

**INTELLECTUAL PROPERTY MANAGERS
CONTRACT AND GRANT OFFICERS
VICE CHANCELLORS - RESEARCH/ADMINISTRATION**

SUBJECT: Genzyme Material Transfer Agreement

Background:

Earlier this year, Genzyme expressed an interest in streamlining the transfer of Genzyme materials to the University by eliminating the need for extensive negotiation of its material transfer agreement (MTA) for each transfer of material. OTT was asked to work with Genzyme intellectual property counsel with a goal of creating a template MTA for use in the majority of transfers of material from Genzyme to University researchers.

The resulting agreement was created with input from campuses and is much less problematic for the University than the previous Genzyme MTA. While both UC and Genzyme expect this MTA to be useful for the majority of transfers of material from Genzyme to University researchers, the agreement does contain some non-standard provisions, as discussed below, and both parties recognize that it may not be acceptable in all situations.

Please note that Genzyme uses two different versions of the agreement: one for the transfer of Genzyme materials that are not currently approved for use in humans (Attachment A) and one for materials that have been approved for clinical use or are on the market, such as murine TGF-beta antibodies (Attachment B). To be clear, neither version of the MTA permits the University to use the material in humans or for diagnostic purposes. The only difference between the two agreements is that the second one includes language regarding adverse event reporting for animal studies due to strict FDA reporting requirements.

Agreement Provisions

In addition to many of the typical provisions found in most industry MTAs, the Genzyme MTA includes the following:

Non-Exclusive, Royalty-Free License

Under the agreement, the University is required to grant a fully paid-up, non-exclusive royalty-free ("NERF") research and evaluation purposes license to Genzyme under the University's patent rights in any invention that relates to the material or its use and is made using the material (referred to in the

agreement as "Reported Invention"). Note that the field of use specifically excludes use for drug screening.

First Right to a Commercial License/Restrictions on Use of Other Funds

Genzyme also receives a time-limited first right to negotiate an exclusive or non-exclusive commercial license to any Reported Invention, subject only to the University's obligations to the U.S. government. Genzyme expects that its material will not be used in any research involving obligations to any other third parties without its written consent prior to use of such funds. This includes for-profit and non-profit entities, as well as state funding. In addition, the University must agree that, to the best of the knowledge of the signatory, after consultation with the Investigator, it has not and will not enter into conflicting agreements with a for-profit entity.

Right of First Refusal

In the event that negotiation of a commercial license proves unsuccessful, Genzyme has a limited right of first refusal, applicable only to licenses that the University offers to a third party on *royalty terms* that are less favorable to the University than the terms *last offered by Genzyme*. The right of first refusal terminates after six months.

Tax-Reform Act

Under the Tax Reform Act of 1986 ("the Act"), the tax-exempt status of financing used by the University for buildings and capital improvements may be threatened when the University enters into sponsored research agreements containing certain IP provisions. The University is required to covenant in its bond indentures that it will not permit the financed facilities to be used in any manner that would violate the private activity use rules or otherwise cause the interest to become taxable under IRS income tax provisions. Since the Office of General Counsel has determined that a provider of material is considered a "sponsor" as that term is used in the Act, these considerations apply to MTAs as well as to research funding arrangements.

With respect to material transfer agreements, the funding (and sometimes additional material) is usually provided by another party. Under the Act, such arrangements are considered multi-party collaborations. In order to prevent the occurrence of a private activity use that would violate the Act, the most any such collaborator may receive under the research agreement/MTA is a non-exclusive royalty-free license to inventions.

In situations where non-University funding will be used in conjunction with Genzyme's material, Genzyme's option to negotiate an exclusive commercial license could take the University outside the safe harbor of the Act. However, in recent guidance from University bond counsel we have been advised that there may be less risk of deeming the use a private activity when there is a very close nexus between the provider's material and the invention to which the provider will receive exclusive rights; e.g. inventions that "necessarily incorporate or necessarily use" the provided material. Unfortunately, it is not clear that the terminology of the Genzyme MTA ("relates to") will pass the test, and Genzyme

would not agree to a stricter limitation on the scope of its exclusive license rights. Accordingly, please be advised that this agreement may not be appropriate for use where Genzyme's material will be used in tax-free bond funded facilities.

For additional information on the Tax Reform Act, please see OTT Guidance Memo No. 00-01 (<http://patron.ucop.edu/ottmemos/docs/ott00-01.html>).

Implementation Issues

While the non-standard provisions above may be manageable in most circumstances, it is recognized that they may be unsuitable for others. OTT recommends execution of the Genzyme MTA by the authorized campus/Laboratory official only after careful consideration of the case-specific circumstances. It is anticipated by both parties that this agreement will be used for the majority of transfers of Genzyme material to the University, however, Genzyme is aware that final decision on appropriateness of these terms is at the discretion of each campus or Laboratory. With respect to the *Principles Regarding Rights to Future Research Results in University Agreements with External Parties* (<http://www.ucop.edu/ott/082699a.html>), the following should be observed:

Informed Participation

Consistent with the Principles, each campus or Laboratory must ensure that all stakeholders are apprised of the impact this agreement may have on them, including:

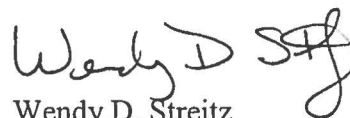
- The researcher(s), his/her department and the campus will be unable to receive any licensing income from Genzyme's research and evaluation use of certain inventions.

Legal Integrity and Consistency

- The campus must ensure that Genzyme material is not used in research funded by or using materials provided by other parties with the exception of the U.S. government, and subject to licensing or option obligations, unless Genzyme gives its prior written consent.
- The campus must ensure that there are no conflicts with the intellectual property requirements of the Tax Reform Act of 1986.

If you have any questions, please contact Dianne Archer at (510) 987-0355 or Dianne.Archer@ucop.edu.

Sincerely,



Wendy D. Streit

Director

Policy, Analysis and Campus Services

Enclosures: A. Material Transfer Agreement for Materials Not Approved for Use in Humans
 B. Material Transfer Agreement for Materials Approved for Use in Humans
 (including marketed material)

cc: Interim Executive Director Tucker
 University Counsel Simpson
 OTT Directors