Statement by

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The Subcommittee on the Constitution

Committee on the Judiciary

It is a great pleasure to speak on behalf of Senate Bill No. 414 dedicated to the maximum utilization of scientific information generated from federally-supported gifts, grants and contracts. I am a recipient of government support in the health research area and have, through my efforts and the efforts of my colleagues, been able to generate some 23 United States patents and 80 foreign patents. This work was supported with a combination of funds from the University of Wisconsin and U.S. Government grants, primarily from the Department of Health, Education, and Welfare (DHEW). In addition, I have had the experience of dealing with the National Institutes of Health (NIH) on a case-by-case basis for permission to file and assign patents to the non-profit organization, Wisconsin Alumni Research Foundation (WARF). I have also had considerable experience with the use of the Institutional Patent Agreement (IPA) between the University of Wisconsin, with WARF as the designee of the University under this agreement, and DHEW. My experience could therefore be of benefit to those of you considering Bill No. 414 since it will illustrate the effectiveness of the IPA system.

As an introduction, I am Harry Steenbock Research Professor and Chairman of the Department of Biochemistry at the University of Wisconsin-Madison. I have recently been honored by being elected to the National Academy of Sciences and have received other awards in recognition of my contributions to the field of nutrition and biochemistry. My work has been devoted to understanding how vitamin D works to promote healthy bone, muscle and nervous tissue. During the course of our investigation we learned that vitamin D had to be changed in the body to functional forms before it could work. This led to the isolation, identification, and chemical synthesis of the active forms of vitamin D. One of these proved to be a new hormone necessary for bone growth and development and for regulating the blood levels of calcium and phosphorus. These active forms of vitamin D and chemical synthetic analogs have been the basis for the patents referred to above. In addition, we have conceived many divergent uses for these activated forms of vitamin D both in medicine and agriculture.

In 1968 we isolated and identified a form of vitamin D called 25-hydroxy-vitamin D. At that time all patents resulting from NIH-supported work were the property of the federal government. Application for rights to the patent seemed difficult since previous attempts by WARF with other inventions from the University were rejected. To meet deadline dates we risked filing the patent application at our own expense. We then applied on a single case basis for permission to file a patent and assign patent rights to WARF, a nonprofit organization that contributes research monies to the University of Wisconsin. After a considerable length of time, and primarily because of the foresight of an NIH administrator, N. Latker, permission was granted. This compound has not yet made its appearance on the market in the U.S. but has finally appeared in France as a treatment for bone disease. The time span is essentially ten years without a product available to the U.S. public. Much of this delay is due to the uncertainty by drug companies regarding investment of capital to develop the compound as a drug without adequate protection. In our continuing work we isolated and identified the most active form of vitamin D found in the body, namely, 1,25-dihydroxyvitamin D_3 in 1971. By that time we enjoyed an IPA with DHEW. WARF was able to quickly negotiate with Hoffmann-LaRoche, Nutley, New Jersey, and assign them a non-exclusive license to develop this substance for the treatment of disease. Roche was, therefore, assured that their investment would be protected and spent considerable sums of money to develop the product by devising a commercially feasible method of preparation, by carrying out the Food and Drug Administration (FDA) required

toxicology and testing. This resulted in a product called Rocaltrol® now available to the American public for treatment of debilitating and previously unmanaged bone disease caused by kidney failure. In large measure therefore the IPA route resulted in an important new medical breakthrough available to the American public in seven years, a remarkably short time for the development of a drug under the American-FDA system. Most important, an industrial company was willing to invest its time and funds to develop the compound. This compound is now being readied for wide use in the treatment of a variety of bone diseases with great promise. Thus the American public, who invested their tax dollars to support our research, will receive in return the benefit of their investment quickly by using the American patent system to its full advantage. Furthermore, from the foreign filings we anticipate that the U.S. will receive considerable income from royalties paid for use of American-developed technology. The IPA has worked extremely well between the University of Wisconsin and NIH and there are several reasons why. I would like to enumerate these reasons.

(1) To begin with, an inventor or research investigator supported by federal research grants is not encouraged to develop new and novel patentable ideas unless there is an institutional agreement that serves as an inducement for that inventor to conceive and to divulge new inventions. Under government ownership of patents there is no feedback of funds to the institution or to the inventor and thus the inventor is deprived of an important inducement to conceive and develop inventions. I believe that without the IPA I would not have been encouraged to file any of the patent applications which are now resulting in clear benefits to the American population and to the U.S. in general.

(2) Especially in the health science field, industrial companies are reluctant to invest large sums of money required to carry out the tests needed for approval by the FDA for a new therapeutic substance unless their investment is protected from invasion by other companies. It is of considerable interest to note that very few government owned patents are picked up and developed by industry as has been demonstrated by Senators Bayh and Dole. If, however, patent protection is available, the companies are willing to invest their funds to develop a new substance for market and treatment of disease, a necessary step for the public to benefit from NIH-supported research.

(3) When an inventor files applications both in the U.S. and foreign countries, foreign industries utilizing American technology are forced to pay royalties to the U.S. thus giving an important boost to the balance of payments. Furthermore, it provides an equal opportunity, if not an advantage, for our companies to compete with foreign companies for the development of American inventions. If patents are not filed by an inventor, or are filed only in the U.S. (as with most government-owned patents) foreign companies can file ancillary patents, develop an invention on the basis of American Technology and then reap profits from the American consumer without paying for the original research. If the system of patentable inventions is discouraged, the primary loser is the American public.

A final point worth making is the question of whether the support of a scientist by a federal grant means that the federal government owns the ideas and concepts originated by the scientist. It seems to me that this may well be an invasion of human rights to have an agency that supports the research work of a scientist assume ownership of the scientist's ideas. This legislation

would rightfully give back some of the ownership to the inventor and his home institution, who can return the products of his inventiveness to support his continued work and the work of his colleagues in that institution. This legislation is extremely important to individuals such as myself and I feel it is extremely important to the tax payers who pay the bills in the first place.

My last comment should, of course, mention that the IPA gives the federal government royalty free use of the patents; and, furthermore, there are march-in rights if the government decides there is abuse of any such patents. There is no question, therefore, that the Federal government is amply protected by this legislation and at the same time greatly encourages the transfer of information from the basic research scientist to our industry who will put the fruits of research in the hands of the public.

Thank you very much for this opportunity to appear before you and express my viewpoints on this extremely important bill.