CHAPTER IV
POST-LEGISLATION CASES

This chapter describes the post-legislation cases from 1992 and 1993. It introduces the cases using the "Level II Analysis" described in Chapter I's section on research design. Using information from the 1994 FLC Winner's Document, all of the FLC 1992-93 awards are organized by federal department or agency and topic area. The topics are based on the interview topics defined in Chapter I's section, "Core Elements of the Government Technology Transfer Process." The following topics are included in the introductory section: technology applications, role of the laboratory researchers and other personnel, technology transfer mechanisms, intellectual property, user benefits/economic impact/outcomes, government gains, elapsed time, and other factors. In order to avoid excessive duplication, topics are addressed primarily with illustrative examples rather than a comprehensive survey of all the cases.

Following the Level II analysis of the 1992-93 group, eight selected cases are examined in greater detail.[1] Because of this more extensive examination, examples for the introductory Level II analysis are largely drawn from the cases not selected. After presentation of the eight cases, the final section of the chapter groups the key data from the eight cases according to the topics.

INTRODUCTION - LEVEL II ANALYSIS, POST-LEGISLATION AWARDS

<u>Departments/Agencies and Technology Applications</u>

The seventeen 1992-93 awards were distributed between laboratories of departments and agencies as follows:

- Agriculture (two technologies) - a technology for testing product quality in the paper industry; and a fat substitute for the food industry,
- Air Force (one technology) - a multiband digital speech processor,
- Army (one technology) - establishment of a geographic information system,
- Commerce (two technologies) - an improved gravity measurement device and optical fiber sensors for use by utilities and manufacturing firms,
- Energy (eight technologies) - a laser method to light up and detect biological samples like genes; a microwave furnace with variable frequencies; an artificial heart pump flow tracking technique; laser lithography technology to etch

[1]Unlike the 1980s cases, none of the laboratory researchers in this group read final drafts of their cases. However, three laboratory researchers read incomplete drafts of their cases as part of the interview process.

semiconductor chips; an advanced process for manufacturing metals; establishment of a microelectronics quality reliability center; a nondestructive ultrasound testing technique; and circuits to measure superconductivity for a variety of uses -- medical, geological, laboratory instruments, etc.

- Navy (three technologies) - glow-in-the-dark light sticks for fishing industry and military operations; technical assistance provided by a laboratory researcher on paints and coatings; and an advanced polymer resin material.

As with the 1985-86 awards, there were interesting examples of technologies from one field of science being applied to totally different fields with successful results. For example, a team of seven researchers developed a software program to meet military needs, then worked to identify civilian applications. They targeted three users and set up a series of technology transfer mechanisms.

Roles of the Laboratory Researchers and Other Personnel

The seventeen 1992-93 awards involved a total of 31 researchers (25 males, three females, and three persons whose initials or foreign names were not identifiable as male or female).

As with the 1985-86 awards, the role of these laboratory researchers varied. However, the 1992-93 researchers appeared to be more proactive early-on in reaching out to users and industry. There are numerous examples, including the following:

- A researcher identified as having an "entrepreneurial spirit"[2] established a center to transfer reliability testing technology. He visited companies across the country to learn about their needs and convince them government laboratories had something to offer.

- Researchers at DOE's Lawrence Livermore National Laboratory developed a laser for x-ray lithography and "cooperated closely" with other researchers at AT&T, IBM, MIT, University of California - Berkeley, the National Institute of Standards and Technology (NIST), and Naval Research Laboratory (NRL) so they could review it.

- Another group of DOE researchers built a new type of circuitry for a superconducting device co-developed by the laboratory and a company.

- A team of DOE researchers explored industry's need for a particular measuring device and then when companies (e.g., General Motors) indicated interest,

[2] 1993 FLC Winners' document.

demonstrated the device.

- A scientist at the Naval Research Laboratory developed a material and helped a licensing company develop manufacturing procedures. He then helped a CRADA partner identify additional applications and refine the manufacturing procedures.

- A DOE scientist developed a metal manufacturing process which avoided metal fatigue and produced a lighter weight material. He "sparked" the interest of potential producers and users by mailing surveys and then focused on working with the interested respondents.

- A NIST researcher developed an advanced optical sensors technology and solicited interest from companies. Many companies responded, and a relationship developed between the laboratory and 3M Company.

Intellectual Property

Only one patent application was noted in the information on the 1992-93 awards. Many more patents were uncovered in the interviews.

Technology Transfer Mechanisms

In the 1992-93 awards, at least thirteen CRADAs were signed or were in the process of being negotiated. CRADAs are new mechanisms allowed by the 1986 and 1989 legislation. For example, six CRADAs allowed various companies interested in a laboratory's metal manufacturing process to test the process for their products. Creation of a Microelectronics Quality/Reliability Center at Sandia National Laboratories led to that laboratory's first CRADA in 1991. The CRADA was so successful that Phillips Semiconductor and National Semiconductor negotiated follow-on agreements. The new center also led to partnerships with Hewlett-Packard, LSI Logic Corporation, and Olin Hunt Specialty Products, Inc. which resulted in new products on the market.

The laboratories and their partnering companies signed nine license agreements in the 1992-93 awards. For example, Quatro Corporation licensed the non-destructive testing system from Los Alamos National Laboratory. The company commissioned a market survey and developed a business plan that balanced company and laboratory interests.

Some of the 1992-93 awards involved combinations of transfer mechanisms. For example, the Cardolite Corporation licensed NRL's advanced resin technology and manufactured and sold resins to the composite materials industry. The Thiokol Corporation signed a CRADA with NRL to work on aerospace applications for the resins and to improve the manufacturing process.

The laboratories used other mechanisms besides CRADAs and licenses in the 1992-93 awards. In order to codevelop the superconductive device, Conductus officially participated in a Laboratory/Industry Exchange Program with the laboratory. Although this program was a DOE program, all laboratories were allowed to engage in personnel exchange programs. In 1992, Conductus and the laboratory entered into a CRADA to share researchers and further refine the technology.

Agency demonstration programs also transfer technologies. DOD uses demonstration programs to help boost the military industrial base. The transfer mechanism used for the lithography laser was a DOD-sponsored demonstration program conducted through the DOE laboratory with Hampshire Instruments, a small company that developed the concept. Hampshire Instruments developed a high-resolution machine, but it lacked the necessary power for industrial applications. So the laboratory's researchers were seeking industrial partners to improve the process for producing circuit boards.

NIST signed an agreement with 3M Company where 3M contributed funding and sent a guest scientist to the laboratory for a year in order to develop a prototype optical fiber sensoring instrument to show potential customers. In negotiating the agreement, 3M became aware of NIST's capabilities, which led to other agreements with the laboratory.

Once it became apparent that the military's Geographic Resources Analysis Support System (GRASS) was beneficial to a variety of users, DOD established a "GRASS Inter-Agency Coordinating Committee" and an "Office of GRASS Integration." To reach private sector users, a non-profit corporation called the "Open GRASS Foundation" was formed. All three mechanisms were intended to reach educational institutions. CRADAs were signed to develop the geographic system for specific user needs.

A researcher at the Naval Civil Engineering Laboratory, an expert in paints and coatings, responded to over sixty technical assistance requests from outside organizations in four years, an average of fifteen a year, at no cost. The scientist responded to questions from companies and state and local governments about surface preparation, failure analysis, and product selection. In responding, the researcher directed them to solutions developed by the Navy and other sources.

User Benefits/Economic Impact/Outcomes

Several companies implemented new product lines and enjoyed product sales and revenues. Several nondestructive testing systems based upon ultrasound technology were sold by Quatro Corporation. In lithography, the United States led the world in producing equipment for manufacturing integrated circuits in the early 1980s, but that lead eroded by 1990. Hampshire Instruments, which was involved in the DOD lithography demonstration, subsequently announced the sale of two systems to major U.S. manufacturers. Cardolite, which licensed NRL's advanced resin, estimated its sales of these materials would be $5 to $15 million within a few years because of the growing number of potential applications.

Other companies have plans or are entering new commercial markets based upon the 1992-93 technologies. One of the companies with a DOE metal processing CRADA was planning to base a new product line on the technology. Conductus based several products on the magnetometer technology that it was marketing. Potential customers included medical diagnostic firms, petroleum surveying companies, electronics manufacturers, and research and educational organizations. The work between NIST and 3M led to new contracts and markets for 3M because the optical fiber technologies offered increased instrument speed and sensitivity.

Several companies experienced cost savings because of new technologies. For example, 3M expected reduced cost because bulk manufacturing costs were anticipated to be quite low.

The clients of the Navy paints expert who provided technical assistance estimated they saved at least $600,000 as a result of the expert advice. This was a result of businesses being able to remove layers of lead-based paint from buildings being remodeled.

The 1992-93 awards included an example of ensuring better quality products. Because of Sandia's Reliability Center, U.S. integrated circuit manufacturers were able to produce circuits with higher quality and reliability. For example, the Center characterized the electromigration tolerance of chemical vapor deposition, performed contrast-induced voltage analysis, and provided other services for industry.

Government Gains

There are several examples of unanticipated government gains in the 1992-93 awards. NASA heard about the optical fiber current sensor that NIST was developing with 3M and decided to sign an interagency agreement with NIST for a small lightweight prototype for NASA spacecraft.

In response to industry demand, the Microelectronics Center at Sandia became a broader "Electronics Center" and the same group of researchers are establishing a "National Center for Ultra-Reliability Engineering."

The Navy researcher's expert advice allowed the Navy to establish unexpected partnerships with private sector companies such as Disneyland (which was able to recoat the channels of the "It's a Small World" ride without draining out the water).

Finally, certain technologies also provided good examples of dual use. The geographic information system was being used by not only the Army, but also the Soil Conservation Service; U.S. Geological Survey; National Park Service; and many other federal, state, and local organizations. It was also used by more than a hundred developing countries.

Elapsed Time

In five of the seventeen awards, the award was made because of the speed in transfering the technology. The awards honored the "rapidity," "swiftness," and "dispatch"[3] with which researchers moved the technologies to the marketplace. The DOE laser lithography method was awarded in 1992. The demonstration for circuit manufacturers was begun in 1990. By 1991, a pre-production prototype was developed for commercial use and sold shortly thereafter. The developer of the metal manufacturing process was awarded in 1992 because he put into place (or began negotiating) six CRADAs in only two years. Developers of the geographic software package were awarded in 1993. Within seven years of the system's debut, land managers around the world were using it.

Other awards provided useful background information on timing. The company co-developing the superconductive device (awarded in 1992) began collaborating with the laboratory in 1989. By 1991, they had produced the first practical device. The NIST researcher developing the new optical sensor was awarded in 1992. He began studying this field in the 1980s, and resolved most of the technical issues by 1989.

On the other hand, one of the awards did not have quick timing. A Navy researcher was awarded in 1992 for developing a polymer. The first patent was issued in 1980. The first license was issued in 1991. Eleven years is not a speedy trip to the market.

Other Factors

This level of analysis uncovered two additional pieces of information which indicated the interconnections between government laboratories, state programs, and legislative representatives. First, the Conductus collaboration with the California DOE laboratory to develop superconducting circuits received grants from the California Competitive Technology Program. Second, Los Alamos National Laboratory and its Quatro teammates met with New Mexico's U.S. senators to work out details for transferring a technology, since the new legislative requirements were not well understood. The transfer was successful and several systems were sold.

SELECTED POST-LEGISLATION CASES

Table D displays basic data for the eight awards selected for further research beyond the 1993 data highlighted above. The eight cases are presented in the next section. They are:

- laser-based method to light up biological samples,
- speech processing coder for telecommunications,
- paper and plastic quality tester,

[3] 1994 FLC Winner's document.

- variable-frequency microwave furnace,
- gravity meter,
- "oatrim" fat substitute,
- chemiluminescent light sticks, and
- flow diagnostics for artificial hearts.

TABLE D
SELECTED POST-LEGISLATION CASE CHARACTERISTICS

CASE #	YEAR	TECHNOLOGY	AGENCY/ LABORATORY/ LOCATION	LABORATORY RESEARCHER(s)	PARTNER(s)
1	1993	Laser-Based Method to Light Up Biological Samples	DOE-Ames Laboratory (Iowa State University, Ames, Iowa)	Dr. Edward S. Yeung	Mr. Craig Ranger (Lachat Instruments, Inc.)
2	1993	Voice Coder for Telecommunications	Air Force - Rome Laboratory (Hanscom Air Force Base, Massachusetts)	Mr. Luigi Spagnuolo, Mr. Terrence Champion	Dr. John Hardwick (Digital Voice Systems, Inc.)
3	1992	Paper Quality Tester	Agriculture - Forest Products Laboratory (Madison, Wisconsin)	Mr. Theodore Laufenberg, Mr. John Considine, Mr. Dennis Gunderson	Mr. Peter Davis (Isthmus Engineering and Manufacturing Co-op), Mr. Curtis Wilson (Bureau of Engraving and Printing)
4	1993	Variable-Frequency Microwave Oven	DOE - Oak Ridge National Laboratory	Dr. Robert Lauf, Mr. Don Bible	Microwave Laboratories, Inc., Mr. Richard Gerard (Lambda Technologies)
5	1992	Gravity Meter	DOC - National Institute of Standards and Technology, Boulder (Colorado) site	Dr. James Faller (Technology Transfer: Dr. Steve ONeil, University of Colorado)	Axis Instruments, Dr. Tim Niebauer (Micro-g Solutions), Dr. Mike Winters (Winters Electro-Optics)
6	1992	"Oatrim" Fat Substitute	Agriculture - National Center for Agricultural Utilization Research (Peoria, Illinois)	Dr. George Inglett	Mr. Stephen Grisamore (Mountain Lake Specialty Ingredients Company), Mr. Mark Freeland (Rhone-Poulenc, Inc.), Mr. Lanny Babbitt (Quaker Oats Company)

7	1993	Chemiluminescent "Light Sticks"	Naval Warfare Center - Weapons Division (China Lake, California)	Dr. Herbert Richter, Dr. Ronald Henry, Mr. Joseph Johnson (Technology Transfer: Ms. Martha Harrington)	Mr. Fred Kaplan (Omniglow Corporation)
8	1992	Artificial Heart Flow Diagnostics	DOE - Pittsburgh (Pennsylvania) Energy Technology Center	Mr. Franklin Shaffer, Dr. Mahendra Mathur (Technology Transfer: Ms. Kay Downey)	Dr. Harvey Borovetz (Presbyterian-University Hospital), Ms. Linda Strauss (Baxter Healthcare)

Case 1 (1993) - Laser-Based Method to Light Up Biological Samples

Role of Laboratory Researchers and Other Personnel

Dr. Edward S. Yeung, principal investigator and developer of this technology, is a widely-acknowledged expert on innovative laser-based technologies for chemical analysis. He won two "R&D 100" awards (annual award by R&D magazine) within three years, including one for this technology in 1991. He was committed to developing a technology that met both scientific and practical user needs. To do this, he worked with the scientists and facilities at six companies and outside institutions. These were: Lachat Instruments, Inc. in Milwaukee, Wisconsin; the Medical Chemistry Department at Northeastern University in Boston; Roswell Park Hospital Division in Buffalo, New York; Sterling Drug, Inc., which is a subsidiary of Eastman Kodak in Malvern, Pennsylvania; Bio-Rad Laboratories, Inc., in Richmond, California; and Pfizer Central Research, Ltd., in England.

Dr. Yeung provided a range of services to each of these organizations so that they could evaluate the technology for different applications and test its ease of use in anticipation of eventually licensing the technology. For example, Dr. Yeung demonstrated the new technology to a representative of Lachat Instruments, reviewing the technology's advantages, applications, key design criteria, and commercial possibilities. After this, he specified the necessary components of a detector for their particular needs. He received those components from the company at his home, assembled them at his laboratory into a working prototype, and then integrated the prototype on-site with instruments the company was using. He shared his expertise on the prototype system with the Lachat employees and assisted the company in all phases of further developing the prototype into a device the company could manufacture and commercialize. With some of the other organizations, his interaction was not as extensive. For example, Dr. Yeung interacted with Pfizer Research by mail.

In addition, Dr. Yeung and his staff publicized the technology through presentations at scientific conferences around the world and through publishing in scientific journals. Related publications include two early articles in *Analytical Chemistry*, dated 1988 and 1991, coauthored with W.G. Kuhr, a post-doctoral associate.[4] There have been additional articles since then.

After the early business arrangements between the laboratory and its industry partners and other users were finalized, Dr. Yeung continued developing the technology. At this point, he solved a fundamental obstacle to further developing and applying the technology: the micro-manipulation of test samples.

The Technology and Applications

This technology uses a laser-based method to "light up" biological structures (such as blood capillary sections or microbores) fluorescently. This way, researchers can detect and monitor biological processes in fine detail. Because the technology is laser-based, a smaller volume of material is needed for detection and measurements than with previous biological detectors. Thus, the technology helps improve analysis and quantification of even very small volumes of materials.

The technology is easy to use; it can even be used by nonspecialists. Also, it requires relatively little set-up time and can be used in a lighted room. (All previous detectors were based upon conventional light sources.)

The Laboratory

Dr. Yeung directs the Environmental Sciences program at DOE's Ames Laboratory, located at and operated by Iowa State University in Ames, Iowa. Ames Laboratory was founded not long after World War II, following successful development of a uranium production process used for the Manhattan project. It currently has a $38 million budget per year and five hundred employees.

