

# Fourth Annual U.S. Small Business Administration 1999 Tibbetts Awards

*...recognizing SBIR technological innovation, economic impact and  
business achievements*

Congratulations to the following **NIH SBIR awardees** who were recipients of the 1999 Tibbetts Awards! These prestigious, national awards, named for Roland Tibbetts, a former SBIR Program Manager who is acknowledged as "founding father of the SBIR Program," are made annually to those small firms, projects, organizations and individuals judged to exemplify the very best in SBIR achievement. The Tibbetts Awards are an initiative of the Office of Advocacy in the US Small Business Administration (SBA) now managed through the Office of Technology. A full list of winners is available electronically at <http://www.sba.gov/sbir/tibbetts/toc.html>

## **Beneficial Designs, Inc.**

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The Small Business Innovation Research (SBIR) program not only helps mankind explore the challenges of outer space; it also helps challenged individuals explore outdoor space. **Beneficial Designs, Inc.**, a small firm in Santa Cruz, CA is opening the out-of-doors for persons with mobility limitations and improving trail information for people of all abilities.

During a 1990 National Council on Disability hearing, **Peter Axelson**, the Director of Research and Development for **Beneficial Designs**, heard comments from several people with disabilities who wanted to access the outdoors but didn't wish to "pave the wilderness." The main obstacle people face in outdoor environments is not a lack of access - but rather a lack of information.

With a 1993 Phase I SBIR grant from the **National Institutes of Health**, Beneficial Designs began research with the goal of providing universal access information about recreation trails. "We recognized right away that we shouldn't be focusing on developing 'special' data for people with disabilities. Hikers of all abilities were interested in the information provided in our trail guides," said Axelson.

A 1994 **NIH** award enabled Beneficial Designs to develop the **Universal Trail Assessment Process (UTAP)**, a tool for trail managers and agencies to inventory their trails for maintenance and accessibility conditions. Trail data can be processed and summarized to obtain typical and maximum grades and cross slopes, minimum widths, surface types, and magnitude and location of obstacles. Termed **Trail Access Information (TAI)**, this data can be presented in signage, maps, guidebooks, audiocassettes, or computerized trail guide formats. TAI can assist individuals in making informed choices about the trails they plan to use and obtain any

necessary assistance or equipment needed to negotiate the trail safely and successfully.

Beneficial Designs is currently working on **TrailWare** software for processing data and developing **TAI** into signage and maps. Trail assessment coordinators are trained through UTAP workshops and a 1999 USDA award has enabled Beneficial Designs to begin developing a program for training UTAP master trainers.

In 1994, Beneficial Designs developed **Interactive Computer Information Trail Guides**, a program that can quickly search a database for trails that match the characteristics desired by the user, and then display access data, maps, text and scenic images for each trail found.

More recently, Beneficial Designs received a 1997 Phase I award from the **U.S. Department of Education** to develop a prototype searchable "**Trail Explorer**" database of trail access information. This prototype led to a Phase II award to further develop and build this Web site in collaboration with federal, state and local trail managers to standardize trail information. The **Trail Explorer Web site** will provide information on public lands with accessibility data on numerous individual trails. This product will enable trail users to make more informed decisions about which public lands to visit and which trails better meet their interests and abilities. It will be especially useful for individuals with disabilities, older adults, parents with young children, and novice hikers. It is scheduled for completion by June 2000.

These trails related projects exposed the need for a method to assess the accessibility of trail surfaces. Through an NIH award, Beneficial Designs has been developing **portable tools for objectively measuring the firmness and stability of ground and floor surfaces**. This work has resulted in a national standard for playground surface accessibility and the development of a national standard for ground and floor surfaces has been initiated.

**NIH awards** have also enabled Beneficial Designs to create improved seating and mobility technologies for wheelchair users. Through the development and evaluation of the **FlexRim Low Impact Wheelchair Pushrim**, Beneficial Designs has found a way to lower the impact forces experienced by wheelchair users during propulsion. The **Back Support Shaping System** was designed to adjust to the different activities of the wheelchair user. This system is now being manufactured by PinDot Products by Invacare Corporation as the PaxBac. Beneficial Designs has also developed the **HipGrip Pelvic Stabilization Device**, which consists of contoured pads that "grip" the pelvis and provide a stable base of support from which to perform functional tasks. A **Universal Canoe Seating System** is being developed as well to provide persons who have limited sitting balance additional pelvic and back support for better comfort and stability and increased paddling efficiency.

