Material transfer agreements: open science vs. proprietary claims

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For academia and industry, MTAs are the means to widely differing ends.

Although the development of pharmaceutical and biotechnological end products has been traditionally based on patents, biomedical research in academia comes from the very different tradition of open science; that is, relatively unrestricted access to fundamental knowledge developed by previous researchers. Research materials were often freely exchanged without formal arrangements. Beginning in the 1970s, however, life science research brought academia and industry closer together.

Industry defends its commercial and property interests by acquiring and protecting exclusivity in the market through patents and trade secrets. In contrast, governments and the academics they fund aim to preserve the flow of ideas through publication or to safeguard the creation of a product thanks to the new knowledge. Sometimes these two missions conflict, as in the case of material transfer agreements (MTAs).

MTAs in practice

Pioneered by industry, MTAs are used in connection with the transfer of materials for safekeeping purposes (for instance, storage in gene banks), research or commercial use. Now increasingly being used by public sector laboratories and academia, they may take a variety of forms, from letters accompanying a shipment of materials to detailed and formally negotiated contracts signed by both parties before a transfer of materials is made in or out of research units. Outbound agreements are often associated with having patent rights to the material in question, whereas inbound agreements may include terms that impose research restrictions that infringe upon academic freedom or the dissemination of research results, and may conflict with specific requirements of funding agreements.

MTAs are contracts that are protected by law. If one of their provisions is not followed, the contract is breached and the wronged party has the right to bring action against the other, such as suing for damages. The transferred material under an agreement may also be protected against certain forms of violation by third parties. Thus, a third party who obtains the material by theft or trickery may be liable for damages.

In industry, MTAs will authorize the exchange of materials between collaborating companies for the purpose of developing a product, prohibit the materials' use or transfer to third parties for purposes other than the collaboration, and define a mechanism for marketing the product. Patent and ownership rights will be precisely defined, but problems sometimes arise concerning the allocation of rights to unexpected inventions arising from the research. A typical solution is for each party to receive a nonexclusive license to any invention emerging from the joint effort. The commercial value of such a license is often small; hence, companies may not attempt to obtain patents on such material.

Nonprofit research units, such as public sector and academic laboratories, want to ensure that the material remains in the public domain while making certain that their association with the material is recognized. Two factors are leading nonprofit research institutions to adopt different strategies. First, exclusivity—obtained through intellectual property (IP) rights—is necessary to ensure that the material can be commercialized. Companies will not use public sector inventions unless they can recoup the costs involved in taking them to market. Second, nonprofit research units look to inventions as a basis for royalties. Since research materials may have important commercial value, their transfer is treated much the same as a transfer of patent rights[1].

Standardization and variables

In the United States, to simplify transfers between nonprofit research institutions, the National Institutes of Health (NIH) published in 1995 the final version of the Uniform Biological Material Transfer Agreement (UBMTA) and the Simple Letter Agreement for the Transfer of Non-Proprietary Biological Material. Although there has been no formal agreement on a format for use when a for-profit entity is providing material to a nonprofit organization, the Association of University Technology Managers (AUTM), the NIH and industry representatives from what was then the Pharmaceutical Manufacturers Association developed a draft agreement in 1992.

At the 2003 AUTM annual meeting, a special interest group on MTAs met for the first time and made a survey of significant issues for academia and industry. For academia, the most significant issues relating to MTAs were: the nonexclusive royalty-free license, with the right to sublicense; the broad definition of materials; the publication restriction; the invention ownership of recipients; the indemnification; the tracking and honoring obligations to the provider; and the definition of invention. For industry, the most important matters were: unauthorized distribution and publication[2].

The provisions of MTAs may vary, depending on the intentions of the parties (see **Table 1**). At one extreme, MTAs may be designed to avoid patent rights on the material or its components. At the other, they encourage patenting inventions deriving from the material and dividing the benefits of such inventions. For academia, the basic restriction is the limitation to publish research results. The agreement wording

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Table 1 Characteristics of material transfer agreements used by nonprofit and for-profit parties

	Nonprofit party	For-profit party
Advantages	Availability of research materials at no cost	Access to expertise not available within company; collaborative opportunity
Disadvantages	Conflicting obligations to provider and financial sponsor; freedom to publish not always guaranteed; usage restrictions difficult to track	Loss of control over materials; loss of competitive edge due to publications
Definitions of material	Narrow definition that includes unmodified derivatives, but excludes variants and confidential information	Broad definition that includes unmodified derivatives, variants and confidential information
Use of material	Indetermination of noncommercial research; distinction between use and transfer of modified material	Control of asset distribution; limited use to laboratory; return of unused material
License rights	Broad, free nonexclusives with right to sublicense; forced joint ownership a problem	Royalty-free, nonexclusives with limited sub-licensable right; in joint inventions, mutual permission necessary to license to third parties
Pre-license patent prosecution	The provider should bear all costs of patent prosecution in return for option grant; split costs for joint inventions not equitable	In sole inventions of recipient, the recipient bears costs and gets recouped under exclusive license; in joint inventions parties split costs
Post-license patent prosecution	It is preferable to control prosecution; alternative, right to veto actions that undermine ownership interests; the licensor (recipient) has the right to continue prosecution on its own and the licensee (provider) loses right if this no longer pays patent costs	It is preferable to control patent prosecution and make patent decisions, freedom to operate in return for bearing risk of development; alternative, if ownership interest is impacted, nonprofit can pursue prosecution
Confidentiality	Avoid obligation if possible; identify clearly in writing all confidential information; may permeate research making publication difficult; need exceptions, e.g., for independent development; should not include research results or data generated by investigator	Written broadly; need to protect corporate assets; competitive environment requires maintaining confidentiality; balance risk against benefit; preserve opportunity for patent protection
Publication	Acceptable delays for review, before submission; acceptable restriction on content, none to confidential information and thesis issues	Limited time delays before submission or to file patents; preserve confidentiality of confidential information
Term and termination	The provider has the right to terminate problematic situations if the material has been used in thesis research; the term on research makes it easier to monitor ongoing obligations	Freedom to terminate and lack of finite research term

