PHARMACEUTICAL MANUFACTURERS Association

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AREA CODE 202-296-2440

C. JOSEPH STETLER
EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL

September 25, 1964

Dr. Neil O. Hines
Assistant to the Director
National Association of College and
University Business Officers
Comm. on Governmental Relations
1785 Massachusetts Avenue, N. W.
Washington, D. C.

Re: Government Patent Policy

Dear Dr. Hines:

This is in response to your letter of September 15, 1964, requesting a brief statement of the problems of principal concern to the pharmaceutical industry in connection with existing government patent policies.

Over the last few years, the pharmaceutical community in the United States has been acutely aware of (1) the accelerating decline of medical research co-sponsored by industry and government coupled with (2) an increased strain on the traditional university-industry bonds which have been such an important segment of this country's efforts in medical research. The former has been largely due to confiscatory policies of certain federal agencies, such as the Department of HEW towards private patent rights and the reluctance of such agencies to recognize that the contribution of industry in providing private financing and know-how to develop and market a drug deserves a compensatory degree of market exclusivity. The latter is caused by unrealistic government patent policies toward academic grantees, refusal to recognize the right to appropriate financial return for them, and the inability of the industry to compete with the government financially for university research facilities. In effect, these policies are rapidly erecting a "Berlin Wall" between the pharmaceutical industry and a heavily financed governmental research program.

The fact is that the public benefit is particularly great when health-related research is conducted creatively, vigorously and enthusiastically. In equal measure, the public benefit is particularly great when the resources of private enterprise are brought to bear in the high-risk activities of perfecting and marketing inventions relating to health. It follows that patent rights in such inventions should be enhanced, not limited, to the end that the public will gain maximum benefit.

Particular reference is made to the concept of compulsory licensing in connection with pharmaceutical products as set forth in Section 1(g) of the Statement. The drug industry's position in opposition to compulsory licensing has been made public and is well known. It is of the utmost importance to remember, however, that in the interest of the public health and the advancement of all of the sciences, contractors (industry or academic institutions), whose superior facilities, know-how and inventive genius are sought by the government, should receive a fair and adequate degree of exclusivity for the results of their efforts whether provided directly or indirectly under government grants. Such an arrangement will serve to give contractors incentive for future work in other important disease areas.

In our opinion the Department of HEW has improperly interpreted the October 10th Presidential statement to encompass situations where the grantee scientist (academic or otherwise who is subsidized by the government) comes for additional help to a pharmaceutical manufacturer, i.e., co-sponsored research. Here, both government, academicians and industry may make substantial contributions to the ultimate invention and the result should be a fair and adequate degree of exclusivity to the manufacturer, recognition perhaps financially of the academicians contribution, with appropriate identification and recognition of the rights of the government.

There is no appropriate encouragement nor realistic recognition in the Statement itself or in HEW interpretations for the manufacturer where the invention is only the first step in producing a definitive product. Despite government subsidy, a fair and adequate degree of exclusivity should be given the manufacturer as an incentive for carrying from the invention stage the initiating, at considerable cost, the lengthy investigations, testing and modifications necessary to bring a specific product of benefit to the public to the market. This is especially needed where the risks of ultimate non-marketability are great, because of uncertainty as to ultimate safety and effectiveness, fast developing progress in science, as well as ever present competitive factors.

At a Government-Industry meeting on patent policies sponsored by the U.S. Chamber of Commerce on February 14, 1964, attended by Dr. David Z. Beckler

effected should establish a central bureau or designate a specific person who on application would give to our several inquiring member firms or cooperating academic institutions a ruling as to the ultimate disposition of patent rights in any situation in which that agencies money is directly or indirectly involved. In this way, (a) individual firms would not only be able to endeavor to advocate an equitable ruling, but they could obtain a decision which is most important to our patent and Research and Development personnel who are asked by their top executives as to whether or not patent-wise it is advisable to expend moneys, facilities, personnel or material in any type of situation in which government money is directly or indirectly involved; and (b) academic institutions may better plan allocations of their facilities and personnel, and likely financial returns from their research contributions.

Briefly, we feel that it is essential that a new and appropriate amendment or supplement be prepared to the October 10th statement, that will give consideration to the foregoing.

In view of our great areas of mutual interest we are most pleased to cooperate in your consideration of the foregoing. We are also pleased to accept the invitation to meet with you and other representatives of your Association at 3 o'clock on Thursday afternoon, October 8. I will be accompanied by Mr. John Worley, Associate General Counsel, P.M.A., and Mr. Louis I. Wolk, Patent Councel, Merck & Co., Inc.

Sincerely yours,

C. Joseph Stetler
Executive Vice President and General Counsel

CJS/bjh