



# Material Transfer Agreement (MTA) in the Context of Scientific Research from the Point of View of German Law

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## ABSTRACT

The exchange of information and materials within the framework of research projects can be managed in different ways. In most cases a so-called "Material Transfer Agreement" (MTA) is necessary.

What looks like a simple ascertainment of rights and duties of the contracting parties, is clearly more fraught with risks than it looks at first sight. An individual arrangement and initial negotiation are necessary to prevent legal risks and not to burden the cooperation between the contracting parties and scientists with legal conflicts and uncertainties. Of course, confidential clauses shouldn't be missing.

While the precise regulations of the scope of work serves the concretion of the subject matter of contract, clauses for the protection of property and IP rights regulate the handling with the research and possible publications regarding the use of the provided materials and their specific ownerships.

The following will deal with the areas of application, the requirements and the regulatory content of this important type of contract.

**Key Words:** MTA, Agreement, Intellectual Property, Publication, German Law, Germany

## INTRODUCTION

If scientists wish to exchange data and/or materials for use in a research project, this exchange can be regulated through a variety of means. The exchange usually takes place after consultation between the Supplier and the Recipient. However, whenever two Parties agree to make an exchange of services (Latin *do ut des*), they enter into reciprocal relationship with each other (Greek *Synallagma*).<sup>1</sup> The legal relationship underlying this exchange is always agreement-based, regardless of whether the Parties executed it in writing, agreed upon orally, or even acted only through implied actions (such as transfer of materials).<sup>2,3</sup> It is completely and utterly irrelevant whether one simply determines that it is a contract<sup>4</sup>, because it depends on the actual legal assessment. The various contractual structures in this context are summarized under the term "Material Transfer Agreement" or "MTA". Depending on the structure of the relevant Material Transfer Agreements, they are similar to loan, lease, purchase, license or gift agreements in terms of contract typology. Thus, the Material Transfer Agreement is a conglomeration of rules

governing the exchange of data or materials for research purposes.<sup>5</sup>

Against this background, there is no single Material Transfer Agreement, because there can be no "one-fits-all" solution that appears from the wording of the contract. Instead of this, it is always necessary to consider the individual case. However, there are ways to treat similar individual cases in the same manner, which makes it possible to reduce the transaction costs.

## CONTRACTUAL PARTNER

The answer to the question of who is the Supplier's contractual partner depends significantly on the owner of the material. In the vast majority of cases, the relevant materials will not belong to the submitting scientist personally, but to the institution in which he/she works and where these materials were generated. However, only persons legally representing that institution can make legally valid statements (for example, enter into a contract) in respect of these institutions.<sup>6</sup> Who this is, after all, depends on the legal form of the respective

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institution. In the case of a Limited Liability Company, for example, this is a managing director in accordance with §35 of the Limited Liability Companies Act (TMG), in the case of university hospitals (depending on the applicable university law) this is the Board of Directors, President and so on. If the relevant institution has an internet presence, you do not need to painstakingly look for the authorized representatives in accordance with the law. A mere glance at the imprint of the homepage is enough, because the institution is obliged to provide information in this regard according to §5 paragraph (1) No. 1 of the Audiovisual Media Service Directive. These legal representatives of institutions, in turn, may be represented. However, this is only possible, if the corresponding Power of Attorney within the meaning of §§ 164 et seq. of the German Civil Code (BGB) has been granted by the legal representative to the following authorized persons.<sup>7,8</sup> Experience has shown that such Powers of Attorney are almost exclusively granted to the second level of management, for example, the Heads of departments or directors of hospitals. Individual scientists are mostly exempt from this practice. It is surprising when the scientists sign the Material Transfer Agreements for their institutions without such a Power of Attorney. In this case, they act as the agents without the right of representation. The situation is no different on the side of the Receiver. So, it is crucial here to consider whether the Recipient receives materials for the research as part of his/her work (as in the case with the most university staff) or as an individual person for his/her private research (in his/her spare time). Only in the latter case the Recipient is entitled and obliged as an individual person to have a Material Transfer Agreement, and only then he/she can sign a Material Transfer Agreement on behalf of itself. However, the Recipient can act in such a position as a representative of an institution, only if he/she can present an appropriate Power of Attorney granted by the actual legal representative.

