or certain trusts. It is important to note that another business entity, such as another corporation or a limited liability company, may not be a shareholder in an S corporation. Another restriction is that there can be only one class of stock in an S corporation.

Limited Liability Company

The limited liability company, or LLC, is a cross between a partnership and a corporation. It has the advantages of a corporation in that the owners are not personally liable for the debts and obligations of the LLC, and there is no limitation on the number of owners. Although an LLC is governed by state statutory rules, these rules allow the owners (called "members") of an LLC to be extremely flexible in their operation of the business. Additionally, an LLC may elect to be taxed as a partnership, resulting in only one level of taxation, at the members' level. Most of the affairs of the business will be governed pursuant to an operating agreement executed by the members of the LLC. The members of an LLC may elect one or more managing member to handle the management of the LLC, but it is not required. A disadvantage to an LLC is that many potential investors are typically more comfortable with a corporation. Also, a corporation is the business structure needed to take a company public. However, if the owners of an LLC want to go public, the LLC can be converted into a corporation.

Sole Proprietorship

A sole proprietorship is the simplest form of business; it is owned and operated by one person. The profits and losses of the business are received directly by the sole proprietor. The major drawback to this form of business is that the sole proprietor is personally liable for the debts and obligations of the business. The sole proprietor is taxed directly on the profits of the business.

General Partnership

A partnership is an association of two or more persons who join together to carry on a trade or business. A general partnership is usually formed by a written agreement, but there are circumstances where an oral agreement or the conduct of the parties will be sufficient to imply that a general partnership exists. The partners share in the profits and losses of the business, but may choose the percentage share of each partner. However, just like a sole proprietorship, the partners are personally liable for the debts and obligations of the business, including those debts and obligations incurred by the actions of other partners. The partners are individually taxed on their share of the partnership's profits.

Limited Partnership

Like a general partnership, a limited partnership consists of two or more partners. However, in a limited partnership, there must be at least one general partner and one limited partner. The general partner is responsible for the management of the business, and is liable for all of the debts and obligations of the business. The limited partners are generally only personally liable up to the amount of their investment in the partnership, but may be liable for all of the partnership's debts and obligations if they are deemed to be participating in the management of the business.

Professional Entities

Many U.S. states require that licensed professionals (such as doctors, architects, engineers, and others as defined by state law) incorporate using an acceptable organizational structure. For example, in New York State, licensed professionals may not set up a general business corporation. The available acceptable organizational structures vary depending upon the state in which you intend to practice the licensed profession, and you should consult with your attorney to ensure an appropriate structure is chosen.

Other Considerations

Selecting the State of Incorporation/Organization

Selecting the state of incorporation or organization of your business is almost as important as selecting the appropriate type of entity to be formed. The law does not require that you form your business in the state where your business is headquartered. In fact, for most companies, the choice comes down to your home state or Delaware. The principal advantage of incorporating or forming your company in Delaware is its well-developed body of corporate law that tends to favor management and majority shareholders. Additionally, the ease of formation and Delaware's relatively low initial and annual filing costs have made Delaware attractive to new and existing businesses for decades.

Another consideration that may drive the selection of state of incorporation is the available resources — such as state and municipal incentives, technology centers, incubators, tax incentives, and community resources. Many venture capital firms may prefer incorporation in Delaware. (See Chapter 2 for further information on funding.)

Cost Considerations

Your choice of entity and state of incorporation may affect the company's tax rates, the amount of your annual filing fees, and franchise taxes. Additionally, if you choose to incorporate your business in Delaware or any state other than your home state, you will be required to file annual reports and pay annual fees/taxes in both the state of incorporation and your home state, and may be required to file in any state in which you are doing business.

Choosing a Business Name

A business name must be one that is not reserved, already in use, or misleading or deceptive to the public. Also, the availability of a business name is determined on a state-by-state basis; i.e., the registration and use of a business name in New York does not necessarily preclude the registration and use of the same business name in Delaware. It is important to have alternative business names identified because of the vast number of current business name registrations. For more information, please see the trademark section of Chapter 3.

Qualifying to Do Business in Another State / Multi-State Business

If a business entity wishes to transact and carry on business in another state, it may need to "qualify to do business" in that state. The qualification process is relatively simple and inexpensive. The failure to qualify in a particular state limits the business entity's rights in that state, including the right to sue and enforce contracts.

Emerging companies will want to consider tax implications for multi-state business. For example, once a company establishes "nexus" in a state (i.e., has a sufficient connection to a state thereby justifying the imposition of that state's taxes on the business), the requirement to pay state taxes or file state tax returns may attach. Careful consideration by both U.S. and foreign companies of tax implications alongside corporate formation issues early in the process can help avoid tax surprises later.

Corporate Governance

The board of directors of a corporation has certain fiduciary obligations with regard to governing the company and specific duties with regard to certain regulated transactions. Individuals involved in corporate governance of emerging companies should be aware of SEC disclosure obligations as well as their duty of care, duty of loyalty, and duty of candor/disclosure. Conflict of interest issues should be identified early and addressed appropriately.

Chapter 2:
Obtaining Funding for Your Enterprise

There are a variety of funding sources available for emerging companies, including friends and family, unrelated angel investors, and venture capitalists. Companies in certain industries may also obtain funding from specific government and quasi-government sources. For example, life science ventures may seek funding from institutions like the National Institute of Health, National Science Foundation, and others.

For emerging companies, it is important to think of financing not as a one-time transaction, but rather as a continuing process where the progress, value, and potential growth of the business are periodically evaluated to determine the need and type of additional financing.

Structuring of Investment

Before soliciting any investors, it is important to consider what role the company wants the new investors to play in the business. If the company merely needs a capital infusion and the investors are not expected to play any sort of role in the operation of the business, then debt, as opposed to equity, may be the preferred method of investment. Conversely, if the investors are to purchase equity in the business, then the founders may want to consider creating and issuing different classes of equity, including voting and non-voting interests. Some investors, such as venture capitalists, will insist upon an active management role in a company as a condition to their investment.

Friends and Family Investors

Soliciting investments from friends and family members to finance a new business venture can be tricky. Some founders find it difficult to ask their loved ones to put their hard-earned money at risk. Other times, founders are concerned that their friends and family members may be upset that they were not invited to "get in on the ground floor" in what all parties hope will be a successful business venture. While this type of funding can by complicated on a personal level, it is often the simplest to complete from a legal perspective. It is important, however, that the financing transaction be fully documented, with all

parties having a firm understanding of their respective obligations, risks, and rewards.

Traditional Angel Investors

"Angel investors" are financially successful individuals who invest in companies during the early stages of development. Angel investors, like friends and family investors, usually invest their own money and may require either debt or equity in the company. Angels usually try to find businesses in industries in which they have prior knowledge or have had personal success. Angel investors generally invest considerably less than a venture capitalist (usually less than $1 million) and are usually more hands-off with the development of the business than a venture capitalist. Finding an angel investor is not as difficult as it once was — many angel investors participate in a system of networking and pooling their resources in hopes of finding the next great start-up company. While getting friends and family to invest in your company might just take a solid business plan, angel investors may make other demands, including liquidity provisions and guaranteed options to invest in future rounds of financing. An overreaching angel investor may cause problems for future investors, so careful consideration should be paid to any legal documentation.

Venture Capital Investors

Venture capital funding is often an attractive option for companies with a limited operating history that have exhausted other early financing possibilities, including traditional bank financing, but yet remain too small to raise capital in the public market. In exchange for the high risk that venture capitalists assume by investing in smaller and less mature companies, venture capitalists usually get significant control over company decisions, in addition to a significant portion of the company's ownership. While venture capitalists may not have the level of expertise in the particular field that an angel investor may have, venture capitalists can bring a great deal of experience in corporate development, as well as connections to important scientific, industry, and business professionals who can aid in recruiting executives, directors, employees, and other investors.

Regardless of the funding source, it is important for companies seeking to raise capital to understand the differing goals of their investors. The company and its founders have a long-term goal of developing and commercializing a specific product and or service. But, for an outside investor, the goal is to receive a return on the investment in as short a period as possible. Many investors, including

venture capitalists, will enter into an investment with a built-in anticipated time, and method, of exit. In many cases, this exit occurs within five years of the initial investment and results in the sale of the private company or an initial public offering.

Ownership Required to Support a 30% Return

Millions of Dollars Invested	Estimated Future Market Value of a Company in Six Years (Millions of Dollars)				
	$20	**$40**	**$60**	**$80**	**$100**
$2	48%	24%	16%	12%	10%
$4	96%	48%	32%	24%	19%
$6	N/A	72%	48%	36%	29%
$8	N/A	96%	64%	48%	38%
$10	N/A	N/A	80%	68%	48%

N/A = Investment would not be made if the present value of the company's estimated future value is less than the investment requested.

