



Testimony of
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Before the House of Representatives
Committee on the Judiciary

Re: H.R. 1937

Mr. Chairman, I appreciate and thank you and the committee for the opportunity to appear before it to present testimony relevant to HR 1937, the Patent Term Restoration Act. I hope, in the few minutes available, to acquaint you with the important and considerable impact which this legislation, when passed, can have on the university community in general, and upon the University of Wisconsin in particular.

First, may I briefly qualify myself. I am now the Director of Licensing for the Wisconsin Alumni Research Foundation (WARF) and have been such for 20 years, following nearly 10 years of service as the Assistant Director of Licensing. I am a member of the Licensing Executive Society an international organization committed to the profession of technology transfer, and currently serve on the Board of Trustees US/Canada.

For the benefit of Committee Members and Staff not so well acquainted with our Foundation as you are, Mr. Chairman, WARF is a corporation, which exists for the purpose of supporting research at the University of Wisconsin in two ways. These are: 1) To provide a channel through which discoveries made at the University can be transferred to the industrial sector, and 2) To grant monies received for the use of such discoveries back to the University to support new research.

WARF is fully set apart from the University but exists solely for the benefit of the University of Wisconsin. The University inventors are not obligated to take inventions to WARF, but do so on a voluntary basis. In turn, WARF's grants are to the University, not back to individuals. WARF has operated in this manner since 1925.

Through the unique combination of the strong life-science research which has long characterized the University of Wisconsin, Madison, and the effective use of the patent system which works so well for chemical inventions, WARF's contribution to the American people has been greatest in foods and pharmaceuticals. Its role in bringing Steenbock's Vitamin D to the U.S. milk supply in the 30's, followed by improved iodine retention in table salt as taught by Professor Hart is widely recognized. These were followed by Prof. Link's discovery of the anticoagulant warfarin which came to mean death to rodents but life to humans.

I take time to mention these because, of course, it is this class of invention which today is most affected by the necessary but time consuming regulation by federal agencies. You will receive extensive testimony from the affected industries which will document and support the substantial public benefit which can accrue from this legislation. Let me

assure you that the universities will also be beneficiaries of Patent Term Restoration.

Because warfarin continues to make a major contribution to the control of rodents even though the patents expired long ago, I thought it might provide an interesting and relevant case history. Our files show that the patent application was filed on April 2, 1945 and the patent issued on September 16, 1947. Licensing efforts with the established marketers of rodenticides failed to generate any licenses. WARF itself undertook to obtain the necessary permits from the USDA to facilitate field testing by pest control. Please recall that these were the 'good old days' fondly remembered by those who today must register such a compound with the E.P.A.

The permit was first discussed on June 1, 1949 with USDA representatives and permission to market on an experimental basis was granted September 1949. By June 29, 1950 the tests were finished and registration completed!!

Licenses were granted on December 1, 1950 and WARF royalty income in 1950 amounted to \$248,394 and averaged \$300,000/year until patent expiration in 1964.

The regulatory delay of only one year - trivial by today's standards, can be presumed to have cost the University of Wisconsin \$300,000 in lost revenues. The time required before

EPA today would probably exceed one year and the loss to the University proportionately increased.

These dollar amounts achieve greater significance in terms of WARF's annual royalty income which in the same period totaled only about \$600,000/year. Hence the lost revenue would have formed a substantial portion of the WARF annual grant to the University of Wisconsin in support of research.

When discoveries are made at the University of Wisconsin the information is promptly published by means of theses, scientific papers, seminars and technical programs. Patentability requirements are not permitted to impede this flow of information. The U.S. patent laws provide, however, that prior publication prohibits the granting of patent protection if the publication of an invention occurs more than one year prior to the filing of a patent application. Thus WARF must make its inventions evaluations and file patent applications promptly to preserve rights, yet the better understanding of the invention and its probable worth is usually developed as the result of later studies. During that rather time consuming process the viable patent term inexorably diminishes.

While an invention may be considered to be complete by a university scientist, his industrial counterpart will consider the project to have only been begun. True public benefit from

the invention cannot accrue until the safety and efficacy of the product is established through expensive and time consuming tests. The task of convincing the market or the market serving delivery systems of the merit of the invention also remains to be accomplished which, too, requires a major investment. Little wonder that only the best of university output reaches the outside world.

It is our task at WARF to cross this interface. This has become increasingly difficult during my career which spans the period during which the federal regulation of foods, pharmaceuticals, pesticides, and other agricultural chemical has become more expensive and time consuming, and the time for the licensee to recoup its investment has grown proportionately shorter.

As do all new product related enterprises, WARF must invest in ten or more inventions to average one that will produce revenue. To lose a large proportion of the patent term to regulatory delay on the successful ones simply reduces either our ability to license new inventions or adversely affects WARF's grant for additional research at the University.

As you may imagine, there are many colleges and universities which own patents and aspire to augment their budgets with patent related income. There is a Society of University Patent Administrators (SUPA), the membership of which represents about

100 such institutions. Although not authorized to do so, I know that I speak for all of them in presenting my support for HR 1937.

University inventions are filed early, resulting in early patent dates, yet suffer long development times which have become ever longer due to federal regulation. HR 1937 will redress this to a major extent. Please work for its passage in the House of Representatives.

If HR 1937 is passed, it will be because you and your colleagues consider it to be in the interest of the public. That being the case, may I ask why should its benefit be limited to inventions approved after its enactment? WARF and many other owners of existing patents have suffered the shortening of the life of currently productive patents. We recommend, therefore, that the bill be modified to provide its benefits to those products which have completed the regulatory review but whose patents have not expired.

Three of WARF's 25 currently commercially used patents were substantially delayed by the regulatory process, but are now in the market place and producing income which will be applied to further University research efforts. We also own patents or patent applications on nineteen other inventions which must,

before they can provide public benefit, pass federal regulatory review.

To summarize: U.S. universities do \$5 billion of research annually with funds supplied by the public through Government agencies. The resulting discoveries and/or technology developed will accrue to the benefit of the public only when industry adopts them and finishes the complex task of readying them for commercial use. Federal regulations slow this process, make it more expensive, but worst of all, increase its uncertainty.

As a result, those of us charged with the responsibility for the transfer, are successful with only those inventions for which the perceived risk is least.

Passage of HR 1937 will change this balance favorably toward more inventions being accepted for development by industry. This will benefit the public, the industry and the university sources of the new product.