Source: reference 2

may give the provider control of publication and may assert that nothing is to be published or otherwise disclosed without the provider's approval, to allow the provider to determine whether its own confidential information has been improperly disclosed, and whether there are new IP rights.

Providers may also assert ownership not only of the physical material, but also of new materials or inventions made by recipients through the use of the provided materials. This not only represents a direct loss, but also can cause indirect damage by limiting the freedom of recipients to continue a line of inquiry because they no longer own their research results. An agreement may award the provider an automatic license for the resulting IP for little or no compensation, so that it can develop commercial products if it chooses. Since the provider of the material is usually not funding the research, the recipient needs to ensure that there are no conflicting obligations between its financial sponsors and the provider.

An agreement term may require that the recipient indemnify the provider against any damage that may occur through use of the material, implying that the provider is not responsible, even if the material was provided without proper warnings about associated hazards or needed precautions.

Equitable ownership of materials is determined in much the same way as ownership of IP. Difficulties may arise when an academic investigator uses two materials from two different providers, or has made one of the materials under company sponsorship. In such a situation, it is quite likely that the terms of the agreements covering the two materials are in conflict. If preemptive MTAs cloud ownership rights, investigators may be restricted in their ability to interact with a future sponsor. Investigators may need a commercial developer to convert an invention into a product, but IP terms in MTAs may prevent the institution from granting rights to a future developer. No sponsor wants to pay for research benefits that it cannot have. In addition, the terms of an agreement may make it difficult to collaborate with other scientists.

Some materials can be very costly to make, and it can be financially unreasonable to supply them to multiple investigators. If this is a deterring factor, the agreement can include the proposal of a one-time fee to allow for cost recovery. Such a fee can reasonably include the cost of materials, the extra labor required to make them, and shipping or other fees[3].

When the material transfer occurs before the filing of a patent application related to the transferred materials, such a transfer may be deemed prior art to the claims and bar patentability of the transferred materials. Although most currently used academic MTAs are adequate for post-filing transfers, confidentiality provisions may be required to avoid the prior art effect of some pre-filing transfers. Whether a pre-filing transfer of an invention whose full utility is not known bars patentability awaits future clarification by the courts.

Additionally, when pre-filing transfers are made, agreements lacking confidentiality provisions may negatively affect academic technology transfer. First, if a patent is invalidated because of such transfers, the institution may not be entitled to royalties from the claimed invention from the licensee. Second, those transfers may be used by prospective licensees to discount the value of the patent, even if a patent has not been

challenged. Third, after discovering those transfers, a would-be licensee may abandon licensing negotiations and develop the technology without a license, knowing that, if sued for patent infringement, an attack on the patent validity could arise.

MTAs are enforceable in countries that respect trade secret law. A caveat can arise from competition law that restricts the use of private agreements to achieve IP goals far beyond those created by patent and copyright statutes. But it is not clear whether in order to be enforceable, the agreement has to be signed by both parties before the transfer of the material, or whether a simple letter included with the transferred material is sufficient to establish an enforceable agreement. If the recipient proposes terms that materially differ from those contained in the letter of agreement, the response, even if it is worded as acceptance, is considered a new offer, to be accepted by the provider. Finally, there is no legal requirement for the provider to verify whether the recipient is living up to obligations included in the agreement; enforceability does not depend on vigilance. Without some monitoring or tracking, MTAs may be effectively meaningless.

Looking ahead

The proprietary claiming wave has been the consequence of high levels of investment in R&D and extraordinary scientific and technological breakthroughs. Although IP rights may sometimes be necessary to motivate industry to develop and disseminate university-based inventions, the trend towards the assertion of IP rights by universities may also impede the progress of science. The challenge lies in distinguishing research results that are better developed and disseminated through open access or under the protection of IP rights. Despite the fact that MTAs provide a safeguard for investments in technology by setting out the conditions for using the material, open science is limited by MTAs.

Unlike patents or copyrights, MTAs do not rest upon codified legal statutes defining specific rights and obligations. Instead, reflecting freedom of contract, parties have wide discretion in setting the terms of their agreements and tailoring them to their specific needs. Transferred material can be regarded as trade secrets. In countries that protect trade secret contracts, MTAs offer a form of IP protection that can go beyond that available under patent law. The increasing complexity involved in the supply of proprietary technologies may raise matters of contract law, IP law, biodiversity and biosafety law, technology transfer and competition law.

ACKNOWLEDGMENTS

The author would like to thank Jean Gilbert for helpful comments on drafts of this article.

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