

News from Birch Bayh

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WASHINGTON, D.C., SEPTEMBER 13 -- A wealth of scientific talent at American colleges and universities--talent responsible for the development of numerous innovative scientific breakthroughs each year--is going to waste as a result of bureaucratic red tape and illogical governmental regulations, Senator Birch Bayh (D.-Ind.) said today.

Bayh said regulations covering procedures that govern the issuance of patents for inventions resulting from government-financed research by universities and small businesses have kept new and potentially beneficial ideas from being marketed.

To rectify this problem, Bayh and Senator Bob Dole (R.-Kan.) announced today they are introducing the University and Small Business Patent Procedures Act. The two Senators were joined at a Capitol Hill news conference by several representatives of academic and scientific research institutions.

"Our nation has become a leader in the world of technology, in part, because we have not been afraid to move on bold, new concepts," Bayh said. "Often, government-backed research programs provide the starting point for medical innovations that ultimately save thousands of lives, or starts the ball rolling on projects that in the end result in new sources of energy."

The Hoosier Democrat pointed out, however, that America seems to be falling behind in the development of new technology. "This trend," he said, "strikes at the heart of our traditional American economic strength--our inventiveness and ability to adapt to a changing world."

Bayh explained current federal regulations have prohibited universities and small businesses from obtaining patent rights on inventions if any of the research leading to the invention was supported by federal money.

"The problem, very simply, is the present policy followed by most government agencies of retaining patent rights on inventions," Bayh said. He noted government sponsored research is often basic rather than applied research. Therefore, many of the resulting inventions are at a very embryonic stage of development and require substantial expenditures before they actually become a product or applied system of benefit to the public.

"It is not the government's responsibility--or indeed, the right of government--to assume the commercialization function," Bayh pointed out. "Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle."

Bayh noted that approximately 28,000 patents are now sitting on government shelves. Untold thousands of other developments have not been patented by the government, but rather have gone unused or underutilized simply because no exclusive rights could be obtained during the critical developmental period, the Senator added.

"Although my first involvement in this issue arose with respect to energy research," Bayh said, "the most dramatic examples of this failed government policy can be found in the area of health research. Numerous developments, including cancer-related drugs and procedures, remain at a very early stage of development and unavailable to the public because the government has not granted the necessary patent rights for industry to expend the sums of money needed for further development, leading to public availability."

Bayh referred to problems that have plagued the development of a new source of alcohol fuels by Dr. George Tsao at Purdue University. The Tsao process--a new method for converting cellulose and cellulostic wastes into alcohol for use as a fuel--has been funded in part by grants from the U.S. Department of Energy. Yet, without exclusive rights that

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would arise from patent protection, no commercial enterprise has been willing to risk commercialization of the Tsao process. Bayh said that although this specific problem after long delay appears now to be solved by a waiver from DOE, the underlying problem remains a very real fact of life with respect to many other research projects.

"The bill Senator Dole and I are introducing will allow universities, non-profit organizations and small businesses to obtain limited patent protection on discoveries they have made under government-supported research, if they spend additional private resources necessary to bring their discoveries to the public," Bayh said. "Our universities and small businesses have a proven capacity to develop the sort of bold, new inventions that our country needs to maintain its leadership in the world economic community. This bill provides a careful balancing of the rights of the federal government to use for itself and the public inventions arising out of research that it helps to support, and the equally important rights of the inventor and the people to see that the inventions attain their full potential.

Bayh said an important provision of the bill will allow the government to recoup its investment in research projects. Under this "pay-back" provision, the federal government would be reimbursed for its research expenditures out of royalties or income in excess of a fixed figure.

"At a time when we want to be careful about how we utilize our hard-earned tax dollars, it seems to me that it makes good sense to have the federal government's investments in research projects pay off," Bayh said. He said too many research dollars now go down the drain because a complex welter of government regulations keep innovative developments from realizing their full potential in the marketplace.

Bayh cited a number of statistics which he said clearly demonstrate the patent problem. The number of patents issued to American inventors has declined year by year since 1971, he noted, adding that during the same time, the number of United States patents granted to persons other than Americans has increased. He went on to say that invention disclosures and patents resulting from federally-funded research and development have also decreased steadily since 1970.

"I have no doubt that one major reason for this decline is the fact that patents have been very difficult to obtain under our existing federal policy," Bayh said. "The incentive for disclosure of inventions is reduced if the inventors conclude the commercialization of the invention will be impossible because no patent will be issued."

The Bayh-Dole bill is expected to be referred to the Senate Judiciary Committee. A copy of the bill, as well as other briefing materials are included in a press packet available at this morning's news conference or upon request.

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SECTION-BY-SECTION ANALYSIS

Outlined below are a number of important features of the bill:

Section 202 provides that each nonprofit organization (defined in the bill to include universities) and small business shall have a reasonable amount of time to elect to retain title to subject inventions. The federal agency may retain title if the invention is made under a contract for operation of a government owned research or production facility, might cause the disclosure of classified information or imperil national security, or if granting patents would not be in the public interest in terms of the purpose to be served by this legislation.

Section 202(c) provides that each funding agreement shall contain provisions to: (1) insure the right of the federal government to receive title to any subject invention not reported to it within the prescribed times of the contract; (2) insure the government's right to receive title to inventions when the inventor does not intend to file for patent rights; and (3) provide that the agency shall have a nonexclusive, nontransferable, paid-up license to use the invention.

Section 202 (c) (7) prohibits nonprofit institutions from assigning rights without the approval of the federal agency; prohibits granting such rights in excess of the earlier of 5 years from the date of first commercial use or 8 years from the date of invention, whichever comes first; and provides that all proceeds shall be used to support scientific research or education.

Section 203 gives the federal agency the right to require the subject inventor or his assignee to grant additional licenses if the agency feels that sufficient steps are not being taken to achieve commercialization. Additional licensing may also be required to alleviate health and safety needs, or under provisions for public use as specified by federal regulations.

Section 204 provides that if the patent holder receives $250,000 in after tax profits from licensing any subject invention during a ten-year period, or receives in excess of $2,000,000 on the sales of products embodying or manufactured by a process employing the subject invention within the ten-year period, that the government shall be entitled to collect up to 50% of all net income above these figures until such time as the amount of government research money has been repaid.

Section 205 specifies that no foreign owned or controlled firm shall be eligible to receive patent rights under this Act unless the federal agency determines that this is the only available means of achieving commercialization; a similar provision covers licensing the invention outside the U.S.

Section 210 will allow federal agencies to grant exclusive, partially exclusive, or non-exclusive licenses on government owned patents to achieve commercialization; the Department of Commerce is authorized to receive patents held by other agencies and to make the necessary steps to determine the market potential of the patent and to receive any fees or royalties due to the government.

Section 211 authorizes the Administrator of GSA to issue regulations regarding such licenses and gives first preference in licensing federal patents to small businesses.

Section 213 specifies that federal licenses be issued only after public notification and opportunity for filing objections and that exclusive or partially exclusive licenses not be granted if the result would be a lessening of competition; the agency has the right to require more licensing if it feels that this is necessary after three years and to require periodic written reports on progress toward commercialization.

A COPY OF THE BILL IS INCLUDED IN THE PRESS PACKET.