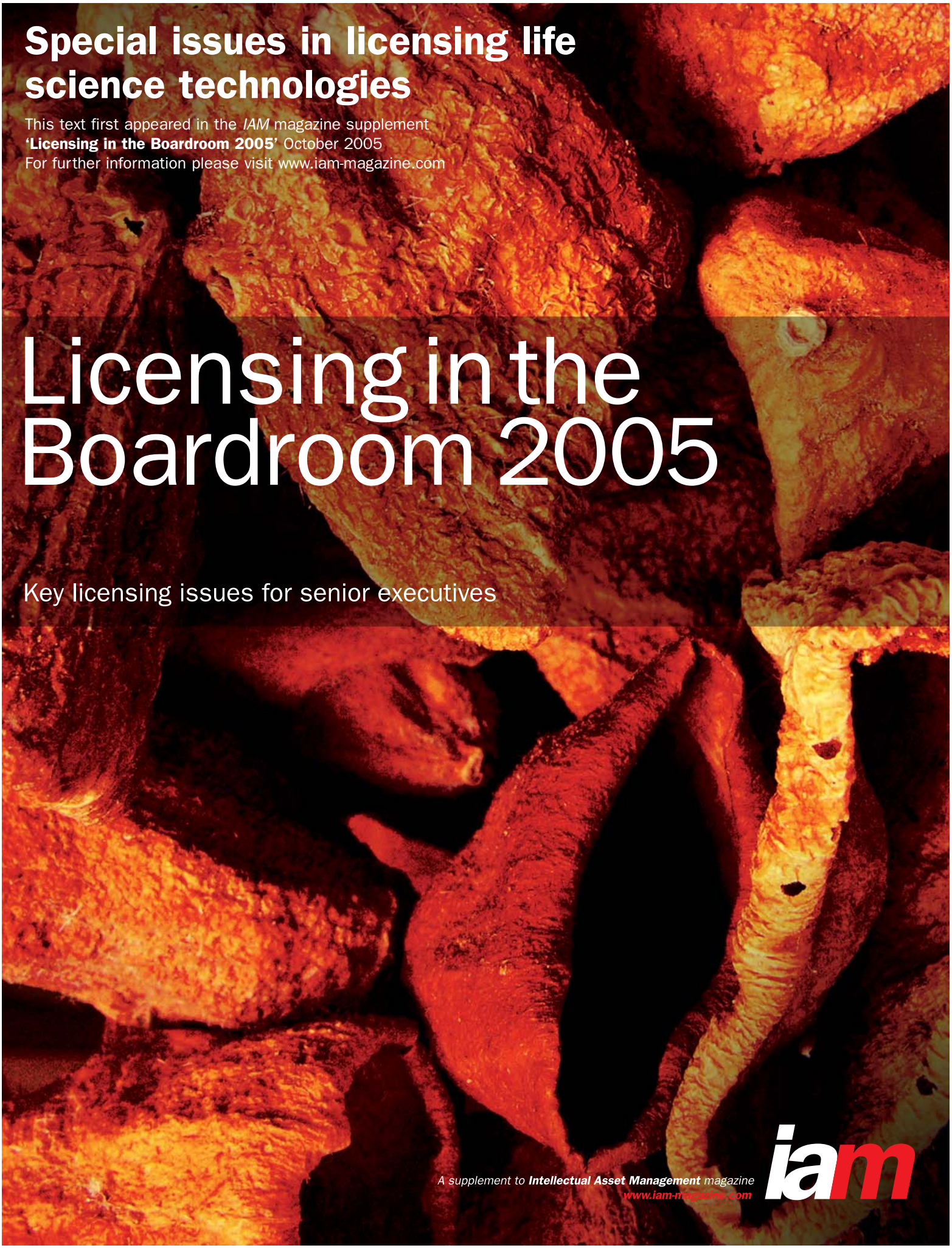

Special issues in licensing life science technologies

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Special issues in licensing life science technologies

Licensing in the life science industry throws up numerous distinctive issues as the process evolves. An understanding of what to expect

By **Laurie A Axford**, Gordon & Rees LLP, San Diego

Licensing intellectual property in the life science industry requires careful attention to particular issues that are sometimes not well understood or adequately addressed by general licensing practitioners. These issues arise during all phases of the licensing process, from initial negotiations through to termination of the licence. The following discussion addresses these issues as they normally occur during the evolution of a licensing relationship.

The parties

The life science industry includes a wide variety of entities, both institutional and private, whose roles in the industry may include any combination of initial research, technology development, manufacturing and commercialisation. As sources for funding in the industry continue to be focused on defined and limited outcomes, fewer entities exist that are capable of carrying out all phases of product development and commercialisation. Hence, the need to in-license and out-license technologies to stay competitive in this industry has increased to the point that licensing is an integral part of doing business.

