COUNCIL ON GOVERNMENTAL RELATIONS
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Date: 9/17/97

FROM: COUNCIL ON GOVERNMENTAL RELATIONS
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TO: Norman Lattker, Esq.

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FROM: Kate Phillips Phillips

SUBJECT: NIH Respause to univ. appeal of DEC

Number of Pages (including coversheet): 11

Comments:

Norm, I thought you might be interested in this latest "compromise" offer by NIH. Acceptance by the schools would mean dropping the appeal. Do you have any particular legal or political reaction?

<Kate

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September 15, 1997

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Janis L. Goddard
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Georgia Tech Research Corporation
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Subject: **Synthesis of Congeners and Prodrugs Contracts**
Purdue (N01-CM-67260); Kansas (N01-CM-67259);
Tennessee (N01-CM-67261); Georgia Tech (N01-CM-67246)
Proposed Contract Language and Guidelines concerning
Greater Rights Determinations, Publication Rights and Royalties

Dear Mr. Pherson, Ms. Moreland, Mr. Devine and Ms. Goddard:

As a result of discussions at our July 25, 1997 meeting, NCI and NIH program, intellectual property, legal and acquisition staff have developed the enclosed proposed contract language and proposed Guidelines for greater rights determinations, publication rights and royalties.

It is proposed to include the language in **Attachment I** as an Advance Understanding in ARTICLE

B.4. of your contracts. **Attachment** 2 is the proposed *Guidelines for Greater Rights Determinations, Publication Rights and Royalties*. Please review the materials and provide any written questions or comments by October 17, 1997. Please call me or send an e-mail message if you have any questions.

Sincerely,

Carolyn L. Swift
Contracting Officer
Treatment Contracts Section
Research Contracts Branch
National Cancer Institute

Attachments: 1 - Proposed Advance Understanding for Contracts
2 - Proposed *Guidelines for Greater Rights Determinations, Publication Rights and Royalties*

cc: Mark Cushman, Ph.D.
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Gunda I. Georg, Ph.D.
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ATTACHMENT 1

Proposed Advance Understanding (ARTICLE B.4.) Concerning Greater Rights Determinations; Publications Rights and Royalties

The contractor is encouraged to request greater rights in inventions it makes under this contract and such rights will be granted to the extent it does not impair NCI's ability to: (1) obtain proprietary compositions and processes from third party providers for evaluation under the contract; and (2) develop congener/prodrug compositions to the point of commercialization.

Unless a third party provider objects, the contractor will be given the name of the provider and an opportunity to negotiate an appropriate disposition of rights in any inventions the contractor may make related to the provider's compositions or processes.

In the case of inventions relating to compositions not proprietary to a third party provider, requests for greater rights will be granted except to the extent that the invention relates to NCI's mission in the development of congeners/prodrugs. Nonetheless, NCI may grant greater rights where the invention relates to NCI's mission if the contractor submits a development and commercialization plan which is approved by NCI.

NCI encourages publication of scientific papers describing research results. However, in certain limited situations (e.g., in the case of proprietary compounds) where the data are related to a provider's proprietary composition or process or will be part of a patent application or will be necessary for regulatory filing, the contractor shall obtain approval of the NCI Project Officer and Contracting Officer prior to publishing the data. Publication will normally not be delayed more than 90 days except for data needed for a regulatory filing or data related to a provider's proprietary composition or process.

ATTACHMENT 2

Proposed *Guidelines for Greater Rights Determinations, Publications Rights and Royalties*

I. LEAD COMPOUND IS PROPRIETARY TO PROVIDER

A. Pre-negotiation of license between Contractor and Provider

1. NCI identifies Contractor for compound

2. NCI contacts Provider, to determine if Provider will enter into negotiations with Contractor, to license Contractor intellectual property rights in advance

3. If Provider agrees, a 30 day negotiation period begins

4. At the end of the negotiation period:

   a. If there is agreement between Provider and Contractor, NCI will submit the compound to the Contractor for congener/pro-drug development, with greater rights to be granted to the Contractor upon request at the time of invention.

   b. If there is no agreement between Provider and Contractor, NCI will submit the compound to the Contractor for congener/pro-drug development, with no commitment with regard to the granting of greater rights to the Contractor upon request at the time of invention.

B. Requests for greater rights at the time of invention

1. If a license has been pre-negotiated with the Provider, greater rights will be granted to the Contractor upon request.

