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Splices of Life and So Much More- A Retrospective of 25 years on Recombinant DNA Cloning, Biotechnology and Technology Transfer

It's become a story of mythical proportions in the biotechnology community. Two researchers meet on a tropical island and, during a nighttime snack, give birth to the basis for reproducing and cloning individual DNA segments. The punch line is that truth is stranger than fiction.

This tropical brainstorm, the Recombinant DNA Cloning technology, was produced by a collaboration between Dr. Stanley Cohen of Stanford University and Dr. Herbert Boyer of the University of California at San Francisco (UCSF) in 1973. Cohen and Boyer's invention laid the foundation of a new industry - biotechnology. But academics, industry and technology transfer offices also now view the Recombinant DNA Cloning technology as a direct and indirect aid in the promotion and progress of research and technology transfer.

Foundation of a New Industry

The consequences of Cohen and Boyer's discovery, from the early debates over the initial findings to the resulting patent process to the industry it engendered are dramatic in scope. Initially there were concerns over the freedom of researchers' works, questions about whether man-made living organisms should be patented, and safety issues stemming from the possible applications of Recombinant DNA Cloning (see "Tiger by the Tail," Niels Reimers, Journal of the Association of University Technology Managers, Volume VII, 1995).

In the early 1980's, biotechnology companies were just getting started as a viable group. Venture capital was also available, noted Jack Granowitz, Executive Director of Columbia Innovation Enterprise (Columbia University), and the venture capital firms were looking for something in which to invest their money.

These firms were eager to invest in innovative technology, and their initial investments paid off as the companies emerged as a new force in medical technology. As the biotech companies expanded, so did the need for leading edge technology.

The Rise of Technology Transfer

In 1981, Congress enacted the Bayh-Dole Act, allowing universities the right to license inventions created with government support without lengthy negotiations with each government agency. As a result of this Act and the interest in new ways to

acquire funding for academic research, university technology transfer offices started springing up all over the country.

"Academic researchers' attitudes 25 years ago were that patenting something, or giving a patent to industry, or developing a company of one's own, was selling out," commented Hugh McDevitt, Professor of Microbiology and Immunology at Stanford. "The major reason that attitude has changed...is the observation by the academic world that a patent accrues to the benefit of the university." And these benefits were allowed to occur due to the Bayh-Dole Act.

When the Recombinant DNA Cloning technology was invented, not only was a new industry created, but so was a new area of technology transfer. Biotechnology licensing accounted for over half of the licenses completed by Stanford's OTL in the 1996-1997 fiscal year.

Before Cohen-Boyer, non-profit technology transfer offices mainly focused on engineering, physics and chemistry. "The biologists and biomedical researchers needed to become acquainted with the value of technology transfer to the university and to the community in general," said McDevitt.

Technology transfer had remained somewhat unfamiliar to biologists because there were not many success stories or known advantages. "Cohen-Boyer came along as the first big commercial success [of university biotechnology transfer]," commented Ashley Stevens, Director of the Office of Technology Transfer at Boston University.

"As the new biotechnology companies started Continued on page 2

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Editor & Writer Kirsten Leute

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> *Director* Katharine Ku

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to be formed," said Granowitz, "universities started becoming interested in technology transfer."

Over the past 25 years, the growth of technology transfer offices has been rapid. Compared with the approximately 30 offices at non-profit institutions in the early 1970's, over 275 offices exist today (AUTM Licensing Survey, FY1991-1995).

Researchers' Reversal

As the royalties started flowing into the university, academics focusing on the biological sciences began to take notice of the advantages of disclosing their inventions to their respective technology transfer offices. The idea of 'selling out' became less and less of a factor, whereas money to further support their school and department was of great interest.

"The change in researchers' attitudes toward technology ownership and transfer has been revolutionary," commented Geoffrey Dellenbaugh, Executive Director of External Relations at the R.W. Johnson Pharmaceutical Research Institute. "In 1974, most academics viewed the industry-sponsored research with suspicion. Today...most academics are well aware of the commercial value of inventions in biotechnology."

Cohen agreed. "Researchers have learned to be aware of when a discovery made in their lab is potentially patentable."

With this change in attitude towards technology transfer has come a new respect for industry and the licensing of inventions.

"Technology transfer offices are now a feature of attraction to academics," noted Stevens. Even if the school is smaller and not as well known, it is a factor in retention of faculty to have a technology transfer program.

"There are three factors which strongly motivate an inventor [to disclose his or her invention to the technology transfer office]," continued Stevens. "One is to see his or her research put to practical use, the second is to help get funding to support his or her research [through sponsored projects] and the third is personal gain via sharing of royalties."

Research for Research's Sake

Twenty-five years ago, academics published their findings without thought of patent restrictions or possible commercialization of the technology. Nowadays, as when the prospect of university technology licensing first became a big issue, a large concern of many researchers is the potential change in perception by researchers of their work.

