TECHNOLOGY COMMERCIALIZATION

AT THE UNIVERSITY OF MARYLAND, BALTIMORE

2003

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REPORT ON FY03 ACTIVITIES

OVERVIEW:

The transfer of technology to the marketplace and the protection of intellectual property created by UMB's entrepreneurial faculty continue to progress in FY03. The Office of Research and Development's (ORD) Technology Commercialization Group (TecCom) worked on behalf of faculty inventors to process 63 new invention disclosures, file 133 patent applications, and complete nine complex and important license agreements. Concerted efforts to obtain legal fee reimbursements from licensees resulted in more than $331,000 in revenues. Interactions with industry in the marketing of UMB technologies consisted of more than 1,000 contacts during the year. A detailed summary of activities follows.

In FY03, successfully executed agreements including:
34 confidential disclosures,
3 options, and 9 licenses.

Currently in negotiation:
15 licenses and 1 option agreement.

INTELLECTUAL PROPERTY: DISCLOSURES

In the last five years, UMB faculty have disclosed nearly 300 inventions to ORD, 63 invention reports were filed in FY03 alone, nearly all (59) from the School of Medicine. TecCom assesses each disclosure for protectability, technical merit, and commercial potential.

DISCLOSURES BY INVENTION CATEGORY:

Invention Category	Number of Disclosures	Percent of Total
Research Tools	21	34%
Therapeutics	14	22%
Medical Devices	13	21%
Diagnostics	4	6%
Drug Delivery	4	6%
Software	4	6%
Vaccines	2	3%
Dental Treatment	1	2%
Total	**63**	**100%**

DISCLOSURES BY PRINCIPAL INVESTIGATOR'S DEPARTMENT

PI's Department	PI's School	Number of Disclosures
Biochemistry	Medicine	20
Other	*see below**	9
Neurology	Medicine	7
Epidemiology	Medicine	5
Diagnostic Radiology	Medicine	4
Surgery	Medicine	4
Pediatrics	Medicine	3
Radiation Oncology	Medicine	3
Anatomy	Medicine	2
Anesthesiology	Medicine	2
Medicine	Medicine	2
Oral Health	Dental	2
Total		**63**

* One disclosure each from Microbiology, Obstetrics/Gynecology, Pathology, Physical Therapy, Physiology, Oncology, and Psychiatry in the School of Medicine, and Oral/Craniofacial in the Dental School, and Pharmaceutical Sciences in the School of Pharmacy.

Intellectual Property: Patent, Copyright, and Trademark Activity

The level of activity in filing applications rose significantly this year, with 133 filings completed, including 47 provisionals, 22 utility applications, 53 foreign country applications, eight Patent Cooperation Treaty applications (PCTs), as well as three copyrights.

In FY03, 18 patents were issued on UMB technologies, a number that will continue to build as FY04 unfolds. In addition, UMB also received a registered trademark for "Castix" for use in conjunction with dental casts used or sold in conjunction with dental articulators and components and accessories. With the addition of these most recent patents, the total number of issued patents on UMB intellectual property is 141.

FILED AND ISSUED FY02 -FY03

	Applications Filed in FY02	Applications Filed in FY03	Issued in FY02	Issued in FY03
Provisional	28	47	0	0
Non-Provisional/U.S.	14	22	7	7
PCT	15	8	0	0
Foreign Country	19	53	6	11
Copyright	6	3	5	0
Trademark	1	0	0	1
Total	**83**	**133**	**18**	**19**

See Appendix A for a list and summary of all issued patents in FY03.

Scientific Review Committee

The Scientific Review Committee (SRC) assists in evaluating and advancing the R & D aspects of UMB invention disclosures by:

— Assessing the merits and validity of the scientific basis of a given invention.

— Identifying important potential applications, uses, and indications relevant to the invention.

— Identifying potential competition from other technologies or other researchers that could affect the marketability of the invention.

— Identifying potential sources of funding and collaboration opportunities.

Because TecCom routinely files provisional patent applications on almost all newly disclosed inventions, the SRC's efforts center on the scientific development of inventions facing the following deadlines:

— Conversion of a provisional patent application to a non-provisional U.S. or PCT application and, subsequently,

— Entering National Phase (filings in individual foreign countries) from a PCT application.

