

# UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

## Chapter No. 604

### PHS Policy Regarding Waivers of the U.S. Manufacturing Requirement in Exclusive Licenses for Contractors' Subject Inventions

#### A. PURPOSE

This Manual Chapter establishes the policy of the Public Health Service (PHS) regarding waiver of the U.S. manufacturing requirement, under 35 U.S.C. § 204, in exclusive licenses to use or sell Contractors'<sup>1</sup> Subject Inventions<sup>2</sup> in the United States.

#### B. BACKGROUND

When a Contractor grants an exclusive license to use or sell a Subject Invention in the United States, 35 U.S.C. § 204 and 37 C.F.R § 401.14(a) require that the licensee agrees “that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.” The agency that funded the Subject Invention may, on a case-by-case basis, waive this requirement upon a showing by the Contractor “that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the Subject Invention substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.”

#### C. POLICY

The PHS, after receiving a request from a Contractor or assignee, will make a determination regarding the grant of a waiver of the U.S. manufacturing requirement required by U.S.C. § 204 on a case-by-case basis. The PHS may grant a waiver of the U.S. Manufacturing requirement when either of the following criteria applies: (1) reasonable but unsuccessful efforts have been made to grant exclusive licenses on similar terms to potential licensees that would likely manufacture substantially in the United States; or (2) under the circumstances, manufacture in the United States is not commercially feasible.

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<sup>1</sup> 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. 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). For the purposes of this Chapter, assignees of the original Contractor will be treated as if they were the original Contractor.

<sup>2</sup> “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 Contractor or assignee requesting a waiver must provide sufficient and detailed information in support of its waiver request.

The PHS may impose conditions upon the grant of a U.S. Manufacturing waiver, as appropriate, to advance the goals of the Bayh-Dole Act and the mission of the PHS.

#### **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 604, which was first approved on March 26, 1998. 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](mailto:Edison@nih.gov), or <http://inventions.nih.gov>.