Even if one can obtain the legal evidence of the proper conclusion of the Material Transfer Agreement from outside, this sometimes has serious consequences for the internal relationship between the researcher and the institution. In such a case, the underlying Material Transfer Agreement shall be considered “null and void” until final approval by the institution.<sup>9,10</sup> If the institution ultimately withholds approval entirely, this does not lead to the complete ineffectiveness of the Material Transfer Agreement, but the scientist acting without authority shall be held liable to indemnify the institution (Ref. § 179 of the German Civil Code). The scientist shall be held liable with its personal assets. According to the authors’ own experience, those scientists who have previously complained about the slowness of the process of negotiating and signing the Material Transfer Agreement are very interested in the legal support of the Material Transfer Agreement from the moment when these consequences of liability became clear to them. Only those who don’t need

to assume liability will be upset by the safety concern on the part of administration.

## **NEED FOR A SEPARATE MATERIAL TRANSFER AGREEMENT**

Taking the above mentioned into consideration, the Material Transfer Agreements are the contracts that must be signed by the legal representatives. Since these representatives themselves shall be held liable towards the institution with their signature, it is only natural that they try to minimize the risks. Therefore, the relevant Material Transfer Agreements must be reviewed before signing. This review process sometimes involves the long-term contractual negotiations. This is where the interests of the researcher and the interests of the institution coincide. This conflict of interest is fueled by the fact that the researchers often seem happy to share their materials and data, while institutions (must) protect and commercialize the research in their possession.<sup>11</sup> Sometimes the contractual negotiation procedure results in the delays in the conclusion of the Material Transfer Agreements and thus to a delayed start of the project.<sup>11,12</sup> The escalation of the contractual negotiations is mainly due to excessive fears of liability and loss of control or the fear of missing out on the commercial opportunities.<sup>4,12</sup>

We consider this assessment to be premature. Aside from the fact that none of the relevant publications provided a database upon which alleged concerns were assessed, and no evidence was provided that the contractual negotiations actually caused delays, the “contractual negotiations” do not fall from the sky. If scientists are aware that the relevant Material Transfer Agreement must go through the formal process of contract review, they can adapt themselves to this procedure and take it into account when planning their project. The potential for disappointment<sup>4</sup> can arise in this context only if scientists do not even expect that contracts will have to be signed.

After the first seriously negotiated Material Transfer Agreement, the negotiation period with the same partner shall be reduced considerably. After exchanging various positions and reaching appropriate compromises, the contracting Parties will come back to the agreed upon version during conclusion of a subsequent Material Transfer Agreement, which can be adjusted without losing much time. In such a case, the changes need to be made only in the event of changes in the fundamental laws or relevant precedent law. Since the Material Transfer Agreement is already a de facto contract, it should always be read and understood beforehand. We do not understand why this activity, which has to be done anyway, creates unnecessary barriers and costs in the research community and in the society as a whole.<sup>11</sup> Wouldn’t it be more profitable for the researcher to deal with it personally and,

if necessary, read into the legal discussions? The costs incurred would be eliminated (and that always seems to be behind these arguments), if you just sign everything at once or do without contracts at all. However why are the scientists, who make such complaints, find it difficult to settle among themselves their labor relations and equipment in their departments? Shouldn't one then use the same argument to do without employment contracts, sales contracts, and so on? The call for a complete rejection of the Material Transfer Agreement is not even made by the scientists.<sup>4,11</sup>

However, to be more specific, the Material Transfer Agreement is not necessary in all cases. When we talk about the mutual transfer of data and materials between the partners within the framework of a specifically-designed research project, on which the partners are working cooperatively, then there should be at least de facto scientific cooperation. It is completely and utterly irrelevant whether it is based on a joint approval notice, EU Grant Agreement, a consortium or a cooperation agreement. It is of the utmost importance that several partners work together toward a common goal. In fact, there will be at least one research cooperation within the framework of a civil law partnership (GbR) (Ref. §705 of the German Civil Code). However, since the partners in this case are quasi-shareholders of the research cooperation, they can exchange the data and materials provided as part of the description of their services, as well as the ownership rights which they already have within the research cooperation based on the relevant cooperation agreement.<sup>13</sup> No additional Material Transfer Agreements are required for this purpose. Therefore, such a solution is appropriate if, for example, the researchers with many "parts" together create a more complicated biological system for practical application. Then this new system will be considered mainly as a joint invention. However, unless the researchers join together in advance to form such a research association, the regulations for the Material Transfer Agreements, which are explained in more detail below, remain in effect. This would mean that the researchers and their institutions would have to deal with the invention clauses afterwards. It is good for those who can then show an appropriate Material Transfer Agreement as a Supplier, in which their contribution to the new system is sufficiently appreciated.

