

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 602

PHS Policy Regarding Waiver of PHS's Right to Obtain Title to Subject Inventions

A. PURPOSE

This Manual Chapter sets forth the policy of the Public Health Service (PHS), comprising the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), for waiving PHS's rights to obtain title to Subject Inventions¹ funded by the PHS when:

- (1) The Contractor² initially elects *not* to retain title under 35 U.S.C. § 202(a) and 202(c)(2) (Declines Title);
- (2) The Contractor initially elects to retain title under 35 U.S.C. § 202(a) and § 202(c)(2) but later decides not to file or not to maintain the patent applications on the Subject Invention required by § 202(c)(3) (Abandons Title); and
- (3) The Contractor elects to retain title under 35 U.S.C. § 202(a) and § 202(c)(2) in order to license patentable biological material and does not file for patent protection as required by § 202(c)(3) (Unpatented Biological Materials).

B. BACKGROUND

The purpose of the Bayh-Dole Act is:

It is the policy and objective of the Congress to use the patent system to 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

¹ "Subject Invention" is defined in 35 U.S.C. § 201(e) as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement...". 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.

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 public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.³

C. POLICY

The policy of the PHS is to make waiver determinations consistent with the Bayh-Dole Act, as well as the missions of the PHS agencies, PHS policy statements and guidance documents. Pursuant to the Bayh-Dole Act, the PHS may, on behalf of the Government, obtain title to any Subject Invention where the Contractor Declines Title, Abandons Title, or, with respect to Unpatented Biological Materials, does not agree to the conditions, if any, set forth by the funding PHS agency. Generally, the PHS policy is not to obtain title from the Contractor when the Subject Invention is broadly available and reasonably accessible.

For all cases in which the Contractor elects title to a Subject Invention all the provisions of 35 U.S.C. §§ 200-212 and 37 C.F.R. Part 401 apply, including that the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to make, use, distribute, or otherwise practice the Subject Invention by or on behalf of the United States throughout the world.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective September 20, 2012, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 602, which was first approved on March 28, 1996. 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>.

³ 35 U.S.C. § 200.