TECHNOLOGY COMMERCIALIZATION

UNIVERSITY OF MARYLAND BALTIMORE

ANNUAL REPORT 2005

TECHNOLOGY COMMERCIALIZATION AT THE UNIVERSITY OF MARYLAND BALTIMORE

REPORT ON FY05 ACTIVITIES

The Office of Research and Development's Technology Commercialization Group (Tec-Com) is adding value to UMB's intellectual property (IP) position by:

- Expanding UMB's IP portfolio with a significant number of new invention disclosures.
- Protecting a greater percentage of inventions with patent applications and copyright and trademark registration.
- Increasing the number of active option and license agreements for UMB IP that could lead to future royalty streams for the University.

INTELLECTUAL PROPERTY: DISCLOSURES

In FY05, UMB researchers disclosed a record **118 new inventions** to Tec-Com – **a 70 percent increase** over the previous record-breaking 70 disclosures received in FY04. Of the 118 new inventions, 102 (86 percent) originated from the School of Medicine, seven from the School of Pharmacy and another seven from the Dental School. Two additional disclosures originated from University of Maryland Baltimore (UMB) administrative offices not specifically associated with any single UMB school.

NUMBER OF INVENTIONS IN FIVE YEARS: **357**

The 118 new disclosures reflect continued growth in UMB collaborations with other institutions and industry. More than one-third of the inventions were generated as a result of collaborations:

- 41 (one-third) involved at least one inventor from an institution other than UMB.
- Four were co-invented with companies.
- Three involved at least one non-UMB inventor AND at least one company inventor.
- Three resulted from collaborations between UMB Schools: two involving the School of Medicine and the Dental School and one involving the School of Medicine and the School of Nursing.

PROTECTING INTELLECTUAL PROPERTY

UMB's patent portfolio continues to expand. At the end of FY05, Tec-Com was managing a portfolio of **470 pending patent applications** and **240 issued patents**. Of the 710 total patents and patent applications, **307 (nearly half) are licensed** to at least one commercial partner. During FY05, **35 UMB patents** were issued and **four copyrights and/or trademarks** were registered with the U.S. Patent and Trademark Office:

- seven U.S. patents issued
- 28 foreign patents issued
- two copyrights registered
- two trademarks registered

140 PATENTS ISSUED IN FIVE YEARS

Profiles of the 35 patents, copyrights and trademarks are provided in Appendix A.

UMB filed **220 new patent applications and copyright and trademark registrations** during FY05:

- 89 provisional patent applications
- 36 U.S. utility patent applications
- 26 Patent Cooperation Treaty (PCT) patent applications
- 64 foreign country patent applications
- three copyright registrations
- two trademark registrations

705 PATENT APPLICATIONS FILED IN FIVE YEARS

Marketing UMB's Inventions

Industry outreach is a critical activity in ORD. In FY05, active marketing efforts to 640 companies resulted in **1,713 company interactions**. ORD works to cultivate industry interest in the portfolio of technologies available for licensing, opportunities for industry sponsored research and the prospect of a collaborative presence in the UMB BioPark.

In FY05, ORD's technology commercialization group initiated 24 meetings with new companies, all of which were valuable in establishing contacts and promoting UMB. Additional valuable outcomes include new licensing and collaboration agreements.

The portfolio of technologies available for licensing included **260 active technologies** as of June 30, 2005: 81 percent of these disclosures were developed by School of Medicine faculty. Each technology represents a novel approach to an unmet need in clinical or research settings.

Agreements in 2005

Fiscal Year 2005 was another record-breaking year for Tec-Com in agreements executed for UMB's intellectual property. A total of **30 license agreements** and **nine option agreements** were signed with a variety of industry partners. The licenses and options included both exclusive and nonexclusive agreements and covered 35 different UMB inventions.

IN FIVE YEARS:

- 47 royalty bearing licenses
- 25 non-royalty bearing licenses
- 15 stand-alone options
- 13 options via MTAs and/or SRAs
- One in-license
- 12 inter-institutional agreements
- One Memorandum of Understanding

Of the 30 license agreements, **19 were non-royalty bearing**. These licenses were free "click-wrap" licenses executed to allow hospitals immediate access to Dr. Vinay Vaidya's (School of Medicine, Department of Pediatrics) "Drug Concentration Optimizer" program. Tec-Com also entered into a royalty-bearing license agreement with HealthProlink, Inc., for the same technology. Going forward, HealthProlink will provide access to the program for hospitals and other users through commercial contracts and service agreements.

