COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005
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Date: 6/18/97

FROM: COUNCIL ON GOVERNMENTAL RELATIONS
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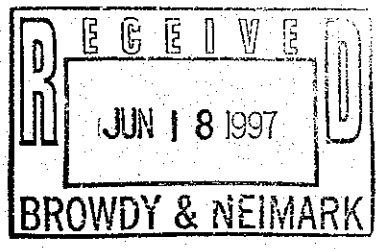

TO: Norman Lorker

TELEPHONE: FAX (202) 737-3528

FROM: Kate Phillips

SUBJECT: Update

Number of Pages (including coversheet): 9

Comments:

COUNCIL ON GOVERNMENTAL RELATIONS
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June 18, 1997

Norman Latker
Browdy and Neimark
419, 7th Street N.W.
Washington D.C.

Dear Norm:

You were very kind to discuss with me the Determination of Exceptional Circumstance (DEC), issued by the National Cancer Institute (NCI) in four contracts to research universities in September 1996. Since I know of your long standing interest in the Bayh-Dole Act and its implementation, I am sending you an update on what has happened since. First, the universities did decide to appeal and I am enclosing the letter prepared by Purdue. Second, the NIH finally responded to COGR's inquiry, in a letter dated May 22, 1997. It answers several questions, except the one whether the NIH could have found an alternate solution in spite of its stated contractual constraints.

The NIH has now invited the universities to a meeting, in advance of the fact-finding process mandated under the appeal, in order to seek a mutually acceptable solution. In addition, I understand that Dr.Tom Mays has left NIH to take a position at Morrison and Foerster in D.C.

I hope all is well with you.

Sincerely,

Kate.

Kate Phillips

PURDUE RESEARCH FOUNDATION

PURDUE UNIVERSITY
1063 Hovde Hall, Room 339
West Lafayette, Indiana
47907-1063 317/494-1833

May 13, 1997

Carolyn Swift
Contracting Officer
National Cancer Institute
OEM, RCB, TCS
Executive Plaza South, Room 603
6120 Executive Blvd MSC 7220
Bethesda, MD 20892-7220

RE: Appeal of the Determination of Exceptional Circumstances:
RFP # NC1-CM-67246-74; Contract #NO1-CM-67260

Dear Ms. Swift:

NOTICE OF APPEAL

Notice is hereby given, pursuant to Federal Acquisition Regulation (FAR) 27.304-1, 37 CFR 401.4, and in accordance with 35 U.S.C. 202 (b)(4), that Purdue University and the Purdue Research Foundation, both non-profit organizations, appeal the Determination of Exceptional Circumstances (DEC) of Dr. Harold E. Varmus, dated 9/26/96, and the corresponding substitution of FAR 52.227-11 Patent Rights - Retention by the Contractor (short form) June 1989 (Deviation) for the Standard Patent Rights Clause (FAR 52.227-11) in Contract Number NO1-CM-67260 between the National Cancer Institute (NCI) and the Purdue Research Foundation.

On September 30, 1996 contract number NO1-CM-67260 was issued to the Purdue Research Foundation (PRF) by the National Cancer Institute. This contract contained a deviation to the standard Patent Right Clause (FAR 52.227-11). This deviation requires the contractor to assign all rights, title, and interest in each subject invention to either NCI or to a collaborating party designated by NCI. This deviation was included in the contract as a result of a Determination of Exceptional Circumstances signed by Dr. Harold Varmus.

In his Determination Dr. Varmus states his conclusion that, "This action will better promote the policy and objectives of 35 U.S.C. 200 et seq, to ensure that the Government obtains sufficient data rights and patent rights in federally supported inventions to meet the needs of the Government and its collaborating parties and to protect the public against non-use or unreasonable use of inventions."

