DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

February 10, 2005

Nicholas P. Godici
Commissioner for Patents
Box Comments
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia, 22313–1450

Attn: Robert A. Clarke.

Dear Commissioner Godici:

The written remarks presented herein are directed to the request for comments on the Changes to Implement the Cooperative Research and Technology Enhancement Act (CREATE) of 2004. This request was announced in the Federal Register, Vol. 70, No. 7, January 11, 2005 at 70 FR 1818. These comments represent the views of the National Institutes of Health (NIH). NIH is the lead agency within the Department of Health and Human Services (HHS) in matters of technology transfer. In addition to providing patent and licensing services to all Institutes and Centers within NIH and the Food and Drug Administration (FDA), it is the lead agency responsible for coordinating and facilitating technology transfer policy functions for NIH, FDA and Centers for Disease Control and Prevention (CDC).

Introduction and Background to Federal Transfer

Legislative Mandate for Federal Technology Transfer

The Bayh-Dole Act of 1980, (Pub. L. No. 96-517, 94 Stat. 3015, as amended) permits recipients of federal grants and contracts to retain title to their inventions developed under such federal funding. In October 1986, Congress also enacted the Federal Technology Transfer Act (FTTA, Pub. L. 99-502, 100 Stat. 1785), which amended the Stevenson-Wydler Innovation Act of 1980. The FTTA, as amended, stimulates transfer of Government-owned technology by offering incentives to both federal laboratories/scientists and collaborating partners in universities, foundations, and private industry.

NIH Advancement of the Technology Transfer Mandate

NIH has engaged in considerable collaborative research activity consequent to the initiatives promulgated by the FTTA. Since fiscal year 1987, NIH has entered into over 1,500 Cooperative Research and Development Agreements (CRADAs) and thousands of other transactional agreements including Material Transfer Agreements (MTAs) and Clinical Trial Agreements

(CTAs). While significant, CRADAs, MTAs, and CTAs reflect only a fraction of the technology transfer activities of NIH. Beyond this research contribution from NIH program and research staff, NIH funds biomedical research at universities and contractor-operated research facilities via research grants and contracts. Funding of extramural grants and contracts constitutes more than 80 percent of the annual budget provided NIH for health research and development.

NIH acknowledges CREATE's benefit by permitting the patenting of inventions that result from collaborative arrangements between researchers affiliated with multiple organizations by considering them as a single entity. NIH supports CREATE's intended purpose and submits for consideration the following comments directed to the implementation of the CREATE Act.

Comments on the Changes to Implement the Cooperative Research and Technology Enhancement (CREATE) Act of 2004.

Based on NIH's understanding of the Congressional Report, H.R. REP. (108-425), NIH does not believe that Congress intended to limit the form of the "*joint research agreement*" under which this Act applies:

> Section 2 also defines the term *`joint research agreement'* as a `written contract, grant, or cooperative agreement.' By doing so, Congress does not intend to prescribe the specific form of the agreement parties must use to benefit from this Act nor to require the writing be contained in a single instrument.
>
> H.R. REP. (108-425) page 9

However, NIH believes that Congress intended that, for the Act to apply, the parties to the *joint research agreement* should agree in writing that they intend to be engaged in an actual collaboration, as indicated in this excerpt from H.R. REP (108-425):

> Congress does intend the writing to demonstrate that a qualifying collaboration existed prior to the time the claimed invention was made and that the claimed invention was derived from activities performed by or on behalf of parties that acted within the scope of the agreement.
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> H.R. REP (108-425) page 9

Accordingly, although "grants" are included in the definition of *joint research agreement*, Congress did not intend a *joint research agreement* to include a grant that does not contemplate a collaborative relationship between the grantor and grantee. While the Act uses the term "grant" broadly, the mere labeling as such absent exchange of information between the parties on the claimed invention is not sufficient to establish a *joint research agreement* for the purposes of

overcoming an obviousness rejection under 35 U.S.C. §103(c). Similarly, a "contract" that does not contemplate a collaborative relationship would not qualify as a *joint research agreement* for the purposes of CREATE.

In promulgating regulations for the implementation of the CREATE Act, it would therefore be helpful, if the USPTO would clearly indicate that a *joint research agreement* requires a "qualifying collaboration" between the parties.