Source: PricewaterhouseCoopers

Venture Debt Funds

In addition to "traditional" venture financing, venture debt funds are becoming a popular avenue to finance emerging companies. Venture debt or venture lending is a type of debt financing provided to venture-backed companies by specialized banks or non-bank lenders to fund working capital or equipment purchases. Unlike traditional bank lending, venture debt is available to startups and growth companies that do not have positive cash flows or significant assets to use as collateral. Venture debt is sometimes considered a hybrid form of financing between debt and equity. Venture debt lenders often expect returns of 12 to 25 percent on their capital, but achieve this through a combination of loan interest and equity returns. The lender is compensated for the higher rate of default on these loans by earning incremental returns from its equity holding in companies that are successful. Equipment financing can be provided to fund 100

percent of the cost of the capital expenditure. Loan terms vary widely and obtaining appropriate legal counsel is recommended.

Complying with Securities Laws

When offering investment opportunities in your company, it is important that you abide by the applicable securities laws, at both the federal and state levels.

The Securities and Exchange Commission (SEC) is the U.S. government agency that regulates and enforces federal security laws. One of the goals of the SEC is to provide the public with *full disclosure* of the shares or other securities and companies that the public invests in, to prevent fraud. The SEC generally requires an entity wishing to offer its securities to the investing public to first register the securities with the SEC. There are, however, some common exemptions to the SEC registration process. Such exemptions generally permit a company to offer its securities, privately (i.e., without advertisement), to a limited number of individuals who either have a high net-worth or who attest to being sophisticated investors who have knowledge and experience in financial or business matters and are capable of evaluating the merits and risks of the investment. A number of these exemptions require notices to be filed in a timely manner with the SEC.

In addition to federal securities law, each state also has its own set of securities laws. Many people refer to these laws as "blue sky laws." Similar to the federal laws, state blue sky laws generally require any company offering securities to residents of its home state to either register with the state or fall within a prescribed exemption from registration. Most states provide exemptions from registration similar to those provided under federal law. However, some states, such as New York, have securities laws that do not coordinate with the federal securities laws.

Companies are strongly advised to obtain legal counsel before any offering or sale of shares or other securities, whether to private individuals or venture capital companies.

Public Financing / Tax-Exempt Bonds

Public financing may be an option for companies with ventures or projects that qualify for tax-exempt financing under §103 and §§141 – 150 of the Internal Revenue Code of 1986, as amended. The interest on tax-exempt bonds is exempt from state and federal taxation and, as a result, allows companies with qualifying projects to obtain financing at rates that are significantly lower than those offered through traditional methods of financing or through angel investors or venture capitalists.

The most common types of ventures and projects that qualify for tax-exempt financing include: (a) airports, docks and wharves, mass commuting facilities, water sewage or solid waste disposal facilities, low-income residential rental projects, facilities for local furnishing of electric energy or gas, local district heating or cooling facilities, or qualified hazardous waste facilities; (b) manufacturing facilities; and (c) facilities for 501(c)(3) organizations.

Tax-exempt bonds are issued by qualifying governmental agencies and will require a company to apply to a qualifying agency for financial assistance. The up-front costs associated with public finance transactions can be substantial because of the number of parties involved, the due diligence required, and the continuing disclosures that must be made. That being said, the substantial upfront costs are usually more than offset by lower debt service payments over the life of the debt that result from tax-exempt interest rates (i.e., the ability to borrow at significantly lower interest rates) and access to the public markets (the public market, unlike most conventional sources of financing provides the option of long-term fixed rates).

Alternative Methods of Financing

More traditional financing methods may not provide the most flexibility or address your specific issues. In addition, studies of angel and venture funding indicate a downward trend of available investment. There are myriad available resources for identifying alternative funding streams — including foundations, government agency grants, bartering for services, creative structuring of consulting agreements, and Small Business Innovation and Research (SBIR) and Small Business Technology Transfer (STTR) grants. Alternative methods of financing may provide funds more quickly than traditional venture funds and may be more flexible. Emerging companies should attend key meetings, talk to competitors and those familiar with their industry, analyze online resources regularly, and stay informed on

alternative funding opportunities through trade journals and trade commentaries.

Foundations

Private foundations are a major source of funding for emerging companies, particularly those that continue to maintain research relationships with universities or other nonprofit institutions. Comprehensive information can be found at www.foundationcenter.org. The top five funders are the Bill and Melinda Gates Foundation, the Ford Foundation, the J. Paul Getty Trust, the Robert Wood Johnson Foundation, and the W.K. Kellogg Foundation. Emerging companies should carefully monitor requests for proposals and consider creative ways to fund ongoing research.

Government Agency Grants

Federal and state government agencies offer many different types of grants for business development and to fund specific types of projects. The Department of Energy, the Department of Defense, the National Institutes of Health, and the Center for Disease Control are prolific sources of funding for emerging companies. At the state level, local municipal resources such as industrial development agencies (IDAs) and other county and city economic development agencies offer incentive programs, grants, and other funding options. Emerging companies should consider all of the available resources and develop relationships with the appropriate contacts within government agencies to access additional funding sources.

SBIR/STTR

Eleven federal agencies participate in the SBIR program and five federal agencies participate in the STTR program, which together award $2 billion annually to small high-tech companies. The SBIR/STTR program works to stimulate technological innovation, increase small business participation in federal research and development, and increase private sector commercialization of technology derived from federal research and development. These programs are highly competitive and structured into three phases. Phase I feasibility grants last for up to six months and can be as much as $100,000, after which grantees can apply for a Phase II grant of up to $750,000 over a two-year research period. SBIR and STTR grants are administered through the individual federal agencies supporting the grant, and emerging companies should evaluate available opportunities from all of the participating agencies.

Small Business Administration (SBA) Funding

In addition to the SBIR/STTR grant programs administered by the SBA in conjunction with other federal agencies, small businesses can also seek to obtain funding directly from the SBA. SBA loans assist borrowers who cannot meet the conventional loan guidelines from commercial lenders. The SBA offers loan programs through certified or preferred lenders or their designated intermediaries. The SBA Web site provides additional information on available Guaranteed Loan Programs at www.sba.gov/financialassistance/borrowers/index.html.

Another SBA program, the Small Business Investment Company (SBIC) Program, provides comparatively inexpensive capital to SBICs to provide equity capital, long-term loans, and debt-security investments. Essentially, the SBIC Program is a "fund of funds." SBIC funding is only available to a company when its net worth is $18 million or less and its average after-tax net income for the prior two years does not exceed $6 million. All of the company's subsidiaries, parent companies, and affiliates are considered in determining the size standard, and for certain industries alternative size standards may apply. Updated guidance on the SBIC program and changes due to the 2009 American Recovery and Reinvestment Act can be found at www.sba.gov/aboutsba/sbaprograms/inv/index.html.

Chapter 3:
Intellectual Property Considerations

Protecting Your Intellectual Property

For many start-up companies, intellectual property is the lifeblood of their business. Intellectual property can include the ideas, designs, processes, and know-how that make your company's products or services unique, establish your brand identity, and ultimately distinguish your company from your competitors. Therefore, identification and protection of intellectual property is critical for start-up companies in all industries.

The term intellectual property generally refers to patents, trademarks, copyrights, and trade secrets. Patents and trade secrets protect ideas and inventions, trademarks and service marks indicate the source of goods or services, and copyright protection is used to protect original works of authors.

Below is a brief summary of the various forms of intellectual property relevant to start-up companies. All emerging companies need to be concerned with not only protecting their own intellectual property, but also understanding the intellectual property rights of third parties.

Patents and Trade Secrets

A patent grants the owner the right to *exclude others* from making, using, offering for sale, or selling the patented product or process during the term of the patent. The term of a patent begins upon issuance of the patent and ends 20 years from the filing date of the application (or from the earliest application if there is a continuous chain of related applications). An understanding of the distinction between the right to exclude others and the right to use an invention yourself is important as it relates to patent rights of third parties — and that includes your competitors. For example, it is possible to obtain patent protection for a product, yet not be able to use or sell the product because a third party has a patent that is broad enough to cover one or more of the product's features. Thus, that third party can exclude you from using your own patented invention. In such cases, it may be possible to take a license from the third-party patent holder,

but this is less likely when the third-party patent holder is a competitor. In that situation, you may want to "design around" your competitor's patent. A patent attorney can help you assess potential modifications to the product that could reduce the risk of a potential patent infringement claim against you.

