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OUTLINE OF PROPOSAL

OUTLINE OF A PROPOSAL FOR DETERMINATION UNDER SEC.8.2(b) OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PATENT REGULATIONS (45 C.F.R. Parts 6-8)

A proposal for a determination under Sec.8.2(b) must lay a factual basis to justify such a determination. It should, in general, include:

1. Information demonstrating that by assigning the invention to the grantee institution the invention will be more adequately and quickly developed for widest use.

2. If available, evidence of interest of a qualified manufacturer, or manufacturers, in developing the invention for the market and the terms of any proposed license.

3. A general description of the development and testing required to bring the invention to the point of practical application.

4. An estimate of the total cost of developing the invention to the point of practical application and a general breakdown of such cost.

5. An indication of willingness to accept the following conditions:

   (a) The inventor shall assign all of his rights in the invention to the grantee institution for administration;

   (b) The grantee institution shall grant to the Government a non-exclusive, irrevocable, royalty-free license for Governmental purposes;

   (c) The grantee institution, and any of its licensees, shall provide written annual reports regarding the development and commercial use that is being made and is intended to be made of the invention, and such other data as may be required;

   (d) The grantee institution agrees that if it, or its licensee, has not taken effective steps within three years after a patent issues to bring the invention to the point of practical application, or has not made the invention available for licensing royalty-free, or on terms that are reasonable in the circumstances, or cannot show cause why they should retain all right, title and interest for a further period of time, the Government shall have the right to require (1) assignment of said patent to the United States; and/or (2) cancellation of any outstanding exclusive licenses under said patent; and/or (3) the granting of licenses under said patent to an applicant on a nonexclusive, royalty-free basis, or on terms that are reasonable in the circumstances;

(e) The Government reserves the right to license or require the licensing of other persons to practice the invention on a royalty-free basis, or on terms that are reasonable in the circumstances, if the grantee institution, or any of its licensees, fails to comply with any of the provisions of the Department's determination, or if the Assistant Secretary determines that the public health, safety, or welfare requires the issuance of such licenses, or that the public interest would otherwise suffer unless such licenses were granted;

(f) Any exclusive license to a qualified manufacturer shall be for a limited period of time, not to exceed 3 years from the date of first commercial sale of the patented item, or 8 years from the date of the exclusive license, whichever occurs first, provided that the licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of this period of exclusivity shall be subject to approval by the Department. Upon expiration of the period of exclusivity, or any extension thereof, licenses shall be offered to all qualified applicants at a reasonable royalty rate not in excess of the exclusive license royalty rate.

(g) Any license shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice. Such license shall also provide that all sales to the U. S. Government shall be royalty-free.

(h) If permitted by its patent policies and the terms of the grant or award under which the invention is made, the grantee institution may share royalties received with the inventor provided that the grantee institution shall not pay the inventor more than 50% of the first $3,000 gross royalty paid under the patent, 25% of the gross royalty income between $3,000 and $13,000 and 15% of the gross royalty in excess of $13,000. The balance of the royalty income, after payment of expenses incident to the administration of the invention, shall be utilized for the support of educational and research pursuits.

(i) Any U. S. patent application filed by the grantee institution shall include the following statement in the first paragraph of the specification following the abstract: "The invention described herein was made in the course of work under a grant or award from the Department of Health, Education, and Welfare."