#### **National Institutes of Health Awards**

Computerized Mapping of Trails for Accessibility	(HD29992)
Trail Data Processing Software (TrailWare)	(HD36538)
Measurement of Surface Characteristics for Accessibility	(HD30979)
FlexRim Low Impact Wheelchair Pushrim	(HD36533)
Back Support Shaping System for Wheelchairs	(HD29983)
HipGrip Pelvic Stabilization Device for Wheelchair Users	(HD36156)
A Universal Canoe Seating System	(HD36944)
Quantitative Hand Strength Assessment Devices	(HD33940)

#### **USDA Awards**

Training Program for Universal Trail Assessment Process Master Trainers  
(99-33610-7523)

**US Dept of Education Awards**

Interactive Computer Information Trail Guides for Universal Access  
(RA94129011, RW95170006)

Trails Web Site with Universal Access Information  
(RW97076011, ED-98-CO-0046)

## **Decision Systems, Inc.**

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**DECISION SYSTEMS** Through its product development, Decision Systems has responded to two national goals. First, a critical goal of Healthy People 2000 and Healthy People 2010 is to improve the adherence of people to medical regimens (e.g., prescription medication adherence and medical appointment adherence). Second, in 1988 the United Nations General Assembly designated the 1990s as the Decade of Natural Disaster Reduction. The products developed by Decision Systems, using SBIR funding, address both of these goals.

**HEALTH CARE** With SBIR funding, Decision Systems developed and clinically validate **TeleMinder** a micro-computer-based automated telephone messaging system designed to improve patients' health care services. First, it is used to telephone and remind patients of a) upcoming appointments, b) preventive healthcare activities such as influenza vaccines, and c) cancer early detection tests. Second, it is used in health management to monitor and preemptively treat complications associated with: a) chronic illness, such as hypertension and diabetes, b) outpatient recovery after surgery, and c) adverse reactions to new medications. Finally, TeleMinder is used to automate lab results reporting.

**DISASTER AND EMERGENCY MANAGEMENT** A third Phase I SBIR Grant, called **Community Voice Mail for Routine and Disaster Services** was awarded to Decision Systems in 1992. The purpose of this grant was to develop a rapid response, high call-volume, automated voice messaging system called TeleMinder-MAPs. An important aspect of this system is that it displays a map of the community. Users outline areas on the map and then automatically telephone community members in these areas. TeleMinder-MAPs was designed for fire, police, and sheriffs' offices.

As an emergency fire and OES response tool, TeleMinder is designed to: a) notify and evacuate citizens prior to or during a disaster, b) monitor the status and provide instructions to large numbers of citizens during an emergency or disaster, c) coordinate follow up services after a disaster, and d) routinely monitor the well being of citizens who are homebound. As an emergency response tool in law enforcement, TeleMinder is designed to serve as a crime prevention and crime-solving tool. Law enforcement use it to notify residents and businesses of ongoing crimes such as bomb threats, shootings, and crime sprees in their area and to give them instructions to avoid becoming victims. TeleMinder-MAPs is used to "canvas" crime affected areas and asks residents and business for help in apprehending criminals.

In routine, day-to-day use, TeleMinder is used by police departments to: a) provide community voice bulletin boards to answer frequently asked questions, b) automate staff briefings, c) maintain close communication with Neighborhood Watch Programs, and d) routinely phone senior citizens and shut-ins to make sure they are okay. District Attorneys Offices use it to contact and either confirm or cancel scheduled court appearances of defendants, police, witnesses, and jurors. Fire departments routinely use TeleMinder to a) advise citizens of fire hazards, b) direct

disposal of toxic materials, c) announce clean-up programs, and d) maintain O.E.S./volunteer personnel and equipment preparedness.

**National Institutes of Health Awards**

Community Voice Mail For Routine and Disaster Services (AG10659)

## **Thermogen, Inc.**

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ThermoGen, Inc. is an international supplier of stable enzyme biocatalysts and biotransformation processes for pharmaceutical, agrochemical, specialty chemical and pharmaceutical intermediate markets. The Company was founded in 1988 by Dr. David Demirjian (President) and Dr. Malcolm Casadaban (University of Chicago) based on the concept of creating stable enzymes for industrial applications.

