Brief History of Federal Technology Transfer

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As early as 1964, the failure to attract industry development of Government funded life science inventions was well known.

Dr. Shannon, then NIH director, characterized the source of the problem before Congress by emphasizing that NIH grantees do not engage in the direct development and manufacture of inventions and it is industry that must bring grantee inventions to the marketplace. But in doing so, an industry developer must decide that the patent rights offered are sufficient to protect the risk investment involved not only for the invention offered, but for the huge number that fail in development compared to few successes. He concluded by saying that NIH's research effort was complementary to that of other elements of society and that it was in the best interests of the American people to assure that the various interests of the

medical research community can interact. The Department's policy to own all such inventions for non-exclusive licensing at most clearly precluded the cooperation Dr. Shannon suggested.

By 1968, while factions in the Department continued to argue policy, the problem had been dramatized by increasing numbers of invention ownership disputes involving inventions assigned to industrial developers by NIH grantee 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 good faith 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 Department Institutional Patent Agreements (IPA's) and then later in the Bayh-Dole Act.

Earlier, 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 Department that minimal government funds were involved in its conception.

Further, Dr. Guthrie, a Department 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 Department.

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 a claim of rights 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 any 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 and license these rights. The changes also included administrative authority that permitted the Department to grant exclusive licenses to industry in inventions made by DHEW employees. NSF followed with similar changes in 1972.

In 1973, the newly established IPA holders formed the Society of Patent Administrators to enhance outreach to industry so as to overcome industry's continuing resistance to development of 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 well over 50% of the annual DHEW extramural funding.

Also in 1976, Dr. Frederickson, then 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.

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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. Simultaneously, Sen. Nelson of Wisconsin conducted hearings as to the legality of IPA's.

Frustrated, organizations having IPA's (led by the University of Wisconsin, Stanford University, the University of California, and Purdue) responded by pressing for legislation to assure continuance of the 1969 Department policies and its further expansion to other federal agencies having conflicting

policies. This resulted in Senators 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 for the first time, statutory authority for exclusive licensing of all other Government owned inventions, the bulk of which were generated by intramural Federal Employees. The Act repealed 22 conflicting agency statutes, many of which were a result of amendments by Sen. Long to Agency Appropriation Acts. Enactment was achieved 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, which received little notice other than from its opponents. This

established for the first time a uniform government patent policy covering all federal agencies conducting research and ended 40 years of the Government requirement 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 Transfer Act of 1986 was enacted, which required decentralizing the statutory licensing authority for government owned inventions created in Bayh-Dole to the Federal laboratories at which the were made. This was intended to put the Federal laboratories on an equal basis with the laboratories covered by Bayh-Dole. The Act also extended the Bayh-Dole principles of an option to future invention rights to industrial concerns in return for their funding a cooperative research and development agreement (CRADA) at a federal laboratory.

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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 and others, the total reached 2.2 billion 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 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 cycle.