Many of the laboratory's senior scientists also hold joint appointments as faculty members; in turn, the university's graduate students serve on the laboratory's scientific staff. As program director, Dr. Yeung oversees the work of five scientists, seven graduate students, and one postdoctoral fellow. He is also a distinguished chemistry professor at the university.

University Involvement

Dr. Yeung designed and constructed two laser-based fluorescent detectors for Northeastern University's research program in High-Performance Capillary Electrophoresis. To do this, he served as an independent consultant to the university for 20 months. Ames

[4]E. S. Yeung and W. G. Kuhr, "Indirect Detection of Native Amino Acids in Capillary Zone Electrophoresis," *Analytical Chemistry* 60: 1832-1834, 1988; E. S. Yeung and W. G. Kuhr, "Indirect Detection Methods in Capillary Separations," *Analytical Chemistry* 63: 275A-278A, 1991.

Laboratory's agreement with Northeastern University made Dr. Yeung available for follow-up questions or problems (similar to the laboratory's agreement with Lachat Instruments).

Funding, Financing

DOE and Ames Laboratory funded the basic and applied research that enabled Dr. Yeung to develop the technology. The Iowa State University Research Foundation provided funding for the patenting process.

Lachat Instruments and Northeastern University reimbursed Ames Laboratory for Dr. Yeung's time, travel, and laboratory expenses. For some of the other company interactions, he did independent consulting, which is an activity commonly performed by university professors.

Intellectual Property

After the invention disclosure at the laboratory, a U.S. patent was issued to Iowa State University in April 1991. There were some extensions to the original patent at later dates.

Technology Transfer Mechanisms

Dr. Yeung's interactions with Lachat, a laboratory instrumentation company founded in 1980, produced a licensing agreement for the laser-based method to light samples. In addition to its corporate headquarters in Milwaukee, Wisconsin, Lachat has offices in England, the Netherlands, and Australia. The company is a world leader in manufacturing quality flow injection analysis systems, automated ion analyzers, and mercury analysis systems. The mercury analysis systems are used to perform real-time quality control measures and U.S. Environmental Protection Agency (EPA) compliance monitoring in laboratories. The company's QuikChem® 1000, 4000, and 8000 series incorporates hardware, Data Quality Management™ expert system software, and chemical formulas. Lachat also markets a distillation system called Micro Dist® and various other pieces of laboratory equipment. To support its customers, the company offers training packages, service contracts, free telephone support, regional users' group meetings, and newsletters.

Dr. Yeung went to Lachat's location in Milwaukee to finish developing the prototype for them. Clauses in the laboratory's original agreement with the company called for Dr. Yeung to be available by phone for sixty days after delivery of the prototype to Lachat and to provide, as necessary, additional services pursuant to developing the prototype into a manufacturable commercial device. Dr. Yeung made follow-up arrangements with the company to help employees learn how to use the prototype and solve any problems.

The technology was also transferred to both public and private research facilities, including Roswell Park Hospital, Sterling Drug, and Bio-Rad. To transfer the technology, Dr. Yeung pursued both short- and long-term funding through contracts with these outside organizations.

User Groups

Almost any industrial, clinical, pharmaceutical, or university laboratory could benefit from this laser technology. For example, for the pharmaceuticals industry, the technology has been used to analyze blood cells. In the near future, it may allow testing of drug efficacy on a cellular basis or even help doctors detect cancer. It will also contribute to the effort to map the human genome. Furthermore, it will help improve monitoring standards for the environmental field.

Barriers to Commercialization

Many people were skeptical about the technical proficiency of this technology because it was so easy to operate. As a result, Dr. Yeung had to work even harder to make outsiders aware of the extensive engineering devoted to making the technology user-friendly.

Other Factors

Since Ames Laboratory is contractor-operated, the University of Iowa negotiated the license with Lachat. Dr. Yeung says this was back in the days when the university arbitrarily granted licenses without requiring any royalty payments. In fact, usually only an up-front fee was requested as a good faith gesture of reimbursement for the cost of operating the license. However, the university did not even stipulate this requirement. So, the company expected quite a lot with no corresponding input.

User Benefits/Economic Impact/Outcomes

Lachat intended to market a spinoff product to the major environmental research laboratories that monitor the level of contamination in drinking water and wastewater. However, Lachat expected the prototype to be more market-ready and was not willing to put extra effort into developing it further. Dr. Yeung said[5] that if Ames Laboratory could produce an immediately marketable product, they wouldn't have bothered looking for licensees. They would have patented and sold it themselves. The laboratory's license with Lachat died, for all practical purposes. Had Lachat's plans been successful, this technology would have been the first of its kind to be commercially available.

The other institutions are still using the technology for research, not commercial purposes. For example, Northeastern University and Roswell Park are using the detector to study biochemical changes associated with the onset of cancer. The illumination concept developed by Dr. Yeung is best implemented with the prototype instrument he built; thus, it is not necessary to

[5] Ibid.

reinvent the instrument. As a result of working with Dr. Yeung's technology, it is possible that these institutions may come up with future patentable developments. However, commercialization of their technology would require use of his instrument in the process.

International Activity

As noted, one of the research facilities using and testing the technology for research purposes, Pfizer, is located in England.

Government Gains

Ames Laboratory is known for its accomplishments in fields like materials science, metallurgy, and superconductivity, although the laboratory also has research programs in biochemistry and the environmental sciences, which are two of the fastest growing areas of R&D. Dr. Yeung's work with these outside organizations and his visibility, internationally, has improved the laboratory's industrial and scientific contacts in those research areas.

Economic Development, Technical Assistance

None.

Elapsed Time

Dr. Yeung began transferring his technology in November 1989. The patent was issued in April 1991, and in that same month he first met with Lachat Instruments. The work with Lachat began in September 1991 and ended in 1993. His work arrangements with Northeastern University spanned from June 1990 to April 1991 and from February 1991 to February 1992.

Case 2 (1993) - Voice Coder for Telecommunications

Role of Laboratory Researchers and Other Personnel

The voice coder technology of this case started as dissertation research at MIT. Researchers at one of the funding agencies' laboratories recognized the potential of the technology early-on and worked with the MIT researchers to develop the concept for digital voice processing. Recognizing the advantages of the MIT-developed technology, Rome Laboratory program managers Mr. Spagnuolo and Mr. Champion were responsible for acquiring funding from the Air Force. They later convinced the Air Force to continue funding the technology, even though it was competing with the recently-established federal standard in this technology area and there were no validated Air Force requirements for this technology. Despite the obstacles, the efforts of the laboratory personnel resulted in this new technology replacing the national standard and the MIT researchers started their own company, Digital Voice Systems, Inc., to commercialize the technology.

Technology and Applications

The technology in this case falls within the realm of telecommunications. It is a voice processor or coder that compresses speech patterns digitally so that they can be sent long distances, transmits the signal, and reassembles at the receiving end. It is a multi-band coder that provides reliable high-quality communications while increasing the capacity of narrowband communications channels.

Conventional technologies that process speech patterns for communication purposes are based upon linear prediction coding (LPC) techniques. Examples of these coding systems are LPC-10, Codebook Excited LPC (or CELP), RELP, VSELP, and so on. Unlike these speech coders, the new "multi-band excitation" coder depends upon sinewave-based strategies. The strategy involves dividing segments of speech into distinct frequency bands and then making a decision as to whether that segment is noise or voice. Traditional coders make a single noise/voice determination for all bandwidths. The voice quality of these coders is low unless they use a "prediction residual" or error signal that helps eliminate the harsh mechanical quality in the speech. (The residual requires a complex process of division into smaller vectors while the computer searches through its codes to find a match.)

This technology is mostly used in digital land mobile radios and mobile satellite telephones. It is also used for voice storage, such as in digital voice answering machines; desktop video conferencing with computers, with no voice lag; and secure communications. An example of the latter application is its use in the secure lines connecting the Pentagon to the White House; for this special application, the coder is used in conjunction with a classified scrambler technology.

The Laboratory

Rome Laboratory was established in 1951 at Griffiss Air Force Base near Rome, New York as the Rome Air Development Center. It evolved from the U.S. Army Signal Corps laboratories established in the early 1900s. By 1990, it had become one of the Air Force's four "super" laboratories. The laboratory is the Air Force's center of excellence in the areas of command, control, communications, computers, and intelligence. It actually comprises more than seventy laboratories all over the country, valued altogether at over a third of a billion dollars.

The Electromagnetics and Reliability branch of Rome Laboratory is located at Hanscom Air Force Base twenty miles west of Boston along Route 128, the well-known technology corridor. This branch of the laboratory develops equipment for telecommunications security and conducts research on antennas and electromagnetic energy from targets and terrain. The branch is designated the lead laboratory for the entire U.S. Department of Defense (DOD) for microelectronics compatibility and maintainability, and has a wide array of unique facilities. For example, the Verona Research Facility has a precision antenna measurement system and a radar system evaluation facility.

DOD laboratories have all undergone reorganization in the past half decade, and Rome Laboratory is no exception. As a result, Mr. Spagnuolo is the Acting Chief of the Applied Electronics Division of the INFOSEC Technology Office within the Electromagnetics and Reliability branch of Rome Laboratory at Hanscom Air Force Base. Rome Labortory is still headquartered near Rome, New York, even though Griffiss Air Force Base has been closed as a result of DOD's Base Realignment and Closure program (BRAC).[6]

University Involvement

The multi-band excitation coder was implemented on portable, real-time hardware by researchers in a laboratory at the Massachusetts Institute of Technology (MIT). The MIT research that produced a new speech model was the thesis project of several students including John C. Hardwick, Daniel W. Griffin, and S.W. Wong. MIT professor Dr. Jae S. Lim was their advisor.

The MIT team published at least four technical papers in the mid- to late-1980s and early 1990s. At least four of these appeared in the proceedings of the International Conference on Acoustic Speech and Signal Processing, an annual conference sponsored by the Institute of Electrical and Electronics Engineers (IEEE).[7] Another paper was published in an IEEE workshop proceedings on Speech Coding for Telecommunications,[8] the IEEE Transactions on ASSP,[9] and the proceedings from a Digital Signal Processor workshop.[10]

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[6]Rome Laboratory was the only military facility at that location to survive the BRAC initiative.

[7]D. W. Griffin and J. S. Lim, "A New Model-Based Speech Analysis/Synthesis System," *Proceedings of the International Conference on Acoustic Speech and Signal Processing (ICASSP) 1985, Tampa, Florida*, p. 513-516, March 1985; J. C. Hardwick and J.S. Lim, "A 4.8 kbits/sec Multi-Band Excitation Speech Coder," *Proceedings of the ICASSP 1988, New York, New York*, p. 374-377, April 1988; J. C. Hardwick and J. S. Lim, "The Application of the IMBE Speech Coder to Mobile Communications," *Proceedings of the ICASSP 1991, Toronto, Canada*, p. 249-252, May 1991; S. W. Wong, "An Evaluation of 6.4 kbits/s Speech Codecs for INMARSAT-M System," *Proceedings of the ICASSP 1991, Toronto, Canada*, p. 629-632, May 1991.

[8]J. C. Hardwick and J. S. Lim, "A 4800 bps Improved Multi-Band Excitation Speech Coder," *Proceedings of IEEE Workshop on Speech Coding for Telecommunications, Vancouver, Canada, Institute for Electrical and Electronics Engineers, September 5-8, 1989.*

[9]D. W. Griffin and J. S. Lim, "Multiband Excitation Vocoder," *IEEE Transactions on ASSP* 36: (8), August 1988.

[10]D. W. Griffin and J. S. Lim, "A Speech Spectral Analysis/Synthesis System," *Proceedings of 1984 Digital Signal Processing Workshop*, p. 5.1.1-5.1.2, October 1984.

Funding, Financing

The early speech research at MIT was supported by university research assistantships, fellowships, and grants and contracts with federal agencies. Federal funding came from the National Security Agency, the Air Force's Electronic Security Command[11] Cryptologic Support Center, Rome Laboratories, and other agencies. The spinoff company, Digital Voice Systems, Inc. (DVSI), has not received any federal funding since its founding.

Intellectual Property

No patents were filed by MIT on the original research. DVSI currently has at least four patents on the coder and several patents pending, both foreign and domestic.

Technology Transfer Mechanisms

Because of the odds against adoption of a competing technology to the existing standard within both DOD and industry, the Rome Laboratory team developed a strategy to push the technology into the marketplace. The team entered the technology in commercial competitions and established a strong presence at standards meetings, presenting favorable and supportive arguments for the technology before relevant committees.

The Association of Public-Safety Communications Officers (APCO) along with the National Association of State Telecommunications Directors (NASTD) stated they were leaning toward adopting the LPC technology as the new digital standard for land mobile public safety radio equipment in North America (at 4.8 kilobits per second). However, Mr. Spagnuolo and Mr. Champion persuaded the APCO/NASTD committee that this technology would not provide acceptable performance in the harsh operational environments in which public safety equipment would be fielded. They encouraged the committee to consider the multi-band excitation coder. To facilitate the evaluation, they volunteered Rome Laboratory as the host laboratory to test the candidate coders under realistic operational conditions. This effort might be considered outside the scope of a federal laboratory, but was consistent with laboratory efforts to transfer helpful technologies to state and local governments. Evaluating the technology at a federal facility improved the evaluation, which was a service to APCO and NASTD.

In addition to the CELP and multi-band excitation coder, other technologies competing in the evaluation included another LPC-based coder called VSELP and another sinewave-based coder developed by Rome Laboratory, the Sinusoidal Transform Coder (STC). The results proved the multi-band excitation coder to be superior, so APCO/NASTD was able to find a better product. The multi-band excitation coder was named the land-mobile radio standard for public safety communication equipment. The standard was known as "APCO/NASTD Federal Project 25." The evaluation was implemented by the Telecommunications Industry Association.

[11]Now the Intelligence Command.

In addition, the new coding technology was represented in the Telecommunications Industry Association's half-rate and full-rate digital cellular evaluations. In the half-rate evaluations, both the multi-band excitation coder and STC placed in the top grouping of coders. In the end, the multi-band excitation coder performed better than the existing national standards technology and was selected as the new standard.

User Groups

Users of this technology are manufacturers of telecommunications equipment, a multi-billion dollar equipment industry. The new coder technology provides the telecommunications industry with major advances in digital speech processing. Communication is reliable and has increased channel capacity within a fixed spectrum. The technology affords increased error protection against acoustic background noise, channel errors, etc., for harsh environments such as in military and land-mobile radio use.

The end users of land-mobile radios are police and fire departments, other emergency service personnel, trucking and delivery fleets, and taxicabs. Many of these users, in both the public and commercial sectors, are in the process of upgrading from analog to digital radios, which require a speech coder such as the multi-band excitation coder. The radios are either hand-held walkie talkies or vehicle-based units. The technology provides four times the channel capacity within the allocated spectrum for these users while maintaining voice quality.

Mobile satellite phones are used in place of cellular phones where there is no cellular service available. They are found in vehicles, trucks, ships of all types, and aircraft. They are used by journalists and reporters, business travelers, and disaster relief and emergency services personnel in rural areas.

Barriers to Commercialization

Traditionally, the communications research communities both within DOD and industry focused on LPC. Rome Laboratory was the only research laboratory developing or supporting sinewave-based techniques. At the time, Mr. Spagnuolo was acting chief of Rome Laboratory's Technology Applications branch in the Boston area. Mr. Champion was director of secure voice research. Both researchers were in the laboratory's Electromagnetics and Reliability Directorate.

Other Factors

The multi-band excitation coder won six out of six of the last standards competitions and/or independent evaluations. These evaluations resulted in adoption by national and international standards groups. Dr. Hardwick, one of the original MIT researchers, noted that negotiations with these standards organizations was "like buying a car." The technology was transferred to the commercial standards organization, and the commercial terms were good. The standards organizations, in turn, collect money from their customers and turn it around to the suppliers.

User Benefits/Economic Impact/Outcomes

The ultimate outcome of the MIT research was a spinoff company, Digital Voice Systems, Inc. (DVSI). DVSI specializes in high-performance speech compression systems based on the multi-band excitation technology. The company sells both hardware and software to other private sector customers.

DVSI developed a software product called the "Improved Multi-Band Excitation" or IMBE™ Speech Compression System. In 1992, *Ocean Voice* magazine noted that this system provided better quality than cellular telephones. DVSI also produces voice coding hardware modules which implement the IMBE speech coding software. DVSI's hardware includes the lower cost IMBE™ VC-20 Voice Codec Module in the 5-inch-square size and the IMBE™ VC-100 Voice Codec Module, the full-duplex version, which is 2 x 2.4-inches. The VC-100 is used in INMARSAT's new Mini-M mobile digital satellite telephone system. DVSI also sells the software by itself, modified for use with other digital signal processing hardware available on the market.

DVSI owns the commercial rights to the voice coding technology. The advantage of DVSI's voice coder is that they offer superior speech quality at lower data rates, which are more desirable. Also, the coders' algorithms are less complex, they require less memory, and can be implemented cost-effectively.

DVSI continues to further develop and commercialize the technology. In fact, the company has recently introduced a new "Advanced Multi-Band Excitation" AMBE® Speech Compression System implemented by an AMBE-1000™ Coder. According to the product literature, the AMBE-1000 has the highest performance voice coder on the market. The AMBE-1000 exhibited better overall performance than the existing standard in the full-rate digital cellular standard evaluations called "IS-54."[12] The AMBE is interesting because the user can select the amount of error correction and can adjust data rates. Also, the coder is available on a single computer chip and is less than an inch square compared with the IMBE VC-20's five square inches. In 1996, an AMBE-1000 cost $99. An order of at least 360 units reduces the price to $65, and an order of 10,000 reduces it further to $38. To order over 100,000 units, a manufacturer would need to contact DVSI for availability and price.