In order to be eligible for a patent, an invention must be novel and non-obvious in view of what is already known in the relevant technical field. Before a company applies for a patent, it can be very useful to conduct a prior art search to understand what is already available in the public domain. A patent attorney can help you in searching and analyzing prior art and can provide guidance on the scope of protection that could be obtained. Generally, prior art can consist of printed publications, including trade journals, scientific publications, online disclosures, patents, and published patent applications. Sometimes your own publication can be used against you, so it always is important to think about filing a patent application if you are considering publicly disclosing your invention. Further, in most foreign countries, disclosing your invention before filing a patent application is a complete bar to patentability. After analyzing the search results, your patent attorney can provide you with a patentability opinion so that a decision can be made whether or not to file for a patent.

Preparation of the patent application requires a thorough understanding of the invention, and therefore it is important to retain a patent attorney who has experience in the technical area of the invention. Preparation of patent applications is a time-consuming process. Drafting of a patent application requires careful consideration of not only the technology involved but also the marketing or licensing goals of the company because patent applications are often used by companies to market their technologies to potential investors. It is also important for start-up companies to build a strong patent portfolio. This may require filing multiple applications to cover different aspects of the technology, but it can be an effective tool for deterring competitors. And depending on the nature of the technology and the goals of the company, a decision can be made whether to seek protection in foreign countries as well. This can get quite expensive, however, and therefore a careful evaluation of potential global markets should be conducted.

Inventorship is an often-overlooked aspect of patents, but it is very important — especially for emerging companies, which (given their limited employee structure) often engage outside contractors. It is crucial to have proper assignments executed by all inventors,

employees as well as any outside contractors. A patent attorney can help you in drafting all necessary assignment documents.

The recent America Invents Act (AIA), which went into effect on September 8, 2011, introduced several changes to the U.S. patent system. A key feature of the AIA is a change from the first-to-invent to a first-to-file system. Under the new system, an inventor who files a patent application first will be given priority over another inventor who files second, regardless of who invented it first. Another change under the AIA makes it easier to challenge competitors' patent applications and patents, and conversely for third parties to challenge your patent applications and patents, so it is important to be diligent about filing for protection of your technologies and to monitor competitors' patent portfolios. A patent attorney can provide you more information about these and other changes to the patent system that could impact your business.

Because the process of patenting requires disclosure of the invention to the public, companies may sometimes wish to protect a particular idea or process as a trade secret rather than patent it. This option has recently become more attractive because another provision of the AIA extends prior user rights to all areas of technology. To keep an idea or process as a trade secret, certain steps need to be taken within the company. The legal requirements that determine whether a trade secret exists and has been properly protected vary from state to state. Generally, substantive efforts must be made to ensure the trade secret is kept confidential, and only those who need to know are permitted access to the details of the trade secret. An intellectual property attorney can help you decide whether to patent a technology or keep it as a trade secret and can also guide you through the requirements for properly safeguarding the trade secret.

Trademarks

Establishing brand recognition — and protecting the trademarks or service marks associated with it — can be a critical component of success for any emerging company. Protecting these marks means protecting the goodwill and quality that your clients and customers associate with your brand. This is crucial for establishing and maintaining brand loyalty.

Trademarks and service marks identify the source of goods or services provided by your company. In its simplest form, a trademark or service mark is a word, phrase, design, or the like. Before selecting a mark and

embarking on a new branding campaign, a determination should be made whether that mark or a mark similar to it is already being used by another company for similar goods or services. Your intellectual property attorney can assist with obtaining and evaluating a search that will identify potentially problematic marks that are registered or have acquired trademark status simply by virtue of another party's ongoing use of the mark.

While a trademark or service mark does not have to be registered to enjoy the full protection afforded by U.S. trademark law, for those marks being used in interstate commerce (or for marks for which you have a bona fide intent to use in interstate commerce), it is advisable to file for a federal trademark registration, and to do so as soon as practically possible.

Copyrights

In the age of digital media, where unauthorized reproduction and distribution of original and creative works is rampant, it is important for an emerging company to take steps to secure copyright protection for a multitude of assets, including software programs, website content, advertising materials, images, catalogs, and more.

Ownership of copyright is not always easy to determine. For example, it is frequently the case that your company itself will be considered the legal "author" and therefore the owner of works made by your employees. However, without the proper agreements in place, works of authorship, such as software, that are created for your company by third parties — and that your company pays for — are nevertheless not owned by your company. Your intellectual property attorney can help you determine copyright authorship and ownership, prepare the necessary agreements, and file for copyright protection.

Depending on the work in question, copyright protection can be one of the most valuable forms of intellectual property protection. It is also generally the least expensive to acquire, and it can protect assets for which patents and trademarks are not available, although copyright protection can overlap with some aspects of patent and trademark protection. Obtaining a federal copyright registration is a relatively simple and inexpensive process (especially compared to patent prosecution), and it entitles the copyright holder to a unique level of protection in the form of penalties to infringers. For example, whereas patent and trademark infringement suits require proving harm to the business (e.g., loss of sales) in order to obtain damages, it is not

necessary to prove such harm when a federally registered copyright is involved. This threat of stiff penalties can be a strong deterrent to competitors who may be considering copying your work. Given this advantage and the relatively low cost, there is almost no reason for an emerging company not to seek federal copyright protection for a variety of routinely produced work, such as website content, advertising materials, instructional manuals, product photographs and catalogs, and the like.

Intellectual Property Agreements

When the time comes to take on a strategic partner, or in- or out-license rights to valuable intellectual property, agreements or licenses may be used to help you achieve your objectives. These are legal contracts that need careful drafting to detail the obligations and actions of all parties. Before entering into any such agreement, an analysis of the legal and business aspects of a potential business relationship should be undertaken. Following this initial assessment, your attorney can negotiate and prepare all forms of agreements related to intellectual property matters. See Chapter 5 of this handbook for more information on this topic.

Respecting the Intellectual Property of Others

Emerging companies need to be concerned with not only protecting their own intellectual property, but also understanding and navigating around the intellectual property of others.

It is a good idea for companies in many competitive industries, especially those in high-technology fields, to obtain a freedom-to-operate opinion (or FTO opinion) from your patent attorney before deciding to introduce a new product or service into the marketplace. An FTO opinion can provide you with an analysis of the patent landscape in a particular area to help you make a sound business decision and avoid incurring potential risk. Additionally, an unfavorable FTO opinion can be an inspiration for new product development in the form of design-arounds, which themselves may be eligible for patent protection.

Another area in which knowing and respecting others' intellectual property can prove critical is in choosing a business name. Thorough research is necessary to make sure a potential name is not already in use by another business. Companies often learn the hard way that, for example, even though a new corporate name may not be registered at the federal level in the form of a registered trademark, it may be

protected at the state level (e.g., in New York or Delaware). Additionally, many names that do not necessarily have federal trademark registrations have acquired trademark rights via their use in commerce. A proper search can reveal these instances and protect against the often-expensive consequences of doing business under a name or logo already owned by another party.

Chapter 4:
Navigating FDA and Other Regulations for Life Sciences Companies

For emerging companies in the biomedical and life sciences industry, getting off the ground requires meeting and overcoming an additional set of challenges: the complex and ever-evolving regulations put forth by the U.S. Food and Drug Administration (FDA) and other U.S. federal and state government agencies.

The biomedical and life sciences industry is a highly regulated field — one that seems to get even more so every day — and companies that do not develop and implement a regulatory strategy early on have the potential to incur significant loss of time, resources, and capital. Some argue that there is so much inherent risk in developing pharmaceuticals and medical devices, a regulatory strategy should actually be the primary driver in the development and marketing processes.

This chapter will provide an overview of the FDA, key concepts, regulatory benchmarks, and other issues critical for companies as they seek to obtain FDA approval for their products and ensure the ability to maintain ongoing compliance after entering the market.

The FDA: An Overview

Keep in mind that the FDA's primary goal is the protection of the public health. Therefore, the scope of its reach is extremely broad. The FDA holds regulatory authority over a wide range of products and services, including small-molecule drugs, biologics, medical devices, orphan drugs, in vitro diagnostics, clinical laboratories, dietary supplements, over-the-counter (OTC) drugs, and generic drugs.

Some emerging companies make the mistake of believing they will not be held to the same standards as large pharmaceutical or medical device companies. That is *not* the case. In short, if your company is involved in this industry, it is crucial that you understand how the FDA works and begin to develop a good relationship with this agency as

early as possible. The FDA is a large and influential government agency and the power differential is often overwhelming to emerging companies. Working with legal counsel experienced in interacting with the FDA can save time and money.

