

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 604A

NIH Contractor Procedures Regarding Waivers of the U.S. Manufacturing Requirement in Exclusive Licenses for Contractors' Subject Inventions

A. PURPOSE

This Manual Chapter establishes procedures for National Institutes of Health (NIH) Contractors¹ to request waiver of the U.S. manufacturing requirement under 35 U.S.C. § 204 in exclusive licenses to use or sell Subject Inventions² in the United States. These procedures apply only to requests by NIH Contractors.

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)(i) 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. PROCEDURES FOR REQUESTING WAIVERS OF THE U.S. MANUFACTURING REQUIREMENT

If a NIH Contractor or assignee (collectively, “NIH Contractor”) seeks a waiver to the U.S. Manufacturing requirement, as set forth at 35 U.S.C. § 204 and 37 C.F.R. § 401.14(i), the NIH Contractor must submit its request to the NIH Office of Extramural Research (OER). The NIH Contractor must submit supporting information to specifically address why a grant of a waiver of the U.S. Manufacturing requirement is necessary and will support public

¹ 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.

² “Subject Invention” is formally defined in 35 U.S.C. § 201 as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement...”.

health. Evaluation of the U.S. Manufacturing requirement waiver request will **not** begin until the NIH Contractor provides sufficient and detailed information to consider a waiver request. Forms and instructions for submissions to OER are available on the Interagency Edison (iEdison) web site (<https://s-edison.info.nih.gov/iEdison/>).

Based on the specific information provided by the NIH Contractor, NIH will consider the waiver request and may grant a waiver upon a determination that either of the following criteria applies: (1) reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States; or (2) under the circumstances, manufacture in the United States is not commercially feasible. Statements by the NIH Contractor must be supported by factual information to be considered. Information that NIH may consider in determining whether either of these two criteria applies includes:

1. Reasonable but Unsuccessful Efforts to License:

- a. The nature of the particular market for the subject invention would suggest a probable range of companies interested in a license is large or small (e.g., a large range would require greater marketing efforts to be “reasonable”). Potentially relevant information might include: The significance of the technology, the availability of alternative products, size and location of intended patient populations, and the degree of regulatory review needed to bring the product to the U.S. market.
- b. Good faith efforts for marketing the technology to companies willing to manufacture in the United States were unsuccessful. Potentially relevant information might include: (i) number of companies contacted; (ii) methods used for marketing and contacting companies; (iii) types of licenses and terms offered to potential licensees; (iv) comparison of terms offered to potential exclusive licensees that will manufacture substantially in the United States versus to licensees that will not; and, (v) responses of companies to marketing efforts.

2. Not Commercially Feasible:

- a. The circumstances that make foreign manufacture necessary;
- b. The state of the U.S. market for the potential product, including what companies, if any, make the same or similar products and where such products are manufactured;
- c. Whether requiring U.S. manufacture will delay entry of the product into the U.S. market, and the effect such delay may have on the public health;
- d. The part or percentage of products arising from the invention that would be manufactured outside the United States;
- e. The U.S. manufacturing capabilities of the Contractor’s licensee and the efforts made by the licensee to locate, develop, or subcontract for such U.S. manufacturing capabilities;

- f. The factors making domestic manufacture not commercially feasible, including the relative costs of U.S. and foreign manufacturing, the alternative products or therapies available, and the size of the intended patient population;
- g. The value or benefit to the United States of permitting foreign manufacture of the technology. Relevant facts may include: (i) the direct or indirect investment in U.S. plants or equipment resulting from foreign manufacturing; (ii) the creation of new or higher quality U.S.-based jobs; (iii) the enhancement of the U.S. skills base in the technology of the subject invention; (iv) the further development within the United States of the technology enabled by foreign manufacture; (v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts; and (vi) other provisions in the exclusive license that will ensure a correlative benefit to the United States (e.g., U.S. manufacture of another product).

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective September 20, 2012, and supersedes in its entirety the NIH Contractor procedures 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 and related NIH policies, 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>.