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THE EVOLUTION OF MODERN TECHNOLOGY TRANSFER

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Louis Pasteur once observed that:

"There is no greater charm for the investigator than to make new discoveries; but his pleasure is heightened when he sees that they have a direct application to practical life".

During Pasteur's lifetime, a significant number of new discoveries reached application to practical life through the investigator's own resources and effort or those of an organization directed by the investigator.

Samuel B. Morse virtually camped out on the steps of the Congress until he was given a grant to build a 40-mile demonstration telegraph line between Baltimore and Washington. Alexander Graham Bell demonstrated the application of his telephone in his own makeshift laboratory and then pursued its marketing through the incentive of his patent position. Edison's hundreds of patents helped fund the reduction to

practice and the licensing of a flood of now every day products from his Menlo Park laboratory.

But as the early and fundamental discoveries in the life sciences evolved, it became clear that the resources necessary to bring them to practical life exceeded what their investigator could provide through their own effort.

In 1885, Pasteur saved a young boy with rabies in his laboratory. Patients flocked from all parts of the world but his office was too small to receive them all. The next year, before the Academy of Sciences, Pasteur declared that "There is a need for prophylactic measures against rabies. An anti-rabies vaccine should be created." The request from "the father of microbiology" resulted in an extensive, international public subscription generating a fantastic burst of generosity that built the Pasteur Institute as a clinic for rabies treatment, a research center for infectious disease and a teaching center, with Pasteur as director.

Today's Pasteur Institute continues its research, funded in part through royalty returns from discoveries made in their laboratories.

Among the examples of investigator driven application of their discoveries, the practices leading to the discovery and application of the cure for syphilis discovered by the "father of chemotherapy", Paul Ehrlich, comes closest to present day practice.

In 1906, at Ehrlich's urging, the Georg-Speyer-Haus Research Institute for chemotherapy was established with its own staff under Ehrlich's direction. The Institute was an interdisciplinary institute formed to define problems to be attacked through exchange of ideas among biochemists, pharmacologists, clinicians and other scientists working inhouse. A percentage of the profits from patents was designated to be reinvested in the institute to cover its operating costs, including the costs of undertaking new research. The German firms of Hoechst and Casella contributed substantially to the initial endowment and also supplied the raw materials used in the department of chemistry's research. In exchange, the two firms received first refusal on any marketable patents. But the choice of research problems was left to be determined solely by Ehrlich and his staff.

It can be agreed that Pasteur and his peers did not view their efforts as technology transfer nor did they need the assistance of a technology manager.

Notwithstanding these few examples, Professor Frederick Cottrell, the inventor of the electrostatic precipitator, recognized,

> "…the ever growing number of men in academic positions who evolve useful and patentable inventions from time to time in connection with their regular work … (who) would gladly see these further developed for the public good, but are disinclined … to undertake such developments themselves" …

He also noted that there was,

> "…a certain amount of intellectual by-products … going to waste … in our colleges and technical laboratories all over the country,"

and that

> "…a number of meritorious patents given to the public absolutely freely have never come upon the market chiefly because what is everybody's business is nobody's business."

He finally concluded that:

> "A certain minimum amount of protection is usually necessary by any

> manufacturing concern before it will invest … to put a new invention on the market."

These observations led Professor Cottrell to donate his patents and their royalty return from the electrostatic precipitator to fund the creation of the Research Corporation in 1913 to serve as the technology transfer agent for investigators isolated from the commercial marketplace.

In 1925, Professor Steenbock made a similar donation of his vitamin D patents to fund the creation of the Wisconsin Alumni Research Foundation (WARF) limited to serve as the technology transfer agent only for investigators at the University of Wisconsin at Madison. These targeted services were intended to provide greater attention to reported inventions than previously provided by universities.

During these early years of the century, the services of Research Corporation and WARF were clearly limited by their resources. The majority of investigators were left to determine on their own whether to pursue moving their discoveries into practical life. Some of these determinations did not produce an opportune result.