Although the benefits of patenting by universities are positive, "the patenting process must not

A S Docket(s)		es Granted by C	TL in the Last (Licensee(s)	Juarter License Type
S76-047	"Monolithic Semiconductor Switching Device"	IGBT's	Fuji	Non-Exclusive
S81-026	"Phycobiliproteins (PE)"	Diagnostics	EG&G	Non-exclusive
S91-041	"NF-AT Antibodies"	Transcription System/ Research	Pharmingen Santa Cruz Biosciences	Non-exclusive Non-exclusive
S94-140	"Antigen-Specific T-cells"	Therapeutics	RW Johnson Research	Excl. Option
S96-113	"Device Jaundiced Newborns"	Therapy for Jaundice	Healthdyne	Excl. Option
S96-139	"Phi-Nx Cell Lines"	Retroviral Screening	Regeneron, Osiris, Ariad Gene Therapeutics	Non-exclusive
S97-025	"Agouti-related Protein"	Anti-obesity Drug Devel.	Chiron Corp.	Non-exclusive
S97-066	"Polysurf"	Software	3DM	Field Exclusive
S97-236	"Gene-disruption Mice"	Screening Tool	Novartis	Non-exclusive

obstruct the way scientists disseminate information," said Cohen.

"The point of academic research is its literal meaning - academic and research," commented Katharine Ku, Director of Stanford's OTL and Sponsored Projects Office. "We believe researchers should pursue their intellectual interests first. Most university patents do not make lots of money, for many reasons not under our control. We hope researchers are not doing 'commercial' research at the expense of curiosity-driven research, in the hopes of royalty revenue."

Industry Know-How

For many years, industry has turned to alternate sources when they wanted to augment their own Research and Development. Judging by the growth of both biotechnology compa-

nies and technology transfer offices, these types of transactions are now more standard.

"I think we're seeing stratification in the product-development 'food chain,'" commented Nan Doyle, Manager of Technology Licensing at Genzyme Corporation. "Very few companies will want to, or be able to, bring a product all the way through from basic/discovery research to the patient's bedside."

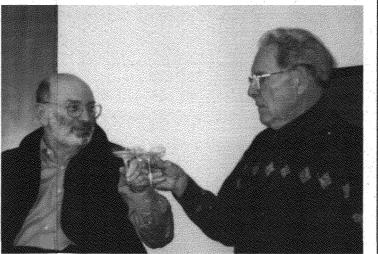
Therefore companies now look more to other resources, especially universities where technology is always on the cutting edge, but also at other stages along the 'food chain.'

"Licensing of technology has increased dramatically," said Niels Reimers, Director Emeritus of Stanford's Office of Technology Licensing, "not just between academia and industry, but also between industry and industry."

Companies are also putting more money into universities via sponsored projects and other industrial affiliations in order to guarantee licensing rights at an earlier stage of development. They look to universities for knowledgable people to aid with research that they have licensed or created on their own as well.

"Universities are not only a source of technology, but of people," commented Granowitz. There was once a negative stigma associated with industry jobs, in the view of academic researchers. This

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Stanley Cohen (t) and Floyd Grolle toasted one another on the eve of Dec. 2, 1997, the day the Recombinant DNA Cloning patents expired.

Floyd Grolle, Renaissance Man

Of all the people in our office, none has as rich and varied a background as Floyd Grolle, Ph.D. During his twenty-five years at Stanford, Floyd has moved from the Health Services Administration program to an Internal Auditor to the Manager of License Administration for Stanford and UC's Recombinant DNA Cloning technology (see page 1 article). But Floyd also had an amazing life before Stanford...

Floyd's schooling alone is impressive. After working on the family farm for many years and taking night classes in engineering, Floyd entered the University of Toledo. While taking pharmacy and engineering courses, Floyd met his wife of 48 years and counting, Barbara.

Finishing his bachelor's degree in Pharmacy and a Registered Pharmacist licensure plus a Master's in Pharmaceutical Chemistry at the University of Michigan, Floyd decided to pursue a Ph.D. in the area of Biochemistry.

Almost four years into the program, just as Floyd was getting ready to write his dissertation, his research advisor left the University. Due to the type of program Floyd was in at the University of Michigan, he would have had to start completely over in order to get his Ph.D.

Instead, Floyd took over his advisor's courses. While teaching, Floyd earned a Master's in Market Research and a Ph.D. in Marketing Management. This was in part due to a sponsorship by McKesson-Robbins, a company which was intrigued at the medley of Floyd's interests.

Floyd's combination of distinctive educational fields produced a great marketable commodity. Graduating with his third degree from the University of Michigan, Floyd had offers from several universities to teach Pharmacy Administration, a relatively new area at the time. But "I wanted to see whether my background would be noteworthy in the pharmaceutical industry," said Floyd.

