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United States Senate

COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON THE CONSTITUTION
WASHINGTON, D.C. 20510

ROBO

October 10, 1978

Patent Letter to:
Indiana Doctors

Dear :

On September 13, 1978, Senator Dole and I introduced the University and Small Business Patent Procedures Act. This bill is designed to cut through bureaucratic red tape that is strangling promising inventions and processes that are arising out of federally supported research. This situation is especially serious in the field of medical research.

The problem is that when the Government insists on retaining patent rights on inventions arising out of its research there is no incentive to private industry to spend the millions of dollars commonly needed to develop and market these discoveries. The Government is rarely able or authorized to make this kind of investment. The result is that all too frequently a promising discovery is left to gather dust on a federal government shelf.

The bill that we introduced would allow universities, small businesses, and nonprofit institutions to retain patent rights on those inventions and processes on which they are willing to spend the necessary private funds to develop and market, while at the same time protecting the legitimate rights of the Government to enjoy the fruits of the research that it has helped to fund.

Many prominent medical researchers attended a press conference that Senator Dole and I held upon introducing the bill. These researchers presented case after case where valuable medical breakthroughs were being held up, in some cases over a year, while patent petitions were being considered ~~at HEW to see whether or not the agency would grant the needed patent protection to insure that the discovery could be developed.~~ For example, Dr. Charles L. Fox, Jr., Professor Emeritus in microbiology assigned to surgery, Columbia University College of Physicians and Surgeons, who is recognized worldwide as an authority on burns and shock therapy, invented the synthesis of silver sulfadiazine that has become the most successfully used treatment in severe burn cases. Dr. Fox testified that a dramatic improvement in burn treatment, which compliments the silver sulfadiazine compound, has been delayed for almost two years because HEW rules forbid transfer of patent rights. Without patent rights even the first stages of FDA approval can not economically begin. As a tribute to the Administration's response in this instance, I should mention that one day after our press conference, HEW Secretary Califano released 30 pending patent petitions, including Dr. Fox's. However, this only underscores the need to create a clear, uniform policy on patent rights, and to eliminate the delays of a case-by-case review. I would like to point out that this delay has nothing to do with testing of products for safety. It relates only to the question of whether the federal government will retain title to the invention or allow title to transfer for commercial development.

There are presently 20 different statutes and regulations on the books that establish patent policies for the agencies. Sometimes there are even different regulations within the same agency on patent rights. The result of this confusion is that there are fewer and fewer inventions being made under federally supported research. The American people who are paying for this work are receiving ~~very~~ too little return for their billions of dollars spent every year on research. If an invention is never developed the public cannot benefit from it. This situation is especially tragic when it involves medical discoveries that are designed to alleviate suffering.

The University and Small Business Patent Procedures Act would allow private researchers to retain patent rights so that these inventions could be marketed. If the discovery achieves a certain degree of success in the marketplace then payment must be made back to the Government equal to its investment.

There is also a section in the bill which would allow the Government to grant exclusive or partially exclusive licenses to private industry on the inventions that it already holds. Presently less than 4% of these Government held patents are being licensed.

There are many other problems which are preventing valuable inventions from being made and used, but I think that the area of Government sponsored research is a good starting place for legislation to solve this problem. I have included a copy of my introductory remarks which explain more about the bill and how it would work. I hope that you will join me in supporting this important bill.

Sincerely,

Birch Bayh
United States Senator

Enclosure