assigned to industrial developers by NIH investigators without notice to NIH.

In the case of Gatorade, Mr. Cade of the University of Florida, frustrated by the Department's failure to timely respond to his request for the patent rights to Gatorade, assigned the invention to Stokely-VanCamp, who thereafter sued the Department for clear title. Under this threat, the Department negotiated leaving the invention to the University of Florida under conditions which were later adopted in Dept. Institutional Patent Agreements or IPA's and then in the Bayh-Dole Act.

In another notorious situation, Dr. Heidelburger and the University of Wisconsin after being publicly accused by Sen. Long's staff of confiscating ownership of 5FU, a breakthrough cancer chemotherapy drug and licensing it to an industry developer, successfully convinced the Dept. that minimal government funds were involved in its conception.

Further, Dr. Guthrie, a Dept. grantee and the inventor of the then preferred test for PKU being marketed by an industrial developer under license, after being publicly pilloried by Sen. Long's staff for confiscating the invention, assigned ownership to the Dept.

These cases had a further chilling effect on industry involvement as they surmised that any amount of government funding touching an industry invention could result in similar claims of right by the Government.

Thereafter, the G.A.O. added additional urgency to resolving the problem by reporting that due to Department Patent Policy precluding transfer of exclusive rights, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

Finally, in 1969, in direct response to these situations, the Department relented and changed its patent policy by establishing a uniform IPA policy that left ownership to grantee institutions who agreed to staff a technology transfer office to manage these rights. The changes also included administrative authority that permitted the Department to grant exclusive licenses in inventions made by DHEW employees to industry.

In 1973, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's resistance to development of in government funded inventions because they were not made in the company's laboratories. (Ironically, this impediment was called the NIH or not-invented-here syndrome).

By 1976, 75 IPA's had been negotiated and executed with institutions who received approximately 80% of the annual DHEW extramural funding.

Also in 1976, Dr. Frederickson, the Director of NIH, agreed with the consent of other Federal research agencies to permit the University of California and Stanford to administer the Cohen-Boyer gene splicing patent under their IPA's. Stanford's non-exclusive licensing of Cohen-Boyer to dozens of commercial concerns sparked the biotech industry.

Notwithstanding, the clear record of increasing licensing by IPA holders, the secretary of the Department, instituted in 1977 a reassessment of the IPA policy which stopped further invention processing on the ground that the introduction of new technology into the marketplace was escalating the price of healthcare which required Department oversight. Legislation was introduced in the Senate to provide the Department with this oversight authority at the same time.

Frustrated and incensed, organizations having IPA's responded by pressing for legislation to assure continuance of the 1969 DHEW policies and its further expansion into other federal agencies having conflicting policies. This resulted in Senator Bayh and Dole introducing what became the Bayh-Dole Act.

In December 1980, in a lame duck session of Congress, Bayh-Dole was enacted with no executive support, establishing for the first time a uniform government patent policy guaranteeing ownership of all federally funded inventions to non-profit organizations and small business but with a limitation on the life of exclusive licenses granted to industry. In addition, it created statutory authority for exclusive licensing of all Government owned inventions, the bulk of which were generated by intramural employees. The Act repealed 22 conflicting agency statutes against formidable opponents including the Attorney General, Sens. Long and Nelson, Ralph Nader, Ad. Rickover of Atomic submarine fame, the Agency administrators of the Acts to be repealed and others.

In 1983, the ownership principles of Bayh-Dole were extended to all other recipients of Federal funding not otherwise precluded by statute by Executive order. This established for the first time a uniform government patent policy covering all federal agencies conducting research and ended 40 years of Government demands for ownership of grantee and contractor inventions as a condition for funding.

In 1984, Bayh-Dole was amended to permit exclusive licenses for the life of the patent.

Finally, in 1986 with strong White House support, the Federal Technology Act of 1986 was enacted, to require de-centralize of the statutory licensing authority for government owned inventions in Bayh-Dole to the Federal laboratories at which they were made. This put the Federal laboratories on an equal basis with the laboratories covered by Bayh-Dole. The Act also extended the Bayh-Dole principle of an option to future invention rights to industrial concerns in return for funding a cooperative research and development agreement (CRADA) at a federal laboratory.

The success of Bayh-Dole can be easily measured by the royalty return to grantees and the increase in research funding to grantees from industry in return for an option to exclusivity in future inventions made by the grantee.

With regard to royalties:

The Unv. of California earned 67M in royalties in '97,

Stanford Unv. 52M,

Columbia Unv. 50M,

Sloan-Kettering 30M,

N.Y. Blood Center 32M,

Unv. Wisc. (WARF) 17M

The grand total in royalties in '97 for all federally funded institutions was 700M.

With regard to research funding to grantees from industry, the total reached 2.2 billion dollars in 1997.

All of the 700mil in royalty income is required by Bayh-Dole to be returned to research minus expenses and a percentage to the inventors.

But more important are unseen successes such as:

1. Greater interest in government research, resulting in:

2. Increased collaboration between industry and government research organizations as foreseen by Dr. Shannon and the movement of personnel between them, resulting in:

3. Expedited delivery of important life science inventions to the public, resulting in:

4. Increased Congressional support encouraged by citizen belief in science and technology.

Hopefully all in a never ending circle.