Floyd chose a job with Upjohn mainly because he could "go on the road" as a Medical Service Representative explaining Upjohn's products to physicians. By the time he left Upjohn for Becton Dickinson, Floyd was the Assistant to the ExecutiveVice President where he worked on the acquisition of companies dealing with plastics. The multi-degreed graduate succumbed to Becton-Dickinson's wooing to aid them in the development of a pharmaceutical business.

From Becton-Dickinson, Floyd moved to G.D. Searle where he was Director of Diversification, then on to SRI International. After working for Stanford's Department of Family and Community Medicine and while conducting internal audits at Stanford, Floyd finally came to OTL in 1982.

Once Floyd started working at OTL, the number of Cohen-Boyer licensees increased, finally reaching 370 in 1997. This was due in part to the burgeoning industry, but in great part to Floyd's diligence. "Floyd vigorously and doggedly went out and negotiated licenses," remarked Dr. Stanley Cohen. "He's done a remarkable job and has been an extraordinary value to Stanford."

When not rounding up Cohen-Boyer licenses, Floyd can frequently be found in his home workshop. Growing up on a farm in Ohio, his father had a cabinet shop, a metal shop and a blacksmith shop. Since the family lived seven miles from town, there was not much entertainment or an easy way to get things repaired. So one of Floyd's enjoyments was creating both fun and practical things.

This tradition continues today. Floyd often constructs much needed additions to the office, but also finds time to craft beautiful, original toys for his eight grandchildren and the children of his coworkers.

As with all of the people in our office, Floyd is a valuable contributor to keeping us cohesive and full of vigor. We are extremely fortunate to have such a clever and multitalented person as a member of our team.

Glennia Campbell, Industrial Contracts Officer

by Kellyanne Ebisui

Glennia Campbell is the new Industrial Contracts Officer at OTL and Sponsored Projects Office (SPO). She can be found here fulfilling the University's contracting needs by negotiating sponsored research agreements with industry. Her liaison role between SPO and OTL further solidifies the working relationship between the two offices.

Glennia originates from Ohio, but was educated at Barnard College of Columbia University, receiving a B.A. in English. She continued her education to earn her J.D. from Northwestern University Law School. She is currently a member of both the New York and Texas Bars and recently passed the California Bar examination.



After law school, Glennia worked for the Bronx Legal Services, dealing with low-income clients in civil cases which included landlord-tenant disputes, civil rights and education issues. She then moved to Texas to work in the Contracts Department at Sematech.

While there, Glennia began doing project planning and contract management for the Lithography Group, specializing in Photomask development activities. She eventually became responsible for managing part of the Contracts Department and then transitioned to doing general corporate and contract law in Sematech's 3-attorney Law Department.

Only a few months new to both the Bay Area and the University setting, Glennia moved to the area as a result of KLA/Tencor's offer to her husband, Frank Schellenberg, for a position as Product Marketing Manager. In the relatively short time Glennia has been at Stanford, she finds she especially likes the people and the university environment.

She has learned a lot from both offices and enjoys the exposure to all of the different technologies. Because her position is newly created, she is continually redefining and learning new facets of her job. She says so far it has been pretty fun and exciting.

Glennia and Frank are avid travelers and have visited many countries, including an eight-country, around-the-world honeymoon. Her favorite countries include Japan, Korea (where she was born), and Italy.

Glennia is a very welcome addition to our offices, and we hope you will get

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a chance to work with her. She may even tell you some great stories about her travels. We hope, however, that no matter how far she travels, she has found a home in the Bay Area and with both SPO and OTL. \triangle

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has lessened to a great extent, especially considering the number of start-up companies created by entrepreneurial faculty and students.

The End of an Era?

All three Cohen-Boyer patents expired December 2, 1997. OTL considers itself incredibly fortunate to have had such an opportunity to help establish biotech licensing as an important mechanism for technology transfer. Patenting the Cohen-Boyer invention "was a once in a lifetime situation that could easily have been overlooked," said Reimers.

"Cohen-Boyer, along with its tremendous success, has had an enormous public benefit," said Granowitz. "It was a win-win situation." While providing support to the same type of research that created the technology, the companies which licensed the technology from Stanford were able to generate products that benefited the entire world.

There is the well-known complaint that if biotechnology companies did not have to license the technologies from universities, the products would not be as expensive. "But did the biotechnology companies reduce their prices on December 3, 1997?" asked Stevens.

The Bayh-Dole Act was clearly the primary factor in facilitating technology transactions and increasing the number of university technology transfer offices. But the Cohen-Boyer invention helped promote technology transfer as a source of intellectual property available to industry and funding to support the research institutions. \triangle

Many thanks to Glennia Campbell for her help editing this article. -KL



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