DVSI, being privately held, is not willing to divulge sales revenues. Dr. Hardwick stated,[13] however, that the company is profitable and has "done rather well" with a "reasonable

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[12]DVSI product technical literature, May 31, 1995.

[13]Interview with Dr. Hardwick, September 23, 1996.

amount of commercial activity." The company averages ten employees. Dr. Lim, the faculty advisory at MIT, is the Chairman of DVSI, and his former students, Dr. Hardwick and Dr. Griffin both hold management positions in the company, as well. In 1992, *Land Mobile Radio News* said "DVSI is the quiet company whose Vocoder [voice coder] will be heard around the world."[14]

International Activity

The MIT researchers entered the technology in the International Maritime Satellite competition, called INMARSAT, which was held in Australia in 1992. INMARSAT is a commercial organization chartered by the United Nations. At the INMARSAT competition, the multi-band excitation coder competed against all LPC-based coders. The test results showed it was superior, and so it was selected as the INMARSAT-M satellite communication voice coding standard. The Australian Satellite group (called AUSSAT) was so impressed, they, too, selected it as their standard. Other organizations such as OPTUS, another global mobile satellite-based service, followed INMARSAT's lead, as well.

Government Gains

An advantage of this new standard is that a manufacturing base is being established that can provide DOD with commercially available, state-of-the-art speech communications equipment demonstrated to be superior in military applications. Also, the skill-base for using the technology is increasing, both in state and local governments and in industry.

Economic Development, Technical Assistance

DVSI received no economic development or technical assistance services.

Elapsed Time

The MIT work in this area began in the early 1980s. Many of the research papers were published while the authors were still affiliated with MIT. Key papers were published in 1984, 1985, 1988, 1989, and 1991. DVSI was founded in 1988. The technology was commercially available from 1988 to 1991, but was not easy to use. APCO/NASTD Federal Project 25 announced its selection of the multi-band excitation coder technology in 1992. Negotiations with INMARSAT were completed by mid-1992. DVSI was issued its first patent in 1993.

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[14] *Land Mobile Radio News* (September 11): 1992.

Case 3 (1992) - Paper Quality Tester

Role of Laboratory Researchers and Other Personnel

During the time frame of this case, Mr. Dennis Gunderson, and Mr. John M. Considine were researchers with the Forest Products Laboratory (FPL) in Madison, Wisconsin, in the Fiber Product Design Criteria Research Work Unit headed by Mr. Theodore L. ("Ted") Laufenberg. This group addresses technological barriers to the use of fiber and paper products. (Mr. Gunderson is now retired, and Mr. Considine does not work at the laboratory any more. Ted Laufenberg is now the laboratory's technology transfer officer, in addition to continuing his work in technical areas as assigned.)

In order to transfer the laboratory prototype version of this paper quality testing technology, the team of three scientists put together a technology transfer plan, including an assessment of the potential market. They contacted over a hundred potential users in all sectors about the commercialization initiative. During this process, three potential equipment manufacturers were identified. Since federal patents were involved, the laboratory solicited CRADA proposals from the three firms on a competitive basis. A panel of technical and administrative staff from the U.S. Forest Service and the University of Wisconsin screened the three proposals based upon pre-determined criteria. Once a CRADA was in place, the research team devoted up to three hundred hours of its expertise to the design and development effort.

FPL scientists are known to publish in a wide variety of publications, including over 100 scholarly journals. Publications involving this technology were published in both the journal[15] and conference proceedings[16] of the Technical Association of the Pulp and Paper Industry (TAPPI), as well as proceedings of the Technical Association of the Graphic Arts.[17] The authors included the team of three scientists, and joint authors from partnering organizations such as the U.S. Bureau of Engraving and Printing and the Swedish Pulp and Paper Research Institute.

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[15]D. E. Gunderson, "A Method for Compressive Creep Testing of Paperboard," *TAPPI Journal* 64 (11): 67-71, Technical Association of the Pulp and Paper Industry, 1981; J. M. Considine, D. E. Gunderson, Peter Thelin, and Christer Fellers, "Compressive Creep Behavior of Paperboard in a Cyclic Humidity Environment -- Exploratory Experiment," *TAPPI Journal*: 131-136, 1989.

[16]T. L. Laufenberg, "Characterization of Paperboard, Combined Board, and Container Performance in the Service Moisture Environment," *Proceedings of the TAPPI International Paper Physics Conference*, 1991.

[17]J. M. Considine and J. F. Bobalek, "In-plane Hygroexpansivity of Postage Stamp Papers," *Proceedings - Technical Association of the Graphic Arts*, 1991.

Technology and Applications

The properties or behavioral characteristics of paper, and similar materials such as wood, change and deteriorate over time due to environmental conditions, such as when they are stored in a warehouse. An analogy would be the way a barn roof eventually may become sway-backed from exposure to moisture. The technology developed in this case allows a paper product such as a sheet or roll of paper to be tested for those performance characteristics like strength, stiffness, and durability. The test for these characteristics is referred to as the paper restraint testing system. The results of the testing are a quantitative assessment of these properties so that the paper industry can conserve fiber (reduce sheet weight) and reduce the use of expensive coatings which enhance printability and stability, as well as fight humidity.

To test sheets of paper or plastic materials, each sheet is held in a controlled environment by a vacuum that holds it flat. The paper is placed under pressure using a compression technique that uses rigid supports. Air is pulled through and around the material, so that differential pressure is applied to each side of the sheet. The machine that does this must also periodically check for moisture-related "creep" (either stretching or, conversely, shrinking or compressing that is time-dependent and load-dependent). This creeping movement can be measured while the material is flat; if it were wrinkled, it wouldn't be possible to measure it.

The Laboratory

FPL is one of eight government-owned, government-operated Forest Service laboratories within the U.S. Department of Agriculture (USDA). About a hundred scientists and technical professionals work at the laboratory, including foresters, botanists, plant pathologists, microbiologists, chemists, and engineers. In addition, the laboratory employs economists and conducts a great deal of market research for its products. Altogether, 350 people are employed by the laboratory. The laboratory also hosts hundreds of consulting visitors every year. The laboratory's users include not only state and private foresters and landowners, but also regulatory agencies, a variety of industrial sectors, educators, legislative bodies, and the general public.

Broad areas being pursued at FPL include research, technology transfer, and cooperative partnerships related to wood and international forest products. Specialty facilities and groups at the laboratory include: a Pulp and Paper Pilot Plant, a Conservation and Recycling Technology Marketing Unit, a Fire Testing Laboratory, and an Institute for Microbial and Biochemical Technology.

University Involvement

Technical personnel from the University of Wisconsin (UW) in Madison, where FPL is based, participated in screening the CRADA proposals submitted by industry. Universities were also part of the network established by the laboratory to assess the technology. For example, UW-Madison received a $25,000 cooperative research agreement for evaluation purposes.

Funding, Financing

FPL receives funds from Isthmus Engineering for the joint work under the CRADA. Also as a result of contacts developed during the CRADA/license solicitation process, the laboratory put into place ten cooperative research agreements totaling almost $1 million. These agreements allowed outside organizations to evaluate the technology and equipment for their applications. In the process of evaluating the technology, paper industry associations, private companies, and other federal agencies identified the type of machine configurations they would require in order to use the technology, and some requested information on availability and pricing.

Examples of the cooperative research agreements included: an agreement where FPL awarded the National Starch and Chemical Corporation in New Jersey a small amount of money to evaluate the "cyclic creep" in linerboards. And several cooperative research agreements totaling $430,000 with the American Forest and Paper Association, particularly the Containerboard and Kraft Paper Groups. Additional cooperative research agreements were granted to seven companies in amounts of less than $10,000 each.

Intellectual Property

There was no invention disclosure. For this technology, patents issued to USDA cover the method for conducting the testing and a portion of the equipment used. However, certain aspects of the machine are not patented, specifically, the design of the machine that simultaneously applies pressure to test for paper creep and to condition the paper cyclically.

Two patents were issued, both entitled, "Method and apparatus for edgewise compression testing of flat sheets," for more than one application, dated August 1982 and May 1984, with Mr. Dennis E. Gunderson listed as the inventor. At least one additional patent was issued to the laboratory's company partner described below.

Technology Transfer Mechanisms

Isthmus Engineering and Manufacturing Co-op is a small designer and manufacturer of automated machines. The company employs about forty employees and is southeast of Madison, Wisconsin. It was selected based on having the best development plan in its CRADA proposal.

Isthmus was founded in 1980. It averages $10 million in yearly sales developing and manufacturing a variety of specialty equipment and instruments, many of which are one-of-a-kind systems. The company has worked with hundreds of customers on thousands of projects ranging from million-dollar dedicated machining centers to hundred-dollar assembly tools. This includes equipment for plastic packaging, processing equipment for the medical industry, and metal weighing and removal equipment for large machining centers. Additional examples are robotic equipment for John Deere tractors, the pump apparatus in hair spray cans, and the machines for manufacturing Rayovac batteries. The company has also been building special machines for the high-volume automotive industry since its inception. So, the company's products run the gamut from foundry equipment to laboratory equipment.

Since 1988, the company has had an 18,000-square-foot facility that houses its equipment. That equipment includes eight computer-aided design (CAD) stations and a computer-aided manufacturing (CAM) system that links the design computers to three computer-numerically controlled (CNC) vertical milling machines. One of those machines is a 21-tool, four-axis machining center with 30 x 60 inches of "travel." The facility also houses eight manual drafting stations and a coordinate-measuring machine capable of one ten-thousandths of an inch accuracy within a 20- x 40- x 20-inch volume, housed in a 68-degree temperature-controlled room. There is an electrical controls department with full programming, fabricating and documentation facilities. The facility also has other necessary milling, turning, grinding, assembly, inspection, painting, and testing equipment.

According to company board member Mr. Peter Davis, the company does relatively little marketing, and gets most of its work through word-of-mouth. When the company quotes a price for building a machine, it includes everything from design to project schedules, operator's manuals, debug, run-off and service after the sale. When a machine is designed, it includes planning for everything including plumbing, wiring, control boxes and switches, coolant, etc. The company also sells machine-related services such as inspection services on a contract basis.

The company is a workers' cooperative (as opposed to the more common users' cooperatives like grocery stores). It was modeled after cooperatives found in the Basque Madrigon region of Spain, as adapted to Wisconsin laws, of course. Potential employees apply to become self-employed members of the co-op. The relatively low entry fee is based upon a stock equalization basis, free of outside influences. Once a year, the performance of each employee is critiqued by all the other employees. This review results in the entire company being involved in setting the yearly earnings for each employee. So, each employee's earnings result from his or her value to the company, as opposed to being set by outside market rates. After two years of attending board meetings, etc., the member can be voted in as a "partner" or board member, and re-elected every two years. As in a participatory democracy, any employee is eligible to run and be elected as a board member or officer. These board members and officers meet every other week to discuss the company's business and make decisions.

Isthmus' one-year CRADA with FPL was focused on gaining machine design and paper physics expertise so the technology could be commercialized. Also, an exclusive license was granted to Isthmus Engineering based upon both patents. The time frame for the license is equivalent to the life of the patents, and its field of use is paper products. The laboratory team has been particularly protective of the company's wishes to maintain confidentiality regarding the terms of their legal agreements with the laboratory.

User Groups

The primary user of this paper testing technology is the paper industry. The paper industry is a major segment of the forest products industry. It produces ninety million tons of paper products a year including boxes, labels, stationary, and raw products like cardboard rolls. In order to avoid defects, most paper products are over-designed or over-processed rather than quality-checked. This inefficiency is compounded as the ingredients for making paper change. Older paper "recipes" involved higher-quality cedar wood fiber. Now that cedar is less available than woods like ash, this presents additional quality issues. When quality testing is performed, the equipment is usually supplied by Scandinavian companies.

Quality testing offers paper manufacturers a better understanding of the effect of moisture, in particular, on their products. This technology compresses the window of time required for testing, because it allows testing before the paper leaves the manufacturing facility. As a result, producers can offer competitively priced products through the use of less-expensive paper coatings, a reduction in the use of wood fiber, and savings in the disposal of scrap paper. The savings amount to possibly tens of millions of dollars overall. Also, the testing will allow the use of different combinations of fibers and increased recycling, so that forests can be saved from destruction.

Barriers to Commercialization

The laboratory team had to deal with several obstacles in attempting to promote the commercialization of this technology. First of all, a paper testing market did not exist at the time this technology was developed, which meant there was no demand for a product in this area. There were no U.S. companies that produced paper testing equipment; the laboratory's technology represented the state-of-the art.

The cooperative research agreements for evaluation purposes helped to "spread the word" about the technology. However, each organization involved in evaluating the technology required a different machine configuration and, consequently, required different methods to analyze the data and interpret the findings in order to be able to characterize the behavioral properties of their paper products. This made comparisons and overall technology assessment difficult.

Other Factors

Mr. Laufenberg notes that technology transfer is akin to giving up your children,[18] so it behooves a laboratory to keep the inventors at arms length from the cooperative research efforts particularly now that they share in the royalties because this could possibly create a conflict of

[18]Interviews with Mr. Laufenberg, September 4, 1996, September 12, 1996, and September 19, 1996.

interest. Creating a buffer between the actual researchers and cooperative research efforts allows more flexibility in a laboratory's technology transfer program. For example, as a technology gets closer to commercialization the scientists become less involved or even ask to be moved off the project, because at what point would the laboratory be able to say that enough effort has been put into their understandably eager marketing efforts? An intermediary can push the technology with less bias toward that particular technology.

User Benefits/Economic Impact/Outcomes

FPL's partnership with Isthmus Engineering and Manufacturing Co-op opened up a new market for the company. Within eight months after the one-year CRADA was signed, Isthmus delivered to FPL a commercial version of the technology called a "Vacuum Compression Apparatus" which was an updated and more refined version of the original prototype. This provided the company visibility which attracted an early order for another machine from New Zealand's Pulp and Paper Research Organization. Isthmus also produced a machine for the U.S. Bureau of Engraving and Printing (BEP) in Washington, D.C. The first machine was provided to FPL at cost in return for the laboratory's technical assistance. The other two machines totalled $250,000 in sales for the company. FPL is still using Isthmus' machine in the laboratory's research projects.

The CRADA with Isthmus Engineering was hailed as a first step toward application of this technology in the paper industry. It "set the stage . . .to take a competitive role in supplanting millions of dollars of paper test instrument sales from their Scandinavian counterparts," according to the FLC nomination form.[19] Initial impacts were apparent in the corrugated container and the fine-paper printing industries. However, the paper testing technology was eventually supplanted in the market by other methods that were less expensive, simpler, and easier to implement. The technology is still being used, for example, in university laboratories doing specialty research that requires sophisticated approaches. But, in terms of the commercial marketplace, the technology was a leading-edge product that created the market need for the type of information generated by this testing technique.

In August 1996, Isthmus delivered a fourth machine for $165,000 to a customer at the University of Maryland working with a consortium of companies in the electronics industry. The Maryland consortium will be using the machine to study the long-term effects of cyclic humidity and changing atmospheric conditions on the corrosion and breakage of computer circuits. Computer circuits were an application that had not occurred to Isthmus Engineering. Silicon chips have joints for chemical and heat dissipation. But because the materials that make up the components of a chip are different, the thin films that are deposited on chips can work loose over time. So, this application for Isthmus' testing machine could open up an entirely new market for

[19]FLC Award for Excellence in Technology Transfer, Statement of Achievement, Submitted by Allen J. Schacht, December 4, 1991.

the company. Peter Davis says[20] the new machine, called a "Thin Film Analyzer," helps to make the company even more diverse. The company was contacted by the University of Maryland through a researcher schooled at the University of Wisconsin who was aware of the Isthmus paper testing machines from his dissertation research.

Meanwhile, Isthmus developed the third generation of the Thin Film Analyzer through advances in computer software and electronics. Its capabilities allow environmentally controlled testing of not only paper and corrugated products, but also many types of materials such as plastics, composites, elastomers, and textiles. This unique testing machine provides information on the material properties, particularly humidity effects. Custom specifications and configurations can be requested to fit user test requirements and facilities.

International Activity

The laboratory also signed a cooperative research agreement that involved in-kind sharing of data with the Swedish Pulp and Paper Research Institute (known as "STFI") in Stockholm. As a result of this relationship, a Cyclic Humidity Conference hosted by FPL in 1992 went international in 1994 and was co-sponsored by both FPL and STFI. The third international conference is slated for New Zealand in February 1997.

Government Gains

Improved testing techniques for paper products will provide savings to American taxpayers in better public-sector methods for printing postage stamps and other government paper products. In fact, the U.S. Treasury Department's Bureau of Engraving and Printing provided FPL with two interagency agreements to evaluate the technology -- $200,000 initially with a follow-on agreement for over $400,000.

Econnomic Development, Technical Assistance

None applied.

Elapsed Time

The technology was patented in 1982 and 1984. The original solicitation for potential industry partners and licensees began in October 1988. The CRADA and license agreements were executed in November 1990, and the CRADA was completed in January 1992. The related cooperative research agreements for assessing the technology were implemented from 1991 through 1993. The jointly sponsored international technical conference was held in 1994. Additional CRADA activity demonstrating test effectiveness for a variety of end uses continued through 1995.

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[20]Interview with Mr. Davis, October 2, 1996.