The FDA is organized into five program centers organized by the products or services they oversee:

- Center for Biologics Evaluation and Research (CBER): products derived from human, plant, animal, or micro-organism sources
- Center for Drug Evaluation and Research (CDER): safety and effectiveness of prescription, OTC, and generic drugs
- Center for Devices and Radiological Health (CDRH): safety and effectiveness of medical devices (including diagnostic products); protection of consumers from radiation
    - Office of In Vitro Diagnostics (OVID): all aspects of in-home or laboratory diagnostic tests; administers the Clinical Laboratory Improvement Amendments (CLIA) for the Centers of Medicare and Medicaid Services (CMS) (Note: CMS is a separate federal agency from the FDA)
- Center for Food Safety and Applied Nutrition (CFSAN): domestic and foreign food supply *except* meat, poultry, and some egg products (which are regulated by the USDA); also regulates cosmetics
- Center for Veterinary Medicine (CVM): safety and effectiveness of animal drugs, food additives, feed ingredients, and animal devices

Three additional areas over which the FDA has authority are: combination products (e.g., drug eluding stents), dietary supplements, and human subject protections (all clinical trials and institutional review boards).

Getting to Market …

The path of any new biomedical or life sciences product – from initial discovery through development and on to commercialization of the finished product – can be divided into three distinct phases:

Product Category	Discovery	Development	Commercialization
Drugs/biologics	Find leads; predict toxicity; evaluate market opportunities	Refine leads; evaluate safety and effectiveness; manufacture test batches	Define scale of manufacturing; manufacture with GMPs*; market, distribute, and sell product
Devices/ diagnostics	Innovation; feasibility assessments	Refinement; predicate assessment; evaluate safety and effectiveness	Manufacture with GMPs; market, distribute, and sell product
Food	Identify ingredients; evaluate potential claims	Evaluate safety; refine labeling and claims	Manufacture with GMPs; market, distribute, and sell product
Regulatory Steps	**Decision to proceed? Categorization**	**Pre-market evaluation and approval submissions**	**Import/export compliance; ongoing compliance**

* GMPs: good manufacturing practices (discussed later in this chapter)

Product Classification and Approval

Early and appropriate product classification – usually at the early end of the development phase – is essential to a viable regulatory strategy and smooth market entry. Each product category implicates a different process for classification and approval and involves differing regulatory requirements and timeframes. The requirements include:

- Drugs: must be shown to be safe and effective for labeled conditions
    - New drugs: must prove this through human clinical trials
    - Generic drugs: must prove bio-similarity to approved reference listed drugs
    - OTC drugs: must meet requirements for safety and effectiveness in their OTC monograph class
- Medical devices: must be either substantially equivalent to marketed devices or be shown to be safe and effective through clinical evaluation

- Food ingredients: must be generally recognized as safe (GRASE) or approved as safe
- Combination products: Innovative technologies often do not fit neatly into an existing FDA product category. Combination products must first establish which regulatory authority will be primary (will it be a drug with device characteristics or a device with drug characteristics?) through petition to the FDA. Typically approval steps are a hybrid application developed in conjunction with the FDA Office of Combination Products (OCP).

Key Regulatory Approval Benchmarks

For each new drug or medical device, the company must complete the appropriate marketing application and submit it to the FDA for approval before introduction of the product into commerce. Below are the basic approvals you are likely to encounter, along with basic criteria required for FDA authorization to market your product.

Drugs

- Investigational New Drug (IND): Does the drug pose reasonable risk to humans in a clinical study? FDA approval to begin clinical trial and regular consultation with the FDA throughout the safety and effectiveness evaluation.
- New Drug Application (NDA): Is the drug safe and effective for the indications on its label? Based upon information gathered under the IND and includes detailed information on commercial manufacturing.
- Abbreviated New Drug Application (ANDA): Is the drug the bioequivalent to a drug already on the market? Requires evaluation of reference listed drugs and patent/exclusivity issues. Significant potential for patent litigation.
- Over-the-counter drugs: Does the product fit within the specific requirements in the regulatory category? If so, it can go to market and be sold without a prescription. However, the assessment of the applicable regulatory requirements (in a document called a "monograph") can be a fairly complex process and may require reformulation of proposed products.

Devices

- Investigational Device Exemption (IDE): Is it reasonably safe to use a significant-risk medical device on human subjects? Following a determination by an IRB on whether the device is "significant-risk," this application includes clinical trial protocols.
- Pre-Market Notification (510(k)): Is the device substantially equivalent to a device already on the market? Requires identification of available predicate devices and accurate regulatory categorization.
- Pre-Market Approval (PMA): Is the device safe and effective for labeled use and indications? Based on information gathered under the IDE and includes detailed information on commercial manufacturing.
- Diagnostics, as medical devices, are subject to the IDE, 510(k), and PMA requirements. However, in vitro diagnostics also go through a pre-IDE process of consultation with the FDA prior to submission of marketing applications (even if ultimately an IDE is not required).

Food and Dietary Supplements

- Food ingredients must be safe before being placed on the market. This is accomplished either through the use of GRASE ingredients or by using ingredients that have been approved as safe by the FDA.
- Bioengineered foods are regulated by FDA, USDA (APHIS), and the EPA (if pesticides are used). A formal consultation with the FDA and appropriate permits from the USDA are necessary to introduce into the U.S. market.
- Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with the FDA nor get FDA approval before producing or selling dietary supplements.

Assessing Reimbursement Options

The system for reimbursement of biomedical and life science products in the United States is a complicated matrix of government payers, private insurance, and cash payment. The landscape for reimbursement is rapidly changing and may be significantly reshaped in the next few years. Recent government mandates for comparative research may impact your ability to obtain government or private insurance coverage for your products. Coverage by payers (and often cash-paying consumers) is driven by documented evidence of improved outcomes, clinical efficiency, and cost effectiveness. Companies should anticipate the need to gather this data to support requests for reimbursement coverage and build appropriate endpoints into any clinical trial or comparative effectiveness studies conducted as part of the regulatory approval process.

The possibilities for product reimbursement should be considered early on in the development phase. FDA approval or marketing authorization does *not* directly correspond to government or private insurance coverage. Generally, an FDA-approved product will be eligible for government or private insurance reimbursement, but such FDA approval does not guarantee coverage. Depending on the market for your product, failure to obtain placement on a Medicare, Medicaid, or private insurance formulary could mean the difference between success and failure for your company.

Medicare and Medicaid reimbursement regulations are complex and tend to vary significantly state to state. Distinctions between hospital inpatient, outpatient clinic or physician office, physician administered, and home use of products can implicate extremely different reimbursement possibilities. Since obtaining a reimbursement "code" for biomedical products can be time consuming, companies should prepare a reimbursement strategy early and pursue reimbursement options simultaneously with FDA evaluations and submissions. Obtaining reimbursement involves working with health care specialty societies, industry organizations, recognized code-setting organizations, and directly with the government and private insurer representatives.

Companies should also be aware of the reimbursement implications of using unapproved products in clinical trials. The facilities and health care practitioners that assist emerging companies with safety, effectiveness, and comparative research may not be eligible to receive government or private insurance reimbursement for using your

unapproved product. This can make clinical trials more expensive for industry sponsors and can impact the willingness of health care providers to participate in evidence-gathering studies.

… And Surviving the Market

Getting a product approved for marketing and distribution is only half the battle. Life sciences companies must continue to comply with an immense number of standards and regulations in order to keep a product on the market — and stay in business.

Current Good Manufacturing Practices and Quality System Compliance

First, drug and medical device manufacturers must meet certain government-defined standards for quality in manufacturing of the product. These standards are known as current good manufacturing practices (cGMP), and they outline the production conditions that could adversely affect a product's quality or alter its nature. Quality system (QS) is the mechanism to achieve cGMP for medical devices. Both cGMP and QS are critical in product development and are major factors in obtaining — and keeping — FDA approval.

Compliance with these standards is critical because they serve as the primary basis for FDA inspections and compliance enforcement. Any product not manufactured in compliance with cGMP is deemed adulterated and could be subject to FDA enforcement. Product changes are monitored and documented by the FDA. Additionally, these standards constantly change because they represent not only customary or state-of-the-art practices used in the industry, but also interpretations of these standards by the courts. Therefore, it is crucial to stay on top of industry and legal developments in this area.

Post-Market Adverse Event/Risk Reporting and Corrective Action Requirements

When an adverse event occurs — that is, when consumers of a product experience an unexpected and negative reaction — the manufacturer is required to report the adverse event to the FDA. Failure to report adverse events can be the basis of a fraud investigation. In some instances, adverse events that occur outside the United States must also be reported to the FDA if the product is marketed in the United States.

Following an adverse event, the company should evaluate whether a formal regulatory report is indicated and conduct root causes analyses to determine the role the product played in the adverse event. Different post-market risk reporting requirements apply to each product category, but in most cases, formal reporting must be done quickly and accurately. Because many adverse event reports are public documents, the narrative of each report should be reviewed by an attorney experienced in product liability litigation *before* it is filed. Doing this will help minimize the risk of exposure to litigation.

Next, the company must decide what corrective action to take to correct the problem noted in the adverse event report and appease the FDA. Corrective actions may involve a product recall, which requires careful coordination with all customers, distributors, and both federal and state authorities to ensure an effective recall and protect the public health.