Life science-related products include, for example, diagnostics, therapeutics and medical devices. Thus, at least one of the parties to a licence in this industry is usually a company owning intellectual property rights relating to one of these three types of products. Additionally, products in this industry are often complex and involve the combination of different technologies, which also leads to an increased need for licensing at some phase during development and commercialisation. For instance, products including some form of nanotechnology sometimes involve a combination of technologies in diverse areas, such as material science, computer science, biotechnology, organic chemistry and electronics.

In addition to technical complexities, entities in the life science industry can have complex business structures, which involve various parent companies having total or partial ownership of multiple smaller entities that sometimes have overlapping interests.

To avoid over-inclusion at a business level, make sure that the parties to a licence agreement are well defined, and that the definition of "Affiliates" does not inadvertently include parties having competing interests, such as an agreement with a subsidiary of a holding company that owns other subsidiaries.

Initial negotiations

As previously discussed, economic forces are leading to an increase in the number of licensing deals that occur upstream in the flow from development to commercialisation. Also, technological complexity leads to an increase in the time it takes to secure patent rights in the industry. For these reasons, initial negotiations usually take place at a time when the parties must exchange both public and non-public information, including know-how as well as subject matter covered by issued patents or pending patent applications.

Such exchanges usually take place after the parties have entered into some form of "confidentiality agreement". However, the form of agreement selected for these initial exchanges of "information" should cover both orally conveyed and written information, as well as less well defined information

embodied in material transferred between the parties. Some licence practitioners will cover such exchanges by a separately executed "material transfer agreement." However, care should be taken to make sure the terms of confidentiality in both agreements (ie, the confidentiality agreement and the material transfer agreement) do not overlap or conflict.

Using a combined "Confidentiality and Material Transfer Agreement", even if the initial exchange of information between the parties will be oral or in writing, will prevent later conflicts when the initial exchange is followed by an exchange of tangible materials, such as chemical formulations, prototype devices, etc.

Following any exchange of information, there is a probability that the information will lead to the development of new and/or improved technology (ie, "improvements"), which may in turn lead to a desire to seek additional patent protection. The ownership of patent rights covering improvements raises a number of issues, such as whether the subject matter of these improvements was an anticipated consequence of the exchange, and whether these developments should be solely or jointly owned.

Make sure the purpose of the exchange is clearly defined in the initial confidentiality agreement, such that any non-permitted use of the exchanged information would constitute a breach of the agreement, and the possible remedy of seeking an injunction against the breaching party to prevent further misuse of the information.

Consider the inclusion of cross-licensing provisions to any new technology derived from the exchanged information for internal uses, with a prohibition on commercial uses, absent an agreement between the parties. This allows for the development of improvements by the recipients of information that may benefit both parties, without allowing for the recipient to enjoy the commercial benefits of such improvements based solely on information from the discloser.

Term sheets

After the prospective licensor and licensee have exchanged information and made a determination that they wish to enter into a licence agreement, it is useful for the parties to discuss the terms of such an agreement in advance of exchanging and negotiating the form of the agreement. These discussions can be initiated by supplying a "term sheet", which includes a summary of the most important licence provisions, such as the following: purpose, field, territory, grant of rights, payment structure and term.

One of the most important provisions in a licence agreement covering technology in the life science industry is the definition of the "field". This is because such agreements often involve diverse fields or combinations of technologies. Accordingly, the "field" of the licence agreement, which defines the metes and bounds or "scope" of the agreement, must be carefully crafted to avoid over-inclusion.

When the scope of the agreement includes a combination of different technologies, define the scope in terms of the combination, and not in terms of the industry. For example, if the prospective licence agreement involves the use of process A to make product B for the treatment of disease C, then the scope of the agreement should be limited to this particular process, product and use.

The licence agreement

As stated previously, licence agreements in the life science industry generally follow the exchange of information under a confidentiality agreement. This initial exchange of information may include some of the most valuable intellectual property assets of the parties, and give rise to improvements that are ultimately covered by new patent applications. Accordingly, confidentiality and improvement provisions should have already been negotiated and agreed upon before entering into the licence agreement. Only rarely is a licence agreement entered into without such an initial exchange of information.

To avoid conflicting confidentiality and improvement terms, the confidentiality agreement can be incorporated by reference into the licence agreement and continue to govern the confidentiality and ownership of improvements during the term of the licence agreement. This prevents the need for distinguishing between information that was exchanged under the confidentiality agreement and information that was exchanged under the licence agreement.

