

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 300

PHS Licensing Policy

A. PURPOSE

This Manual Chapter sets forth the policy for licensing inventions owned in whole or in part by the US Government, as represented by the Public Health Service (PHS).

B. BACKGROUND

The primary mission of PHS laboratories is to pursue new knowledge through the conduct and support of research to improve the health of the American people. Pursuant to the Stevenson-Wydler Technology Innovation Act of 1980 (Pub. L. No. 96-480) and the Federal Technology Transfer Act of 1986 (Pub. L. No. 99-502), as amended, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), were given a statutory mandate to ensure that new inventions in which the U.S. Government obtains an interest are transferred to the private sector and commercialized in an expeditious and efficient manner.

The ability and willingness of private sector technology transfer partners to commercialize new inventions can be critical to realizing the benefits of PHS-conducted research. This typically requires a robust licensing program for PHS inventions.

C. POLICY

PHS generally seeks to license biomedical inventions when a license will facilitate and attract investment by commercial partners for further research and commercial development of the invention. A license is often necessary when the invention is directed to a preventive, diagnostic, or therapeutic product. Licensing also could occur when necessary to encourage a commercial partner to keep important materials or products available for research use.

PHS often licenses biomedical inventions that have been patented. Patent protection generally is not sought by PHS where further research and development is not necessary to realize the invention's primary use and future preventive, diagnostic, or therapeutic uses are not reasonably anticipated. For example, PHS will typically not seek patent protection for research tools, e.g., transgenic mice, receptors, or cell lines, because such materials can be licensed effectively without patent protection, under royalty bearing biological materials licenses, or distributed to the research community through non-royalty bearing material transfer agreements. For research tools, the public interest is served primarily by ensuring that the tool is widely available to both academic and commercial scientists to advance

further scientific discovery. Secondly, a financial return to the public is obtained through royalties on the rare research tool that has significant commercial value.

In addition, some inventions may be transferred to the private sector most expeditiously through publication, and PHS may determine for any given invention and circumstance that patenting and licensing is unnecessary and could inhibit broad dissemination and application of the invention.

In contrast, for inventions with, e.g., potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is typically the primary vehicle for transferring the invention to commercial partners. Due to the importance of effective licensing, particularly patent licensing, to the development and availability of new products arising from PHS inventions, the PHS licensing program is governed by the following principles in marketing, negotiating, executing, and monitoring licenses to PHS inventions:

- The PHS licensing program is consistent with the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice (the “NIH’s Research Tools policy”), 64 Fed. Reg. 72,090 (Dec. 23, 1999) and Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413 (Apr. 11, 2005).
- Normally PHS seeks to ensure development of each invention for the broadest number of possible applications to maximize the availability of the invention to the public.
- PHS seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the invention. This enables as many companies as possible to obtain commercial development rights, resulting in the concurrent development of many potential applications and the further promotion of the invention’s utilization by the public.
- PHS seeks to ensure that commercial partners expeditiously develop the licensed invention.
- PHS seeks to ensure that inventions commercialized under PHS licenses are brought to practical application, offered and maintained for sale, and made reasonably accessible to the public. PHS enhances public access to the benefits of its invention by fostering the development of competing products for the same or similar applications.
- PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries.
- PHS seeks to obtain a fair financial return on the public's research investment through negotiating royalty-bearing licenses and obtaining payment of patent expenses from licensees.

- Where appropriate, PHS seeks to negotiate and obtain public benefits from licensees consistent with expeditious commercial development and accessibility of the invention.
- Normally, no license applicant shall be awarded a license if that applicant 1) has a current PHS license for use of a PHS invention and is delinquent in the payment of any royalties or fees due the PHS or is not meeting any commercial development milestone under the license agreement or 2) is on the General Services Administration (GSA) list of persons and organizations barred from doing business with the Federal Government. License applications shall also be considered in view of applicant's compliance with prior and/or existing royalty and fee obligations and commercial development milestones.
- PHS monitors the performance of PHS licensees and ensures that its licensed invention is fully developed, through the modification or termination of a license, in the event that a licensee is unable to fully develop the rights granted. For example, modifying an exclusive license to a non-exclusive one, or narrowing the fields of use, allows PHS to license the invention to other companies for further development and sale.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective December 8, 2010, and supersedes in its entirety the policy in PHS Technology Transfer Policy Manual Chapter 300, which was first approved on October 25, 1995.

E. ADDITIONAL INFORMATION

For information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or <http://www.ott.nih.gov/contact-us> .