<u>Case 4 (1993) - Variable-Frequency Microwave Oven</u>

Role of Laboratory Researchers and Other Personnel

Dr. Robert J. ("Bob") Lauf is a senior development staff member in the Metals and Ceramics Division at Oak Ridge National Laboratory (ORNL). His expertise is in materials science. Mr. Don W. Bible is a development staff member in the laboratory's Instrumentation and Controls Division. Mr. Bible's expertise is in electrical engineering. Their work required using a microwave furnace for firing ceramics related to the fusion energy program. The microwave tube they used for heating plasma material in a reactor was the size of a person.

Eventually, Dr. Lauf and Mr. Bible conceived the idea of a variable-frequency, as opposed to fixed-frequency, microwave furnace, which would eliminate the hot and cold spots in the furnace. These are similar to the dead spots common to kitchen-sized microwave ovens that necessitate rotating food in the oven. The idea was that they could map the location of the dead spots and program the microwave furnace to change back and forth to different frequencies, a technique called "sweeping." Sweeping was used in radar jamming: a radar screen will lighten up when a blizzard of various frequencies is applied.

When they shopped for a traveling microwave tube that could sweep, they found the power level on most of the commercially available traveling microwave tubes was too low. In their networking, a colleague mentioned a small company in North Carolina producing high-power traveling microwave tubes, so Lauf and Bible tracked down Microwave Laboratories, Inc., a defense contractor in Raleigh, North Carolina. The military initially funded construction of the company's facilities because they needed a particular type of traveling microwave tube. Thus, the company's product line centered around high-power traveling microwave tubes and other broad-band products. The company had defense contracts during the Gulf War related to electronic warfare.

When Dr. Lauf and Mr. Bible contacted the CEO of Microwave Laboratories, it happened to be after the Gulf War when the company's business was down. The CEO, Carl Everleigh, immediately invited the researchers over even though he was initially skeptical of their idea. (He is quoted in a journal article as saying he thought they were crazy!) However, since he had previously worked with microwave heating applications, the laboratory researchers were able to convince him that the concept of a variable-frequency microwave furnace was feasible.

So Microwave Laboratories "donated" a $50,000 traveling microwave tube to ORNL (a piece of hardware about the size of an arm), and ORNL bought the "refrigerator-sized" $60,000 power supply. Subsequently, Dr. Lauf and Mr. Bible built a large prototype of the first variable-frequency microwave system. Microwave Laboratories designed and built a smaller bench-top version. ORNL and the company worked closely together, achieving synergism in their skills and expertise.

The two researchers continue to take initiative in identifying industrial and scientific processes that might benefit from this invention. Their knowledge of chemistry and microwave diagnostics allowed them to explore the processing of diamond films. They can explain benefits to potential users in many industries and refer them to the company.

The researchers presented their research results related to the prototype machine at a Materials Research Society symposium on microwave processing of materials.[21] Most of the major microwave processing groups were represented at the symposium. Dr. Lauf said[22] they were practically laughed out of the symposium, since it was thought that traveling microwave tubes were unaffordable.

Technology and Applications

In-roads are being made using the tunable (or programmable) variable-frequency furnace to process coatings and diamond films for semiconductors. Using the furnace, very uniform plasma etching can be obtained on a circuit board. This level of uniformity is difficult to achieve with other such processes. Also, the furnace is effective in applying synthetic diamond films on industrial saw blades, for example.

The technology is also currently being used for heat treatment (or "sintering") of ceramics, as well as the curing of resins. Potential longer-range applications include better cooking effectiveness in food processing and analytical chemistry applications.

Also, there are a variety of industrial applications for this technology in other fields, particularly high-energy nuclear physics. In this area, it would be used to improve ion sources on particle accelerators.

The Laboratory

ORNL was built in 1943 on an almost 3,000-acre site in Oak Ridge, Tennessee. The laboratory was part of the World War II Manhattan Project to produce the atomic bomb. The laboratory's original mission was to produce plutonium for that effort. Today, ORNL is a major DOE multi-program R&D laboratory with an operating budget of over $530 million and a staff of over 5,000. About 4,400 guest researchers spend time at the laboratory every year; one-third of them are from industry.

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[21] D. W. Bible, R. J. Lauf and C. A. Everleigh, "Multikilowatt Variable Frequency Microwave Furnace," *Materials Research Society Symposium Proceedings 1992, San Francisco, California, Volume 269,* 1993.

[22] Interview with Dr. Lauf, September 4, 1996.

University Involvement

There was no university involvement in this case.

Funding, Financing

The ORNL researchers obtained funding from three sources to enable them to work on the microwave project. First, conceptual development and design was supported by the Advanced Industrial Concepts Materials Program out of DOE headquarters (now called the Office of Industrial Technologies or OIT). OIT helps industry work with seventeen of the thirty DOE laboratories. OIT has supported more than sixty-five R&D projects that resulted in new technologies being used by industry.

Second, ongoing R&D and funding for the ORNL researchers to be involved in the company-funded CRADA were provided by the laboratory technology transfer program of the Office of Energy Research at DOE headquarters. Created in 1992, this program maintains "quick-response centers" at non-defense DOE laboratories such as ORNL. The program provides technical assistance to small businesses, and promotes CRADAs and personnel exchanges, among other activities. (For fiscal year 1997, DOE's overall funding for this program will be about $20 million. Not only is this funding less than previous years, but it is also restricted to high-risk CRADAs at five DOE laboratories, including ORNL, in three specific technology areas: intelligent manufacturing, tailored materials, and sustainable environments. However, as a result of this cutback, some of the other DOE offices are providing funds for DOE laboratory researchers to be involved in CRADAs. For example, in this case, the DOE Office of Industrial Technologies picked up the laboratory's involvement.)

Third, capital funds to build the large prototype variable-frequency microwave furnace were provided by the Advanced Manufacturing Program at DOE's Y-12 Plant. The plant is located about five miles from ORNL and began operating in 1943 to produce uranium for the Manhattan Project. The plant has an annual budget of over $600 million and a staff of approximately 5,000. The Y-12 Plant is part of DOE's defense programs, as opposed to its civilian energy conservation programs. However, as the government has ended its weapon manufacturing effort during peacetime, the plant's mission has changed. Today, it dismantles nuclear weapon components returned from the national arsenal, maintains a stockpile of nuclear materials, and produces "special" nuclear materials. Most programs at the Y-12 Plant work closely with the nearby ORNL researchers. The plant's capabilities encompass all phases of the design process: from conceptualization to specifications, prototype construction, and an integrated manufacturing process configuration. Another manufacturing program located on the Y-12 Plant site is DOE's Centers for Manufacturing Technology. Facilities available to outside users -- industry, universities, and other government agencies -- include everything from machine tools to gear and thread technologies. A toll-free telephone line is available for those interested in accessing the plant's facilities or arranging technical assistance or consulting projects.

Intellectual Property

The first patent for the "Variable-frequency microwave furnace system" was filed by Martin Marietta Energy Systems, now called Lockheed-Martin Corporation and was issued for a polymer curing application of the furnace. Lockheed-Martin operates ORNL. Dr. Lauf and Mr. Bible are the registered inventors.

Another patent was issued with the co-inventors listed as Dr. Lauf, Mr. Bible, Arvid Johnson (a company scientist), and Dr. Robert J. ("Bob") Markunas, Associate Director of the Center for Semiconductor Research at Research Triangle Institute (RTI). RTI is an independent non-profit organization in Research Triangle Park, North Carolina. RTI had worked with Microwave Laboratories to test the processing of diamond films for semiconductors via plasma-deposited methods. This was reported at a 1993 conference on diamond synthetics in Heidelberg, Germany. Dr. Markunas and the company scientists also worked together to come up with ideas for improved control systems.

Three additional patents relating to the CRADA work with the company are still pending. Dr. Lauf has a portfolio of twenty patents and fifteen pending. On the role of patenting, Dr. Lauf said[23] scientists should get into the practice of patenting first and then publishing. Once an article is published, the scientist still has a year grace period when a patent can be filed without losing the opportunity. Also, the scientists should find customers before they patent because it is impossible, he said, to get a customer without telling them what you have. He added, however, that if technology transfer officers do that, the patent rights will be lost to the company. Dr. Lauf said it is important to let the market indicate the applications. He says few good ideas are transparently obvious from the beginning. For example, the concept of getting better uniformity in a microwave furnace by sweeping the frequencies seems obvious "once you know it works, of course."[24]

Dr. Lauf also remarked that the young scientists employed by his partnering companies are always anxious to show him their latest advances and to get advice regarding their patent portfolio. They talk by phone at least once a week and write many joint publications and patents. He said[25] it is important to get them involved in the technical work early-on so they can be included on the patent, which helps to make it broader.

[23]Interview with Dr. Lauf, September 4, 1996.

[24]Interview with Dr. Lauf, September 4, 1996.

[25]Ibid.

Technology Transfer Mechanisms

ORNL asked the Microwave Laboratories CEO to sign a proprietary information agreement (the same type of agreement as a non-disclosure agreement, or confidentiality agreement). The laboratory eventually granted a non-exclusive license to the company, the first license related to microwave processing to be signed at ORNL. Ultimately, a three-year CRADA was initiated to further develop the technology and demonstrate new applications. On the three pending patents related to the CRADA work, the laboratory licensed the technology to others and split the royalties with the company.

Both Dr. Lauf and Mr. Bible commented on the technology transfer process and personnel. Dr. Lauf said technology transfer officers worry about the time and money invested in "loser" technologies, but that they end up spending more money trying to assess and identify winners. For licenses, laboratories receive an up-front fee from a company and running royalties based upon a percentage of the company's sales related to that technology. Dr. Lauf commented[26] that technology transfer personnel don't consider it their business to monitor the laboratory's licenses, consequently the laboratory scientist has no way of knowing whether he is getting his "fair cut" of the royalties. A similar problem, according to Mr. Bible,[27] is that laboratory scientists are not allowed to be involved in legal negotiations related to their technologies, so they have no idea about the details of the agreements that are signed. On a related note, he added that in their negotiations the legal staff often commit the technical staff to things that can't be done.

Dr. Lauf felt that consideration of the royalty payments to the laboratory scientists should be secondary to the overall legal agreements between laboratories and companies. However, Mr. Gerard of Lambda Technologies (described below) commented that it is important that a percentage of the royalties go to the laboratory inventors, so that they have an investment in his company's success.[28]

User Groups

The ultimate customers of the company's products will include users for whom conventional (fixed-frequency) microwave sources are ineffective, inefficient, or difficult to control. For example, an athletic shoe company is making plans to use the furnace to cure resin adhesives that attach soles to the bottom of shoes.

[26]Interview with Dr. Lauf, September 4, 1996.

[27]Interview with Mr. Bible, August 28, 1996.

[28]Interview with Mr. Gerard, September 19, 1996.

The largest potential market is probably diamond film processing. This area includes an estimated $10 billion market for the electronics industry alone. There is a projected $10 billion market for other mass production uses.

Barriers to Commercialization

Both Dr. Lauf and Mr. Gerard commented[29] on the need for exclusive licensing, probably because the company was only granted a non-exclusive license. Dr. Lauf noted that a laboratory's first mission was to get the technology out with fairness of opportunity since they are taxpayer-supported. But a project also has to make business sense. A company can't raise capital unless it gets an exclusive license at least for the first several years or at least one that is limited to fields of use (even with different applications). Mr. Gerard also made the comment that a company needs a window of exclusivity. Even up to the late 1980s, in his experience, a company couldn't get this with DOE laboratories. Now, an ORNL license (through Lockheed-Martin) can be exclusive for one or two years, after which the laboratory will usually retain the right to license the technology to other companies.

Dr. Lauf also says that Congress is getting the message that these issues are not "corporate welfare," but the leveraging of federal R&D money. He added that Lambda Technologies has communicated with its congressional representatives about this.

Other Factors

Mr. Gerard feels the key to their success so far is that they have maintained a close relationship with the DOE inventors, fostering an interpersonal relationship and consulting with them on new ideas. He commented[30] that, even if no new technology results from the CRADA, it keeps them in the loop and bridges a gap. (Other technology is likely as the technology continues to mature through the CRADA.) Also, the relationship with the laboratory researchers helps to streamline the process of working with ORNL.

Dr. Lauf separately commented that he believes the lessons learned in this case are for laboratory researchers to be in good communication with their company CRADA partners. Dr. Lauf says that the business and legal people can do the paperwork involved in CRADAs, but they can't do the necessary technical hand-holding. So, it's the scientists that end up driving the commercial process. It is apparent from his stories that Dr. Lauf serves as a mentor to others in both the laboratory and the company, such as the company's younger, very technical employees, who are recently out of graduate school. Dr. Lauf said these hard-working group of "kids" are at the right place at the right time because "the machine and market are ready" in spite of Microwave Laboratories going out of business. Working together, they encourage each other to

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[29]Interview with Dr. Lauf, September 4, 1996; interview with Mr. Gerard, September 19, 1996.

[30]Interview with Mr. Gerard, September 19, 1996.

work long hours, and as Dr. Lauf believes there is no substitute for hard work.[31] Also, they are always on the lookout for new customers, and they go after awards that might contribute some visibility to their effort.

User Benefits/Economic Impact/Outcomes

Microwave Laboratories developed and marketed a new product line based upon the variable-frequency microwave, which included its traveling microwave tube as a component. The products included furnaces, applicators, processing systems, and traveling microwave tube amplifiers. The power levels were high, ranging from 200 watts to two kilowatts, and the frequencies ranged from 900 megahertz to 16 gigahertz. These products were cited in the company's 1992 Annual Report as the cornerstone of a strategy to reduce its dependence on defense-related product lines. After the Gulf War, however, the military's need for Microwave Laboratories' products declined drastically. To make matters worse, the company experienced a quality control problem on one of its Navy contracts. As a result, the company's inventory built up; eventually, the company became insolvent. The company's CEO is now with another company in the microwave business.

Four people from the microwave heating part of Microwave Laboratories spun off to become Lambda Technologies, a privately-owned company in Raleigh, North Carolina. Dr. Lauf described Lambda as "a phoenix rising out of the ashes." (Certain DOE publications relate that, upon the successful development of the new technology, Microwave Laboratories "formed" the new company.) Lambda Technologies acquired Microwave Laboratories' inventory of parts and its jointly developed patents and licenses providing rights to the special tubes. However, all of the intellectual property had to be renegotiated with Lockheed Martin since it was not transferrable. (One of the reasons for this, according to Dr. Lauf, was that the laboratories often give better terms to smaller firms than to larger ones. He added that this often causes venture capitalists difficulty, because it means large firms often can't assume intellectual property rights when they acquire a small firm.[32])

As opposed to Microwave Laboratories, the new company's only product is the variable-frequency microwave oven. After delivering a prototype system to DOE, the company introduced its first standard product in April 1996. They are producing two to three units a month of this research equipment (mostly for university laboratories). The company anticipates that this line of products will grow to significant numbers, possibly 30,000 to 50,000 units. Microwave ovens are often used in scientific laboratories to heat and dry, but conventional microwave ovens do not perform these jobs well because they don't have either uniform energy distribution or controllable energy distribution for selective heating. Lambda Technologies' product is called "Vari-Wave," and it is a multi-functional microwave oven that can serve as a

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[31]Interview with Dr. Lauf, September 4, 1996.

[32]Interview with Dr. Lauf, September 4, 1996.

research tool, an analytical tool, or a measurement tool. It can be used for drying, selective or rapid heating, composite and epoxy curing, polymerization, organic synthesis, electronic bonding, moisture and gravimetric analysis, and reaction kinetics. There are three standard Vari-Wave models, each of which offer varying power wattages, gigahertz frequency ranges, and sizes (basic dimensions are 24 x 28 x 21 inches, and weight is less than 100 pounds). Also, a single-function version of the basic model is available. The oven's microprocessor is interactive; the desired parameters can be set up using a keypad and monitored on a control panel. Each model is optionally available with "Vari-Data," which is an off-line PC-based software/hardware interface capability. With Vari-Data, temperature and time can be pre-programmed and operator observations are menu-prompted and recorded.

Lambda Technologies employs a couple dozen employees, including engineers with backgrounds in materials science, chemical engineering, and microwave design. By the year 2000, the company hopes to do in excess of $50 million a year, although the business could be projected to be as much as $100 million. The company now has two production floor sites and plans to expand its product lines. It was slated to open a new 12,000 square foot facility in January 1997 that will employ about twenty people. At the main Lambda facility, the company maintains a materials laboratory and a wide range of Vari-Wave and other high-power variable-frequency microwave systems and associated equipment.

Lambda Technologies was re-capitalized with a bank as a major creditor. A venture capital group brought in an entrepreneur from the Northwest, Mr. Richard S. ("Dick") Gerard as President/CEO. Mr. Gerard had a previous track record of building three other high-tech start-ups. Dr. Lauf attributes the success of Lambda's start up to Mr. Gerard's coming on board when he did. A new PhD graduate was scheduled to begin work with Microwave Laboratories on the day the company closed its doors. The venture capital firm that invested in Lambda Technologies temporarily hired the graduate as their employee. He wrote R&D funding proposals for Lambda Technologies that resulted in a DOE Small Business Innovation Research grant that involves an adjacent technology to the variable-frequency microwave technology. The new company was also able to secure some other contract R&D funds.

Lambda Technologies' had a CRADA with DOE that was a hold-over from Microwave Laboratories that was closed out. They signed another CRADA with DOE, initiated in their second year.