Inventors provide overviews of their inventions and the related R & D activities. Each presentation is directed toward: defining the invention; showing critical data and results that led to it; outlining the strategy for further development; and reviewing the time, resources, and funding required to advance the invention. Each presentation is followed by a discussion session to identify potential hurdles, opportunities, and unanswered questions that may be important for successful development of the invention.

The SRC reviews approximately 50 inventions per year. SRC input is a key part of TecCom's overall technology development and evaluation procedure.

SRC ACTIVE MEMBERS (JUNE 30, 2003)

Name	Title	Department or Center	School
Howard B. Dickler, MD	Associate Dean	Research and Graduate Studies	Medicine
Renty B. Franklin, PhD	Professor	Oral and Craniofacial Biological Sciences	Dental
Alexander D. MacKerell, PhD	Associate Professor	Pharmaceutical Sciences	Pharmacy
John J. Sauk, DDS	Assistant Dean and Chair	Oral and Maxillofacial Pathology *(as of 7/1/03, Diagnostic Sciences and Pathology)*	Dental
John W. Warren, MD	Professor	Division of Infectious Disease	Medicine
Steven S. Wasserman, PhD	Associate Professor	Center for Vaccine Development	Medicine
Larry L. Augsburger, PhD	Professor	Pharmacy Practice and Science	Pharmacy

Industry Marketing Efforts

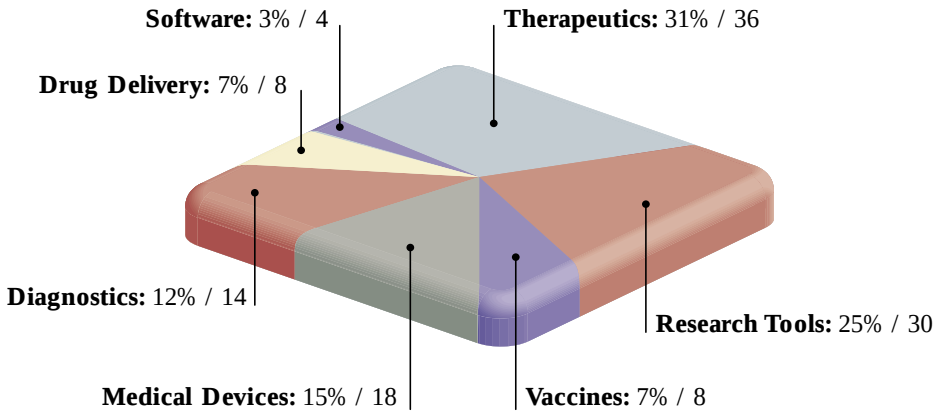
TecCom marketing staff worked to promote UMB technology to **503** companies in FY03, logging **1,064 contacts** throughout the year. From cold calls to potential licensees, responses to requests for more information through Web site hits and direct e-mail, meetings at industry functions such as BIO 2003, and license negotiations, TecCom is deepening its industry outreach and impact.

Technologies Available for Licensing

There are currently 118 active technologies on the ORD docket, marketed by TecCom to potential licensees. Nearly 85% are from School of Medicine faculty.

The portfolio includes:

TECHNOLOGIES ACTIVELY MARKETED, BY CATEGORY



Seventeen technologies are being marketed by our partners under Memorandum of Understanding, IIAs, or other collaborative agreements as follows: UMBI with eight technologies, and one each by the University of Minnesota, Duke University, Boston University, NIH, Dartmouth, the University of Aberdeen, UMCP, Massachusetts General Hospital, and Notre Dame University.

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In five years, UMB has executed 38 licenses.

10 to start-ups

20 to small companies

8 to large companies

Enterprise Activity: Licensing

FY03 licensing activity resulted in the execution of nine agreements on UMB technologies. Three option agreements and one inter-agency agreement were also completed during the year. In FY02, four licenses were completed. See details below.