2. If a license has not been pre-negotiated with the Provider, greater rights generally will not be granted to Contractor upon request.

   a. The Government may require the Contractor to assign rights to the Provider or to the Government

   b. Greater rights may be granted to the Contractor, with the requirement that the Contractor license exclusively to the Provider or to the Government, with a Government right to sublicense

C. Patent filing*

1. Disclosure will be delayed up to 90 days by all parties, to enable the filing of patent applications.

2. Filing

a. Contractor shall have first option to prepare and file patent applications on which Contractor employees are sole or joint inventors

b. If Contractor elects not to file, licensee/Provider (in the case of greater rights granted to Contractor and licensed to Provider) or NCI (in the case of rights retained by NCI) shall have the right to file

3. Expenses

a. If Contractor files, filing costs will be borne by the Contractor

b. If licensee/Provider files, filing costs will be allocated according to Contractor/Provider agreement

c. If NCI files, filing costs may be recovered in share of royalties

4. Patent prosecution

a. If Contractor files, and invention licensed in advance to Provider, authorities will be determined by Contractor/Provider agreement

b. If Contractor files while NCI retains rights under the DEC, NCI shall have an associate power of attorney

D. Publication rights

1. Non-regulatory data

a. NCI will have a minimum of 30 days (and up to 90 in the case of those disclosures related to a patent application filing) to review all proposed publications, to ensure, in consultation with Provider, that no data necessary to a future regulatory filing is disclosed

b. Non-regulatory data constituting a disclosure shall be delayed until patent filing

2. Regulatory data shall not be published without the approval of the Provider

E. Royalties*

1. Sole Contractor inventions

a. For those inventions licensed directly to Provider by Contractor, royalties will flow to Contractor

b. For those inventions licensed by NCI to Provider, royalties will be shared based on relative contributions to invention, and to administration of the patent application and license

2. Joint Contractor/NCI inventions

a. For those inventions licensed directly to Provider by Contractor, royalties will be shared based on relative contributions to invention

b. For those inventions licensed by NCI to Provider, royalties will be shared based on relative contributions to invention, and to administration of the patent application and license

II. LEAD COMPOUND IS NOT PROPRIETARY TO A PROVIDER, BUT IS WITHIN THE MISSION OF THE NCI

A. Requests for greater rights at the time of invention

1. Requests for greater rights to aspects of inventions that are not related to the mission of the NCI will generally be granted

2. Requests for greater rights to aspects of inventions that are related to the mission of the NCI (that are under continued development by the NCI) will generally not be granted

B. Requests for greater rights during continued development of a congener/pro-drug by NCI will generally not be granted, unless:

1. the Contractor submits a development plan which is approved by the NCI for the continued development of the congener/pro-drug

2. the Contractor enters into a licensing agreement, approved by the NCI, with a third party for the continued development of the congener/pro-drug

C. Requests for greater rights when NCI discontinues its development of a congener/pro-drug will generally be granted

D. Patent filing*

1. Disclosures will be delayed up to 90 days by all parties, to enable the filing of patent applications

2. Filing

a. Contractor will have the first option to prepare and file patent applications on which Contractor employees are sole or joint inventors

b. If Contractor elects not to file, NCI shall have the right to file

3. Expenses

a. If Contractor files, filing costs will be borne by the Contractor

b. If NCI files, filing costs may be recovered in share of royalties

4. If Contractor elects to file while NCI retains rights under the DEC, NCI shall have an associate power of attorney for patent prosecution

E. Publication rights

1. The publication of non-mission-related data shall be delayed until patent application filing

2. Mission-related data

a. NCI shall have a minimum of 30 days (and up to 90 days) to review all proposed publications, to ensure that no data necessary to a future regulatory filing is disclosed

b. Non-regulatory data constituting a disclosure shall be delayed until patent application filing

c. Regulatory data shall not be published without the approval of the NCI, or the third party licensee (if any)

F. Royalties*

1. Sole Contractor inventions

a. For those inventions licensed directly to third party by Contractor, royalties will flow to Contractor

b. For those inventions licensed by NCI to third party, royalties will be shared based on relative contributions to invention, and to administration of the patent application and license

2. Joint Contractor/NCI inventions

a. For those inventions licensed directly to third party by Contractor, royalties will be shared based on relative contributions to invention

b. For those inventions licensed by NCI to third party, royalties will be shared based on relative contributions to invention, and to administration of the patent application and license

* N.B. Interinstitutional agreements (through the NIH Office of Technology Transfer) may be necessary to accomplish cooperative patent filing and prosecution, licensing, and sharing of royalties.

Lead Compound Proprietary To A Provider

Lead Compound Not Proprietary To A Provider