During Lambda Technologies' first year and a half, they solidified the base technology and built the intellectual property into a variety of applications. Lambda Technologies' next phase focuses on pursuing new and longer-term applications and developing additional types of customers and market niches. In addition to the standard research equipment they are already selling, the company is marketing equipment which would be used in a production environment, and they are gearing up to respond to customer orders. Mr. Gerard talked about applications like glueing components onto a computer circuit board or heating plastic and rubber products like shoe soles. Adhesive curing and working with polymers doesn't require as much power as the heating of ceramics. There is also the possibility of reviving the military hardware and radar applications. Mr. Gerard feels it is important to fund both research <u>and</u> production applications, as well as something in between. If requested, the company will develop custom-designed ovens to specification. He noted that it is important to coordinate the transition of the technology as it is perfected from concept to commercialization.

International Activity

At least two foreign patents have been filed in more than one application area.

Government Gains

A technology developed exclusively for military hardware, the traveling microwave tube, was adapted for civilian use in the new variable-frequency microwave furnace. It's successful commericalization is contributing to the economy.

Economic Development, Technical Assistance

Another aspect of Lambda Technologies' next phase of growth is the development of the company's own financing.[33] Mr. Gerard did not mention connections with locally available business assistance.

Elapsed Time

The license agreement was signed, and initial license fees paid, in February 1992, less than three months after filing the patent application in November 1991. The ORNL researchers presented the Materials Research Society paper in 1992 and published in 1993. In 1994, Microwave Laboratories closed and Lambda Technologies was founded.

<u>Case 5 (1992) - Gravity Meter</u>

Role of Laboratory Researchers and Other Personnel

Dr. James ("Jim") Faller is chief of the Quantum Physics Division and chairman of the Joint Institute of Laboratory Astrophysics (JILA) in Boulder, Colorado. At the time of the transfer, he was senior scientist at NIST and a fellow at JILA. Dr. Faller is one of the world's leading experts in measuring gravity. It was the subject of his dissertation at Princeton, and he soon developed an international reputation in the field. The researchers led by Dr. Faller at JILA are highly regarded by their colleagues in laboratories in Austria, Germany, England, Italy, France, Canada, Japan, the former Soviet Union, and Finland. Dr. Faller is the principal

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[33]Interview with Mr. Gerard, September 19, 1996.

investigator of the group's projects. He has published more than ninety scientific papers (particularly on the gravity meter technology).[34] He also designed and built one of the first instruments deployed on the Moon by Apollo 11. Dr. Faller has received many honors and awards, including the Department of Commerce's Gold Medal and election to Fellowship in the American Physical Society.

Dr. Faller developed the mechanical, electronic, and optical (laser) technology incorporated into the JILA gravity meter. He was the primary technical expert throughout the development of the technical specifications and work statement of the original competitive solicitation. Once the contract was in place, he advised the NIST contracting officer's technical representative (COTR) who, at the time, was the NIST division chief. The FLC nomination form stated that the COTR "relied heavily" on Dr. Faller's technical advice. Dr. Faller's participation in the project was considered "critically important" when the sudden unavailability of a unique material necessary for a component required major redesign. And, he had primary responsibility for testing and evaluation of the instruments once they were delivered by the contractor.

Technology and Applications

Traditional gravity measurement devices are based upon relative measures rather than absolute measures of changes in local height relative to the center of the Earth. NIST/JILA developed an absolute gravity meter that makes absolute measurements of the Earth's gravitational field five to ten times more accurately than previously possible. In measuring the Earth's crust and density, it can detect changes smaller than a centimeter in relation to the center of the Earth. A unique portable first-generation device with ultra-high accuracy, national decisions are based upon its measurements.

The Laboratory

NIST works with industry and other outside organizations to develop and apply technology, measurements, and standards. NIST's technical work is performed in eight operating units or laboratories (focused on physics, chemistry, electronics, materials, manufacturing, buildings/fire research, computing, mathematics, and technology services) located in Gaithersburg, Maryland, and Boulder, Colorado. For these laboratories, NIST has a $740 million annual operating budget, and for congressionally-appropriated programs run by NIST, it has $260

[34]Examples are: J. E. Faller, "Precision Measurement of the Acceleration of Gravity," *Science* 158 (60), 1967; J. E. Faller, M. A. Zumberge and R. L. Rinker, "A Portable Apparatus for Absolute Measurements of the Earth's Gravity," *Metrologia* 18 (145), 1982; J. E. Faller, M. A. Zumberge and J. Gschwind, "Results From an Absolute Gravity Survey in the United States," *Journal of Geophysical Research* 88: 7495, 1983; J. E. Faller and I. Marson, "'g' -- the Acceleration of Gravity: Its Measurement and Its Importance," *Journal of Phys. E: Scientific Instruments* 19 (22), 1986; J. E. Faller and I. Marson, "Ballistic Methods of Measuring "g" -- The Direct Free-Fall and the Symmetrical Rise-and-Fall Methods Compared," *Metrologia* 25 (49), 1988; J. E. Faller, G. Peter, R. E. Moose, C. W. Wessella and T. M. Niebauer, "High Precision Absolute Gravity Observations in the United States," *Journal of Geophysical Research* 94: 5659, 1989.

million in funding.

NIST equipment and facilities available to industry focus on fire research, large-scale structures testing, computer network security, polymer composite fabrication, and transverse electromagnetic cells. The institute has a number of highly specialized facilities such as a ground screen antenna range and mechanical behavior facility.

The overall NIST staff numbers some 3,000 at both the Gaithersburg and Boulder sites. NIST is proud of the fact that it now implements an average of one CRADA for every three researchers on its staff. Since 1988, NIST has implemented 582 CRADAs.

University Involvement

The NIST Boulder site and a laboratory of the National Oceanic and Atmospheric Administration (NOAA), also a part of the U.S. Department of Commerce (DOC), are co-located in the same building in Boulder, Colorado. The research in this case, however, did not take place at NIST's Boulder site. It occurred at JILA, a cooperative research venture of NIST and the University of Colorado located on the university's Boulder campus. The laboratory is sponsored and run jointly by the university and NIST. JILA's research interests relate to gravitational physics, among other areas. One of its missions is to develop state-of-the-art precision instruments to measure the Earth's gravity or "g," a fundamental measurement in physics.

The NIST employees at JILA report to NIST's Physics Laboratory in Gaithersburg, which conducts research on quantum, electron, optical, atomic, and molecular physics. JILA's research is also centered on ionizing radiation used in medicine, the focus of an earlier NIST Physics Laboratory case study in this dissertation series. The Physics Laboratory has highly specialized equipment, such as polarized electron microscopes, scanning tunneling microscopes, and a synchrotron radiation source.

Employees of both NIST and the University of Colorado freely intermingle at JILA; the chain of command is invisible. JILA is unique in terms of its structure. Probably the only analogy to JILA is the federal-university biotechnology collaboration at the University of Maryland called CARB, Center for the Advancement of Research on Biotechnology. The difference between JILA and DOE's university-operated laboratories is that in the case of JILA, the University of Colorado is an equal partner, not a contractor.

JILA has a total of about 250 employees. This includes eight full-time NIST professionals and fifteen university professors. Each organization allocates funding for faculty salaries, overhead, and direct expenses, with NIST's contribution to the university laboratory being in the form of block grants. As part of the arrangement between NIST and JILA, NIST pays sixty percent of Dr. Faller's salary; the other forty percent comes from other sources such as grants that he negotiates through the university. Dr. Faller can earn up to 100 percent of what his federal salary would be.

Funding, Financing

The funding for the absolute gravity meter came from different organizations at different points in its process. Funding for most of the fundamental R&D underlying the technology transfer was provided by NIST and the Defense Mapping Agency. NOAA provided the bulk of the funding for the 1990 procurement through its Advanced Technology branch. Each of the two initially procured instruments cost NOAA $250,000. NOAA also provided partial support for Dr. Faller's time spent on development activities related to the procurement. In addition, two gravity meters were purchased by the military for about $300,000 each. So, in total government agencies purchased instruments for approximately $1.4 million.

On the commercial side, two of the three principals of the company JILA selected to transfer the technology to invested almost $1 million of their own money to develop the gravity meter. Other follow-on investment for development of a more compact version of the technology was funded with $250,000 Phase I and II SBIR grants through NOAA.

Intellectual Property

There is no patent on this technology. Dr. Faller said that until about five years ago, NIST urged its researchers to publish, giving the laboratory up to one year to file for a patent. Apparently, during those years, NIST did not provide incentives to its researchers to initiate patent applications within the deadline. If Dr. Faller had patented the gravity meter, he said he would have received $2,500 plus fifteen percent of the royalties returned to the government. To make matters worse, when Dr. Faller received his FLC award, he learned at the awards presentation that his counterpart award recipients at DOE each received $10,000 just for getting the award.[35]

For follow-on commercialization efforts, the absolute gravity meter was a proprietary instrument.

Technology Transfer Mechanisms

To transfer the gravimeter, NIST initiated a competitive public solicitation through *Commerce Business Daily* and subsequently signed a five-year procurement contract with Axis Instruments Company, a small high-tech start-up in Boulder, Colorado. The contract stipulated that Dr. Faller and his group at NIST/JILA would design and develop the gravity meter technology, while Axis would manufacture the instrument.

Axis' agreement with NIST was a procurement contract mechanism where the product was to be built to the customer's specifications. Dr. Faller said, in hindsight, they should have used a CRADA rather than a traditional production contract, but they didn't know about

[35]Interview with Dr. Faller, July 8, 1996.

CRADAs in 1992.[36] Among other requirements, the contract specified that the first two field instruments be delivered to NIST within two years. As part of its original contract, NIST had retained an option to purchase as many as six additional instruments for its own laboratory use three years beyond the initial production period at $250,000 each. NIST certified the gravity meters and turned them over to NOAA. NOAA provided most of the funding for the contract and participated in developing the solicitation and selecting the contractor, while NIST supervised the contractor's performance.

User Groups

The Axis principals were former instrument makers with JILA. Axis undertook aggressive marketing efforts. According to the company's marketing brochure, Axis Instruments was formed

> "to design, manufacture and market the finest quality, high-precision scientific instruments -- mechanical, optical, electronic, and vacuum. We offer cost effective, 'one-stop' design, prototype development, manufacturing and marketing service."

NIST encouraged the formation of the company, and encouraged it to market and sell gravity meters to other customers. The NIST contract was the company's first major contract, but it subsequently won contracts to build more "FG5 Gravimeters" for the Canadian, English, and French governments. In exchange for a gravity meter, Axis acquired the prototype for a new type of iodine laser from the Bureau International des Poids et Mesures (BIPM) or International Bureau of Weights and Measures in Paris, France. Before that, Axis used a less accurate laser in its gravity meter, and the French laser was used as a laboratory physicist's instrument only. The French measurement bureau gave the company circuit diagrams describing how to make the laser as well as international manufacturing and marketing rights. In return, Axis agreed to pay a royalty to BIPM on each one sold. The laser is a component of the gravimeter; it is also a stand-alone device available to both commercial and private laboratories.

In the meantime, the company appeared to have high expenses with salaries, rent, and purchased equipment and parts. The president of the company attempted to sell the company to large manufacturers like Texas Instruments, but they were not interested in Axis' relatively small market. In mid-August 1993, Axis had to let go of its technical employees and was left with management only. They made it through the initial stages, but eventually, Axis went out of business.

Subsequently, Dr. Tim Niebauer, the Axis chief scientist who had developed the original prototype for Axis (and Dr. Faller's graduate student at the university), bought the rights to the gravity meter from Axis and the Axis equipment inventory. He agreed to pay back the Axis founders a certain amount for each instrument sold. He moved the company to a "low-rent" area

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[36] Interview with Dr. Faller, July 8, 1996.

and hired back only four of the Axis employees. The new company, Micro-g Solutions, began selling instruments and eventually moved to a better location. They bought a former supermarket/dance hall on the main street of Erie, Colorado. Being eager to attract a high-tech firm, the Erie municipal officials granted the company an exception to city zoning regulations so that they could manufacture in the middle of town.

Another of the original Axis principals, Dr. Mike Winters, obtained the rights to the Paris iodine laser and he and his wife formed a separate company called Winters Electro-Optics, Inc. Since the laser is a component in the gravimeter, Micro-g Solutions buys the part from Winters Electro-Optics. Dr. Winters was the fourth person brought in to Axis Instruments, hired when Dr. Faller convinced the Axis founders they needed a physicist to build the laser used in the gravity meter. Dr. Winters did the development work required to turn the French iodine laser into a product and integrate it into the gravity meter. So, Winters Electro-Optics now pays what was previously Axis' royalty responsibility to BIPM. They have the same agreement as Axis had with BIPM, and they can use as much of the design as they want. Winters Electro-Optics also currently has a two-year CRADA with NIST.

Winters Electro-Optics was "financed" through an agreement with Axis whereby they would handle the warranties in return for the Axis laser inventory and related equipment such as oscilloscopes. In responding to the warrantees, it was easier for Dr. Winters to replace the existing lasers with his new one for free. So, basically giving away about ten lasers comprised Dr. Winters' start-up costs. Dr. Winters is pleased to report that the only outside money used in the course of starting up his business was $5,000 to $10,000 borrowed from relatives.

Dr. Winters says the laser is a perfect product for a very small company, although the market will eventually saturate. Their major competition is the National Physical Laboratory (NPL) in Great Britain, which has recently been privatized. However, NPL has access to markets in Malaysia and Singapore that Winters Electro-Optics does not have. Dr. Winters says it is not feasible to use agents overseas because they don't know his product, and distributors often raise their price in those locations. On the other hand, being smaller, the company has to go outside for machining work unlike Micro-g which has its own machine shop.

A gravity meter can be used to measure, for example, a rising sea level due to global warming. Also, exploring for oil reserves requires tools that measure gravity, among other things. For oil prospecting, absolute gravity measurement saves time and labor over relative gravity measurement. Relative instruments involve repeating measurements over several days. The instrument goes back and forth, aimed at a series of distant sites, a labor-intensive and time-consuming process. An absolute gravity measurement tool would require only one visit to the same site. In addition, NOAA requested two absolute gravity meters for field use by its Climate and Global Change Program at the same time that other organizations were also expressing an interest.

Barriers to Commercialization

When the contract was issued with Axis, NOAA's requirements included a new level of compactness and robustness for several critical parts within the gravimeter. Therefore, NIST was in the process of designing certain improvements and preparing the necessary engineering documents. This made negotiating the contract difficult because the design of the instrument was evolving while it was being negotiated.

Other Factors

In this type of joint scenario with NIST and the University of Colorado, it is common to have inventors from each organization involved in one invention. When this happens, an invention disclosure is filed with each organization. Then, the two technology manager officers cooperate to move the technology forward.[37] The procedure is to select a lead party from one of the organizations in order to file and market the invention, negotiate the license, collect the licensing fees, and share them with the other party. Who is chosen as the lead depends upon such criteria as how many researchers are from each organization, their seniority, and existing institutional portfolios. If there are two inventors, they each receive half of the royalties.

In negotiating the license, the university's motivation is to get funds into the university. The university will usually entertain several companies. The company most likely to commercialize and that offers the highest royalties is awarded the license. On the other hand NIST, as a high-profile public institution, doesn't like to favor one company with selection over another (in the case of exclusive licensing) unless it was the only way to get the technology commercialized.

NIST is not as adamant about patenting either. NIST will allow the university to patent, but reserves the right to says it may still make the technology available for free. In this case, it becomes useless for the cooperating university to patent.

In the case of a CRADA that involves solely NIST personnel on the non-company side, it would be put into place by NIST rather than the university. So it is apparent that the fluidity between the two organizations creates both challenges and opportunities due to the differences in their philosophical approaches, procedures, and cultures. Dr. Faller's former graduate student[38] noted that NIST employees are still reluctant, even in 1996, to talk with or work with companies. They are afraid that, as government employees, they would create a problem in fairness of access. The technology transfer officer for the university, Dr. Steve ONeil, says NIST takes very seriously its position as a "high-profile public institution" in the state and the nation and

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[37]Since JILA is part of the NIST Physics Laboratory headquartered in Gaithersburg, it works with the NIST/Gaithersburg technology transfer office rather than the NIST/Boulder office.

[38]Interview with Dr. Niebauer, July 25, 1996.

impresses this upon its employees.[39]

The four University of Colorado campuses made $1.6 million in royalties last year, yet Dr. ONeil says they almost broke even on their technology transfer efforts. This is because twenty-five percent of this return went to the inventors, twenty-five percent went to the relevant department, and twenty-five percent went to the university's general research account. The remaining $400,000 was used to pay for expenses involved in technology transfer activities such as marketing and administrative staff, patent searches, attorneys, etc. So the issue of how to keep incentives high and still recoup enough to keep the technology transfer function operating is problematic. Dr. ONeil added that out of several thousand faculty and employees at the university, only a handful understand technology transfer.

User Benefits/Economic Impact/Outcomes

Axis's customers included the University of Colorado, local businesses in Colorado, and private individuals such as independent inventors as well as international governments. The company built up to revenues of about $3 million a year, and twenty employees.

