

ABA Q&A



The Laws of Licensing in the Biomedical Community

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Why is licensing critical to the biomedical community?

Licensing provides a mechanism for parties with different types and levels of expertise and financial resources to collaborate so that biomedical technology can make the long, arduous journey from the laboratory bench to the patient's bedside. Biomedical technology involves unique challenges, as it must be proven to work safely and effectively in vitro (i.e., in the laboratory outside of a living organism), then in animal models, and then in humans. For example, licenses permit universities' basic research to be translated into diagnostic tools and patient treatments by conveying to companies the rights and incentive to commercialize.

What are some key licensing provisions?

It is critical to properly identify the technology, whether know-how, patented or patent-pending and in which countries, and rights others may own in underlying technology. It is important to determine at the time of license negotiation how to clearly identify ownership and exploitation rights in new technology arising from the relationship.

The field of use of the technology should be clearly spelled out, indicating type of disease, route of administration, etc. If appropriate, one should define whether the technology may be licensed to an entirely different field, such as agriculture.

The extent of exclusivity and whether sublicenses are permitted should be clear, as should whether other licensees have already been, or might in the future be, granted a license. Geographic boundaries should be stated.

An early stage company or university licensor should consider a reach-through license, wherein a stream of royalties is provided for, even if the basic technology licensed is itself no longer covered by a patent at the time the product is commercialized.

Payments, whether royalties or milestones, should consider the length and risk of the development process. Indemnification and product liability provisions should be included. The licensee should consider the costs of obtaining other licenses from third parties for rights needed to develop the technology.

How do I avoid problems?

The licensee should be required to exercise due diligence in the development and commercialization process, with clear requirements set forth. Excellent communication between the parties should be maintained throughout the term of the license to be sure the parties' goals are met. During negotiation of the license, parties should consider what would happen to potentially valuable technology developed, should the relationship sour, not an uncommon occurrence due to inherent uncertainties involved in the development process.

Susan Stone Rosenfield is an attorney with Fennemore Craig P.C. She focuses on all aspects of intellectual property, including the adoption, defense, and enforcement of copyright, patent, trademark and trade secret rights. Her practice also includes the negotiation and drafting of agreements involving pharmaceuticals and biotechnology including confidentiality, research and development, drug manufacture and testing, animal study, clinical study, joint development and related agreements.