

# UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

## Chapter No. 309

### PHS Policy for Handling Requests Related to the U.S. Manufacturing Requirement for PHS Inventions

#### A. PURPOSE

This Manual Chapter establishes the Public Health Service (PHS) policy for handling requests by PHS license applicants or licensees related to the application of the U.S. manufacturing requirement for PHS inventions.

#### B. BACKGROUND

Under the Bayh-Dole Act of 1980, licensing of federally funded technologies must be in accordance with 94 Stat. 3019 and 35 U.S.C. § 200-212, which impose a preference for U.S. manufacturing. The PHS, which includes the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), normally licenses a federally owned invention with the requirement that any products embodying the invention or produced through the use of the invention (e.g., products made through the use of an invention directed to a method) are manufactured substantially in the United States. Specifically, under the relevant regulation, 37 C.F.R. § 404.5(a)(2):

A license granting rights to use or sell under a Government owned invention in the United States shall normally be granted only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. However, this condition may be waived or modified if reasonable but unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in the United States or if domestic manufacture is not commercially feasible.

#### C. POLICY

Consistent with 37 C.F.R. § 404.5(a)(2), licenses will normally include a commitment that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. Requests for waivers of the requirement may be granted on a case-by-case basis upon a determination by PHS that either (1) reasonable but unsuccessful efforts have been made by PHS to license the invention to a company with a U.S. manufacturing capability; or (2) under the circumstances, domestic manufacture is not commercially feasible. An approved waiver should be tailored in scope to the specific circumstances supporting it.

Requests for waivers of the U.S. manufacturing requirement in connection with *prospective* licensing of PHS inventions should be directed to the lead agency negotiating the license – specifically, the NIH Institute or Center (IC) or the CDC, as appropriate – and all requests for waivers of the U.S. manufacturing requirement in connection with *existing* licenses should be directed to the lead agency handling license compliance – specifically, the NIH Office of Technology Transfer’s (NIH OTT) Monitoring and Enforcement Unit (MEU) for NIH licenses, and the National Institute of Allergy and Infectious Diseases (NIAID) Technology Transfer and Intellectual Property Office (TTIPO) for CDC licenses. All requests regarding FDA inventions, whether before or after a license has been executed, will be referred to the FDA Technology Development Officer (TDO).

#### **D. EFFECTIVE DATE**

The policy set forth in this Manual Chapter is effective (February 11, 2021), and supersedes in its entirety PHS Technology Transfer Policy Manual Chapter 309, which was approved on December 08, 2010.

#### **E. ADDITIONAL INFORMATION**

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, [nihott@mail.nih.gov](mailto:nihott@mail.nih.gov) or the Division of Technology Transfer and Innovation Policy, Office of Science Policy National Institutes of Health, NIH, [SciencePolicy@od.nih.gov](mailto:SciencePolicy@od.nih.gov). For CDC contact [tto@cdc.gov](mailto:tto@cdc.gov). For FDA contact [techtransfer@fda.hhs.gov](mailto:techtransfer@fda.hhs.gov).