

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 607

PHS Policy on Determinations of Exceptional Circumstances Under PHS Funding Agreements

A. PURPOSE

This Manual Chapter sets forth policy of the Public Health Service (“PHS”) for making a Determination of Exceptional Circumstances (“DEC”) with respect to a Funding Agreement¹ “[i]n exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the Bayh-Dole Act].” 37 C.F.R. § 401.3(a)(2).

B. BACKGROUND

The Bayh-Dole Act, 35 U.S.C. §§ 200-212, permits Contractors² to elect title to Subject Inventions.³ In exceptional circumstances, however, the Bayh-Dole Act authorizes the funding Agency to modify the terms of a Funding Agreement by restricting or eliminating the Contractor’s right to title, or to retain title itself, to Subject Inventions, when doing so better promotes the policy and objectives of the Act.⁴

These objectives, as set forth in the language of 35 U.S.C. § 200, are:

[T]o promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the

¹ Under 35 U.S.C. § 201(b), a “Funding Agreement” means any contract, grant, or cooperative agreement (but not a Cooperative Research And Development Agreement as defined under 15 U.S.C. § 3710a).

² Under 35 U.S.C. § 201(c) and 37 C.F.R. § 401.2(b), as expanded by Executive Order 12591 (Apr. 22, 1987), a “Contractor” means any person, business firm, or nonprofit organization that is a party to a Funding Agreement.

³ Under 35 U.S.C. § 201(e), a “Subject Invention” is any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

⁴ 35 U.S.C. § 202(a).

public against non-use or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

C. POLICY

The policy and objectives of the Bayh-Dole Act are generally best served by using the standard patent rights clauses provided in 37 C.F.R. § 401.14 and the Federal Acquisition Regulations (FAR), as applicable. In exceptional circumstances, changes to, restriction of, or elimination of Contractors' rights to elect and retain title in Subject Inventions will better promote the policy and objectives of the Act.

Each proposed DEC is made by PHS in accordance with 37 C.F.R. § 401.3 and the Federal Acquisition Regulations (FAR), as applicable. "Before utilizing [the exception of 37 C.F.R. § 401.3(a)(2)], the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable." 37 C.F.R. § 401.3(e).

More specifically, PHS policy requires that the proposed DEC must address the corresponding statutory and regulatory requirements:

- (a) The restriction or elimination of the right to elect or retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code. *See* 37 C.F.R. § 401.3(a)(2).
- (b) The DEC seeks "only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the [standard patent rights] clause might be modified along lines similar to those described in 37 C.F.R. § 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at 37 C.F.R. § 401.15." 37 C.F.R. § 401.3(b).
- (c) "In cases when 37 C.F.R. § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. § 200." 37 C.F.R. § 401.3(e).
- (d) A copy of "each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. §202(b)(4) and [37 C.F.R. § 401.4]." 37 C.F.R. § 401.3(e).

Further, under PHS policy, notification of the proposed DEC should be provided to potential Contractors.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective March 14, 2013 and supersedes in its entirety the policy in PHS Technology Transfer Policy Manual Chapter 607, which was first approved on December 9, 1999. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the NIH Office of Technology Transfer, (301) 496-7057, or <http://www.ott.nih.gov/contact-us> , or the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources, (301) 435-1986, Edison@nih.gov , or <http://inventions.nih.gov> .