We believe that not only will the DEC fail to promote those policies and objectives, but in fact will work to the detriment of the policies and objectives of 35 U.S.C. 200. In addition, we believe that NCI has demonstrated an abuse of discretion by imposing the DEC without the benefit of consultation with the contractors in advance, and by failing to follow proper procedures for imposing a DEC referenced by FAR 27.303

Carolyn Swift
National Cancer Institute
Notice of Appeal Letter
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The DEC deprives contractors of ownership of all contractor inventions created under this contract. NCI's vague rationale for this is that, "Collaborators have indicated that they will not submit their compounds to the program where their intellectual property rights may be lost, infringed, or adversely affected by contractors employed by the Government." There is no empirical data cited which supports this conclusion. If a DEC can be imposed on the basis of such unsupported assumptions, then this DEC will set an extremely dangerous precedent.

We offer this analysis of the policies and objectives of 35 U.S.C. 200 as support for this appeal:

> The DEC will not "promote collaboration between commercial concerns and non-profit organizations, including universities." The DEC places great value on the collaborator's contribution to the commercialization process but ignores, if not discounts completely, the key role played by the university contractors. The DEC deprives us of our ownership rights and our right to benefit from commercialization of our intellectual property. With no opportunity to benefit in any way from such collaboration, there is no incentive to collaborate. From the commercial concern's perspective, they have no reason to collaborate with us under the conditions imposed by the DEC since we bring nothing to the table.
>
> The DEC will not "ensure that inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise." Free competition and enterprise create the incentives for inventors to invent. When inventors are deprived of their right to own what they create, they will stop inventing. When university researchers lose their freedom to publish and use their work to further education and research, they will become more and more reluctant to work under contracts which impose those kinds of restrictions. The Government will then be faced with a shortage of qualified bidders making fair and open competition for these contracts impossible. This DEC runs absolutely counter to the notions of free competition and enterprise.
>
> The DEC does nothing further "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor" than what the Bayh-Dole Act originally intended. Universities have a fine track record of commercialization of their inventions and collaborating with industry. NCI has failed to bring forward a single example of where universities have hindered the commercialization of a new compound or therapy for the treatment of cancer or AIDS.
>
> The DEC is unnecessary "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions." The Bayh-Dole Act contains a "march in right" provision which addresses this concern.
>
> The DEC does not "minimize the costs of administering policies in this area." NCI's costs of administering its programs will likely rise as a result of the DEC. Now universities bear the cost of transferring their technology to the market place. These costs are substantial and there is a significant risk that they will not be recovered. By imposing the DEC, NCI has chosen to assume these costs and risks.

It is our contention that NCI has failed to provide any factual support for its claim that the DEC will better promote the policies and objectives of 35 U.S.C. 200.

We are also appealing this DEC because we believe NCI's actions leading up to the DEC constitute an abuse of discretion. The facts supporting the appeal on this basis are as follows:

> The procurement process was flawed by the insertion of the deviated FAR 52-227-11 clause into the contract when it did not appear in the RFP. We received no notice of this material change in the Government's requirements in this RFP. According to FAR 15.606, the Contracting Officer is required to issue a written amendment to the solicitation when a change in the Government requirements is made. We must assume that the Contracting Officer was aware of this requirement and that a conscious decision was made within NCI to not comply with it.

The procedures for imposing a DEC were not followed by NCI. These procedures are set forth in FAR 27.303. These regulations require that before using any of the exceptions the agency shall prepare a written Determination including a statement of facts supporting the Determination. Further FAR 27.303 also requires an analysis justifying the Determination. The regulations state "this analysis shall address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200." A review of the DEC discloses no finding of fact and certainly not the specific analysis required by the regulations. These actions are not compliant with the regulations. We must assume that these actions were the result of conscious decisions made within NCI.

The deviated FAR clause employed by NCI in this contract is not compliant with the regulations. FAR 27.303 states that the standard clause is to be used "with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception." In the DEC Dr. Varmus states his concern to be with analogs to compounds submitted by collaborators. The deviation inserted into our contract encompasses all inventions made by us under this contract. A modification tailored to the specific, fact supported concerns is a requirement of the regulations. Again, we must assume that NCI was aware of the regulations and made a conscious decision to not comply.

The decisions made by NCI which lead to NCI's non-compliance constitute an abuse of discretion on the part of NCI.

We request that this appeal be decided according to FAR 27.304.1. This will require the decision come from one level above Dr. Varmus.