ThermoGen has received SBIR support from the **National Institutes of Health (NIGMS, NIDDK, NCI, NHLBI)**, the National Science Foundation, and the Department of the Army to pioneer technologies that are now key in the industry. The firm prospects for enzymes and uses accelerated evolution to enhance them. Custom enzyme discovery and implementation tools include proprietary enzyme libraries and gene banks, biocatalyst engineering and evolution systems (such as ThermoGenetic stabilization and ThermoFusion systems), and methods for rapid enzyme/mutant screening and process optimization. Patents have been allowed for ThermoGen's esterase collection, directed evolution systems and *Thermus* expression system.

The fine chemicals industry is now reaping the results of highly directed research efforts in biocatalysis. ThermoGen is a "trailblazer" (Chemical Engineering, July 1998) in biotransformation development; biocatalyst discovery, and has established new methods of screening enzymes and evolving proteins. These diverse catalysts are stable and effective.

ThermoGen was formed with funding support from the SBIR program. Today the Company has leveraged this investment and successfully commercialized the technology in several industries. Growth is expected to continue in chemical applications (such as fine and pharmaceutical intermediates) and commodity enzyme markets (such as food, Ag, and textile enzymes). Of key importance, the field of chiral drugs has undergone fundamental change. The most telling change is the maturity of a whole generation of single-isomer chiral drugs coming off patent. ThermoGen is a leading innovator in enzyme technology for chiral compounds with its ThermoCat® enzymes and screening kits for esterases and alcohol dehydrogenases. ThermoGen sees rapid discovery and accelerated evolution of industrial enzymes changing the way business will be conducted in the future. ThermoGen has reduced the time required to develop a complex biocatalyst from two years to six months with new improvements imminent.

### **National Institutes of Health Awards**

Thermophilic Enzymes Accessed Via <i>Thermus</i> Genome	(CA 81578)
In Vivo Protein Engineering System	(CA 62646)
<i>Thermus</i> Expression System	(GM 52228)
Thermophilic Gene Transfer System	(GM 43039)
Transposon based tools for Thermophilic Organisms	(GM 46600)
Thermostable Enzymes Via <i>Thermus</i> Genome Sequencing	(HG 01671)
Thermostable Esterases and Lipases	(HL 57773)
Hyperbilirubinemia Treatment with Cloned Thermo-Enzymes	(HD 26225)

## **Bioanalytical Systems, Inc.**

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Bioanalytical Systems, Inc. (BAS) is a leading manufacturer of specialized instrumentation and accessories for liquid chromatography, in vivo sampling (microdialysis and ultrafiltration), and electrochemistry. BAS products have been well received in drug metabolism research, pharmacokinetics studies, and pharmaceutical analysis. A new division called BAS Analytics was formed in 1991 to offer customized contract Bioanalytical services to the pharmaceutical industry. Bioanalytical Systems, Inc.'s goal to have a 50:50 mix between product sales and contract services was achieved two years ahead of schedule. Many of the world's top 25 pharmaceutical manufacturers are BAS customers.

Bioanalytical Systems, Inc.'s instruments are used in research laboratories worldwide to carryout neuroscience research, environmental research, pharmaceutical research, clinical chemistry, and forensic science. In addition to its West Lafayette headquarters, BAS has offices in Lawrence, Kansas; Mahwah, New Jersey; State College, Pennsylvania; and also operates facilities in the United Kingdom.

### **Economic Impact**

BAS has received numerous SBIR grants over a 15-year period totaling \$3 million. Those grants have played a tremendous role in affording BAS the opportunity to take on some higher risk projects. Several of these have been exceedingly successful, resulting in the sales of millions of dollars worth of products to the research community around the world. BAS Analytics, the contract research arm of the company, grew out of the team assembled to complete SBIR projects. BAS Analytics has participated in the development of drugs now selling over \$10 billion/year from the largest pharmaceutical companies. BAS clients include Eli Lilly, Pfizer, Abbott, Glaxo Welcome, Roche, and others.

