

Licensing and the Consultant

Major concerns are reviewed; basically, there must be something for everyone

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"Many shall run to and fro, and knowledge shall be increased." This statement by the prophet Daniel characterizes the current interest and activity in corporate biotechnology licensing and consulting. Although licensing and consultantship arrangements are not new to the corporate world, the increasingly high numbers of such arrangements in the biotechnological areas are new. Academic institutions and biotech start-up companies are actively pursuing agreements that are receiving the public's attention and interest.

I will address some general requirements and concerns of the corporate partner in licensing situations where the corporation is the licensee, i.e. the party acquiring rights, and is hiring an outside consultant.

Underlying any licensing and consultantship arrangements is the principle that there must be something in it for everyone. For the corporation, that "something" is often ideas or new technology or products with commercial potential. For the licensor or consultant, particularly when the licensor is an academic institution or a smaller specialized company, relationships with industry often provide the means of generating grants for research. They also provide continued viability, and they can open avenues for developing and commercializing the fruits of research.

We must also remember that, particularly in the biotechnology area, a licensing situation often arises as a result of a collaborative or funded research arrangement between the partners or a consultant making an invention or discovery in the course of his or her consulting relationship with the corporation.

COMMON CONCERNS

Following are some major concerns the corporate partner is likely to have that are common to licensing and consultantship arrangements:

Clean Title

Those who receive materials, technology, or information are always concerned with getting what they pay for.

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This is a real and extremely important issue, as can be seen in the recent controversies involving Genentech, Hoffman-LaRoche, and the University of California concerning the KG-1 interferon-producing cell line, and that involving the University of California at San Diego and Hagiwara concerning ownership and rights to a particular hybridoma. To ward off the specter of dispute, it is advisable to search diligently and inquire into title and, as a second-line defense, to include in any agreement warranties of ownership and the right to transfer title.

Rights to Future Inventions

Any consultantship or other agreement that includes research, testing, or development should provide for disposition of title to inventions and discoveries that result from the research or consultantship. In most cases, the corporate partner will strongly prefer to own the fruits of research it pays for or, particularly in the case of consulting, that arise from the consultantship or from corporate information made known to the consultant. This is a particularly sensitive and important area because it may involve progeny or derivatives of research materials.

Exclusivity

Because of the high risk involved in research and development and in subsidizing failures, many corporate licensees require worldwide exclusivity, particularly when a product is licensed. Part of this requirement is the need for strong patent protection. As regards intermediates, processes, or products for which lead time or position in the marketplace is paramount, exclusivity may or may not be as crucial. Licensors may require licensees to use their "best efforts" or "due diligence" to commercialize the licensed subject matter within a reasonable time or to provide premarketing payments, make payment of minimum annual royalties, or furnish a remedy if the licensee fails.

Remedies include monetary payments, rights to terminate the license, conversion of the exclusive right to a nonexclusive one, or return of rights to undeveloped subject matter. When a university or the government owns and licenses subject matter, the corporate licensee must recognize that, unfortunately, exclusivity may be available only for a limited time as a matter of policy or because of federal funding of the research.

Confidentiality

Proprietary information made available to partners to a license or other agreement must remain confidential and not be disclosed to third parties without the corporation's consent. Sometimes universities or consultants perceive confidentiality obligations as counter to traditional concepts of openness and free communication. They may be

unable to control the actions of faculty, students, and technicians. Solutions for this dilemma include limiting disclosures by the corporate partner to nonproprietary information, provisions that obligate the partners to use "reasonable" efforts to maintain confidentiality, and allowing the noncorporate partner to decide whether it wants to receive proprietary information.

Publications

A prime topic of interest and importance is publication review and restrictions on the academicians' "sacred" right to publish. From the corporate viewpoint, publication restrictions are necessary to safeguard worldwide patent rights. Without a solid, worldwide patent position unprejudiced by too early publication, there may be little a potential licensor has to offer a potential licensee.

Publication review and restriction, however, need not be obnoxious. A reasonable and common arrangement is one in which publications are made available for comment prior to submission for written or oral publication.

Publication may be delayed only for purposes of filing patent applications within an agreed upon length of time. Invariably, the corporate party will want to identify any patentable inventions and seek appropriate and timely patent protection, even if the consultant or research partner does not.

Publicity

Public disclosure of the existence and terms of an agreement can be a sensitive issue. Although both parties may desire to reap the benefits of good publicity, it is common industry practice not to disclose the details, especially the financial ones, of any arrangements. Many state universities are subject to "sunshine" laws, according to which meetings of the institution's governing body, which in fact must approve the terms of agreements, are open to the public.

For many of the newer high-technology companies, disclosure of a lucrative deal conducted with a big company is bound to provoke a positive response on Wall

Street and may even be mandated by the securities regulations. To avoid premature or excessive disclosure, license and research collaboration agreements should state that any public disclosures will be agreed upon by the parties and that the texts of such announcements will be approved by the parties prior to public release.

Conflicts of Interest

Is the consultant or the biotech company performing similar services for, and perhaps promising or creating expectations of similar rights to, a competitor? Going hand in hand with this problem is the fear that proprietary information may be disclosed, inadvertently or otherwise, to a competitor or to the public, for example by disclosure to a consultant's students. One way to address this issue is to include in any agreement that the consultant, licensor, or contractor does not have and will not undertake conflicting obligations. In the appropriate circumstances, the agreement can stipulate that the arrangement is exclusive, thereby prohibiting the consultant, licensor, or contractor from performing services for any other party.

CREATING PRODUCTIVE RELATIONSHIPS

By entering into research, licensing, and consulting arrangements with government, academia, or specialty company partners, industry is in a better position to extend and enhance its research activities. Even if a particular arrangement does not work out or does not ultimately result in a marketed product, at least an ongoing relationship has been created that may well continue to be productive or may be continued in a different form at a later time.

This relationship building, information generating and sharing, and a more equitable spreading of the risks and costs of experimentation, as well as the potential profits, are the real pay-offs to both parties.

Increased awareness and attentiveness to the problems of such interactions on both sides will serve to minimize the running to and fro and maximize the increase of knowledge.