Provisions relating to the ownership of improvements, which are included in either the confidentiality agreement or the licence agreement, can also inadvertently conflict with other obligations the inventors may have to their employers. For example, most employers in the life science industry require their employees to sign employment agreements that oblige them

to assign their rights to any inventions conceived during the course of their employment to their employer. If later agreements entered into by the employers require the inventors to assign their rights to other parties, conflicts can arise, unless the employment agreement and the later executed agreement are not carefully drafted to avoid such conflicts.

Ownership of patent rights normally tracks inventorship, unless other agreements are entered into establishing non-inventors as owners. Besides employment agreements requiring employees to assign their rights to employers, the assignment itself is the most common form of a transfer of rights from an inventor to another entity. Such assignments should be obtained promptly and recorded with the appropriate patent office when required to perfect the transfer of ownership.

With respect to improvements made under either a confidentiality agreement or a licence, the joint ownership of such improvements raises other issues in the United States, because of the US patent laws relating to "prior art". More particularly, "prior art" in the US includes patents that are not "commonly owned" at the time the invention was made. The scope of common ownership was recently expanded in the US by the passage of the CREATE Act on 10th December 2004. Under the new law, both patents covering subject matter owned by the same entity and patents covering subject matter that was "subject to an obligation of assignment" to the same entity are now considered to be commonly owned and excluded from being prior art to one another.

While providing an important additional exclusion from prior art, the new law also includes certain conditions that must be met in order to take advantage of this new prior art exclusion. For example, the owner(s) of the initial technology and the owner(s) of the improvements must be "parties to a joint research agreement" that was in effect at the time the invention was made. In addition, the patent application covering the improvements must contain a statement naming the parties to the agreement.

Under the CREATE Act, the term "joint research agreement" is defined as "a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention". Although the legal interpretation of this and other terms in the Act will likely evolve as these terms are applied to particular factual scenarios, it is reasonable to interpret this definition as also applying to the initial exchange of information between the parties under a confidentiality agreement, if such agreement includes the purpose of performing "experimental, developmental, or research work". This is usually the case in the life science industry, when the initial exchange of confidential information includes an exchange of materials to be tested.

To promote the ability to rely on the CREATE Act to exclude older patents from being prior art to improvement patents, consider reciting language from the CREATE Act in the initial confidentiality agreement. For example, include a recital in the preamble that the exchange of information is to perform "experimental, developmental, or research work", if this is, in fact, part of the scope of the exchange.

In addition, as ownership of improvements that does not track inventorship usually contravenes employment agreements between inventors and their employers, as well as excluding the reliance on the CREATE Act exclusion, ownership should usually flow from inventorship, and other exchanges of rights between parties to a licence agreement should be accomplished through cross- licences or sublicences.

Term and termination

The term of a licence agreement that includes rights to existing and future patents usually corresponds to the expiration of patents that cover products and processes developed under the agreement. However, the term of an agreement covering know-how, in addition to patented technology, can also be tied to a calendar date or the last sale of a product incorporating the know-how.

Termination of a licence agreement does not usually relieve the parties of many of their obligations under the agreement, such as the payment of royalties and confidentiality obligations. Hence, most licence agreements include a list of the conditions under which the parties are permitted to terminate the agreement, along with a list of the licence provisions that will survive the termination.

The list of provisions that survive termination should include the provisions relating to payment, confidentiality, ownership of improvements and the required cooperation of inventors and their employers to cooperate in the pursuit of patents covering improvements.

Gordon & Rees LLP
101 West Broadway, Suite 1600, San Diego, California 92101, USA
Tel +1 619 696 6700
Fax +1 619 7124

www.gordonrees.com

Laurie A Axford
Partner
laxford@gordonrees.com

Laurie Axford is a partner in the San Diego office of Gordon & Rees LLP, and a member of the firm's Intellectual Property group. Her practice focuses on all phases of patent prosecution, including forming initial patent strategies for new technologies and managing complex existing portfolios. She has written and prosecuted patents covering inventions relating to organic chemistry, biochemistry, biotechnology, nanotechnology, synthetic polymers, textiles, small molecules, assay devices, business methods and drug delivery systems. Her industry focus includes a large cross-section of life science-related fields including diagnostics, therapeutics, medical devices and consumer goods.

Additionally, Ms Axford assists clients with highly complex patent issues including global licensing, litigation support, opinion work, post-prosecution proceedings (with a particular focus on re-examinations and international oppositions), business-related due diligence and other advanced-level matters for clients in the institutional, corporate and financial sectors.