BAS has partnerships with Purdue University as well as the University of Kansas, both of which have involved SBIR projects. The company also sources many components from various sheet metal shops and machine shops in Indiana and it exports over 50% of its products. BAS is actively engaged in studies devoted to central nervous system diseases, diabetes, cancer, and AIDS and is participating in several global clinical trials associated with these diseases.

Prof. Peter Kissinger, CEO of BAS, stated that "The SBIR program has been a great way to leverage our considerable talents. We have always doubled or tripled the Federal support to complete projects and bring them to market, but those initial unencumbered grant dollars enabled us to take bold steps that we might have otherwise been reluctant to take as a small business. We compete with giants by approaching niche markets and unique technologies, which typically are ignored by the large companies. The key has been to attract talent. Postdocs [Post-Doctoral students] we have brought in on SBIR grants years ago are now among our most valuable professionals."

### **National Institutes of Health Awards**

Separation-Based Biosensor for Pharmaceutical Applications	(GM 52272)
Mercury Thread Electrode for Determining Lead in Blood	(ES 06991)
Rational Development of Derivatization reagents—LC-EC	(GM 55446)
Ultrafiltration Probes for Leptin and Cytokine Research	(DK 54592)

## **Science and Engineering Services, Inc.**

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Dr. Hyo Sang Lee received his bachelor's degree in Physics from Seoul National University in 1970, his Master's and Ph.D. degrees in from Lehigh University in 1976 and 1980 respectively. He is an expert in the area of lasers and electro-optical system development, medical optics and lidar remote sensing. He has "hands-on" experience in organizing and managing a firm from formation through a decade of developmental stage growth. Dr. Lee has extensive experience in multi-disciplinary R&D program management and worked on electro-optics instrumentation, optical system development and scientific research. In particular, his innovation and involvement with the pseudo-random modulation (PRM) correlation technique is unique. He is the inventor and sole researcher for PRM technology in conjunction with the near IR noninvasive tissue diagnosis. He has been the principal investigator on a number of SBIR programs for **NIH**, NASA, DoD, and NSF in the development of a unique PRM lidar system and unique solid state laser systems for space applications and differential absorption lidar (DIAL) measurements. Currently, he is leading programs to develop a various electro optics sensors for medical applications as well as atmospheric remote sensing. He is well experienced in the development of tunable solid state laser systems based on alexandrite and LiSAF crystals. He worked on various NASA programs as a laser scientist for high altitude airborne flight laser development. He has participated in airborne lidar measurement of atmospheric pressure and temperature. In addition, he was involved with detector response characterization and airborne lidar system development. He has been a consultant on the high altitude sounding of atmospheric temperature and ozone, multi-beam microwave altimeter development, and MARS lidar altimeter system link analysis and performance modeling. At present, he is the President and CEO of Science & Engineering Services, Inc. in Burtonsville, Maryland.

### **National Institutes of Health Awards**

Tunable IR Laser Mass Spectrometer for DNA Analysis	(GM 53885)
IR MALDI Ion Trap Mass Spectrometer for DNA Analysis	(HG 01968)
Noninvasive Photoacoustic Intracranial Pressure Monitor	(NS 37275)
Clinical Test of NIR/PRM Sensor for Head Injury Diagnosis	(NS 38394)
Compact LISAF Laser Multiphoton Fluorescence Microscope	(RR 13091)



## **Microwave Medical Systems, Inc.**

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Microwave Medical Systems, Inc. ("MMS") is a development-stage company that conceives, designs and manufactures medical devices. All of these devices use microwave technology. Microwaves can be used to generate heat, measure and monitor temperature, and measure motion. Combining these capabilities with proprietary software, MMS has developed products that are unique in their ability to heat blood, fluid or tissue to a specified temperature and to maintain that temperature at a consistent level. MMS was founded by Kenneth L. Carr. Prior to the founding of MMS, Dr. Carr was the Technical Director and Group Vice President of M/A-COM, Inc.

MMS has successfully qualified for and received 16 SBIR Phase I and 11 Phase II grants. These grants have enabled the Company to develop its technology, apply for and receive FDA permission to market five of its resultant products, and launch its first products into the marketplace. Without the support of the SBIR Program, this would not have been possible.

