The National Institute of Food and Agriculture's Procedures for Requests for Waivers of the U.S. Manufacturing Requirement in Licenses to Extramural Inventions

The National Institute of Food and Agriculture (NIFA) has authority to waive the preference for United States industry requirement when a contractor assigns or licenses a contractor owned invention (35 U.S.C. 204). Extramural institutions may request such a waiver on behalf of its licensees. NIFA complies with 35 U.S.C. 204 in making determinations regarding the grant of a waiver of the U.S. manufacturing requirement. Section 204 states:

> *Notwithstanding any other provision of this chapter, no small business or firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of such invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that 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 that under the circumstances domestic manufacture is not commercially feasible.*

The approval process requires that grantee organizations and contractors provide information and justification for the request as outlined below. In addition to addressing the questions, any other information which the contractor believes pertinent to why the assignment is necessary and in the public interest may be submitted.

After filling out the form, e-mail the request to the bayhdole@nifa.usda.gov for disposition. Please note that the review by NIFA that can lead to the approval of U.S. Manufacturing waiver request will not commence until the answers to the questions and all pertinent information has been received by the NIFA. Should you have further questions, please direct inquiries to contact Tekila Gray (202-401-0951) or Sharon Lumpkin (202-401-0162).

All fields marked with an asterisk (*) are required.

***Inventor 1**

Prefix ____ First Name _____ Middle Initial ____ Last Name _____

Email Address _____

Contact Number _____ Fax Number _____

Grantee/Contractor Organization _____

Grantee/Contractor Address _____

City _____ State _____ Zip Code _____

Inventor 2

Prefix ____ First Name _____ Middle Initial ____ Last Name _____

Email Address _____

Contact Number _____ Fax Number _____

Grantee/Contractor Organization _____

Grantee/Contractor Address _____

City _____ State _____ Zip Code _____

Inventor 3

Prefix ____ First Name _____ Middle Initial ____ Last Name _____

Email Address _____

Contact Number _____ Fax Number _____

Grantee/Contractor Organization _____

Grantee/Contractor Address _____

City _____ State _____ Zip Code _____

***Invention Information**

Invention Title _____

Invention Report Number[1] _____ Invention Docket Number _____

Invention NIFA Grant Number(s) _____

Reasonable but Unsuccessful Efforts to License

*Discuss the significance of the technology, including the availability of alternative products, the size of intended patient populations, whether requiring U.S. manufacture will delay entry of the product into the U.S. or foreign markets, and the effect such delay may have on the U.S. and foreign public health.

*Identify the past marketing strategy and efforts for the technology, including the number of companies contacted, the methods used for marketing and contacting companies, the types of licenses and terms offered to potential foreign licensee and those offered to U.S. companies to marketing efforts.

Not Commercially Feasible

*Discuss the factors that make domestic manufacturing not commercially feasible, including the relative costs of U.S. and foreign manufacturing, the licensee's manufacturing capabilities within the U.S. and the efforts made by to locate, develop, or contract for such manufacturing capabilities, and any other circumstances that make foreign manufacture necessary.

*Identify the part or percentage of product arising from the invention that would be manufactured outside the U.S.

*Identify any value or benefit to the United States of licensing the technology even if it will not be manufactured in the United States, including

I. The direct or indirect investment in U.S. plants or equipment, such as for marketing or packaging;
II. The creation of new or higher quality U.S. –based jobs;
III. The enhancement of the domestic skills base;
IV. The further domestic development of the technology
V. A positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts; or
VI. Cross licensing, sublicensing, and reassignment provisions in the license which seek to maximize benefits to the U.S.

*Inventor 1 Signature _____ Date _____

*Inventor 2 Signature _____ Date _____

*Inventor 3 Signature _____ Date _____

(additional information and signatures inventors may be attached)

If you have questions about this form or the process, contact Tekila Gray (202-401-0951) or Sharon Lumpkin (202-401-0162)

[1] – An invention record must be created and all required reporting milestones must be met in iEdison before this request will be processed.