We request that the DEC be withdrawn and the standard FAR clause 52-227.11 be restored.

Purdue and NCI share the same objectives of providing new drugs and therapies for the treatment of cancer and AIDS to the public as efficiently and rapidly as possible. To this end, we are most receptive to bringing the issues discussed in this appeal to an amicable conclusion that serves these shared objectives.

Authorized contacts for discussion of these issues are myself by phone at 765 494-1063 or e-mail lepherson@sps.purdue.edu, or Douglas W. Sabel by phone at 765 494-4186 or e-mail dwsabel@sps.purdue.edu. We both can be reached by fax at 765 494-1360.

Sincerely,

Larry E. Pherson
Director

DWS/rh/ 03157001.doc
cc: Kim Moreland, University of Kansas
Michael Devine, University of Tennessee

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Building 31 Room 11A48
Bethesda MD 20892-3100

MAY 22 1997

Mr. Milton Goldberg
President
Council on Governmental Relations
1200 New York Avenue, N.W., Suite 350
Washington, D.C. 20005

RECEIVED
JUN -5 P3:46
COGR

Dear Mr. Goldberg:

Thank you for your recent letter, dated January 2, 1997, to Dr. Harold Varmus, Director, NIH. In your letter you expressed concerns over the actions taken by the National Cancer Institute (NCI) in determining that exceptional circumstances exist relating to contracts offered under the NCI's Developmental Therapeutics Program (DTP). Your letter to Dr. Varmus has been forwarded to me for response. I'm glad to have the opportunity to clarify the issues raised in your letter.

I agree with you that research universities are essential partners in conducting biomedical research and effectively transferring those results to the private sector to better serve the public health. NCI has a long tradition of collaborating with university researchers as well as strongly supporting a vast array of academic research programs. I further agree that, overall, the university research community has demonstrated an outstanding record of performance in effectively developing and commercializing inventions as provided under the Bayh-Dole Act.

However, while NCI's recent actions in determining exceptional circumstances may appear to be unprecedented for NCI, such actions are not unprecedented in the biomedical research area and have been invoked in instances related to other drug development contracts at the NIH. NCI has determined that, in instances in which we are collaborating with a pharmaceutical or biotechnology company, the transfer to the private sector of potential therapeutic agents synthesized under contract could possibly be blocked or delayed if the contractor creates a patentable invention, such as a new method of synthesis. The retention by the contractor of these rights can delay the NCI's collaboration in the overall development of a new drug. Two examples reflect our concerns:

a) The first involves the NCI discovery of a new class of potential therapeutic agents - calanolides. The discovery of the calanolides arose as part of the Natural Products screening program from samples of plant material obtained from another country under a collection agreement. The collection agreement obligated NCI to provide for the sharing of benefits with the source country from which the development of new drugs arose. NCI licensed its patent rights in the calanolides to a small pharmaceutical company. However, a university researcher, under an NCI contract

for drug synthesis, invented a new method of synthesis of the calanolides. While we encouraged the contractor to seek patent rights in order to protect these compounds, and enable the NCI to fulfill its obligations to the source country under the collection agreement, the university's representation of its interests in the new method of synthesis has complicated the development of these new drugs and delayed an NCI collaboration in this area. After two years, the NCI has finally been able to conclude negotiations with the company for a collaborative research and development agreement (CRADA).

b) The second example involves the development of another potential therapeutic, PMZ-1, which was also originally identified under the NCI's drug screening program. After almost two years of negotiation, NCI reached agreement under a CRADA for the development of this agent. NCI agreed to provide, among other contributions, drug synthesis and analog development, using, in part, services under one of the DTP contracts with a university chemist. One primary concern of the CRADA collaborator was NCI's ability to confer consolidation of patent rights, since the composition-of-matter patent on the compound is held by the CRADA collaborator, not the NCI.

The National Institute on Drug Abuse reached an analogous conclusion for the same reasons in several of its drug development contracts. Additionally, the fact that NCI has limited the area of consideration to only those contracts that represent sequential steps in the focused area of drug development further supports our view that the DTP contracts do represent exceptional circumstances. Without the ability to consolidate and "package together" patent rights that may arise during the process of drug development, the NCI could be delayed or precluded from then transferring new drugs and all related patent rights to the private sector for further commercial development.