37 C.F.R. § 1.71 Detailed description and specification of the invention.

While NIH appreciates the USPTO's objective of keeping the Rules of Practice straightforward and true to the language of the CREATE Act, NIH raises the following three issues directed to the clarification of § 1.71 "Detailed description and specification of the invention."

a) NIH agrees that the specification should disclose or be amended to disclose the names of the parties to a *joint research agreement*. However, before an applicant is permitted to invoke CREATE, the USPTO should require the applicant to notify the other party that owns the prior art to be disqualified of their intention to invoke the CREATE act and to affirm in writing that such action is intended. It is also suggested that the specification of both patent applications should disclose the names of the parties to the *joint research agreement*.

b) NIH notes that the legislative history supports a conclusion that Congress intended that the *joint research agreement* not be in any particular form. Therefore, the USPTO should clarify in 1.71(g)(1)(i), or where appropriate, that any document which (1) establishes the nature and scope of the research to be conducted by the parties and (2) is executed by all of the parties be considered a *joint research agreement*. Furthermore, the USPTO should clarify that the "executed date" of that *joint research agreement* is the date of the signature of the last party to execute the *joint research agreement* or the date of award of a grant or contract.

c) The USPTO is requested to reconsider the requirement that the specification be amended to provide a concise statement of the 'scope of the claimed invention' as this requirement might create unintended prosecution history estoppel. This unintended consequence could prevent the applicant from enforcing the patent on a third party in a way that would otherwise have been permitted. NIH generally supports the Notice function that providing a statement regarding the "scope of the claimed invention" would serve. However, as stated above, NIH believes that the provision of such a statement as currently proposed has severe, unintended consequences that undermine the purpose of the CREATE Act. Therefore, NIH proposes an alternative if the USPTO elects to maintain the Notice requirement. NIH suggests the USPTO amend the regulations to

include an example of an acceptable "concise statement of the invention" as being: "At least one claim of this patent application/patent and at least one claim of the patent or patent application cited as prior art under 35 U.S.C. 103(a) falls within the scope of the same *Joint Research Agreement* relied upon to invoke the CREATE Act."

37 C.F.R. § 1.104 Nature of examination.

NIH raises the following two issues directed to §1.104 "Nature of the examination."

a) NIH requests the USPTO to clarify the term 'made' as it is used in 37 C.F.R. Part I §1.104(c)(4)(A), *et seq*. NIH notes contradictory meanings of the term rooted in the patent statutes. 35 U.S.C. Part II Chapter 18 §201 defines the term 'made' as conceived or first actually reduced to practice in inventions made with federal assistance. However, 35 U.S.C. §102(g) uses the phrase "invention was made" but does not define it. Its meaning as commonly used has resulted from judicial interpretation. In practice, assessing patentability under §102(g) involves determining if both conception and reduction to practice have occurred. It is important, therefore, that the USPTO define the term "made" to render §1.104(c)(4)(A) *et seq.,* unambiguous.

b) For purposes of paragraph (c)(4)(i) of this section, " . . . the term '*joint research agreement'* means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention." NIH believes that Congress did not intend a *joint research agreement* to include a grant or a contract that does not contemplate a collaborative relationship.

37 C.F.R. § 1.109 Double patenting.

NIH acknowledges that an obviousness-type double patenting (ODP) rejection will be made in an application or patent under reexamination if the application or patent under reexamination claims an invention that is not patentably distinct from an invention claimed in a commonly owned patent. This ODP rejection will be made regardless of whether the application or patent under reexamination and the commonly owned patent have the same or a different inventive entity. A judicially created ODP rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(c). NIH wishes to raise the following related to the terminal disclaimer:

a) NIH asks the USPTO to put procedures in place that address how it will handle a situation in which the first filing applicant refuses to sign a terminal disclaimer.

b) The USPTO is silent as to whether an ODP rejection will be made against both the first to file and the later filed application during patent examination, if both are pending.

Because CREATE extends the 'common ownership' provision of 103(c), it is possible that the patent application of the first filed might be rejected under ODP rather than being permitted to issue (presuming no other matters precluding patentability are present). It is preferable that should the ODP be predicated upon a pending application, the application of the party of first filing should be permitted to issue to avoid creating a legal and financial burden for the party of first filing. In addition, there may be situations where the party of first filing would not agree that the invention claimed by the party of second filing was within the scope of the research plan. Therefore, the USPTO should put procedures in place that would permit the first filing application to issue if the presumptive double patenting rejection would be the only outstanding rejection precluding patentability.

c) It is unclear whether or not a collaboration within the meaning of the CREATE Act requires that the work underlying the patents and/or patent applications at issue actually be performed under the auspices of one or more *joint research agreement*s where the parties to the same *joint research agreement* are also the only owners or assignees of the involved patents and/or applications. It is suggested that the USPTO require a party filing a terminal disclaimer aver that the conflicting work of both parties was performed pursuant to the same *joint research agreement* relied upon to invoke the CREATE Act.

In conclusion, NIH thanks the USPTO for the opportunity to present our views. Please feel free to contact us, if we can be of further assistance.

Sincerely,

/s/

Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer