

January 10, 1978

PATENT BRANCH, OGC  
DHEW

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The Honorable Gaylord Nelson  
United States Senator-Wisconsin  
Senate Office Building  
Washington, D.C. 20510

Dear Senator Nelson:

I am writing to comment on the 13 December 1977 information release concerning the hearings which were held by the Monopoly Subcommittee on Small Business on the federal government's patent policies.

The Wistar Institute, a non-profit, independent biomedical research organization, is holder of a Department of Health, Education and Welfare Institutional Patent Agreement under which certain rights associated with patented inventions developed either in whole or in part through HEW-sponsored research are granted to Wistar while HEW retains certain rights unto itself. Under this HEW Institutional Patent Agreement, The Wistar Institute has obtained patents on a number of vaccines and viral strains developed as a result of many years of painstaking basic biomedical research. The Wistar Institute, carrying out its responsibilities under the HEW Institutional Patent Agreement, has vigorously pursued licensing arrangements with pharmaceutical firms which result in effective and safe vaccines being made available to the public in the United States and throughout the world. Wistar-developed vaccines which are now available include those against human rabies and rubella (German measles). Wistar holds patents for vaccines against several other viral diseases and is conducting research which is expected to result in patentable viral strains and vaccines against diseases such as hepatitis and varicella (chicken pox).

The monetary return to The Wistar Institute from these licensing arrangements is modest by any standards. Our licensing agreements call for royalties of between three (3) to six (6) percent of sales by the licensees generating annual income for The Wistar Institute of less than \$100,000. (Our total annual operating budget is approximately nine (9) million dollars.) It is gross misinterpretation of these data to assert that, "The American people are being robbed blind" by organizations such as The Wistar Institute basing the assertion on the income generated

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through licensing arrangements allowed and encouraged by HEW. In addition, The Wistar Institute does not profit in any way from the U. S. Public Health Service's employment of vaccines based on Wistar-held patents because the HEW Institutional Patent Agreement specifies that Wistar grant to the U. S. government royalty-free licenses.

As you probably know, there are very few firms in the United States which produce vaccines and other biological materials. In addition, the number of such firms is diminishing to the vanishing point. The reasons for this are many and complex. Among them are the high development costs, strict governmental regulations administered by the Bureau of Biologics of HEW, etc., leading to commercial risks which few U. S. pharmaceutical firms are willing to take. Those who still remain in the field do so because they market products which are unique. The uniqueness is preserved by license agreements between the producer and the organization which holds the relevant patents. If the patent for human rabies vaccines held by Wistar were held by the federal government instead and thereby potentially available to all pharmaceutical manufacturers, there would be no effective human rabies vaccine available to the public because no commercial organization could justify the risks inherent in high development costs and limited market if that limited market were available to and shared among a number of manufacturers. One regrets this situation but to ignore that it exists would sound the death-knell for the development and eventual marketing of new vaccines against a wide spectrum of viral diseases of even greater effectiveness and safety to the public.

It may be that there are improvements needed in the patent policies of the federal agencies. Certainly a thorough investigation of present policies and their implementation is warranted and should be welcomed by everyone concerned. However, those of us from non-profit research organizations who have HEW Institutional Patent Agreements assert that these agreements represent a system which is working to the ultimate advantage of the most important element of the concerned constituencies, namely, the American public. We hope that our voice will be heard by your subcommittee as you carry out your study on the patent policies of the federal agencies.

Sincerely yours,

Warren B. Cheston  
Associate Director  
for Administration

lcs

bcc: Dr. Koprowski  
Mr. Latker ✓  
Mr. Putney