Marketing and Labeling Issues

Product labeling is another area of concern for drug and medical device manufacturers. In the eyes of the FDA, "product labeling" includes not only labels that appear on the product, but also marketing materials such as Web sites, promotional materials, and all statements made by salespeople associated with the sale of the product. The FDA monitors marketing claims, so it is important that the disease or symptoms mentioned in product labeling are limited to the scope of the approval received from the FDA. Labeling claims can also change the product category — for example, transforming a dietary supplement into a drug product. Additionally, post-approval changes to labeling may implicate additional approvals or submission updates.

There are many business risks life sciences companies should be aware of in connection with product labeling. "Off-label" promotion, or promoting the product for uses not approved or allowed by the FDA, is prohibited and can cause the company to incur serious risk. Recent off-label enforcement actions have resulted in multi-million-dollar settlements that can cripple a company. Emerging companies should work closely with counsel to ensure that labeling and advertising strategies are appropriate for the U.S. market. Competitor complaints are another significant area of risk for companies, as trade complaints often spark FDA investigations. Companies also face risk in the form of regulatory violations as well as exposure to product liability risk in all 50 states.

To comply with FDA labeling guidelines, product labels should (among other requirements) include the name and location of the manufacturer, should be in English, and cannot contain false or misleading statements. Additionally, all claims made on the label must be substantiated and companies must obtain regulatory approval of physical labeling content for certain products (PMA devices, prescription and OTC drugs, and certain health claims for food). Remember that how the product will be promoted and used determines its success in the marketplace, so it is a good idea to *begin* the regulatory approval process (as early as design of clinical trial protocols) with the *end* labeling in mind.

FDA Investigations and Enforcement

An investigation or enforcement action by the FDA can have many negative effects on your company, including a disruption in business, a decrease in investor confidence, and damage to your company's reputation with the FDA. If the FDA spots what it deems to be deficiencies (often involving compliance with GMP or QS standards) as the result of a scheduled or surprise inspection, it may issue your company an "untitled letter" or a warning letter, institute a product recall or seizure, impose a civil fine, or even refer the case to the Department of Justice for a criminal investigation.

Companies should always keep an eye out for potential enforcement issues, even in the early stages of establishing a U.S. market presence. There are three areas the FDA is currently focusing its enforcement efforts on: biomedical and life science industry relationships with physicians (research funding, sponsorship of CME programs, and marketing practices); off-label marketing of products (particularly when government health care programs such as Medicare and Medicaid provide product reimbursement); and post-market reporting requirements for safety risks and adverse events. Violations in these key areas can be the basis of an FDA enforcement action and/or a federal or state lawsuit involving the False Claims Act, the primary law concerning fraud against the government. The False Claims Act is a powerful enforcement tool that applies if it is deemed the accused company's activity "caused" a health care provider to submit a claim where an illegal financial relationship existed or where fraud was involved. Cases involving the False Claims Act can result in the assessment of both civil and criminal penalties, as well as treble damages.

Other Regulatory Agencies and Issues

Biomedical and life sciences companies also face compliance requirements from other regulatory agencies, including the Federal Trade Commission (FTC), U.S. Department of Agriculture (USDA), Customs and Border Protection (CBP), and Consumer Product Safety Commission (CPSC), as well as broad federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA) and the Anti-Kickback Statute.

The FTC

The primary jurisdiction of the FTC, as it relates to the biomedical and life science industry, is oversight of OTC drug and non-restricted medical device advertising. The FDA's broad interpretation of "labeling" causes it to interact with the FTC's "advertising" jurisdiction. FTC rules prohibit "unfair or deceptive acts or practices" and misleading claims in product labeling, and all advertising must be truthful, fair, and substantiated.

The USDA

The USDA jurisdiction is complementary to the FDA's CFSAN. The USDA has primary authority over meat, poultry, and some egg products. Two primary offices within USDA that life science companies may interact with are the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS). FDA and FSIS share the authority for ensuring the safety of the U.S. food supply and therefore coordinate on import of food products (including dietary supplements) and inspections and enforcement activities aimed at food manufacturing facilities. APHIS oversees the permit process for importing certain food products into the United States. And products containing alcohol are regulated by a separate agency – the Department of Justice Bureau of Alcohol, Tobacco, Firearms, and Explosives.

The CBP

CBP coordinates closely with FDA to review all biologics, cosmetics, medical devices, and electronic products that emit radiation that are offered for import into the United States. In fact, the FDA maintains special teams that have offices at border crossings and take primary responsibility for the regulatory review of products referred by CBP. Emerging companies should consider carefully the interaction of FDA with CBP and monitor FDA Import Alerts and border actions.

The CPSC

While FDA regulates a large portion of the products that consumers purchase, the agency has no jurisdiction over many household goods. The Consumer Product Safety Commission (CPSC) is responsible for ensuring the safety of consumer goods such as household appliances (excluding those that emit radiation), paint, child-resistant packages, and baby toys.

The HIPAA Privacy Rule

The HIPAA Privacy Rule requires privacy and security protections to be applied to identifiable personal data. HIPAA compliance is required not only by direct health care providers, but also by companies that interact with health care providers (called "business associates"). Many biomedical and life science companies are considered to be business associates and may need to establish specific policies and procedures to ensure that protected identifiable data is not improperly disclosed or misused. Emerging companies should be aware that many states also have their own requirements for protecting a person's health information that can be more restrictive than the protections required by HIPAA.

Anti-Kickback Statute

The Medicare and Medicaid Patient Protection Act of 1987, better known as the Anti-Kickback Statute, is designed to prevent abusive business arrangements between life sciences companies and physicians that may result in increased cost to government programs, overutilization of health care items, a decrease in the quality of care for beneficiaries, limits on patients' freedom of choice, or restriction of fair competition.

The Anti-Kickback Statute prohibits "knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce, or in return for, purchasing or ordering of items or services for which payment will

be made in whole or in part under federal health care programs." This includes any type of remuneration — indirect or direct, overt or covert, cash or in kind — to a physician in return for referring an individual or for recommending or arranging for purchase, lease, or ordering items or services paid for, in whole or in part, by a federal health care program. Violations of this statute may result in civil monetary penalties, criminal penalties including felony charges, and exclusion from federal health care programs. Biomedical and life science companies should carefully evaluate these risks when interacting with health care practitioners in the United States.

Chapter 5:
Licenses and Other Commercial Relationships

Licenses, joint ventures, collaboration agreements, research and development arrangements, and virtually all other commercial relationships define success by the value they bring to the parties involved in the transaction. Value, however, is incredibly difficult to define. Ask a business person, an engineer, and a lawyer from the same company what the value of a particular transaction is and you will be likely to receive three different answers. Why? Value is subjective and depends on your position in the transaction.

All commercial relationships and transactions involve three intertwined domains: (1) the business domain; (2) the technology, services, and/or product domain; and (3) the legal domain. Each of the three domains has a greater or lesser role depending on the specific commercial relationship or transaction. Sometimes it is clear which will take the starring role. Other times, it is not so obvious which domain is most critical and which domain is playing a supporting position. In each case, however, all of the domains need to be carefully thought through and precisely blended to ensure the transaction's objectives are being met.

Begin each transaction and business relationship with a simple exercise involving the handful of topics listed below. This exercise will help you understand your own perspectives and motivations, the technology and products/services, and the legal domains, as well as the other party's perspective. Clarity will allow the relationship's structure to evolve naturally. Failure to do your due diligence here will result in not achieving optimal value, and could even result in failure or legal troubles.

Consider the following five key points in analyzing all of your transactions:

1. *Know what success looks like and what the road will be to get there.* It is not uncommon for parties to spend the bulk of their business negotiations discussing and defining pricing, functionality, specifications, and license particulars, such as

exclusive territories. These issues are naturally critical. It is equally important, however, to clearly define appropriate checkpoints, milestones, service levels, audits, and ongoing relationship governance. Ensure that all parties are in lockstep.

2. *Know who presently owns what, and whether such ownership is to be adjusted during or at the end of the engagement.* Understand what you own going into the relationship, and memorialize what you expect to own throughout and at the end. Document which party owns intermediate work products. Determine and assign all of the intellectual property rights in a manner that makes sense in view of your intellectual property objectives. You also need to ensure the obligations your customers have placed on you regarding your delivery of end products and services and the intellectual property rights therein map accordingly to your individual commercial relationship agreements.