Micro-g grew to seven or eight employees and became successful, selling four instruments in 1995, and four as of mid-1996. The projected revenues for an anticipated product from SBIR-funded research are $10 million per year. Also, NIST and Micro-g Solutions have a CRADA to continue development work on the absolute gravimeter. JILA is trying to be more aggressive in getting the gravity meter in a form that outsiders can use. The laboratory is becoming more industry-oriented, bringing in corporate executives to communicate user requirements to the laboratory personnel. Micro-g Solutions' president, Dr. Niebauer,[40] noted that the gravity meter market was not a bad market, but also not such a huge market that any one company would have spent ten years as NIST did in developing the gravity meter to where it would be commercially viable. He also noted that a CRADA was not necessarily an appealing business deal for companies. Unless the CRADA is structured in a certain way, it won't make money for the company because there is no specific goal (like a product that makes money) and no deadline. Furthermore, the company can't provide direction to the government employees working on the CRADA: they can only access information and ask specific questions. The CRADA is based upon the good faith of both parties that useful research will ultimately result from the CRADA work. Companies don't normally do business that way, he said. So CRADAs are useful for ideas, but not necessarily for products.

In summary, including the NIST 1990 contract, eighteen gravity meters were sold, representing approximately $5.4 million in sales at an average of $300,000 each. (Axis sold eight; Micro-g sold ten). Overall, the government has recovered about a third of this, $1.8

[39]Interview with Dr. ONeil, August 29, 1996.

[40]Interview with Dr. Niebauer, July 25, 1996.

million, in taxes from the two companies. On average, over a period of five years, ten people were employed by Axis and Micro-g Solutions. Micro-g Solutions has eight or nine employees, and Winters Electro-Optics has two employees. Winters Electro-Optics provided the first ten lasers for free and donated one to an institution. So the company actually sold roughly forty lasers at $32,000 each, totaling $1,280,000 over three years, providing a little over $425,000 a year in gross revenues.

International Activity

In the early 1990s, before being transferred to the private sector for mass production, six of the NIST instruments were being used at various sites around the world and more were in demand. Early on, gravity meters were sold by Axis Instruments to BIPM, Canada's Geological Survey, and the National Environmental Research Council of England.

Micro-g Solutions sold four gravity meters to the Japanese government. Having experienced several major earthquakes recently, the Japanese have devoted large amounts of funding to their earthquake science programs, which purchased the instruments. Also, Italy purchased an instrument to monitor Mount Vesuvia. Mount Vesuvia is dormant but not dead and, unlike many other volcanoes, has many people living on it. Belgium and Australia also bought gravity meters. A gravity meter was even sold to China; for this sale, there was a great deal of export-related paperwork. Transfer of the gravity meter to all of these countries has helped the United States' balance of trade payments.

Government Gains

The original NIST contract stipulated the delivery of the first two gravity meters to NIST (for NOAA). Since then NIST has purchased one additional instrument for use in its Gaithersburg, Maryland, laboratory in anticipation of a new mass standard for kilogram replacement. This area of the standards community is becoming more active because the absolute gravity meter makes it possible for a new standard to be adopted. A device less expensive and not quite as precise would allow wider audiences to avail themselves of this level of accuracy. It is predicted that the standards in this area will change between 1998 and 2002.

Economic Development, Technical Assistance

There were state-funded incubators available in the area, but neither Axis, Micro-g, nor Winters Electro-optics chose to be affiliated with these facilities. Dr. Tim Niebauer, president of Micro-g, noted that economic development services and banking institutions were not that helpful. On the other hand, he referred to the useful federal government research funding programs as an "engine for the future."

Elapsed Time

NIST has invested in gravity measurement research at JILA since the early 1960s. In the mid-1980s, Dr. Faller and the NIST researchers began developing a portable absolute gravimeter. In 1989, NOAA requested the two gravity meters which set in motion the 1990 procurement process. The gravity meter technology was transferred to the firm in late September 1990 through the contract. The first two instruments were delivered to NIST in the Spring of 1992. At that time, NIST undertook a six-month testing and evaluation phase. So the actual technology development phase for those particular instruments took about eighteen months, which is quite fast!

Axis was actively in business from April 1990 to the summer of 1993. Winters Electro-optics was founded in September 1993.

<u>Case 6 (1992) - "Oatrim" Fat Substitute</u>

Role of Laboratory Researchers and Other Personnel

Dr. George E. Inglett, a specialist in biopolymer materials at the National Center for Agricultural Utilization Research (NCAUR), invented the technology to manufacture a natural fat substitute and food additive called Oatrim. Early in his research, Dr. Inglett provided information on the technology to interested companies and responded to specific questions. Papers about the technology were published in *Food Technology*, the journal of the Institute of Food Technologists[41]; USDA's *Science of Food and Agriculture*[42]; and conference proceedings of the American Chemical Society.[43]

After Oatrim's announcement at the American Chemical Society conference, Dr. Inglett received thousands of industrial inquiries. Consequently, he arranged a technology transfer conference at the laboratory, which was attended by approximately seventy industry representatives. More than half of the seventy companies attending the conference applied for licenses to the technology. Three were granted non-exclusive licenses.

Once Oatrim was licensed, Dr. Inglett assembled an information packet on the technology that included the names and addresses of the licensees producing the material. At this point, he

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[41]G. E. Inglett and S. B. Grisamore, "Maltodextrin Fat Substitute Lowers Cholesterol," *Food Technology* 45 (6/June): 104, 1991.

[42]G. E. Inglett, "OATRIM Cuts Fat, Cholesterol in Ice Cream," *Science of Food and Agriculture* 2 (2): 4-5, 1990.

[43]G. E. Inglett, "OATRIM Products With Elevated Beta Glucan Contents as Natural Fat Substitutes," Fourth Chemical Congress of North America, New York, New York, August 25-30, 1991, *Abstr. Pap. American Chemical Society* 202 (1-2), 1991.

hosted corporate visits to the laboratory to review equipment and processing needs.

Dr. Inglett invited an engineer from ConAgra, the first company to start a pilot plant, to spend several days at the USDA Peoria laboratory to participate, first-hand, in Oatrim processing. Dr. Inglett also visited the pilot plant site in Mountain Lake, Minnesota, to consult with plant personnel and corporate management and analyze the initial product. Like ConAgra, Rhone-Poulenc Food Ingredients relied heavily on Dr. Inglett and maintained close contact with him during the product development phase.

In addition, Dr. Inglett initiated "human studies" of Oatrim. The first such study was carried out by nutritionists at the USDA/ARS center at Beltsville, Maryland, using two dozen volunteers. The results of the five-week study were published in the December 1993 issue of ARS' *Agricultural Research*. As expected, the results showed a decrease in "bad" LDL without a decrease in "good" HDL cholesterol. Volunteers improved in their ability to process sugar from their meals, an indication of their "glucose tolerance" that is linked to diabetes. Also, surprisingly, most of the volunteers lost an average of 4.5 pounds during the study, despite increases in their caloric intake. And, a 1994 article in *Science News* noted that "nobody in the Oatrim research test complained about being hungry."

Subsequently, Dr. Inglett conducted additional research to improve processing of the product and to address problems associated with scale-up from laboratory to industrial production. For example, he experimented with various food products and created an ice cream substitute that fared well with the taste panels. Also, he searched for varieties of oats containing higher levels of cholesterol-fighting beta glucan.

Technology and Applications

Oatrim is a bland, rich, creamy gel derived from oat starch that has less than one calorie per gram compared to nine calories per gram for fat. It remains stable when frozen, cooked, or left at room temperature. It causes no change in flavor or loss in textural quality (that is, it "has the feel of fat on the tongue") upon incorporation into many foods including dairy products of all types, dressings and sauces, meats and cereals.

Oatrim has the double benefit of lowering blood cholesterol levels in the blood while it reduces fat intake because it decreases artery-clogging LDL cholesterol and increases levels of beneficial HDL cholesterol. This is because Oatrim is the only fat replacer on the market that contains beta glucan, the soluble fiber in oats.

The Laboratory

NCAUR is one of the four major centers in USDA's Agricultural Research Service. It is located in Peoria, Illinois. Within NCAUR, there are a number of "individual laboratories" for bioscience, food and fiber, industrial products science, crop protection, and natural toxins.

Funding, Financing

One of the licensees, the Rhone-Poulenc/Quaker Oats partnership found the difference in scaling up from small "bench-top" levels to full-scale production to be "world's apart."[44] Mark Freeland[45] of Rhone-Poulenc said Dr. Inglett's original work was good science, but was done on such a small scale that the partnership found it necessary to invest millions of dollars and a great deal of time into formulating the Oatrim ingredients for incorporation into mass-production levels. The partnership produced over twenty million pounds every year as far back as 1993. Mr. Freeland said the companies probably should have better understood that they were getting into a "laboratory process." They didn't appreciate how difficult scaling up to full production would be. The companies still believe in the technology and are not abandoning it, but they are at the end of their investment in product development. The only feasible new investments at this point would be made to increase capacity or tweek the production process or re-launch the product.

The companies also experienced problems and devoted a great deal of money toward technology development. They noted that any grain product has an inherent cereal flavor, and they found that the original Oatrim had a weakness as a fat replacer because it had an oat flavor that didn't work well with cheese and ice cream products. Particularly with higher levels of production and use, the oat flavor crept in.

Intellectual Property

So far, Dr. Inglett has produced three types of Oatrim from oat flour or bran. The U.S. patent listed in the FLC's midwest regional directory as available for license is: "A method for making a soluble dietary fiber composition from oats."

The technology is also easily applied to other crops such as barley and corn. Thus, a second patent involves barley, as follows: "A method for making soluble dietary fiber compositions from cereals." Dr. Inglett is listed as the inventor on both patents.

Technology Transfer Mechanisms

Non-exclusive licenses were granted to three companies in the early 1990s, described below. With the keen competition for the technology, it is presumed that these licenses were probably somewhat above average in fees and royalties paid to USDA and Dr. Inglett.

ConAgra Specialty Grain Products Company: The first license was with ConAgra Specialty Grain Products Company in Omaha, Nebraska. ConAgra, Inc., also headquartered in

[44] Interview with Mr. Babbitt, October 4, 1996.

[45] Interview with Mr. Freeland, October 11, 1996.

Omaha, is a $25-billion company with over 83,000 employees, the second largest food manufacturer in the United States behind Kraft Foods.[46] ConAgra is comprised of a number of independent operating companies which it owns, including: Armour^{R}, Banquet, Butterball^{R}, Chun King, Eckrich^{TM}, Hebrew National^{R}, Hunt's, Knott's Berry Farm^{R}, La Choy, Mamacita's, Marie Callender's^{R}, Orville Redenbacher's^{R}, Peter Pan^{R}, Reddi Wip^{R}, Sargeant's, Steak Express, Swift Premium^{R}, Swiss Miss^{R}, Taste o'Sea, Van Camp's, Wesson^{R}, and many others.

Rhone-Poulenc, Inc.: A license was also granted to Rhone-Poulenc, Inc., a $16 billion French company based in Cranbury, New Jersey, with more than 140 offices throughout the world including major facilities in Canada and Mexico. The company's primary North American laboratory facilities produce meat, poultry, and seafood in Washington, Pennsylvania; brew and make wine in Chicago, Illinois; provide dairy culture in Madison, Wisconsin; and, perform general food research at their headquarters in Cranbury, New Jersey.

Rhone-Poulenc Food Ingredients, a world leader in R&D on food applications, has annual sales in excess of $300 million. Its core products and typical applications include: phosphate blends used as leavening in baked products and other uses; "performance ingredients," including fat replacers, for salad dressings and sauces; stabilizer systems for dairy products; and starter cultures and and Direct Vat^{TM} inoculants for cheeses, yogurt, etc. Some of their well-known brand ingredients include: MicroGARD^{R} to extend shelf life, Assur-Rinse^{TM} Safety Wash to remove bacteria during beef and poultry processing, and Rhodigel^{R} to maintain sauce viscosity. The company's tag line is, appropriately, "Your Food-Tech Partner^{SM}."

Quaker Oats Company: A license was also granted to Quaker Oats Company headquartered in Chicago, Illinois. Quaker Oats is a $6 billion retail-oriented food company with sales based largely upon a wide variety of oat-based products as well as Gatorade^{R} and Snapple to supermarkets. The Quaker Oats Industrial Cereal Group sells large quantities of wheat flour products to bakeries and grocery stores. This amounts to $40 million in business for the company, but it is less than one percent of the overall company business.

Rhone-Poulenc/Quaker Oats: Rhone-Poulenc Food Ingredients and Quaker Oats Company's Industrial Cereal Group formed a partnership in April 1992, splitting expenses and profits fifty/fifty. Instead of building a plant right away, the companies reduced their risk by partnering and proving the validity of the technology first. Rhone-Poulenc contributed process development, engineering, and applications. In addition to technical services, Rhone-Poulenc brought a sales organization to the partnership, since it can call on General Mills, Pillsbury, Kellogg, Kraft, and other food retailers that could be considered competitors to Quaker Oats. Quaker Oats' contribution was their specific expertise related to oats, since the company represents more than a century of experience with oat technology. The partnership's development work related to the process of scaling up the production is being carried out at the Quaker Oats' operation in Cedar Rapids, Iowa, which specializes in flour and oat production.

[46] Internationally, Nestle is largest.

The scaling up process produced reasonable quantities for analytical testing and screening of applications.

User Groups

Food companies are the immediate users as they incorporate the product into their processed food products. For example, Oatrim is used in dozens of varieties of no-fat cheeses.

The ultimate end users are adult customers who are concerned about their health. According to the National Cholesterol Education Program, more than fifty percent of all adults in the United States have an increased risk of heart attack because their blood cholesterol levels are above the desirable range. Americans derive about thirty-seven percent of their calories from fat, as opposed to the thirty percent maximum recommended by nutrition experts.

Back in 1990, the market for non-fat foods was a mere $750 million. In 1995, a record 1,914 fat-modified products were introduced to the commercial market, according to the editor and publisher of *New Product News,* Lynn Dornblaser. By the year 2000, experts are projecting a multi-billion-dollar industry, although introductions of new products may level off by then. Oatrim is expected to share in at least $100 million of this market and create new markets in combination with wheat and meat products in particular.

Barriers to Commercialization

Because Oatrim is a food product, it required approval from the U.S. Food and Drug Administration (FDA). But since it is made from all-natural fiber ingredients with natural enzymes, it did not face major regulatory hurdles and years of safety tests to get to the market. ConAgra filed a petition for FDA approval by “self-affirmation” through an FDA method known as GRAS (“Generally Recognized as Safe”), which takes months instead of years. Using this process, the company convened a panel of paid experts to review the product information. Once all criteria and panel recommendations were met, the product was submitted to the FDA as information for the file. At that point, ConAgra assumed the liability. By comparison, Procter & Gamble’s highly publicized Olestra took seventeen years to obtain FDA release for limited distribution only, using strict production standards, and just for certain applications like snack foods -- potato, corn, and tortilla chips and crackers.

As with other cases in this series, one reason the product has been slow to influence the market is that it is new to industry. Therefore, it requires education; for example, potential customers need to get product samples.

Finally, the first-hand experience of the partners indicated that joint ventures and alliances of this type depend upon a number of factors for success in the long run. Apparently, they are easy to describe and conceive, but hard to manage because they are heavily affected by the differences in relationships, personalities, businesses cultures, and even nationalities. All of this makes decision-making difficult. For long-run success, the individuals involved have to be motivated to avoid the risk of alienation.

Other Factors

The Mountain Lake partnership and USDA at ARS-Peoria formed a CRADA. Dr. Inglett, a Peoria biochemist Richard Greene, and researchers from the Mountain Lake partnership did some additional processing to Oatrim which resulted in a new fat substitute called Z-trim which has zero calories per gram.[47] Under that CRADA, any inventors involved, including company inventors, are given first right of refusal to a new invention. Dr. Inglett introduced Z-trim at an American Chemical Society meeting in August 1996 and held a laboratory-hosted announcement of Z-trim in early October 1996.[48] Like Oatrim, Z-trim is made from all-natural ingredients. It replaces fat (removing calories) and adds fiber. It is flavorless, made from the hulls of soybeams, oats, peas, rice, or bran from corn or wheat. The hulls are processed into microscopic pieces, dried, and milled into powder. In powder form, Z-trim absorbs up to twenty-four times its weight in water: when cool, it forms a fat-like gel that supplies texture qualities such as moistness and smoothness. USDA taste test panelists rated highly some brownies made with Z-trim.

A 1996 edition of *Time*[49] said the following: "Just three weeks ago, a U.S. Department of Agriculture researcher presented a fat substitute made from the hulls of oats, corn and soybeams. If it is remotely palatable, it is sure to sell. History suggests, however, that it won't make much difference. Depite the arrival of Olestra last winter, despite NutraSweet and one percent milk, despite an estimated $33 billion spent every year on diet books, over-the-counter medications, health-club memberships and low-calorie foods, the flab still remains, entrenched solidly on waists, hips and thighs."

Regardless of *Time* magazine's cynicism, the Mountain Lake partnership has the first right of refusal on a potential exclusive license to the Z-trim invention. The patent for Z-trim was filed by USDA in November 1995. In the meantime, USDA is not sharing information on Z-trim.

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[47]Somewhere in between Oatrim and Z-trim, Dr. Inglett developed "Oatrim-10." A one-ounce chocolate bar, for example, contains a gram of soluble beta-glucan from Oatrim-10, a half gram of Z-trim, oat fiber, corn syrup, milk chocolate, and artificial sweetener.

[48]"USDA Develops No-Cal Fat Substitute," *The FLC Newslink* (December): 4, 1996; "USDA Fat Buster," *Technology Transfer Business* (Winter): 39, 1997.

[49]*Time* (September 23): 63, 1996.

User Benefits/Economic Impact/Outcomes

The users and partners are discussed below in turn.