PROFILES OF AGREEMENTS EXECUTED DURING FY03

Agreement Type	Company or Institution	UMB Inventor(s)	Department and/or Center	Technology
License	Microscience, Ltd.	Hone, Powell, Lewis	CVD	DNA Bactofection
IIA	University of Aberdeen	Flajnik	Microbiology	Shark Antibodies
License	Upstate USA, Inc.	Hamburger, Xia	Pathology	EBP-1 Antibodies
License	UPM Pharmaceuticals, Inc.	Hollenbeck, Jiang	Pharmaceutical Sciences	Aqueous Sustained-Release Suspension Dosage Form for Highly Water Soluble Electrolytic Drugs
License	Pharmacia & Upjohn Company	Ross, Doyle, Abruzzo	Medicine; Greenebaum Cancer Center	Breast Cancer Resistant Protein
License	Pfizer, Inc.	Ross, Doyle, Abruzzo	Medicine; Greenebaum Cancer Center	Breast Cancer Resistant Protein
Option	PEM Technologies, Inc.	Mease	Diagnostic Radiology	Preparation of F-18 Labeled Annexin V
License	Articulation Innovations	Siegel, Gunderson	Restorative Dentistry	Trademark for "CASTIX"
Option	Guided Delivery Systems, Inc.	Downing	Surgery	Minimally Invasive Diagnostic and Surgical Procedures Inside of a Beating Heart
Option	Prowess, Inc.	Earl, Shepard, Yu	Radiation Oncology	Direct Aperture Optimization for Radiation Therapy
License	Sequella, Inc.	Lakowicz	Biochemistry	Drug Compliance Monitor
License	Prowess, Inc.	Earl, Shepard, Yu	Radiation Oncology	Direct Aperture Optimization for Radiation Therapy
License	Pfizer, Inc.	Hassel	Greenebaum Cancer Center	Cancer therapy or prevention pathway involving UBEIL, ISG15, UBP43

These agreements position UMB's intellectual property across industry, in small start-ups like Articulation Innovations, in growing Maryland biofirms like Sequella, and in pharmaceutical giants such as Pfizer and Pharmacia.

Enterprise Activity: Start-Ups

TecCom works to establish new companies around the technologies in its portfolio. The team works actively with faculty to develop business plans, establish management structures, and identify sources of capital to get these start-ups off the ground. The UMB Life Sciences Park will provide incubator space for such companies beginning in early 2005.

Licenses with Start-Up Companies

Currently, UMB has active license agreements with five start-up companies (*see profiles*). The corresponding license agreements cover 16 UMB technologies. ORD anticipates two additional licenses with new start-up companies in FY04.

PROFILES OF ACTIVE START-UPS

Company Name Date(s), License(s) Executed	Inventor(s) Names	UMB Technologies Originally Licensed (Titles)	Technology Still Licensed?
UPM Pharmaceuticals, Inc.			
7/1/97	Not Applicable	License defines basic IP relationship and use of proprietary information	Not Applicable
1/30/01	Habib, Augsburger, Shangraw	Cushioning Beads and Tablet Comprising the Same Capable of Forming a Suspension	Yes
12/05/02	Hollenbeck, Jiang	Aqueous Sustained-Release Drug Delivery System for Highly Water Soluble Electrolytic Drugs	Yes
Genta, Inc. (originally Androgenics)			
9/2/97	Brodie, Ling	Androgen Synthesis Inhibitors	Yes
3/1/00	Brodie	Androgen Synthesis Inhibitors	Yes
3/1/00	Brodie, Njar	Steroids Useful for Androgen Synthesis Inhibitors	Yes
3/1/00	Brodie, Njar	Novel 17-Azolyl Aza Steroids Useful as Androgen Synthesis Inhibitors	Yes
AuRx, Inc.			
9/11/97	Aurelian	Vaccine Composition for Herpes Simplex Virus and Methods of Use	Yes
9/11/97	Aurelian, Smith	Virus Construct and HSV1/2 Assay	No
9/11/97	Aurelian	Nucleic Acid Uptake and Release Vehicle (UTARVE)	No
9/11/97	Aurelian, Kulka, Calton	Nucleic Acid Uptake and Release Vehicle (UTARVE II)	No
6/2/01	Aurelian, Gyotoku, Calton	Prevention of Recurrent Viral Disease	Yes
Artemis, Inc.			
10/24/01	Schwarz	3-HANA Derivatives	Yes
10/24/01	Schwarz	NMDA Antagonists	Yes
10/24/01	Schwarz	NMDA Antagonists (new compounds)	Yes
Articulation Innovations, LLC			
6/12/02	Siegel, Gunderson	Breakaway Devices for Stabilizing Dental Casts and Methods of Use	Yes
1/10/03	Siegel, Gunderson	Trademark "CASTIX"	Yes

In addition, as a result of its collaboration with the School of Medicine's Department of Epidemiology, UMB has equity in Intralytix, a Baltimore-based company developing bacteriophage.