The academic research community can be assured that the NCI is not interested in obtaining patent rights, except and to the extent that such patent rights are the only means whereby we can ensure that potential therapeutic agents are made available to the public as soon as possible. It was only after thorough discussion, consideration of the issues, and deliberation over several options that a decision to issue a determination of exceptional circumstances (DEC) was made. It should be noted that options considered, other than the DEC, did not eliminate situations that might delay drug development, thus creating a concern for our therapeutic research and development program.

I would also like to address the two primary issues raised in your letter to Dr. Varmus. The first issue is whether NCI's actions were necessary in view of the research community's longstanding implementation of the Bayh-Dole Act and the legislative intent of the Congress in authorizing university researchers to elect title to inventions and subsequently commercialize them. As outlined above, we believe our actions were necessary in order to ensure that the coordinated efforts of the several contracts employed by DTP to screen new agents, synthesize new compounds, prepare and formulate the compounds for preclinical and clinical study, as well as to

conduct preclinical studies using these compounds were not delayed. NCI's action was needed to make certain that the contractor's legitimate efforts to protect its patent rights does not compromise NCI's resource intensive efforts to develop new drugs to the point that they are ready for commercialization. Legislation passed by Congress recognized that the federal laboratories should more effectively transfer their research results to the private sector through the formation of partnerships and collaborations. This mandate was legislated in the Federal Technology Transfer Act of 1986 and subsequent amendments. While I agree that the intent of the Bayh-Dole Act was not to place government as an intermediary between the research community and the private sector for the development of university inventions, the NCI as a federal laboratory also has a mandate to protect as well as transfer its inventions to the private sector. We try very hard to strike the appropriate balance between these similar mandates.

It is also important to understand that NCI has been very judicious in issuing a DEC for a very small number of recent contracts. In fact, these four DTP contracts combined, amount to $767,043, representing a very small percentage of the $122,000,000 annually awarded by NCI in research and development or R&D support contracts. Clearly, this does not represent a larger effort to interfere with the university contractors' efforts to commercialize their inventions under NCI funding. In fact, the vast majority of NCI's funding agreements do not include such restrictions.

I would also point out that, following discussions among NIH and university representatives, as well as with a representative of your organization, NCI has agreed to restrict the implementation of the DEC to only those compounds determined to be proprietary. Further, the Special Works Clause will be implemented in a manner that provides only for a reasonable and limited period of review of information prior to its disclosure and publication. NCI has no interest in inhibiting or interfering with a university researcher's ability to present and publish his or her data to the scientific community. In fact, the NCI encourages such publication and dissemination of research results.

You should also recognize that the DEC allows contractors to request greater rights, which the NCI will freely grant in all cases that do not preclude our ability to transfer new drugs to the public. NCI remains committed to relying upon the research community to effectively translate the creative and innovative research results to the private sector to promote the public health and stimulate the biotechnology and pharmaceutical industries.

The second issue that you raised concerns the submission of compounds by universities under the DTP screening program. The NCI has no desire to restrict the free-flow of scientific research and publication. NCI's DEC was not intended to, nor did it result in, a restriction of research. However we'd like to highlight a concern for universities submitting compounds to NCI's program, that are further synthesized by NCI contractors, who in turn invent new methods of synthesis or formulation. Without NCI's DEC in these contracts, university researchers submitting compounds may ironically find their patent rights compromised by other university contractors who elect title to their new methods of synthesis. With NCI holding the patent rights

that may arise under these four DTP contracts, we would be better able to ensure that patent rights held by university researchers over their compounds would not be affected by patent rights that may arise with NCI contractors. The DEC gives the NCI the ability to ensure the successful and effective transfer of only those few compounds that need to be further developed.

I hope this provides you with sufficient information to allay your concern regarding NCI's decision to issue the DEC in the limited circumstances described as well as our overall intentions in this regard.

Sincerely,

Richard D. Klausner, M.D.
Director