ConAgra: ConAgra's brand name for Oatrim is TrimChoice. When Oatrim was first introduced, then-CEO Mike Harper leveraged the benefits of TrimChoice for its independent operating companies manufacturing Healthy Choice™ products. These ConAgra companies were strongly encouraged to incorporate TrimChoice into their products, and ConAgra was soon picking up orders from its food manufacturers on a regular basis. The original pilot plant was in place for only a few months in order to define the process parameters needed for large-scale production. Widespread product marketing began in 1991, while the actual TrimChoice commercial plant in Mountain Lake, Minnesota, was being completed. The company began full-scale production there in the Fall of 1991. The manufacturing facility in Mountain Lake was very automated, employing only nine people, which kept ConAgra's operating costs low. ConAgra's first Oatrim-related food, an extra lean (96 percent fat free) ground beef product, sold in the Midwest under the Healthy Choice brand name.

With a change in top management in 1992, ConAgra began offering TrimChoice to other companies outside the ConAgra family, and, according to Steve Grisamore,[50] then sales manager for new product development, the company sold a lot of TrimChoice to other companies. In February 1993, ConAgra formed a fifty/fifty profit-splitting joint venture with A.E. Staley Manufacturing Company of Decatur, Illinois. Staley is a publicly traded Fortune 500 company, like ConAgra, owned by a foreign sugar company called Tate and Lyle. This partnership created a stand-alone company called Mountain Lake Manufacturing. (Mr. Grisamore became General Manager of Mountain Lake, although he is based at corporate headquarters in Omaha.) Con Agra contributed the R&D and manufacturing expertise, and Staley originally contributed the sales and marketing expertise to the partnership.

Healthy Choice is an overall $1.2 billion brand for ConAgra. It had its own Internet site before this became commonplace. The ConAgra 1996 annual report stated that its Healthy Choice products were important contributors to earnings growth for the year, particularly the soups and fat-free cheeses. Healthy Choice products that enjoyed successful debuts in 1996 were hot sandwiches, ice cream, and processed deli luncheon meats. The Oatrim ingredient is listed on the labels of hundreds of products as "hydrolized oat bran." According to the company's yearly financial reports, ConAgra's gross margin increased in 1996 due to margin improvements in various of its businesses. This included specialty food ingredients, which also contributed to the company's pre-tax earnings increase.

In July 1996, some changes were made to the Mountain Lake partnership, and the name was changed to Mountain Lake Specialty Ingredients Company. Media articles indicated that

[50]Cheryl Pellerin, "Lowering Cholesterol: An Oat-Based Fat Substitute ConAgra is Speeding to Market," *Technology Transfer Business* (Fall): 25, 1992.

Staley is not actively handling TrimChoice any more. The product competes with its own starch-based fat replacers. However, Staley is still a half-partner in the Mountain Lake venture.

Rhone-Poulenc/Quaker Oats: The partnership introduced its product in national markets and sells to fifty to sixty companies. Quaker Oats had hopes of high sales within a short period of time. Lanny Babbitt of Quaker Oats' Industrial Cereal Group said[51] that for a company this size, "significant sales" would translate into $10 - 100 million, a level they have not yet reached, with an approximate one-year commercialization period. Mark Freeland of Rhone Poulenc Food Ingredients stated[52] that Rhone-Poulenc's average time frame for a product going from "ground zero" to being a commercial success is five to seven years. Rhone Poulenc has also been disappointed in the growth of the business. Given the heavy interest in low-fat products, the company would have liked to have seen more growth by now. At four years of development, the company is within the framework for new product development and still has good expectations.

However, representatives of both companies noted they are already improving their market position with a new version of the technology that was launched in September 1996 based upon revisions to the original Quaker™ brand Oatrim. Their product was re-named Beta-Trim, related to the fact that it contains five percent beta-glucan. They enhanced their technical process to separate the soluble from the insoluble fiber, which makes the ingredient virtually flavorless. This expands the market to the more delicate food products such as processed cheeses with low- or no-fat content (versus, say, Mexican hot sauces). The product material states that . . ."Beta-Trim gives reduced fat foods the mouthfeel, texture, and taste consumers expect from full-fat products . . .and provides lubricity and creaminess of foods that starches and maltodextrin cannot provide." As a result, they feel their partnership could soon experience some breakthroughs. For example, a Rhone-Poulenc newsletter[53] notes:

- "New production techniques that remove the 'oaty' taste from some Oatrim products have led to stunning successes in both hard-pack and soft-serve ice cream mixes."

- Also, "Working with one of our Oatrim family of fat-replacers, a well-known producer of high-quality franks has successfully marketed a totally fat-free hot dog that has all the characteristics of its full-fat counterparts. Taste, texture, bite, juiciness -- they're all there. Only the fat is missing."

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[51]Interview with Mr. Babbitt, October 4, 1996.

[52]Interview with Mr. Freeland, October 11, 1996.

[53]"Losing the Fat, Winning the War," *Focus on Food Ingredients*, Rhone-Poulenc Food Ingredients, 5th Anniversary Issue, p. 3.

At the same time, the partnership is experimenting with various combinations of Beta-Trim blended with their other products such as Raftiline^R/Raftilose^R, hydrocolloids, phosphates, and dairy cultures to develop more versatile food ingredient systems. Next month,[54] the Rhone-Poulenc/Quaker Oats partnership will bring together a professional taste panel at the Quaker Oats facility in Barrington, Illinois, to compare their "old" and "new" Oatrim. They intend to identify and measure the results quantitatively using human taste buds instead of machinery.

International Activity

Since the USDA waived its right to foreign filing, Dr. Inglett chose to patent Oatrim outside of the United States and, based upon that foreign patenting, he granted ConAgra an exclusive worldwide license outside the United States.

The Rhone-Poulenc/Quaker Oats partnership subsequently negotiated a sub-license from ConAgra, Inc. for rights in fourteen countries. In other words, wherever ConAgra could sell, the Rhone-Poulenc/Quaker Oats partnership could also sell in those countries by paying royalties to Con Agra. However, Con Agra "let go" of some of their international patents by not paying the annual fee in certain countries, so the patents are no longer in place in eight of the fourteen countries. Therefore, each organization is now selling the product in only six foreign countries.

Government Gains

The conversion of oats, which is a raw agricultural farm commodity, into a value-added product has helped the United States' balance of trade in this area. So, the government has indirectly realized a benefit from Oatrim.

Economic Development

None was provided.

Elapsed Time

Dr. Inglett recognized the potential for Oatrim in 1988. A patent application was filed in early 1990. Subsequently, in April 1990, the development of Oatrim was announced at a trade association conference while the patent was still pending. A conference about the technology was held at the Peoria laboratory in May 1990. In June 1990, the first company, ConAgra, signed a license with the laboratory for rights to the technology. (Apparently, the U.S. Patent and Trademark Office must have issued a statement that the technology had passed initial screening, and was a likely candidate for a patent.) The first Oatrim product reached the market in November 1990 as part of a product sample distribution of pilot plant quantities about six months after the license was granted. Widespread product marketing began in 1991 while the

[54]Interview with Mr. Freeland, October 11, 1996.

pilot plant was being completed. Overall scale-up from bench-top to commercial production was accomplished in record time by ConAgra.

By the end of 1991, Oatrim was licensed to the two additional companies. All three license negotiations were based merely upon the patent application being filed. The patent was issued in February 1991. The Rhone-Poulenc pilot plant arrangements were completed in 1992 to 1993. In the meantime, Rhone-Poulenc partnered with the third licensee, Quaker Oats. So, all three companies moved quickly to get the technology into the marketplace. "Human" tests were conducted in 1993.

An article in *Science*[55] noted that all-natural fat replacers take four years to get to the market; apparently, the journal was on the mark vis-a-vis Oatrim. Dr. Inglett's award from the FLC noted that it "honored the dispatch with which he moved the technology into the commercial mainstream." Steve Grisamore, (then) sales manager for new product development for ConAgra, was quoted in the Fall of 1992 as "attributing the speed [of commercialization] to a concerted corporate effort to get [the product] to market, and to excellent cooperation from Dr. Inglett."[56] He said[57] the amount of time involved in going from bench-top to commercialization, eleven months, was "unheard of" and would normally take eighteen to twenty-four months.

Case 7 (1993) - Chemiluminescent "Light Sticks"

Role of Laboratory Researchers and Other Personnel

Dr. Herbert Richter, supervisory research chemist, has directed a group of chemists in the Weapons Division of the Naval Warfare Center at China Lake, California. Dr. Richter's team has been developing new "energetic materials," propellants, and explosives. Members of the team receiving the FLC award for technology transfer were Dr. Ronald Henry (now deceased), senior scientist among the research chemists, and Joseph Johnson (retired), physical science technician, who loaded and evaluated the experimental formulations.

Over the years, the team performed a series of tests for luminescence on a variety of chemical compounds. The compounds selected for this application exhibited the most sustained, temperature-resistant, and non-flammable luminescence. All of the mixing of compounds was performed using various glass laboratory vials. Two smaller vials contained the chemicals; these vials were enclosed within a larger vial before they were broken to create the mixture. Field tests were sometimes performed under adverse conditions; at one point, the team did night testing in

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[55] Constance Holden, Random Samples editor, "Another Fat Substitute," *Science* 273 (September 13): 1495, 1996.

[56] Cheryl Pellerin, "Lowering Cholesterol: An Oat-Based Fat Substitute ConAgra is Speeding to Market," *Technology Transfer Business* (Fall): 25, 1992.

[57] Interview with Mr. Grisamore, September 20, 1996.

the cold in Alaska, which included a harrowing helicopter ride.

In order to create user awareness, Dr. Richter worked with George Linsteadt, the first ORTA officer at China Lake. Mr. Linsteadt was also one of the FLC's founders and later its administrator upon retirement from Navy work. Mr. Richter cooperated with the subsequent ORTA officers as well.

Dr. Richter created a sample kit containing products in a variety of sizes and chemicals. The team performed countless demonstrations and provided data for potential manufacturers and for government agencies (Department of Transportation (DOT), the Forest Service, and state and local safety agencies). Some of the demonstrations were dramatic: for example, a DOT demo involved dropping a light stick from a third story window to the street below. The interest created by the glow stopped traffic for several blocks. They also briefed many military officials both within and outside of China Lake.

Also, many papers (including Navy technical notes, monographs, and publications) covered this technology over the years, and it has been discussed at many conferences. As noted, the papers and data were shared with interested parties from the beginning, and licensees resulted from these early contacts.

One of the contacts was interested in having Dr. Richter serve as a consultant to them in the early 1980s. For a number of years, DOE and other departments and agencies have had provisions where their laboratory scientists could be hired out. (DOE's program, for example, is called "Work-for-Others.") However, the military services, for the most part, do not take part in this practice.

Technology and Applications

"Light sticks," like those novelty items that glow in the dark are created when chemical compounds, each containing a dye and a catalyst, are mixed together. The fluorescent dyes determine the color of the item. The light produced by this chemiluminescent mixture is long-lasting and resistant to environmental extremes such as heat, sand, or snow.

The technology was developed at the China Lake site of the Naval Warfare Center as a marker to locate downed pilots and to illuminate potential targets for airplane bombs. The devices are visible from the air, produce little heat, and can be scattered to form a very large visible signal without starting a fire. (Putting together certain chemical compounds often starts a fire.)

The Laboratory

The China Lake laboratory covers over a million acres of the Mojave Desert in southern California. It was founded in the early 1940s as a facility to test rockets developed at the California Institute of Technology (CalTech) in Pasadena, California, and as a Navy proving ground. It was known as the Naval Weapons Center for several decades, then as the Naval Air Warfare Center, and now as the Naval Warfare Center. The facility employs some five thousand civilians, including one thousand scientists and engineers doing R&D, and about five hundred military personnel. The China Lake facility has an estimated annual operating budget of about $800 million per year.

University Involvement

CalTech does not have a role with the China Lake facility at this point. The Jet Propulsion Laboratory at CalTech became one of the nine official NASA field centers when NASA was created in 1958.

Funding, Financing

Over the years, the research in this case was sponsored by the Navy. Support was received from the Office of Naval Research, the Naval Air and Naval Sea Systems Commands, and the Marine Corps. Support was also received from the Army. Funds to file the patents for the technology came from the Marine Corps Exploratory Development Program.

Intellectual Property

There are two current Navy patents for the technology which cover "The latest advances in chemiluminescent technology offering improved color delineation and longer staying power under adverse conditions." Dr. Richter, Dr. Henry and Mr. Johnson are listed as the inventors.

Omniglow Corporation holds 99 percent of the chemiluminescent patents worldwide. It has patented processes for: multicolor Lite-Rope^{R} necklaces; white, red, pink and purple fluorescers; Lightwrap^{R} glowing strips; Flex-Stick^{R} fishing lures; S.E.E.^{TM} Systems; and Speculite^{R} lightsticks.

Technology Transfer Mechanisms

An early license was signed some time in the mid-1970s with a company called either Chemical Devices Corporation or Coolight. Later license agreements were signed in May 1989 with American Cyanamid Corporation and in July 1989 with Omniglow, Inc. in Novato, California. Omniglow was the successor to Chemical Devices Corporation. The duration of the license agreements was about 4.5 years for each, extending to the end of 1993. Both licenses were revocable, non-exclusive licenses so the companies could use the inventions to produce light sticks, light wands, and safety lights.

Early on, both licensees indicated they were happy with their licensing arrangements, and one of them indicated a desire to work further with Dr. Richter. Dr. Richter said[58] CRADAs were "talked about" at that time, but still not commonly done at China Lake. For example, a China Lake CRADA announced in the laboratory's weekly "Rocketeer" newsletter in 1996 took almost ten years to sign, from 1986 when the CRADA legislation was enacted. The CRADA involved Thiokol Corporation, a major multinational company and a leader in "energetic" materials. Now, however, the Naval Warfare Center's Weapons Division pursues CRADAs more actively.[59]

In the early 1990s, Omniglow filed a lawsuit against American Cyanamid that alleged that the company had illegally filed a light-stick-related patent excluding the government from rights to the technology which actually belonged to the government. (Presumably, this would apply to the other government licensee, as well) The government decided not to join in prosecuting the case. Yet, Omniglow won the case and in 1993 as a result ended up acquiring the division at American Cyanamid that manufactured light stick products. Since then, the rest of American Cyanamid has been bought out by American Home Products, an $8.5 billion acquisition. As a result of all of this, Omniglow wrote a letter to the Navy canceling both of its license agreements to pay royalties to the Navy (by now, it had also acquired the American Cyanamid license), saying the licenses were no longer needed.

During the course of the licenses, the companies paid the China Lake laboratory over $86,000 in royalties. Of this, $25,000 was paid to the three inventors. The remainder was used to fund other research at the laboratory. A China Lake "Success Story" sheet states that this "provided an incentive to other [laboratory] inventors with potentially licensable patents."[60] In the Navy laboratories, the inventor receives at least twenty percent of the royalties. If there is more than one inventor, the twenty percent is split among them. Also, having a patent in itself, gives the scientists credit when it comes time for promotions and other benefits. (Dr. Richter noted that if he had had the foresight to file a patent on a frisbee made with the chemiluminescent materials, he'd be a millionaire now![61]) The other eighty percent of the royalty income can be used by the laboratory. Dr. Richter said the Navy often uses the income as seed money to fund exploratory, high-risk ideas.

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[58]Interview with Dr. Richter, August 7, 1996.

[59]Some recent Naval Warfare Center - Weapons Division CRADA titles include: "Color-neutral electrically conducting polymers"; "Ring vortex projection for medical applications and law enforcement"; and "Electronically steerable antenna systems for autos, boats, and aircraft."

[60]"Chemiluminescence Technology," no date (finalized August 1996), released by the NAWC Weapons Division Technology Transfer Office, p. 2.

[61]Interview with Dr. Richter, August 7, 1996.

User Groups

The field of use of this technology ranges from novelty items to equipment for search and rescue dogs to wear for night searching. This is a technology that has such wide-ranging fields of use, that the number of potential user groups of products made with light sticks is practically limitless.

Barriers to Commercialization

When serious efforts to transfer the technology began in the late 1980s, the Naval Weapons Center, as it was called then, did not have extensive licensing experience. Also, the interested industry partners had never licensed federal technology. Because of the lack of experience in formal technology transfer, working through the process was time-consuming.

User Benefits/Economic Impact/Outcomes

Before it was acquired by Omniglow, American Cyanamid sold a significant number of light sticks to state and local governments and commercial markets including the fishing industry.

Omniglow Corporation was a small start-up business when it signed its original license with China Lake. The company was founded in 1986 with a staff of three, a small laboratory/production facility in Novato, California, and one basic light-stick product. As a result of the license signed within three years of the company's founding, the company was able to enter into the defense market. Today, the company has a staff of three hundred, over a hundred products, a 20,000 square foot facility in California, and a second 180,000 square foot production plant in West Springfield, Massachusetts. Omniglow is now a publicly traded company and the largest producer of chemical light products in the world. Their markets include not only the defense marketplace, but also markets for novelty and retail products, industrial safety, and biomedical products, and commercial and recreational fishing.

Omniglow sells chemiluminescent products to more than twenty-five military and law enforcement organizations worldwide, including all the major defense departments and law enforcement agencies. Omniglow sells over fifteen million units, amounting to some $150 million worth of lights sticks, to DOD each year. The use of light sticks by the U.S. Government dates back to the Viet Nam conflict. More than 20,000 units were used in that war. At that smaller level of production, and with the lack of an industrial base to manufacture light sticks, some of those light sticks may have been produced at China Lake at that time. Since the early 1990s, the Omniglow quality assurance team has supervised production of more than 250 million chemiluminescent devices overall. Omniglow's non-infrared military line currently consists of 1.5- to 15-inch Cyalume[R] and Snaplight[R] light sticks; PML[R] personnel marker lights; S.O.S. light sticks; and Liteshape[R] stick-on buttons. The infrared line is also available in many such versions.