3. *Know what your risks are, and know your business partners' risks, too.* Negotiate with your customers, service providers, and vendors for certain rights in the event your circumstances unexpectedly change, such as if there is a failure to obtain appropriate regulatory and governmental clearances (for example, FDA or other approval or security clearances), a cancellation or reduction of ordered goods or services, a stoppage of payment, or going out of business. Some form of a disaster recovery and business continuity plan should be considered for nearly every commercial relationship and may be a deal-stopper in others. Plan in advance for the situation where your customers, service providers, or vendors become incapable of providing or receiving goods or services. Account early on in the relationship for rough times by allowing sourcing directly from other vendors, priority when capacity or resources are limited, or access to the technology others own or license.

4. *Know where the exit points in the relationship are.* While it is well understood that no one likes to discuss difficult issues and that businesses just want to streamline the paperwork to get the deal done, nothing lasts forever, and sometimes you need to get out of a relationship. Agreements always provide termination rights in the event of a breach of the agreement by the other party, which sounds great. Most agreements, however, are heavy on near-worthless legal representations and warranties (and disclaimers thereof) and almost always silent on the business and technology

terms that are critical for success. It is difficult to assert a customer, service provider, or vendor is in breach of an agreement when they are missing deadlines or delivering inferior products or services when the agreement is silent or unclear on such points. Accordingly, one needs to discuss and document critical items. Define when a series of minor headaches turns into a full-blown migraine and what your remedies are.

5. *Know what the exit strategy is.* Agree up front on what the unwinding of the engagement will look like. Is it possible to make a clean break, or are there ongoing obligations, such as a need for continued access to data, payments for royalties, inventory sell off, transition services to a third party, and knowledge transfer? How long will one party provide the items previously mentioned, and under what terms? It is always easier to agree on the exit strategy at the beginning of the relationship when everyone is friendly than at the end when there is a good chance one of the parties will be less than accommodating.

Build Accordingly

Structure the relationship and underlying contract for success by employing all three domains — the commercial, the technology and services, and the legal — in the right proportions in view of what is important to the transaction. Build an agreement with a framework flexible enough to provide everyone the ability to adapt as situations require, but rigid enough to ensure important obligations are continuously met. Structuring agreements with the business, technology and services, and legal domains in the proper proportions will give you the best chance of succeeding with all of your commercial relationships.

Industry-Specific Complications

Emerging companies should also consider any industry-specific restrictions on their business relationships. Some examples of restrictions that can complicate licenses, manufacturing agreements, and arrangements for research and distribution in the life science industry include:

- The Anti-Kickback Statute restrictions on industry-physician relationships within the United States
- Export contracts (on technology and products)
- The Foreign Corrupt Practice Act restrictions on interactions between certain public companies and foreign government officials (including government-owned hospitals, clinical trial approval agencies, national health insurance boards, customs officials, and patent agencies), which can impose significant impediments to international interactions
- Manufacturing supplier and purchasing controls imposed on medical device and drug companies that can impact the structure of contractual relationships
- Regulatory definitions specifying ownership of regulatory approvals (NDAs, 510(k)s, etc.) and restrictions on the transfer of regulatory approvals
- Data privacy and security requirements, including HIPAA, the EU Data Protection Directive, and numerous state law requirements imposing specific privacy and security protections on personal data (such as that collected in clinical trials or maintained to comply with post-market reporting requirements)

Emerging companies should evaluate the restrictions applicable to their industry that could similarly impact effective and profitable business relationships.

Open Source Software

For emerging companies in almost any field, but especially software and internet companies, the use of open source software (OSS) is common due to OSS's perceived low cost. OSS is functionally just like traditional software—there are open source word processing programs (like that of OpenOffice.org), web browsers (like Mozilla Firefox and WebKit), and computer operating systems (like Linux and Mac OS X). There are important differences, however, in the way OSS is licensed. While there are almost 70 OSS licenses tracked by the Open Source Initiative, the licenses generally meet the following criteria:

1. *Free redistribution*. The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale.

2. *Source code*. The program must include source code and must allow distribution in source code as well as in compiled form. Where some form of a product is not distributed with source code, there must be a well-publicized means of obtaining the source code for no more than a reasonable reproduction cost, preferably by downloading it from the Internet without charge. The source code must be the preferred form in which a programmer would modify the program. Deliberately obfuscated source code is not allowed. Intermediate forms such as the output of a preprocessor or translator are not allowed.

3. *Derived works*. The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software.

4. *Integrity of the author's source code*. The license may restrict source code from being distributed in modified form only if the license allows the distribution of "patch files" with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software.

5. *No discrimination against persons or groups*. The license must not discriminate against anyone or any group of people.

6. *No discrimination against fields of endeavor*. The license must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research.

7. *Distribution of license*. The rights attached to the program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties.

8. *License must not be specific to a product*. The rights attached to the program must not depend on the program being part of a particular software distribution. If the program is extracted from that distribution and used or distributed within the terms of the program's license, all parties to whom the program is redistributed should have the same rights as those that are granted in conjunction with the original software distribution.

9. *License must not restrict other software*. The license must not place restrictions on other software that is distributed with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open source software.

10. *License must be technology neutral*. No provision of the license may be predicated on any individual technology or style of interface.

Source: Open Source Initiative, http://opensource.org/docs/osd

OSS is popular with emerging companies because it is generally free to use. Software and Internet companies also take advantage of the ability to modify OSS and/or incorporate the software into larger projects.

In the past, attorneys counseled their clients against any use of OSS. This advice was based on the "viral" nature of OSS. In particular, under clause three of the above OSS definition, any derivative works must be distributed under the same license terms as the original work. In other words, once software is open source, it is always open source, and products into which an emerging company has incorporated the software will also be open source. This can limit the commercial value of those products.

Additionally, certain OSS licenses further restrict the rights of developers who create derivative works from software. For example, version 3 of the GNU General Public License requires software developers to license certain of their patent rights along with any derivative works.

In more recent years, new OSS licenses have come into use that impose fewer restrictions on software developers. For example, Creative Commons has created several licenses that are much less restrictive, although they may not technically fall under the Open Source Initiative's definition of open source. In fact, some licenses are primarily concerned with providing attribution of the original author.

Because of these recent developments, the previous dogmatic approach to counseling away from the use of any open source products is not always the best approach. The best advice related to open source licenses is to know what you are getting into. Read the licenses of any software you would like to use, and understand the terms under which you can (1) use the software and (2) develop and distribute derivative works. If the terms do not fit with your company's business model, look for alternative software or develop the software in-house. If the terms are compatible with your business model, congratulations—you have probably saved considerable time and money.

Chapter 6:
Minimizing Product Liability Risk

Liability Risks

One of the most important things a start-up company can do to protect its future is to take early steps to minimize liability risks. The technology and products produced by emerging and well-established companies alike — especially those in highly regulated industries like life science — necessarily expose those companies to product liability lawsuits. While every product is unique and should be specifically discussed with counsel, there are some general steps that all companies should take to protect themselves from future lawsuits.

Product Development and Testing

During the development phase of a product, a company should seek to identify any potential risks that the product may pose to persons or property. To the extent possible, the company should seek to eliminate any foreseeable risks. If the risks are inevitable — i.e., inherent to the product — the company should determine whether the benefits of the product outweigh the risks. If the answer is affirmative, then the company must consider ways to protect itself from liability such as contracts, warranties, or insurance.

Before a company embarks on product testing, it should assess the potential risks associated with the testing and make a determination as to whether insurance would be an appropriate way to insulate the company during the testing phase. The types of insurance available will vary depending on the type of testing, the product, and the location of the product development and testing. Regardless, counsel can assist you in locating the appropriate insurance broker to assist the company in evaluating the insurance possibilities.

In the early stages of design and product testing, all testing should be well documented. Any unfavorable results should be discussed immediately with counsel. Failure to rectify the problem could provide unwanted and unnecessary ammunition against the company in any future product liability lawsuits.

In addition, where the product is being tested in a clinical trial, participants must be informed that the product is in the trial stages and should be required to sign a release. Careful attention should also be paid to appropriate screening of all participants. As discussed in Chapter 4, it is imperative that companies comply with all regulations governing their studies and testing.

Suppliers, Manufacturers, and Distributors

Once a product is ready for production, the company will begin to rely heavily on certain suppliers, manufacturers, and distributors. The production process presents an entirely new set of risks. First and foremost, you should treat the supplier, manufacturer, and distributor selection process as though it is a rigorous interview. You will want to determine each company's history including their safety and quality control, what type of insurance coverage each company provides, and what the company's indemnification requirements are.

You may also want to consider the location of each supplier, manufacturer, and distributor, since some countries make it nearly impossible to legally reach their companies should a dispute arise between you and your supplier, manufacturer, or distributor.

Finally, once you have selected your supplier, manufacturer, and distributor, you should seek assistance from counsel in obtaining and entering into a legally binding agreement. For example, you may want an agreement that requires your supplier to provide only materials of a certain quality or grade. You may also wish to require your manufacturer to conduct quality control testing and to indemnify you for any manufacturing defects. Likewise, your distributor may want you to agree to indemnify it against any future lawsuits. These agreements can help put your company in a favorable position and can assist in minimizing any risks arising out of these relationships.