Highlights of recent royalty-bearing licenses:

- **Johns Hopkins University (JHU)** and the **Public Health Service (PHS/NIH)** entered into an Inter-institutional Agreement with UMB allowing JHU to license "Cross Linked Polymer Matrices and Methods of Making and Using Same," an invention that resulted from the collaboration of faculty at the three institutions.

- **Cartilix** licensed the rights to "Cross Linked Polymer Matrices and Methods of Making and Using Same" from JHU. Cartilix is a California start-up company dedicated to developing polymer materials that will regenerate cartilage. Initial disease applications include treatment of arthritic joints. The Cartilix polymers, designed and characterized at JHU, the NIH and UMB, are designed to provide a scaffold that promotes tissue regeneration by the patients' own stem cells.

- **Ortho Clinical Diagnostics**, a division of Johnson & Johnson, has licensed rights to "A Novel Antiproliferative Factor From Patients with Interstitial Cystitis," as well as a related patent application jointly owned with the National Cancer Institute. Ortho will fund developmental research in the lab of Dr. Susan Keay in the Department of Infectious Diseases, and commercialize a diagnostic test for interstitial cystitis (IC).

- A novel method for improving bioavailability of drugs has been exclusively licensed to **Xenoport**. Xenoport is a biotechnology company in California that specializes in conjugating drugs to molecules that are actively transported across the intestinal wall in order to improve drug absorption. The patent, "Bile Acid Containing Prodrugs With Enhanced Bioavailability," is currently pending, and was invented by Dr. James Polli and his colleagues in Pharmaceutical Sciences.

- "Engineered Proteins for Analyte Sensing" was invented by members of the Center for Fluorescence Spectroscopy in collaboration with UMBC and UMBI. It has been licensed to **Becton Dickinson and Company**. Commercial applications for this very broad patent will range from clinical diagnostics such as hospital-based blood testing to research applications sold through BD Biosciences Clontech.

- **Alba Therapeutics Corporation** is a Baltimore-based, biopharmaceutical start-up company that has licensed the intellectual property portfolio surrounding the "zonulin" pathway. Zonulin was discovered by Dr. Alessio Fasano and his group at the Mucosal Biology Research Center (MBRC). It is

an endogenous signaling pathway, which allows for the transient, reversible, physiologic opening and closing of tight junctions, at will. Alba has initiated drug development of the first lead candidate for treatment of celiac disease, and sponsored continued discovery research at the MBRC.

Profiles of the 11 royalty-bearing licenses as well as the nine option agreements are provided in Appendix B.

Appendix A -- UMB Issued Patents: FY05

Title	Country(ies) of Issuance	UMB Inventor(s)	UMB School(s)	UMB School(s)
Enterotoxins of Shigella flexneri 2A	Australia Germany France Great Britain	Fasano, Levine, Noriega, Nataro	Medicine	Medicine, Pediatrics, Center for Vaccine Development
Bioactive Glass Compositions and Methods of Treatment Using Bioactive Glass	South Korea	Litkowski, Hack	Dentistry	Restorative Dentistry
Method for Introducing and Expressing Genes in Animal Cells and Live Invasive Bacterial Vectors for Use in the Same	Japan	Hone, Powell, Lewis	Medicine	Medicine, Center for Vaccine Development
Low Frequency Modulation Sensors Using Nanosecond Fluorophores	United States	Lakowicz, Gryczynski	Medicine	Biochemistry
Cystine Knot Growth Factor Mutants	Australia	Weintraub, Szkudlinski	Medicine	Medicine
Isolation and Characterization of the csa Operon (ETEC-CS4 Pili) and Methods of Using Same	United States New Zealand	Altboum, Levine, Barry	Medicine	Medicine, Center for Vaccine Development
Plasmid Maintenance System for Antigen Delivery	Australia New Zealand	Galen	Medicine	Pediatrics, Center for Vaccine Development
Apparatuses and Methods for Performing Minimally Invasive Diagnostics and Surgical Procedures Inside of a Beating Heart	United States	Downing	Medicine	Surgery
Methods of Identifying Bacterial Genes Incompatible with Bacterial Pathogenicity and the Use of Such Genes as cadA to Reduce Pathogenicity in a Bacteria or to Combat Pathogenic Bacterial Infections	United States	Fasano	Medicine	Pediatrics
Helical Electron Beam Generating Device and Method of Use	United States	Ma	Medicine	Radiation Oncology
Breast Cancer Resistance Protein (BCRP) and the DNA Which Encodes It	Australia	Ross, Doyle, Abruzzo	Medicine	Medicine, Pathology
Novel C-4 Substituted Retinoids	Australia	Njar, Brodie, Nane	Medicine	Pharmacology & Experimental Therapeutics
Methods and Apparatuses for Evaluation of Contrast Agent Uptake Based on Parametric Images	United States	Beche	Medicine	Diagnostic Radiology
Cells Expressing Fusion Proteins of Immunoglobulins	United States	Scott, Zambidis	Medicine	Surgery, Microbiology & Immunology
Inducing Tolerance with with Tolergenic Fusion Proteins	*	Scott, Zambidis	Medicine	Surgery, Microbiology & Immunology
MOUTHPOWER	United States Trademark	Not applicable	UMB Dental Museum	Not applicable
EdgeTrack: Edge Extraction and Tracking Program	United States Copyright	Stone	Dentistry	Oral/Craniofacial Bio Science
Concentration Optimizer	United States Copyright	Vaidya	Medicine	Pediatrics
Get Fit Maryland	United States Trademark	Not applicable	Not applicable	Not applicable