Similarly, police and public safety agencies use light sticks as flares and in place of flashlights. Omniglow's various-sized green and thirty-minute high-intensity red, yellow and white light sticks are used by police for traffic control and by emergency services personnel for hazard identification.

Since 1990, Omniglow has sold novelty items to wholesalers, retailers, and distributors in more than thirty countries. In the United States, Omniglow toy and novelty products can be found on more than 5,000 store shelves including major retailers such as Toys 'R Us, Wal-Mart and K-Mart. This includes products such as 4- and 6-inch Lite-Up^R and Glow Stick^R light sticks, and Magic in the Night^TM earrings, bracelets, and eye glasses. In addition, Omniglow sells 22-inch necklaces and other products directly to major amusement parks such as Disneyland, Walt Disney World, Universal Studios, Six Flags, Tokyo Disneyland and Euro-Disney.

Omniglow's first biomedical product, the Speculite^R light stick, is being developed and marketed in cooperation with The Trylon Corporation. It involves proprietary technology utilizing chemiluminescence as an endoscopic light source. Speculoscopy has received FDA approval, and the Speculite light stick is being distributed through major women's health care providers both in the United States and overseas.

As of 1993, Omniglow had invested at least $100,000 to develop its non-governmental markets (anticipated annual sales in that area were two to five million units). This includes expansion into cold weather applications and industrial safety. The company is particularly excited about its new industrial safety product called Snaplight^R Emergency Evacuation System or S.E.E.^TM system. The S.E.E. system includes the company's unique hexagonal design that increases the light generated by a light stick. Other applications being explored include a new approach to measuring pollution from smokestacks using light stick technology.

Also, Omniglow provides light-stick materials and instructions to high school classrooms so that students can perform chemiluminescent experiments in their science classes.

International Activity

In 1990, Omniglow expanded into the commercial fishing fleet market. In the deep sea fishing industry, luminescent baits attract big fish such as swordfish in the dark, low temperatures of ocean waters around the Arctic and Alaska. These are areas where these fish were never caught in the past. (Dr. Richter created and tested some of the original fishing lures, but he said[62] the Navy did not want to spend the $3,000 it would have cost at that time to file a patent for this application.) Tests showed that light sticks could improve a catch by as much as thirty percent. Since 1991, Omniglow has been working with the Japan Tuna Association (JTA) to further develop the chemiluminescent technology for this industry. JTA is the economic and

[62] Interview with Dr. Richter, August 7, 1996.

political arm of the largest tuna fishing fleet in the world, representing more than 2,000 members with 750+ vessels. Omniglow now markets 4-and 6-inch Snaplight[R] and Cyalume[R] light sticks and patented Flex-Stick[R] lures to commercial fishing fleets.

By 1994, in addition to a Domestic Sales and Marketing Office in Pompton Plains, New Jersey, Omniglow had established three sales offices in: Toronto (in the province of Ontario) Canada; Portsmouth, England; and Tokyo, Japan. Omniglow also has three joint venture facilities under construction or consideration in the People's Republic of China, Indonesia, and Eastern Europe.

Government Gains

Although light sticks were originally developed specifically for military targeting, they ended up providing countless other military benefits. These benefits serendipitously became evident as early as the Viet Nam war, as the following examples illustrate:

- It was discovered that the chemical mixture could be put into aluminum cigar tubes and used by Army troops in place of flashlights which required traditional batteries that corroded in the humid forests of southeast Asia.

- At one point during the war, the military actually documented the number of pilots and jets that were saved because the pilots could hold light sticks in their mouths, shining them onto the dials if the cockpit lights failed. Normally, if this happens, pilots must eject, possibly into enemy territory. In the meantime, the light sticks were attached with rubber bands or velcro to the doors of the aircraft.

- Other uses included: landing helicopters, emergency lighting for Navy divers, arm bands for groups of parachutists close to the ground at night, tips for the wings of Air Force jets, helicopter markings, and man-overboard float lights.

In 1991 and 1992, during Operation Desert Shield and Desert Storm, the invisible infrared light stick was standard military issue for covert signaling and marking to identify allied soldiers and reduce the risk of friendly fire. Omniglow's infrared product was the industry standard. During the Gulf war, Omniglow provided the government with millions of high-quality light sticks on short deadline. As a result, Omniglow was elected as a member of the U.S. Military Quality Vendor Program.

Economic Development

None.

Elapsed Time

The technology was under development from 1962 to the late-1980s. Over this twenty-five year period of time, light yields from the light stick compounds increased by a factor of 10,000. Because of the lengthy duration of the research, informal transfer to the chemical industry was going on for many years. The light stick was considered "invented" in 1973. Shortly after that, it was patented for the first time. That original patent has since expired. Dr. Richter "went on the road with his show" in the mid-1970s. The technology was first licensed in the 1970s. The early license, also, has long since expired. Two updated patents were issued to the Navy in December 1986 and April 1987. Also, in 1986 Omniglow was founded, and the company licensed an improved version of the light stick that same year. Omniglow was awarded its first contract with the DOD in 1989. Efforts to more formally transfer the technology began in mid-1988. Another license was signed with American Cyanamid in 1989. In 1990, Omniglow began selling novelty items both in the United States and abroad.

Case 8 (1992) - Artificial Heart Flow Diagnostics

Role of Laboratory Researchers and Other Personnel

Mr. Franklin D. Shaffer, a mechanical engineer, was the principal investigator on several projects to develop a system for flow analysis at the Federal Energy Technology Center (FETC) in Pittsburgh, Pennsylvania. He was the key developer of the system at FETC's Fluid Analysis Laboratory. Dr. Mahendra P. Mathur was a supervisory physical scientist in the Fundamental Combustion Group at the laboratory. These two FETC researchers trained researchers at the medical company that they worked with under a CRADA to use FETC's fluorescent technique and helped them to set up the system. The FETC researchers also visited Stanford's research center, met implant patients, and observed implant surgery in the operating room.

The group of laboratory scientists co-wrote at least ten papers published in journals or conference proceedings, each involving a combination of authors from the FETC laboratory, Presbyterian-University Hospital, and Baxter Healthcare. These included, for example, articles for the IEEE International Conference on Pattern Recognition,[63] the National Fluid Dynamics Congress,[64] a Cardiovascular Science and Technology Conference,[65] the Journal of Applied

[63]R. Srinivasan, R. Singh and F. Shaffer, "Analysis of Pulse-Coded Particle Tracking Velocimetry Data," *IEEE International Conference on Pattern Recognition, Copenhagen, Denmark, September 1991.*

[64]F. Shaffer, M. Shahnam, M. Mathur, J. Edmann, H. Borovetz, R. Schaub and J. Woodard, "Particle Image Velocimetry on the Surfaces of a Pericardial Trileaflet Valve," *National Fluid Dynamics Congress, Los Angeles, California, June 22-25, 1992.*

[65]J. Woodard, F. Shaffer, R. Schaub, L. Lund, H. Borovetz and J. Antaki, "Flow Visualization of the Novacor Left Ventricular System," *Cardiovascular Science and Technology Conference, Bethesda, Maryland, December 2-4, 1991.*

Optics,[66] and an International Conference on Mechanics of Two-Phase Flows.[67]

Technology and Applications

In order to study the flow of coal-based fuels, FETC scientists developed a Flow Analysis Laboratory. This work was headed by Mr. Shaffer, who eventually patented a flow imaging technique called Fluorescent Image Tracking Velocimetry (FITV). Part of that system is the accompanying computer software. The FITV system uses pulsed-laser light to excite microscopic, fluorescently dyed particles that are added to a fluid. The fluorescent emission of the particles is viewed with digital photography, making the flow visible and measurable. With multiple exposure photography, the particles are tracked, thus revealing the motion of a fluid. This data is then used to measure flow properties such as velocities, streamlines, and shear stresses.

These same techniques, once refined, were applied to blood flow, coded according to pulse and measured in the same way. Low blood flow velocities near surfaces can promote blood clotting, the nemesis of artificial hearts. FITV allows researchers to identify and eliminate areas of low blood flow velocities. Once some initial problems were overcome, it was the first time blood flow was visualized and measured on the internal surface of an artificial heart.

The Laboratory

The Pittsburgh Energy Technology Center consolidated, effective December 1996, with Morgantown Energy Technology Center in West Virginia to become the Federal Energy Technology Center with two “campuses.” The subject of this case is the FETC laboratory in Pittsburgh, Pennsylvania, with over three hundred researchers specializing in coal and liquid fuels. It has been a major DOE single-program laboratory for over fifty years. Unlike many of DOE’s major laboratories, it is government-operated rather than contractor- or university-operated. FETC is actually located in a suburb south of Pittsburgh, sharing over 200 acres with the Bureau of Mines and the Mine Safety and Health Administration (which is part of the Department of Labor). The site is the nation’s largest federal research complex focused on coal. FETC’s budget is over $175 million per year.

University Involvement

About ten to twenty organizations in the health care field produce artificial hearts, including Baxter Healthcare, which created an artificial heart pump called the “Left Ventricular

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[66] E. R. Ramer and F. D. Shaffer, “Automated Analysis of Multiple Pulse Particle Image Velocimetry Data,” *Journal of Applied Optics* (November): 1991.

[67] F. D. Shaffer and E. R. Ramer, “Pulsed-Laser Imaging of Particle-Wall Collisions,” *International Conference on the Mechanics of Two-Phase Flows, Taipei, Taiwan, June 1989.*

Assist Device" (LVAD). Novacor Laboratory in Oakland, California (eventually bought out by Baxter Healthcare) designed the pump. It is now manufactured by the Baxter Healthcare Novacor Division.

The Baxter LVAD was approved by the FDA for clinical testing; therefore, the Baxter laboratory is testing the pump at Presbyterian-University Hospital associated with the University of Pittsburgh in Pennsylvania, at Stanford University's Falk Cardiovascular Research Center in California, and at St. Louis University in Missouri. The Baxter LVAD is also being tested extensively in Europe where regulations are less stringent than in the United States.

In their efforts to perform the FDA clinical trials, Presbyterian-University Hospital and the University of Pittsburgh's School of Medicine felt they did not have the proper blood flow analysis techniques they needed. Therefore, Dr. Harvey Borovetz, professor of surgery and director of biomedical engineering approached the (then) Pittsburgh Energy Technology Center to request assistance with measuring and analyzing the flow of blood through the LVAD heart pumps.

Since FETC has a well-funded Flow Analysis Laboratory, it made sense to try to apply a flow analysis technique, which is normally used to analyze the flow of fuel through pipes, to analyzing the flow of blood through an artificial heart pump. In explaining the technology, FETC ORTA officer Kay Downey noted that, in terms of this application, blood clots are like slurries.[68]

Funding, Financing

Because this was one of DOE/FETC's first CRADAs, the agency was not sure how to handle the receipt of private industry funds when Baxter offered it; therefore, this particular CRADA and the follow-on CRADA did not involve private funds. The equipment from Presbyterian-University Hospital and Baxter set up at FETC was valued at $500,000.

Intellectual Property

A patent was issued to DOE for the blood flow analysis technique. Frank Shaffer is listed as the inventor. Also, Baxter Healthcare has a new patent on its LVAD.

Technology Transfer Mechanisms

In order to cooperatively test the heart pump, the group of pump designers and testers signed a multiple-partner CRADA with FETC. Partners in the CRADA are FETC, Presbyterian-University Hospital, and the University of Pittsburgh's Schools of Medicine and Engineering. Baxter Healthcare was not an official CRADA partner, but worked in the laboratory under the

[68]Conversation with Ms. Downey.

auspices of the University of Pittsburgh. The LVAD and a cardiac simulation flow loop were set up at FETC's facility. Up to six researchers at a time from the hospital and from Baxter worked in the FETC laboratory for about three months. To accommodate Baxter's extensive needs, an FITV system was set up at Baxter's laboratory in California. Eventually, FETC-like systems were set up at each of the LVAD testing centers.

User Groups

The ultimate users of artificial heart pumps are critically ill patients with heart diseases. Using a heart pump bridges the time gap between heart failure and transplant of a donor heart. This allows a certain number of patients to lead productive lives, although many do not survive until a heart is available.

The intermediate users of the heart pumps are the health care organizations that make use of them in their practices. Mr. Shaffer said, however, that the market is small since there are only ten to twenty health care companies in the world making artificial hearts. Although the market is small, most heart pump manufacturers are now using this technology.

Other Factors

The FLC nomination form notes an interesting point, and that is that this case "represents technology transfer in its finest sense, because it embodies the application of technology from one discipline, fundamental engineering in fossil fuels, to a quite different one -- medical technology." Every year, some 30,000 to 50,000 patients wait for heart transplants, yet only about 2,000 donor hearts are available each year; therefore, speed of development was critical in this case.

User Benefits/Economic Impact/Outcomes

The CRADA proved to be helpful, and certain medical constraints were overcome because of FETC's FITV system. The test data allowed the researchers to experiment with various blood pressures and rates for the artificial heart pump hooked up at FETC. Ultimately, they tested it on patients with artificial hearts at the hospital. Data from the FETC research contributed to patient management, transplant operation techniques, and heart pump redesign. Of the three applications, pump redesign is the longest process.

When this CRADA began, the Baxter LVAD was approved by the FDA for testing under an "investigational device exemption," which involved limited clinical trials at certain clinical centers of excellence on human patients. Through the clinical testing, it was revealed that blood clotting in the LVAD was a serious problem and that the measurement methods being used by Baxter were inadequate. Through the work with FETC and the use of FITV, the Novacor LVAD was redesigned to eliminate the clotting problem. The new design then had to go through eighteen months of animal testing and finally was approved for clinical use in 1995. It was approved for investigational testing again in April 1996.

It was quickly apparent that the application of fuel flow analyses to artificial hearts was successful. In fact, it was so immediate that the CRADA was amended early-on to include measurements of hemodynamics in an artificial lung invented by a University of Pittsburgh heart surgeon, Dr. Brack Hattler. The Hattler artificial lung "oxygenator" consists of a pump surrounded by fibers that release oxygen into the blood stream. Like the artificial heart, the artificial lung was also set up in FETC's laboratory. A progression from the animal testing phase to clinical tests occurred around 1993, and the measurements have been successful.

The Pittsburgh hospital was very pleased with the CRADA work jointly performed with FETC. Dr. Borovetz[69] at the School of Medicine noted that this satisfaction stemmed from several factors. For one thing, they had access to expensive equipment that the university wouldn't have been able to afford. But more importantly, he added, "All that equipment wouldn't have meant anything if it weren't for the Frank Shaffers of the world." He said the project would not have succeeded without Mr. Shaffer at the laboratory helping. As a result of Mr. Shaffer's involvement, it was a "big winner," resulting in a superior pump, which Mr. Borovetz claims has been one of the high points of his career. Mr. Shaffer was willing to be a true partner, not just show them the equipment, he said.

The CRADA-related work in the Baxter laboratory is still active and has a high priority. Baxter Healthcare has made some money on the device overseas, but will not realize revenues in the United States until they can overcome all the regulatory hurdles and sell it on the open market. Each state-of-the-art blood pump costs $80,000. In any case, profits are difficult to measure because the tremendous development effort has cost many millions of dollars.

More recently, the FETC analysis technique was applied to the development of other artificial organs. Now most of the companies around the world researching artificial organs use the flow analysis technique and have facilities that duplicate the original FETC facility. This includes laboratories in Europe, Australia, and Korea.

International Activity

Baxter Healthcare's widest application of their LVAD is now in Europe (England, France, and Germany), where FDA approvals are not relevant. In Europe, the Baxter LVAD is being used not only as a bridge to transplant, but it is also being permanently implanted in older patients who are not good candidates for heart transplants.

[69] Interview with Dr. Borovetz, September 16, 1996.

Government Gains

The FETC flow analysis technology continues to progress and is benefitting from the input of researchers in the medical field. The imaging technology is also used in research being done in other laboratories within FETC.

Economic Development

None.

Elapsed Time

The early jointly authored scientific papers were published from 1989 to 1992. The original CRADA was signed in January 1991. The term of duration was five years (to January 1996). This CRADA, now expired, was followed up by a new CRADA to extend the FITV technique with a small fiber-optic line that will be used to identify and measure blood and cancer cells.

POST-LEGISLATION FINDINGS SUMMARY

Appendix D summarizes the findings for each of the selected post-legislation cases organized according to the questions addressed in the interviews. They appear in Appendix D after the pre-legislation summary. Whereas, the earlier Level II analysis (appearing in this chapter as the introduction) addressed only certain key questions for the seventeen FLC awardees for the years 1992 and 1993, the appendix addresses all of the questions for the selected cases documented in this chapter using the same order as is used for the "Pre-Legislation Findings." The responses to the "Other Factors" question are incorporated into the next chapter. In the appendix, the cases are presented under each topic in the following order:

a. Laser Method to Light Samples
b. Voice Coder
c. Paper Quality Tester
d. Variable-Frequency Microwave Oven
e. Gravity Meter
f. Oatrim Fat Substitute
g. Chemiluminescent Light Stick
h. Artificial Heart Blood Flow Analysis.

The next chapter compares the findings from the cases in the pre-legislation and post-legislation time frames.