Thus, the Material Transfer Agreement is necessary, only if there is no legal relationship with the relevant counterparty through the research project, i.e., the counterparty is a third party. The routine case is when a scientist needs a specific plasmid, cell line or mouse for its project and the Supplier of these materials bears no relation to the implementation of the project. However, the way of arrangement of the release and signing procedure so that it would run without much tension is a purely organizational matter. Even in practice, with particularly "simple" procedures (with a very complex legal content of the clauses), it has not been without verification

and signature (Ref. ordering of plasmids via Addgene). According to the current Quality Guideline and Anti-Corruption Compliance Guide, the verifier and the signer shall not be the same person.

At this stage, the Material Transfer Agreement should also be distinguished from the contract research project. In the framework of the contract research projects, the Supplier (Customer) shall transfer its product to the Recipient (Contractor) so that it can carry out a project planned by the Customer or scientific research on the issue specified by the Customer. Thus, in the legal sense the contract research is a scientific service that also includes clinical trials of drugs and medical devices, if the researcher/physician generates the patient data and samples for the Customer/Sponsor.

Understood in this manner, the transfer of material through the Material Transfer Agreement shall be possible only in cases when there is no talk about the contract research and when it takes place outside of research cooperation.

## **NORMATIVE CONTENT OF THE MATERIAL TRANSFER AGREEMENT**

As a normal exchange agreement, the Material Transfer Agreement must contain, among other things:

- Scope of services (determination of the material to be transferred, the obligation to deliver the material and the intended use of the material to be transferred)
- Prohibitions on use (e.g., for the Human subject research) and prohibition of disclosure without Supplier's consent
- Costs / fees
- Confidentiality
- Protection of property rights and intellectual property rights
- Liability

For each of these clauses, there are different areas of concern. Some of them are presented below:

### **Scope of services**

The core of each exchange agreement is the determination of the services payable in each specific case.<sup>14</sup>In a point of fact, the Material Transfer Agreement is a contract that governs the transfer of data or materials from a Supplier to a Recipient. First of all, it is of the utmost importance that the things to be transferred should be defined very precisely. This makes the checklist function of the contract negotiations too clear, because this is exactly where it is determined whether the materials are suitable for the expected research purpose. Therefore, it is also important for the Recipient to determine the purpose for which the materials will be used. At the same time, it guarantees that the Recipient cannot use the materials

for other purposes without the repeated consent of the Supplier. This is neither a hindrance to research and nor unnecessary patronage. The person who owns the materials has a vital interest in their use only with its explicit consent. Since the underlying ethical principles of what researchers are allowed or not allowed to do vary from country to country, the Supplier would otherwise have to accept that the material is used by the Recipient in a way that would be prohibited in its own country. In such a case, the legal and media echo could be devastating, if the Supplier had not prohibited this type of use. Against this background, the prohibitions on the use of material directly on human subjects or for diagnostic and therapeutic purposes are understandable.

In that context, the drafts of the Material Transfer Agreements often “forget” to oblige the Supplier to provide the material. On the one hand, this is important in order to receive revenue, if the delivery does not take place. However, the precise wording also determines which of the partners bears the transportation risk.<sup>15</sup>In particular, if the materials are provided on a fee paid basis, it is important to determine which of the partners bears the transportation risk, if the materials are lost during the transportation or become defective (for example, due to interruption in the cold circuit). Depending on the situation, either the payment would have to be made despite the non-receipt of materials, or the Supplier would have to send new material without additional payment.