The first of these products is the **ThermoStat 900 IV Fluid and Blood Warmer**, used by trauma teams and physicians when a patient needs infusions of high volumes of fluid or blood. This product represents the first time passive microwave radiometry has been employed to noninvasively measure and control the temperature of fluids in motion.

In 1995, the Massachusetts Technology Collaborative (MTC) recognized MMS for "Exemplary Performance in the Development and Commercialization of Technology through the Federal Small Business Innovation Program."

In 1996, the U.S. Army Medical Research and Materiel Command selected MMS as its Army *Success Story* for its contributions in critical patient care. The *Success Story* is presented in their publication entitled "Creating Tomorrow's History."

MMS's portfolio of patented products and processes is extensive and continually expanding.

### **National Institutes of Health Awards**

Microwave Device for Myocardial Ablation	(HL 46580)
Microwave Device for Detecting Air Emboli	(CA 52345)
Controlled Intracavitary Prostate Cancer Hyperthermia	(CA 61404)
Thermal Characterization of Human Breast Tumors	(CA 73261)
Microwave Sterilizer for CAPD Connector	(DK 38242)
Early Detection of Neonatal & Pediatric Extravasations	(HD 29994)

## **AVANT Immunotherapeutics, Inc.**

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AVANT Immunotherapeutics has used the SBIR program to **advance a revolutionary vaccine, designed to prevent or treat atherosclerosis**, into clinical trials. This vaccine has the potential to enhance the management of this disease, and reduce the cost of such treatment.

Atherosclerosis is a progressive condition leading to arterial blockage and reduced blood flow. Clinical manifestations of the disease include many forms of cardiovascular disease, the number one cause of death in the United States, including heart attack, stroke, and peripheral vascular disease. Atherosclerosis can also contribute to other conditions such as hypertension and chronic kidney failure. While a high level of low-density lipoprotein (LDL, "bad cholesterol") is a key risk factor for developing atherosclerosis, a high level of high-density lipoprotein (HDL, "good cholesterol") has been shown to be protective. Some individuals with atherogenic cholesterol levels will be given one of the daily cholesterol-lowering drugs called statins. While these drugs do provide some reduction in the risk of developing or advancing atherosclerosis, their use is limited due to the high annual cost for lifetime treatment and compliance problems. In addition, while these drugs lower LDL they only marginally raise HDL.

Understanding that there was a large unmet need in the management of atherosclerosis, scientists at AVANT undertook a program to combat the disease by modifying the relative levels of cholesterol carried by LDL and HDL in the blood. A molecule, called Cholesteryl Ester Transfer Protein, or CETP, mediates the movement of cholesterol from HDL to LDL. It was reasoned if this protein was inhibited less atherogenic cholesterol levels might be achieved, and in particular HDL levels might be raised. A novel strategy proposed by AVANT scientists was to make a vaccine that would result in the inhibition of CETP. This vaccine approach, since it might only need to be administered once every several months, would have a significantly reduced cost, compared to once-a-day pills, and would likely have fewer compliance problems. Further, with a reduced cost of treatment, patients that were not considered to be at sufficient risk to warrant the cost of a statin prescription, may be eligible to be given this vaccine. This ability to justify early intervention alone might result in a significantly decreased or delayed incidence of clinical atherosclerosis in the United States.

AVANT Immunotherapeutics applied for, and received, SBIR funds to help finance experiments demonstrating the feasibility of this vaccine concept. Following the success of those early experiments, significant additional work was done with this vaccine, both in research and development, and it has now entered into Phase I clinical trials. If clinical trials are successful, this vaccine has the potential to greatly enhance the clinical management of atherosclerosis.

### **National Institutes of Health Awards**

Peptide Vaccine to Prevent/Treat Atherosclerosis

(HL 59122)

## **Evening Star Productions**

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Evening Star Productions is a television and video production company that develops commercial programs and projects that have social significance. The three underserved markets that are targeted include: 1) entertainment and educational programs for older adults, caregivers, and children; 2) health care promotion and risk reduction programs for older adults and caregivers; and 3) promotion, education, and information programs for Baby Boomers, eldercare programs for employers, and corporations interested in targeting the rapidly growing 50+ market.

Evening Star has developed many Small Business Innovative Research (SBIR) multimedia projects and projects funded by corporations, private foundations, and **The Department of Health and Human Services**. The company also provides strategic development planning to Procter & Gamble, MetroHealth Medical Center, the Rock and Roll Hall of Fame and Museum, and many other major corporations.

