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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

OFFICE OF THE
GENERAL COUNSEL

March 13, 1972

TO : Holders of DHEW Institutional Patent Agreements

SUBJECT: Information Item No. 6

In recent months we have been asked on a number of occasions how compounds generated under DHEW grants are handled under our institutional patent agreements. This was the subject of a special section in DHEW Regulations, which I am attaching for your use and distribution to investigators synthesizing compounds with DHEW support. Please note in particular that the special agreement between the screening organization and the university required by Section 8.8(c)(2) is unnecessary if the university is an institutional patent agreement holder. All that is necessary is an agreement between the parties meeting the conditions of 8.8(c)(1). This agreement is usually drafted by the screening organization with the consent of the university.

Sincerely yours,

Norman J. Latker
Chief, Patent Branch

Enclosure

Send copies to V Pres. R. Lorenz
Exec. Dir of WARF - Ed Roster

(6-10-10 continued)

§8.8 Screening of compounds generated under DHEW grants and awards

(a) General Policy

(1) Chemical compounds having potential medicinal and other utilities are often synthesized or identified during the course of research financed under DHEW research grants and awards. Reporting, filing patent applications on, and determining ownership in inventions relating to such compounds pose problems which require special attention. After a compound has been synthesized, it generally will not constitute a patentable invention under the patent laws of the United States until a specific utility for the compound has been established. It is the policy of the Department that all compounds synthesized or identified during the course of grant-supported research should be adequately screened and tested in Government or nongovernment facilities in order that all possible utilities may be ascertained and that any promising compounds may be fully developed for widest possible use. The Department encourages the utilization, whenever appropriate, of the screening services of the Cancer Chemotherapy National Service Center and the Walter Reed Army Institute of Research.

(2) It is the policy of the Department notwithstanding anything to the contrary under patent law of the United States or requirements of U.S. Patent Office practice, to acquire no ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant funds.

(b) Screening performed with use of grant funds

Where nongovernmental facilities are utilized for screening services to be performed and paid for by the grantee (as used in this section, the term "grantee" refers to awardees in addition to grantee institutions) with grant funds, the grantee shall obtain an agreement with the screening organization providing that the screener shall promptly report to the grantee the details of any positive findings of utility for the compound and that all invention rights relating to the compound and its utility shall, as between the grantee and the screener, vest in the grantee. Upon receipt of such report of positive findings, the grantee shall promptly forward copies to DHEW. Ownership of all invention rights to the compound or reported utilities shall be subject to the disposition by the Assistant Secretary (Health and Scientific Affairs) as provided by the terms of the grant or award in accordance with Section 8.2, except that where the grantee institution has entered into an Institutional Patent Agreement with the Department pursuant to Section 8.1(b) above, ownership of the invention rights shall be in accordance with the terms of that Agreement.

(c) Screening performed without the use of grant funds

Where screening is to be performed at nongovernmental facilities without the use of grant funds, the grantee may proceed to have compounds screened under one of the following arrangements:

(6-10-10 continued)

(1) Institutional Patent Agreement -- Where the grantee institution has entered into an Institutional Patent Agreement with the Department under Section 8.1(b) of the Department Patent Regulations, the grantee shall enter into an agreement with the screener which shall be consistent with, and will permit the grantee to fully comply with its obligations under such Institutional Patent Agreement. The agreement with the screener shall, as a minimum, provide that ownership of patent rights to inventions resulting from the screening process shall vest, depending on the law of inventorship, in the grantee, the screener, or both, except that such agreement may leave to screening or testing organizations ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant awards. The grantee shall administer all invention rights to the compound and all other invention rights vested in the grantee in accordance with the terms of the Institutional Patent Agreement.

(2) Patent Agreements for Screening -- Where an Institutional Patent Agreement is not in effect, the grantee shall enter into an agreement with a screener to govern disposition of rights to inventions resulting from the screening. Such agreements shall be in the form prescribed by or as may be approved by the Department and shall be consistent with the policy set forth in (a).

(3) Determination of Invention Rights Prior to Screening -- Where a grantee has not entered into an Institutional Patent Agreement, it may, prior to making arrangements for screening, petition the Assistant Secretary (Health and Scientific Affairs) requesting a determination that invention rights pertaining to an identified compound be assigned to the grantee for administration, pursuant to the provisions of Section 8.2(b) above. Determinations under Section 8.2(b) normally permit the grantee to grant exclusive licenses for a limited period of time. Such petition must demonstrate that an assignment is required in order to achieve effective screening of the compound and any resulting inventions will thereby be more adequately and quickly developed for widest use.