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Technology Licensing — From First Steps to Executing a Plan

June 1, 2004

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If you are a start-up company or a spin-off from a university performing R&D in an incubator lab, you may want to begin the licensing process. But, where do you start? Inventors and scientists often find themselves in this position. Fortunately, a variety of business development resources are available. Unfortunately, the most appropriate resources may be costly and difficult to find.

The following provides a brief overview of how to get started and some of the important issues to consider. There are five basic steps to the technology licensing process:

- Create clear and solid intellectual property for your technology platform.
- Understand your technology and its commercial viability and market value.
- Decide which market segment provides the most opportunity for your technology's applications.
- Create a business plan for approaching and obtaining licensees and establishing business alliances.
- Execute the plan.

IP ISSUES TO CONSIDER

Intellectual property (IP) is the foundation of any technology licensing strategy. IP rights must be legally recognized and enforceable in a court of law. In the biotech and pharmaceutical industry, patents are commonly used to protect and enforce IP rights. Work with an experienced patent attorney who understands the commercial and business implications of the technology. Carefully prosecuted patent applications lead to patents with valid and enforceable claims that provide broad coverage for your technology and that, in turn, will attract business partners and licensees. Invest time and capital in creating and maintaining a comprehensive IP portfolio — potential licensees will carefully evaluate its strength and breadth before considering a business arrangement.

Types of IP Protection. There are different types of IP protection to consider and various avenues to follow to obtain the most effective IP protection, including patents, trademarks, copyrights, and trade secrets. You should consider all of the possibilities. Here are some examples.

- A patent may protect a new drug or compound, as well as a method of making the drug or compound and methods of treating a given disease.
- A trademark may confer a different scope of protection. For example, the life of a trademark may extend beyond the life of a patent, thereby providing a longer period of protection. Additionally, a trademark indicates a single source for the goods or services covered by the trademark. Thus, if wisely implemented in a marketing campaign, a trademark will help increase brand recognition and brand loyalty.

- Keeping the method of making a product, such as a drug or compound, a trade secret may be more desirable for a variety of reasons. For example, a patent will confer protection for a limited period of time, whereas a trade secret lasts as long as it does not become public. Thus, trade secret protection may extend beyond the life of a patent.
- Since method claims are difficult and costly to enforce, one should consider whether keeping a trade secret would be relatively less expensive and easier to implement.
- Marketing materials for a product or service may be protected under copyrights.

Geographical Areas for IP Protection. Consider the geographical locations where your technology will be used, and select the type of IP protection that is compatible with your business purposes and most desirable to your potential business partners and licensees.

Obtain Legal Opinions. Before investing valuable time and money in R&D, seek a patent attorney's advice about your technology and your company's proposed activity — for example, researching and developing the technology, licensing the technology, and entering collaborations relating to the technology. You may want to seek one or more of the following legal opinions.

Patentability opinions analyze whether a given invention is patentable in view of the prior art. Prior art refers to information that is publicly known in a given technological field and includes patents, published patent applications, journal articles, and the like. Seek this type of opinion to evaluate whether obtaining patent protection is possible and economically feasible.

Freedom-to-operate opinions examine whether a proposed activity would, more likely than not, be found by a court of law not to infringe another party's IP rights. For example, a patent does not confer the right to practice; it only grants the right to exclude. In other words, having a patent neither prevents nor protects you from infringing the claims of a patent. Thus, seek this type of opinion before engaging in certain activities, such as investing significant time and money in the development of a technology.

Validity and invalidity opinions examine whether IP rights, such as the claims of a patent, will be deemed by a court of law to be valid or invalid and therefore enforceable or unenforceable. For example, a validity opinion helps to determine whether you want to obtain the patent rights of another — in other words, license in their technology by becoming an assignee or licensee of the patent. An invalidity opinion helps a company decide whether or not to proceed with a proposed activity that likely would be deemed by a court of law to infringe the rights of another. A proposed activity may fall within the scope of a patent claim, but the patent claim may be invalid and unenforceable. Thus, an invalidity opinion is often combined with a freedom-to-operate opinion or non-infringement opinion.

Non-infringement and infringement opinions analyze whether a certain activity would, more likely than not, be found by a court of law to infringe certain IP rights, such as the claims of a given patent. A non-infringement opinion helps determine whether or not a proposed activity would, more likely than not, be found by a court of law to infringe the IP rights of another, in order to evaluate whether to engage in the proposed activity or not. An infringement opinion helps determine if another party is infringing one's own IP rights.

AREAS OF FOCUS

Typically, there are many possible applications for a particular pharmaceutical technology platform or product. Determining which application(s) is the best to focus on and invest in is difficult. For companies with limited resources, it is cost prohibitive or impossible to develop each potential commercial application. Accordingly, the first application(s) should meet an unmet need in the market, have reasonable timelines (time-to-market), and attract companies for partnership. In the best-case scenario, you will have a commercial application that is near term with a reasonable market.

Before you invest significant time and capital in R&D and IP protection, ensure that the chosen technology application has solid commercial viability. Survey and analyze the competitive landscape to determine your competitive advantage. It is important to understand the commercial value of your technology in order to negotiate the best business arrangement with a potential licensee. Even the best technology, without a clear business plan including an understanding of the potential market and competition, will not garner the value it deserves.

THE BUSINESS AND LICENSING PLAN

Create one business and licensing plan for your technology platform, including the various potential business partners and licensees you will approach. There are many partnering options, and the route you select depends on your company's given situation. Some questions to consider are:

- At what point do we need money?
- With whom should we partner? Pharmaceutical companies (large or small, generic or specialty), biotech companies, chemical companies, or ingredient suppliers?
- When do we want to partner? After a particular milestone, such as positive animal data or phase 1 clinical development?
- How do we want to partner? Platform license, field of use, co-development, or joint venture?

PLAN EXECUTION

Once you develop a business plan, a non-confidential package including presentations, brochures, and any non-confidential data should be compiled and sent to potential licensees. It is important to qualify the licensee prior to sending the information. Introduce your company via telephone or email to determine general interest and to determine the correct contact person within the organization. Do not blindly send out non-confidential packages to your contacts. This does not work well and may create an unfavorable impression.

Be meticulous in researching the potential business partner or licensee, and discover why they need your technology platform. Study the company's product pipeline, current development projects, and the types of licensing arrangements and business associations they have formed in recent years, including those involving technologies similar to yours. Business development and licensing professionals expect you to be prepared to discuss both your technology platform and how its potential benefits specifically relate to their product pipeline and marketed products.

HELPFUL RESOURCES

There are more steps and issues to consider than presented here. Professional organizations, such as the Licensing Executive Society (LES), are valuable resources. Many consulting firms have experience and expertise in business plan development and licensing strategies, and they are willing to work under various fee schedules, including success fees, flat fees, and royalties.

If you need licensing expertise, consider using an outside consultant to help prepare the business plan. Obtaining expert advice early will help prevent or minimize mistakes that waste resources and contacts. Contacting technology-scouting professionals at your target organization too early is risky. Companies often go forward with technology introductions before a business plan is in place or before the appropriate

data have been produced. After an introduction is made and the target company forms an opinion of your technology, it is often extremely difficult to change the organization's perception. Therefore, be deliberate and meticulous in forming your business plan and creating your non-confidential package and presentation.

If your company has experience in successfully creating a business development and licensing plan, you may not need an outside consultant early in the process. However, it may be necessary to use consulting assistance in areas where your contacts are weak, such as in another country or in a particular field outside your area of expertise. Consultants will use their industry contacts to open doors that might otherwise remain closed.

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