Continued Risk Management

Once your company's product is ready for public use, it is critical that you continue to minimize day-to-day risk by: (1) reviewing all packaging, labeling, and instruction materials, (2) ensuring continued FDA or other regulatory compliance, and (3) maintaining appropriate insurance.

One basis for product liability suits is a failure to warn. These suits are based on the product's labeling, manuals, and packaging. In the United States, warnings must be prominently displayed and easy to

understand. Individual states also have state-specific labeling requirements. For example, California requires that any product that may come into contact with a person's mouth or otherwise be ingested must contain a specialized warning if it contains any of the chemicals listed in California's Proposition 65 list. Since labeling requirements can be incredibly specialized, all labels, warnings, manuals, or any other literature relating to the product should be reviewed by counsel prior to production.

For products that fall within the jurisdiction of the FDA or another regulatory body, it is imperative that the company continue to comply with the appropriate regulations. Failure to do so can result in significant fines or in your product being pulled from the market. Counsel can assist you in ensuring that all regulations are being followed.

Finally, we return to a very important topic – insurance. Once a product is being sold in the marketplace, it is imperative for a company to maintain insurance. Product liability suits can result in multi-million-dollar verdicts and settlements. In addition, each suit may cost anywhere from $50,000 to several hundreds of thousands of dollars to defend. Most start-up companies, even the most successful ones, cannot absorb these types of costs. It is therefore important to obtain affordable insurance that will help the company cover these costs if a suit should arise.

Chapter 7:
Handling Employment, Immigration, and Benefits Issues

Small or emerging businesses often make the mistake of believing they do not need to concern themselves with many legal aspects of the employment relationship, especially when friendships or family relations help constitute the bond between an employer and its employees. For example, it is a common assumption that only larger companies have to deal with issues such as avoiding wrongful termination suits, implementing anti-discrimination policies, and the reporting and disclosure requirements of various benefits programs.

However, that is not the case. No matter the size of your company, it is critical to establish and maintain a work environment and benefits programs that comply with all applicable federal and state laws and regulations. Working closely with your employment and benefits counsel to take proactive steps in these areas early on not only can help your company avoid potential risks and pitfalls at the outset – it also can play a significant role in helping you attract, hire, and retain the workforce your company needs to succeed.

Employment Law Basics

Navigating the myriad state and federal laws protecting employees is treacherous for even the most established employer. Companies hiring their first employees may not be aware of the risks that could befall the unwary – with regard to hiring, firing, managing, and paying employees, and also with regard to retaining independent contractors.

All employers, no matter how small, must comply with state and federal fair pay, minimum wage, and overtime laws. This may not be as easy as it sounds. Many employers often assume – incorrectly – that their employees who are compensated on a salary basis need not be paid overtime. For example, despite a scientific background, some research personnel may be "non-exempt" under the Fair Labor Standards Act, and therefore entitled to overtime.

All employers must also take care to ensure compliance with state workers' compensation and disability insurance requirements, as well as the proper withholding and remittance of employment taxes. New employers are likely to be subjected to audits conducted by state and federal officials in connection with any of these issues.

Moreover, even relatively small employers are charged with ensuring that all employment decisions are made without regard to applicants' or employees' race, religion, gender, age, disability status, military status, genetic characteristics, or membership in any other protected class. Even frivolous complaints of discrimination can be costly to defend, and employers are well advised to implement policies and practices to best avoid, and then defend against, these types of claims. Not to be forgotten are state and federal laws requiring employers to provide periods of unpaid leave for certain medical conditions, and to accommodate individuals with disabilities.

Finally, it can be tempting for a small company to hire independent contractors in an effort to avoid all these employment-related obligations and liabilities. This is not so easy, however. State and federal laws have their own standards for determining who is and who is not an independent contractor. Misclassification findings against a company can result in the imposition of back taxes and sizeable penalties.

Of course, the above is only a very basic overview of the employment law issues emerging companies may face. Be sure to discuss your company's specific circumstances and needs with counsel.

Immigration

The success of a company is wholly dependent on the strength of its employees. To this end, it may be necessary to employ foreign talent in order to achieve a company's short- and long-term goals. Your U.S. immigration counsel can work with you to secure work permits to legally employ foreign nationals you wish to hire.

Employment Visas

Whether you are a research and development company in need of an engineer, a biomedical company in need of a scientist, or a software development company in need of a systems analyst, your immigration counsel can help you obtain work authorization for the most talented workers from anywhere around the world.

The following temporary categories are often used by persons entering the United States for business purposes or to pursue temporary employment in the United States:

- B-1: visitor
- E-1/E-2: investor
- H-1B: professional/specialty occupation
- L-1: intracompany transferee
- O-1: extraordinary ability
- TN: professional worker (NAFTA)

Your immigration counsel should have extensive experience in obtaining visas in all of these categories in order to effectuate a smooth and timely adjudication process for you and your employees.

Permanent Resident Status

Your company may want to sponsor an employee for permanent resident status (also known as obtaining a "green card"). With certain exceptions, there are three steps involved in becoming a permanent resident under employment-based immigration procedures: (1) labor certification; (2) approval of an employment-based petition with United States Citizenship and Immigration Services; and (3) approval of applications for permanent residence by the employee and his or her spouse and any children under the age of 21.

It is important to note that there are certain employment-based immigration classifications that are exempt from labor certification, including classifications for intracompany managers or executives, persons of extraordinary ability, and outstanding researchers and professors. Persons with advanced degrees or who are of exceptional ability, and whose work in the United States benefits the country's national interest, are also exempt from labor certification.

Employee Benefits

One of the first things a prospective employee will ask about is the benefits program your company offers. What type of medical coverage will you offer? How long must employees work at your company before they are eligible to participate in your benefits program? What other fringe benefits do you offer to make your company a more attractive place to work? Even at a start-up point, it may be important to have a medical plan and some arrangement for tax-advantaged retirement savings.

A well-designed employee benefits program is essential to attracting and nurturing the talent that will make your company successful. The basic components of a benefits program include welfare benefit plans, a retirement plan, and other deferred-compensation or incentive compensation arrangements.

Your benefits counsel can work with you to evaluate proposals from brokers, financial institutions, and insurance companies, and give you objective advice in establishing a program that complies with applicable federal and state laws and complements your business's unique needs, goals, and resources.

Welfare Benefit Plans

There are a wide variety of welfare and fringe benefit options that are promoted and sold by brokers and consultants. Your benefits counsel can help you keep it simple and meet your objectives in choosing among:

- Group health and dental plans for active employees and retirees
- Health savings accounts (HSAs), flexible spending accounts (FSAs), and health reimbursement arrangements (HRAs)
- Cafeteria or flexible benefits plans
- Disability and group life plans
- Other fringe benefit arrangements

Compliance Is Key

The regulation of welfare benefit plans, particularly medical plans, has been changing dramatically in recent years. Compliance with regulations – and staying on top of developments – is critical to avoiding risk, investigation, or interruption in your benefits plan.

Some basic areas of concern include:

- **Plan documents:** Maintaining legally required welfare plan documents
- **Disclosure obligations:** Maintaining and distributing legally required plan descriptions and other disclosures
- **Consistency and coordination:** Providing consistency by coordinating the terms of plan documents, insurance policies, and plan descriptions
- **COBRA:** The Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) provides the temporary continuation of group health coverage at group rates for certain former employees, their dependents, and others
- **HIPAA:** The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule is intended to protect the privacy of individually identifiable health information

Tax-Qualified and Nonqualified Retirement Plans

Tax-Qualified Retirement Plans – 401(k) Plans and other Funded Retirement Plans

To establish, maintain, and operate effective and efficient tax-qualified retirement plans and trusts, work with your benefits counsel to:

- Choose an appropriate type of plan — SEP, SIMPLE, 401(k), or defined benefit — to meet your objectives
- Analyze service provider proposals and cost structures
- Create plan and trust documents, using individually designed or prototype plan documents
- Develop effective plan administrative procedures and guidelines (e.g., procedures for qualified domestic relations orders or plan loans), committee charters, and delegations of responsibilities
- Keep plans in operational compliance
- Organize and handle internal and external audits of plan operations; utilize self-correction programs, as needed
- Provide risk management advice to minimize liability exposure

Executive Compensation Programs

Non-Qualified Deferred Compensation Plans

When qualified retirement plans are unable to generate desired benefit levels for highly compensated employees and executives, companies may implement non-qualified deferred compensation arrangements. Your benefits counsel can work with insurance brokers and financial institutions to establish:

- Supplemental executive retirement plans and mirror 401(k) plans
- Salary continuation agreements
- Rabbi trust arrangements
- Split-dollar insurance arrangements

Complex rules govern these types of arrangements. Before any of these programs are adopted, it is important that you are confident that the program is legally sound and does not expend your assets on financial products that do not serve your objectives.

