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## United States Senate

COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON THE CONSTITUTION

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Dear Colleague:

The Senate will soon resume its consideration of S. 414, the University and Small Business Patent Procedures Act. This bill was unanimously reported out of the Senate Judiciary Committee after careful consideration of its merits and deserves very serious consideration by the Senate in this time of lagging American innovation. We can no longer afford to allow the results of our multi-billion research efforts to remain isolated from the public.

This bill addresses a serious and growing problem: Hundreds of valuable medical, energy, and other technological discoveries are sitting unused under government control, because the government, which sponsored the research that led to the discoveries, lacks the resources necessary for development and marketing purposes, yet is unwilling to relinquish patent rights that would encourage and stimulate private industry to develop discoveries into products available to the public.

The cost of product development exceeds the funds contributed by the government toward the initial research by a factor of at least 10 to 1. This together with the known failure rate for new products, makes the private development process an extremely risky venture, which industry is unwilling to undertake unless sufficient incentives are provided.

Nowhere is the patent situation more disturbing than in the biomedical research programs. Many people have been condemned to needless suffering because of the refusal of agencies to allow universities and small business sufficient rights to bring new drugs and medical instrumentation to the marketplace.

For example, Department of Energy and Department of Health, Education, and Welfare procedures of reviewing all of the requests for patent rights from universities are resulting in delays of almost 2 years. In many cases these inventions could make significant contributions to the health and welfare of the American people, but are being frustrated by this present patent policy.

he Senate Judiciary Committee held extensive hearings on this bill. The Committee heard many examples of potentially important discoveries being delayed or frustrated by the present patent policies. The Committee noted in its report on S. 414 that not one drug had been marketed by HEW when it insisted on retaining patent rights prior to a liberalization of its policies in 1968. The Comptroller General of the United States, Mr. Elmer B. Staats, testified forcefully in favor of S. 414 because of the adverse affects of the present patent policy confusion. The Comptroller General testified that the present policies are not even consistent -- the GAO had identified 20 different patent arrangements in place in the various agencies.

The present policies were originally based on the presumption that the agency would retain ownership of any patent that came from its reported research even when the agency had no intention or ability to develop and use it. This policy has proven to be so ineffective that it has been gradually revised since President Kennedy's Memorandum and Statement of Covernment Patent Policy issued in 1963.

The present burden of this patent policy confusion is placed primarily on universities (which are presently conducting 70% of the basic research in the country) and on small businesses. Because inventions made by these contractors coming from basic research they do not represent marketable products and require substantial time and money before they are ready to be sold. It has been estimated that the cost of this product development exceeds the cost of initial research by a factor of 10 to 1. When government agencies retain ownership to these inventions the result is simple—no one markets them because there is no incentive to do so without patent protection! The end result is that many promising inventions—especially mediciens—are never delivered to the public. It should also be noted that the agencies are rarely funding 100% of this research but under present policies if their share is even a small percentage of the total funding the agency can insist on retaining patent rights!

- S. 414 is based on the favorable experiences of the Institutional Patent Agreement (I.P.A.) program which has been in effect since 1968. These are agreements made with universities and nonprofit organizations that allow these contractors to retain patent ownership to the inventions that they make while working for the government. This program has been so successful in delivering new products to the public that the General Services Administration adopted a rule making I.P.A.s available to all agencies. There is absolutely no evidence of any economic concentration having resulted from this program— but there is impressive evidence that the I.P.A. program has delivered many important medical discoveries to many suffering people.
- S. 414 takes this very successful program and extends it to small businesses who are working for the government. There is abundant evidence that greater economic competition will result from a closer relationship between our small businesses and the agencies. In those instances where the agency desires to fully develop and use the patent the agencies will be able to retain ownership under the provisions of S. 414. The thrust of this bill is that in those instances where the government cannot develop these products they should not be left to gather dust in some agencies' shelves; they should be left to the inventor so that they can reach their potential in the marketplace where the public can benefit from them.

S. 414 also includes a payback requirement that would require the reimbursement of the government from the profits that a successful invention makes. No one is getting a free ride from this bill!

This concept has been endorsed by President Carter in his innovation speech of October 31, 1979, supported by the President Carter's Domestic Policy Review on Innovation and Productivity, has been endorsed by Mr. Ky P. Ewing, Deputy Assistant Attorney General, Antitrust Division in his testimony to the House Committee on Science and Technology, is supported by the Comptroller General of the United States, Mr. Elmer B. Staats, is supported by the recent White House Conference on Small Business, the National Small Business Association, the Society of University Patent Administrators, and with the exception of Admiral Hyman Rickover by every witness who appeared (or asked to appear) before the Senate Judiciary Committee. It should be pointed out that every representative of a government agency who has appeared before the Judiciary Committee, the Commerce Committee on the House Science and Technology Committee has advocated revising the present policies because of their ineffectiveness.

We urge you to look at the record on this bill. We are confident that if you do you will be able to join us in support of S. 414!