A. PURPOSE

This Manual Chapter describes the procedures for handling allegations of infringement of patents in which the U.S. Government has an ownership interest and which are administered by the National Institutes of Health (NIH).

B. BACKGROUND

The primary mission of the Public Health Service (PHS) research laboratories is to pursue new knowledge through the conduct and support of biomedical research to improve the health of the American people. In 1986, Federal laboratories, including PHS research laboratories at the NIH, Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in those laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner.

The Government owns, in whole or in part, thousands of patents and patent applications covering the work of PHS inventors, many of which are reported to the NIH Office of Technology Transfer (NIH OTT) for centralized management. This portfolio represents an investment of millions of dollars in securing the intellectual property rights and an even larger investment in the research that produced these innovations. The public investment in this portfolio reflects a determination that obtaining patent protection encourages the commercialization of inventions made in PHS laboratories.

The Government's ability to use its intellectual property portfolio as a tool to develop technology is diminished by infringement. First, infringement discourages the licensing and development of Government technologies if non-licensees can practice the invention without cost. Second, competition by infringers reduces sales of licensed products and the consequent royalty income to the Government. Third, infringement reduces the inventors’ incentive to report inventions.

Diligent enforcement of patent rights deters infringement and encourages licensing of PHS technology. PHS recognizes, however, that there are benefits and costs associated with enforcing its patents, and it will consider each in its determination whether to pursue any particular enforcement activity.
C. PROCEDURES

1. Initial Investigation of Alleged Infringement

In the case of an alleged instance of infringement of inventions in which the U.S. Government has an ownership interest and which are administered by the NIH OTT, the NIH OTT shall be responsible for the initial investigation. The NIH OTT will establish an infringement record and assign an investigator. If the invention is exclusively or co-exclusively licensed, NIH OTT will determine whether the licensee wishes to pursue the infringement on behalf of NIH. Otherwise, NIH OTT will consult with the Technology Development Coordinator (TDC) from the agency paying for patent prosecution to determine if they wish the matter to be pursued. (If multiple ICs own the patents in question, the NIH OTT will consult with the TDCs from each IC.)

2. Investigating the Alleged Infringement

If the alleged infringement is covered only by the claims of a pending patent application and merely prospective, NIH OTT may decide to contact the prospective infringer and offer a license to the application. Where a patent has issued, the NIH OTT will investigate whether the alleged infringer has indeed infringed the patent. This decision may be informed by the opinion of one of OTT’s outside patent law firms and the HHS Office of the General Counsel, which will be kept strictly confidential. If it is determined that the patent has been infringed, NIH OTT may demand that the infringer take a license if, in its discretion, NIH OTT believes that doing so would advance the interests of the Government. The relevant TDC(s) will be routinely apprised of the situation.

D. EFFECTIVE DATE

The procedures set forth in this Manual Chapter are effective December 08, 2010, and supersede in their entirety the procedures in PHS Technology Transfer Policy Manual Chapter 206, which were first approved on November 9, 1995.

E. ADDITIONAL INFORMATION

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