Stock-Based Compensation

Both publicly traded and privately held businesses can implement a variety of stock-based compensation programs. Among these programs are:

- Stock option plans
- Employee stock purchase plans
- Employee stock ownership plans (ESOPs)
- Phantom stock plans
- Restricted stock plans
- Global stock plans

Your benefits attorney can guide you through complex tax and benefit rules that must be considered in these arrangements. This is especially true for equity-based programs of employers who are not publicly traded.

Specialized Compensation Programs

For executives and senior staff, there are specialized compensation programs that can be developed in addition to deferred and stock-based compensation programs. Some examples include:

- Golden handcuff and change-in-control agreements
- Performance-based or incentive compensation arrangements

Consideration of the tax consequences must take into account not only current taxation, but also include planning for future situations such as going public or an acquisition.

The increased use of S corporations and other "flow through" business entities such as limited partnerships and limited liability companies allows for great flexibility for tax planning, but it presents special challenges in structuring an appropriate form of equity-based compensation.

Executive compensation programs are being subjected to greater restrictions and increased regulation, and compliance with these rules (e.g., the tax rules under 162(m), 409A and deduction limitations, as well as with FICA withholding requirements) is critical for the above programs.

Chapter 8:
Additional Considerations for Foreign Entities

The U.S. market remains attractive to foreign entities because of its size and relative ease of entry, despite the complexity of the U.S. legal system and the fear of litigation.

Nearly all of the information provided so far applies to domestic as well as foreign entities. Foreign corporations face additional legal issues, a number of which will be covered in this section.

But first, a simple piece of advice: When in Rome, do as the Romans do. The management of a foreign entity must adapt to U.S. methods of doing business. The source of law in civil law countries is principally based on codes. By contrast, in common law countries, such as the United States, much of the law is developed through case law. One result is that U.S. contracts tend to be longer and more detailed than their civil law counterparts simply because there is little fall back on codes; rather, the terms of the relationship must be defined. This is the way we do business in the United States, although differences have attenuated, and so the foreign entity must comply in order to succeed.

Immigration / Formation of Entity

Before forming a U.S. subsidiary, a foreign company must think about the foreign personnel it wants to transfer to the United States. To qualify as an E visa employee, the employee must have the same nationality as the principal investor/shareholders of the U.S. company. To qualify as an L visa employee, the individual must have been employed by a foreign parent, subsidiary, or affiliate of the U.S. entity for at least one year on a full-time basis. A business visitor visa, or B-1 visa, allows employees of the foreign company to visit the United States to represent its interests. The B-1 visa does not allow the individual to be employed by the U.S. company (employment is related to the function of the individual and not the source of their salary). Citizens of visa-waiver countries can by-pass the B-1 visa application process altogether and enter the United States as visitors for 90 days or less under the visa waiver program.

Capitalization / Creditors' Rights / Transfer Pricing

An investment made by a foreign shareholder in a U.S. corporation must be characterized basically either as capital or shareholder loan. There are no minimum capital requirements for most activities, except that the capital (at risk investment) must be sufficient to anticipate at least initial needs, and so it is tempting to characterize the money invested as a shareholder loan: the money is not at risk, and if properly structured, the interest on the loan should be deductible from the taxable income of the U.S. entity, subject to certain "anti-stripping" limitations contained in the Internal Revenue Code.

However, potential creditors of the entity are entitled to a reasonable amount of assets, and so, depending on the activity, it may not be feasible to have minimal capital, such as $1,000, or $5,000.

In addition, U.S. tax authorities will not accept a ratio of loan to capital that is excessive, otherwise the interest burden will eliminate U.S. taxable income. The determination of what is considered excessive is based on the particular facts and circumstances of each situation. Case law will generally allow a loan/capital ratio that is in the range of three to one or four to one in most cases. There is no set ratio, and this issue is actually part of the broader question of transfer pricing, which broadly refers to amounts charged by one member of a group to another. These amounts are varied and include the price of products charged by a manufacturer to its foreign subsidiary, royalties paid for the use of intellectual property, fees charged for a variety of consulting services, the cost of software development, etc. Tax authorities will look at all these payments together to see whether they are too high. The authorities generally require extensive information reporting for transfers between related parties.

Coincidentally, although the U.S. fisc prefers that products sold by a foreign entity to its U.S. subsidiary be priced as low as possible in order to generate higher U.S. taxable income, U.S. Customs prefers to see a high product price in order to generate higher customs duties.

One more tax point. A foreign corporation can generally sell goods to a U.S. corporation without paying any taxes on the resulting U.S. income if it is not considered to be "doing business in the United States," or if it can claim certain benefits under a U.S. tax treaty. However, the foreign corporation will become liable to U.S. tax if it acquires too many indicia of presence in the U.S. These are not necessarily obvious. For example, if a foreign corporation appoints a

U.S. agent who not only solicits orders, but can also accept them on behalf of the foreign corporation, then the foreign company may be deemed to have a U.S. tax presence, or what is known as a permanent establishment. Most industrialized countries have bi-lateral tax treaties with the United States in which these indicia are listed. It should be noted, however, that individual states of the United States are not bound by the treaties and can apply their own rules of tax presence. This is a true minefield, and one must be very well counseled in order to minimize tax exposure.

Customs

The agency known as U.S. Customs and Border Protection (CBP) has a number of different functions. In addition to its primary mission of protecting the United States from terrorism, CBP also attempts to facilitate international trade by engaging in the following activities (as noted on the CBP Web site):

- Protecting U.S. businesses from theft of intellectual property and unfair trade practices
- Collecting import duties, taxes, and fees
- Enforcing trade laws related to admissibility
- Regulating trade practices to collect the appropriate revenue
- Maintaining export controls
- Protecting U.S. agricultural resources via inspection activities at the ports of entry

Many freight forwarders (the companies that arrange the transport of goods), including many foreign freight forwarders, act also as U.S. customs brokers. A customs broker is necessary in order to process goods into the United States properly.

Dispute Resolution / Choice of Law

Most foreigners believe that U.S. litigation is overly expensive and intrusive. The natural reaction is to opt for litigation in the foreign country, assuming that your U.S. clients / suppliers agree. Yet this can be a costly mistake.

Assume a foreign entity licenses intellectual property to a U.S. company. If the U.S. licensee breaches the agreement, for example by sub-licensing without authorization, then it will take a long time before the aggrieved foreign manufacturer can stop the unauthorized activity. First, a final foreign judgment will need to be obtained, and then that judgment will have to be enforced in U.S. courts. Preliminary remedies

will not be available. Years could elapse. In that situation, access to U.S. courts would be preferable.

Arbitration may be a good option. The matter can remain entirely confidential. Arbitration will tend to be quicker. Because the procedure will be simplified, legal fees should be lower, though that may be offset by the cost of the arbitrator(s). The arbitration clause can be tailored very specifically. Arbitrators can be selected because of their expertise. A number of dispute resolution entities have developed excellent international arbitration rules, and can administer the dispute fairly and efficiently. Most industrial nations are parties to a convention for the recognition and enforcement of arbitral awards.

One might consider a multi-level dispute resolution clause. For example, if there is a dispute, the executives of the parties try to negotiate a resolution; if they fail, the matter can be submitted to non-binding mediation; and if mediation fails, then the matter is submitted to arbitration or litigation.

The choice of the law that will apply to the contract is also a question that can have drastic, unforeseen effects. Civil law, for example, protects agents and sometimes distributors. Absent its exclusion, an international treaty governs international sale of goods.

Conclusion

These are just a few questions that a foreign corporation must analyze as it approaches the U.S. market. One must also tackle the problem of language, and the more subtle, yet no less important, issue of cultural differences. Therefore, it is crucial to utilize a law firm that has experience with these matters and can help you find your way to success in the United States.

Hodgson Russ Jumpstart Plan

We know emerging companies face enormous demands on their time and resources on the way to a successful launch. That is why we offer our Jumpstart Plan to help make the process easier. After consulting with you to determine your unique legal needs, we'll prepare a custom suite of legal services to cover the basics you need to get started — all at a special package rate designed for emerging businesses.

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At Hodgson Russ, we are proud to provide innovators and visionaries with creative, business-focused legal advice to help guide them through their initial launch and through all stages of growth. Our attorneys have extensive experience assisting emerging companies with the full range of their legal needs, including everything from entity formation and day-to-day operation to complex transactions, dispute avoidance and resolution, and navigating complex regulations in many industries.

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For more information, please visit www.hodgsonruss.com.

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