* *The Countries of Issuance are Belgium, Switzerland, Germany, Denmark, Spain, France, Great Britain, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Austria*

Appendix B -- Profiles of Agreements Executed During FY05

Agreement Type	Company	UMB Inventor (s)	Department and/or Center	Technology
License	Alba Therapeutics, Inc.	Fasano and many others	Pediatrics	Zonulin portfolio
License	Xenoport, Inc.	Polli, Maeda, Coop, Lentz	Pharmaceutical Sciences	A Bile Acid Pro-drug Acyclovir
License	Hemerus Medical, Inc.	Hess	Pathology	Improved red blood cell storage solution
License	VMRD, Inc.	Dumler	Pathology	Method of Growing Rickettsiae in Ixodes Scapularies Tick Cell Culture & Preparing Antigens & Vaccines of Rickettsiae: Cloned genes of Ehrlichia equi and the agent of human granulocytic ehrlichiosis
License (amended)	Novamin Technology, Inc.	Litkowski, Hack	Restorative Dentistry	Prevention of Dental Sensitivity utilizing Bioactive Materials; Bioglass Toothpaste for Periodontal Disease
License	Ortho-Clinical Diagnostics, Inc.	Keay, Warren, Hise, Kleinberg	Medicine	A Low Molecular Weight, Heat Stable Antiproliferative Protein in Urine from Interstitial Cystitis Patients; Synthetic antiproliferative factor; An antiproliferative factor from interstitial cystitis patients in a novel frizzled 8 protein-related sialoglycopepetide
License	Becton, Dickinson & Company	Lakowicz, Tolosa, Eichhorn	Biochemistry	Engineered Proteins for Glucose Sensing
License	Zymed Laboratories	Kalvakolanau	Oncology	Identification and development of monoclonal antibodies against a novel anti-cancer protein, GRIM-19
License	Trophogen Incorporated	Weintraub, Szkudlinski	Medicine	Analogs of Cystine Knot Growth Factors; Mutants of Thyroid Stimulating Hormone and Method Based Thereon
License	HealthProlink, Inc.	Vaidya	Pediatrics	Concentration Optimizer
License	Cartilix, Inc.	Silverman	Surgery	Cross-linked Polymer Matrices and Methods for Making and Using Same
Option (2)	Thales Optem	Tang	Neurology	Spatial light modulators for fluorescence microscopy
Option	BBI	Barletta, Constantine, Edelman	Pathology	Development of immuno-PCR (IPCR) for the detection of ultra-low levels of prion protein in blood and tissues
Option	StemCo	Trisler, Bever, Goolsby	Neurology	CD34+ haematopoietic stem cell culture
Option	KMT Hepatech	Sacci, Azad	Microbiology and Immunology	Malarial animal model having a chimeric human liver
Option	Erimos Pharma	Khanna	Family Medicine	A new use for EM 1421 for the treatment of cervical dysplasia
Option	Protein Polymer Tech	Ghandehari, Hatefi	Pharmaceutical Sciences	Recombinant polymers for systemic gene delivery; Recombinant polymers for matrix-mediated gene delivery
Option	GloboAsia	Hoag, Qin	Pharmaceutical Sciences	Formulation of flavored slow-dissolving tablet of botanical extract from the dry flower and flower bud of Sophora japonica L. (Fam. Leguminose)
Option	Intradigm	Mixson	Pathology	Highly branched HK peptides are effective carries of siRNA