Commercialized SBIR projects include the nationally distributed thirty-minute television program, Changes, for older adults hosted by Nick Clooney airing on the new FOX Health Network. Another is the award-winning television program and video series **Living Well: A Guide to Healthy Aging**. This program airs on PBS and the FOX Health Network. The five part video and print series is sold on QVC, Borders Books and Music, and other outlets. This product is endorsed by and promoted with the American Society on Aging, OASIS, The United Nations International Year of the Older Adult, the Alliance for Aging Research, and many other aging and disease organizations. Living Well recently received a Bronze Award at The National Mature Media Awards, co-sponsored by the National Associations of the Area Agencies on Aging. Another SBIR project, **Geezbo's Alley**, was the first multimedia Fast-Track SBIR funded by the **National Cancer Institute**. This show was directed by the Director of the After-School specials and developed with The Rock and Roll Hall of Fame and Museum and Bob Keeshan, "Captain Kangaroo".

Other television programs produced and developed by Evening Star include The Appalachians, a 4 hour PBS documentary film, CD, and book, and Web site; Executive Producer of Manny's Music Mecca, a series of children's health promotion television programs; Executive Producer of John Glenn: The Third Age Begins Now for The United Nations International Year of the Older Adult; Executive Producer Integrative Medicine:Body, Mind, and Spirit hosted by Naomi Judd, a thirteen week series and one-hour documentary on The America's Health Network and The FOX Health Network, and the documentary Standing in the Safety Zone narrated by the US Surgeon General.

### **National Institutes of Health Awards**

Developing Video and Print Library of Healthy Aging Programs (AG 12080)  
Health Promotion for Children—Multimedia Music Programs (CA 75465)

## **YES Technologies (Yellowstone Environmental Science, Inc.)**

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Dr. Hunter and his co-inventors at YES have invented and patented technologies in a variety of fields that address important national needs. Examples of his technologies are:

**Datagator™** flow metering technology-Accurate metering of wastewater flows in aging sewers that experience infiltration of groundwater and inflow of storm water has challenged sewerage agencies for decades. This technology allows communities to focus maintenance and rehabilitation efforts on the portions of sewerage systems in greatest need. It also facilitates billing industries that discharge into those systems for their fair share of system costs. The technology was licensed to TN Technologies, a Baker Hughes/Thermo Electron subsidiary and, more recently, to Renaissance Instruments of Austin, TX, and is sold worldwide. In 1993, it won an R&D 100 Award as one of the year's 100 most technologically significant products.

Pipeline rehabilitation technology-This technology allows underground water, sewer and natural gas pipelines to be repaired in situ without excavation. It was sold to a pipeline rehabilitation contractor.

**WiseCap™** child resistant packaging technology-The need to reduce the frequency of childhood poisonings while allowing older adults access to their medications led to the development of the WiseCap technology. In 1992, it won an R&D 100 Award. The technology was licensed to Sandoz Pharmaceuticals (now Novartis) and is currently under evaluation by Comar, Inc., a major packaging manufacturer. BIC, the cigarette lighter manufacturer, has purchased child-resistant lighter designs from YES that are based on the principle. It has also been applied to "containment" of children in car seats.

Cyanide-free gold ore processing technologies-These biotechnologies are aimed at reducing the environmental impacts and perceived health risks of precious-metals ore processing. One technology is used to liberate precious metals from sulfidic ores or concentrates. A second is used to recover gold, silver and platinum-group metals. They have been licensed to a gold producer in the Philippines.

**Hazardous waste treatment/bioremediation technologies**-These are the first bioprocesses that allow mixed hazardous wastes that contain carcinogens like benzene (a component of many fuels) and trichloroethylene (TCE, an industrial solvent) to be removed from anoxic, contaminated groundwaters.

**Invention management software**-This patent-pending technology facilitates the process of obtaining information from inventors "just in time" to produce good management decisions and high-quality patents. Dr. Hunter uses the technology in his patent agent practice and YES is seeking licensees.

### **National Institutes of Health Awards**

Network Software for Invention Evaluation and Protection	(GM 50907)
Expert System for Recombinant DNA Invention Disclosure	(HL 58327)