Of course, care must be taken to ensure that the Supplier delivers the materials in proper condition – a legal expert would say they must be “free from defects”<sup>16</sup>. The researcher shall not bear expenses for the loss of time and funding due to contaminated viral cultures and so on, especially when it comes to the commercial Material Transfer Agreements.

### **Confidentiality**

As soon as the purpose for which the materials will be used is disclosed to the Supplier, the Recipient has a strong interest in the Supplier keeping this information secret. At the same time, the privacy statement for the Supplier supplements the prohibitions on use that are imposed on the Recipient. However, at least in Germany, the confidentiality provisions in the contracts should supplement the confidentiality provisions that already exist under the Trade Secrets Act and in the context of pre-contractual negotiations (§§ 311 para. (2), 241 para. (2) of the German Civil Code). Even if the Material Transfer Agreement is not ultimately concluded, the information transferred during the negotiation of the contract shall be kept secret by the partners.<sup>17</sup> When entering into the Material Transfer Agreement, the provisions of the agreement only supplement this protection and make it clear to the signatory that, for example, the purpose of the study and the specifically-designed research project are facts requiring confidentiality.

The usual provision in a contract that prohibits the transfer of materials to third parties without the consent of the Supplier should be considered in the same context.

### **Protection of property rights and intellectual property rights**

The protection of the right of ownership of the materials and the protection of existing intellectual property rights in this regard (Foreground IP), as well as the regulation of the intellectual property rights arising from their use within the framework of the research project (Background IP) also interact with the terms of use and confidentiality. All these areas supplement each other and therefore need to be coordinated with each other. From the German perspective, a distinction needs to be drawn between the ownership of materials or data carriers, relevant intellectual property rights (e.g., copyright, trademark rights, title rights, patent rights) and research results obtained through the use of materials, including their property rights and intellectual property rights.

Unlike research cooperation, the Material Transfer Agreement only concerns the transfer of data and materials, and not the joint research. Thus, many of the excessive provisions used in the scientific research are redundant. In most cases, it has been established that the ownership of the material remained with the Supplier. Exceptions are possible, but rare. In particular, the industry partners do not simply hand out materials. Therefore, the ownership remains with the Supplier, and this also applies if this material is included in the respective modifications by the Recipient. If you produce such modifications not as part of research cooperation, but through the Material Transfer Agreement, you will always need to obtain the approval of the Supplier of the material when transferring the modifications to third parties. In a similar way, the commercial use of the modification must be agreed upon with the Supplier. Therefore, there is another point that is usually regulated, namely the fact that the commercial use of the material is reserved for the Supplier. This is evident in the industrial companies, but it is the same in the public institutions such as universities. In accordance with the relevant Higher Education Acts of the federal states and budget requirements, the universities cannot simply renounce the intellectual property rights created by them, to which they are entitled. There are also aspects of the competition law and the issue of illegal subsidies, if the universities allow third parties to use their intellectual property rights for commercial purposes.

Of course, for the mere provision of data/materials, the Supplier should not be granted any rights to the research results of the Recipient or even to other inventions resulting from the research of the Recipient that were not made through the use of materials. These Reach-Through conditions<sup>11</sup> most often occur when the Supplier of the material is a commercial partner and mostly in the context of research grants. Rather

than viewing this as a fundamental evil<sup>4</sup>, it should be kept in mind that the contracts are also concluded in order to bring conflicting interests to a fair balance. In principle, inventions that lead to a patentable expansion of the material are definitely have relevance to the Manufacturer/Supplier and can be transferred to it. On the other hand, it should be clear that inventions (or know-how) arising within the framework of the project, using the materials but not based on the materials, can only be inventions of the institution without the right of access of the Supplier. In this context, particular attention must be paid to the definition of material under the relevant Material Transfer Agreement, on the one hand, and modifications that should be made, on the other hand. The latter are usually assigned only to the Recipient, although there are also a wide variety of regulations here. For example, modifications that include materials can only be used for commercial purposes, if the Parties have previously entered into a separate license agreement. Such regulations may seem redundant in most cases, in view of the current background of the lack of practical commercial usability of the materials.<sup>11</sup> However, today no one can predict whether such materials will acquire commercial value in the near future. Above all, the individual scientist should not assess the way in which the institution as a whole assesses the value of the materials under consideration. However, the Material Transfer Agreement should cover these particular imponderables, since the universities are also legally required to adhere to the economic point of view in the framework of research activities.