For example, in 1929, Fleming discovered the utility of penicillin, but unlike Pasteur or Ehrlich, made no identifiable effort to bring it into practice beyond its publication. Patent protection was not pursued.

Absent a champion, the benefits of penicillin languished until Florey and Chain devised a method to produce it economically in volume and, prompted by World War II, the Department of Agriculture began manufacture and distribution in 1941.

The huge increase in funding of research and development by the Federal agencies proposed by presidential science advisor Vannevar Bush following World War II brought with it the establishment of a patchwork of different policies covering the ownership of inventions resulting from this funding. Outside the Department of Defense, the policies were heavily weighted in favor of government ownership, resulting in either dedication to the public or non-exclusive licensing of the government's patent rights.

By the 1960's, it was clear to the science management at the National Institutes of Health that their Department's title policy was an impediment to

industry development of the life science inventions resulting from N.I.H. funding.

In 1963, Dr. Endicott, the Director of the National Cancer Institute vigorously pursued the Department (DHEW) until it amended its regulations to provide for industry ownership of new uses of industry compounds submitted to the Institute's cancer chemotherapy screen.

Dr. Shannon, the N.I.H. Director, emphasized before Congress 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 and suggested that the Department's patent policy impeded this interaction.

The problem was dramatized by increasing numbers of invention ownership disputes involving inventions assigned without notice to NIH to industrial developers by NIH grantee investigators motivated, as was Pasteur, to see their direct application to practical life.

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 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 the Department's 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 suggested that any amount

of government funding touching an industry invention could result in a similar claim of right by the Government.

Thereafter, in 1968, the G.A.O. added additional urgency to resolving the problem, by reporting that due to Department Patent Policy, inventions resulting from all of NIH's medicinal chemistry grants could not find the necessary industry support to continue development.

Finally, in 1969, responding increasing internal pressure, the Department changed its patent policy and established a uniform institutional patent agreement policy that left ownership to grantee institutions who agreed when they requested an agreement to staff a technology transfer office to manage and license these rights. The conditions attached to these agreements reflected the accepted practices of Research Corporation and WARF. NSF followed with similar changes in 1972. Thereafter, the HEW and NSF staff responsible for IPA policy joined together in a long series of interagency discussions aimed to establish the IPA policy throughout the government agencies.

In 1974, 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).

In that same year, members of the Society found their political legs by assisting in preventing the inclusion in legislation creating the Energy Research and Development Agency of a requirement for government ownership of inventions resulting from its funding.

By 1976, 75 IPA's had been negotiated and executed with institutions who received well over 50% of the annual DHEW extramural funding, and GSA regulations expanding the IPA policy to the rest of the government agencies, otherwise covered by statute, were accepted by the interagency Federal Council for Science and Technology (FCST) and published.

Also in 1976, Dr. Frederickson, the Director of NIH, agreed with the consent of the FCST 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 start of the biotech industry.

Notwithstanding the clear record of increasing licensing by IPA holders, Joe Califuno, the Secretary of the DHEW, instituted a 1977 "reassessment" of the Department 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 initiated hearings to discuss the legality of IPA's and the GSA regulations expanding their use to all government agencies.

The Califuno and Nelson actions served as the flashpoint for organizations having IPA's to pursue legislation to assure continuance of the 1969 Department policies and their further expansion by the GSA regulations to other federal agencies having conflicting policies. Led by the University of Wisconsin, Stanford University, the University of California, and Purdue, the IPA community, over a

period of two years, were so successful in making their views know to the Congress that Bayh-Dole passed the Senate by a vote of 91-4.

Some suggest that the primary purpose for Bayh-Dole is the production of income for those that participate in the conception and delivery of inventions to the marketplace. I do not believe that was the primary motivation of the Act's architects. Income, which was a distant possibility at the time of enactment, was viewed only as a collateral benefit of success. The Act is structured so as to assist investigators in their pursuit of direct application of their discoveries to practical life up to the point of either success or definitive failure. As such, investigators intuitively understand that the Act provides to them the possibility of their advancing mankind, as Pasteur presumed was their wish, which explains their growing enthusiasm to participate.