The publication clauses should also be read in this context. Granting of the right to the Supplier to work as a co-author of the Recipient's publication is rarely required and seems too important for the mere provision of the material. From our point of view, it is understood that the planned publication is submitted to the Supplier for review before publication in conjunction with the abovementioned invention provisions. The sole objective of the Suppliers is to see, whether he/she considers the intellectual property rights to the material as sufficiently protected by the publication. Since the Recipient is also bound to secrecy in the case of duly executed Material Transfer Agreements, it should not be afraid of publication at an inopportune time. In this case, the use of the draft publication for other purposes or premature publication by the Supplier is prohibited by the relevant clause. We do not see any disadvantage for the publishing scientist, but of course this depends on the appropriate design of the rules of publication. However, if the scientists continue to suspect that the Suppliers are actually trying to compensate<sup>11</sup> their nonexistent research units with these Material Transfer Agreements, the violation of the confidentiality provisions could be supplemented with appropriate contractual penalties or the materials would have to be purchased from another source. This is exactly where the extent of importance of the competent expert examination becomes apparent. Would it be so much

to gain, if such Material Transfer Agreements were simply signed without verification? For a scientist, the situation could get worse. Complaining that the world is so unfair is an irrelevant argument in this case. If you sign something, it is your fault, when you did not read and understand it beforehand. There are many people who try to exploit such naivety –*homo-homini lupus*.

## **SPECIAL ISSUE: CROSS-BORDER MATERIAL TRANSFER AGREEMENTS**

Whenever the delivery of materials involves a cross-border delivery, which happens in most cases, it raises some significant legal issues, which the respective legal departments will try to resolve.

First, there is an issue of the applicable law. For a legal practitioner, it is of great importance which law has to be applied to the contract and its interpretation in the event of disagreement. This is a big problem for lawyers, who have been trained in the relevant national context, but the legal systems of two countries are like apples and pears. Therefore, it is practically impossible to demand from a lawyer in Germany the “legal release” of a contract concluded under French law. Each lawyer knows only its own law and therefore can ultimately be held responsible only for risks from its own legal sphere.

The legal practitioner can reduce this problem by resorting to the cross-border standards. At least, if the materials are provided on a fee paid basis, you will fall within the scope of the United Nations Convention on Contracts for the International Sale of Goods (unless otherwise expressly stated in the text of the contract). In Europe, if you can't come to an agreement about applicable law because each side insists on its own national law, it makes sense to abandon the relevant rules altogether. Within the EU Regulatory Framework, the provisions of the Rome I-VO / Rome II-VO / Rome IIA-VO Regulation would then apply, whereby the place of performance will probably be the most important factor.

## **CONCLUSION**

It should have become clear that even supposedly simple Material Transfer Agreements are not associated with low risk. On the contrary, they are fraught with many legal risks and, above all, an individual development is necessary for each individual case, which depends largely on the respective goals and objectives of the partners. Since the Material Transfer Agreement is a contract, it must be negotiated on an individual basis, even though negotiation time may be cut prohibitively through the use of the standards and clauses that have already been agreed upon for the same circumstances.

We do not understand the demands<sup>12</sup> from the scientific community that the restriction of liberty to negotiate, to which the parties are entitled, by means of “take it or die” clauses will push things on. This would only be possible, if the provisions used were designed in such a way as to produce a fair balance between the interests of the Supplier and the Recipient. Thus, even clauses declared (on a unilateral basis) by either Party as non-negotiable must be verified by another Party. The fact that these clauses are not supposed to be negotiated does not mean that the legal risk inherent in most of them seem to vanish into thin air. However, this in turn increases the pressure on the contracting partner as to whether he/she is willing to take that risk or not. Administrations and legal representatives of institutions, who will be held personally liable for their decisions, will not want to take risks in case of doubt. This is not very helpful to the scientists, who therefore do not have access to the materials. It is also important that the respective partners specify their mutual interests at least once at the beginning, come to an agreement about the relevant provisions, and then refer to them again in the subsequent, under the stipulation that they refer to the same life circumstances.

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