Technology Development Funding: UTDF

Since the inception of the Maryland Technology Development Corporation's (TEDCO) University Technology Development Fund (UTDF) program in late calendar year 2000, UMB faculty have submitted 21 research proposals for consideration by TEDCO's review committee. Of the 21 UMB proposals submitted, 12 have been awarded funding. The total UTDF program funds awarded to UMB faculty currently stands at $616,990.

In FY03, five awards were made to UMB faculty. As stated, these projects hold great potential for commercial development. They are summarized in the table.

TEDCO UTDF AWARDS TO UMB FACULTY FY03

Principal Investigator	UMB School	Department and/or Center	UTDF Award Amount	Title
Edelman	Medicine	Pathology	$45,474	Quantitative Real Time PCR to Determine Titers in Lambda Phage Preparation
Regenold	Medicine	Psychiatry	$50,000	Diagnostic Blood Test for Bipolar Disorder
Njar	Medicine	Pharmacology & Experimental Therapeutics	$25,000	Therapeutics in Cancer
Mixson	Medicine	Pathology	$50,000	Antibacterial Properties of Cationic HK Peptides
Aurelian	Medicine	Pharmacology & Experimental Therapeutics	$50,000	ICPdeltaRR Mediated Neuroprotection in Excitotoxic Stroke Models

Two UMB faculty were awarded grants through the Small Business Administration's Small Business Technology Transfer Program. This highly competitive program provides funding in phases to joint ventures between small businesses and university researchers. Richard Dutton, MD, is working with Active Signal Technologies, a Maryland company, to investigate noninvasive techniques for assessing cerebral pressure in trauma patients. Alessio Fasano, MD, is working with Nair Consultants, LLC, also a Maryland company, to assess noninvasive methods of monitoring bowel disease in pediatric patients.

The Maryland Technology Development Corporation's (TEDCO) University Technology Development Fund provides grants to Maryland universities in support of pre-commercial research on university intellectual property to increase the likelihood of commercializing that intellectual property.

UMB Technology: Impact in Industry

Following is a list of companies with whom UMB has an existing license, agreement, option, or equity interest:

A & G Pharmaceuticals, Inc.
Active Pass Pharmaceuticals, Inc.
Affinity BioReagents, Inc.
Alberta Research Council, Inc. and University of Saskatchewan
Altarex Corporation
Antex Biologics, Inc.
Artemis Neuroscience, Inc.
Articulation Innovations, LLC
AuRx, Inc.
Berna Biotech (SSVI)
Bio-Med Associates
Biometrics, Inc.
Biospherics, Inc.
CEL-SCI Corporation, Inc.
CYAD Pharmaceutical Corporation
Cylex, Inc.
Deus Technologies, LLC
Dol Com, LLC
EntreMed, Inc.
Essex Corporation
FluorRx, Inc.
Focus Technologies, Inc.
Gene Delivery Alliance, Inc.
Genta, Inc. (Androgenics)
GlaxoSmithKline
Guided Delivery Systems, Inc.
Hartech, Inc.
Imperium, Inc.
Inhibitex, Inc.
Integrated Diagnostics, Inc.
International Pharmaceuticals and Biotechnology Laboratories, LLC (IPBL)
Interthyr Research Foundation, Inc.; previously Interthyr Research Corporation
Intradigm Corporation
Intralytix, Inc.
JDA, Inc.
LakoFluor, Inc.
Microscience, Ltd.
Mistral Security, Inc.
NanoFluor, Inc.
Neurobiotex
Next Breath, LLC
NitroSci, LLC
NovaMin, Inc., formerly US Biomaterials, Inc.
NovoVascular, Inc.
Nucletron, Inc.
NutraMax Laboratories, Inc.
Orbigen, Inc.
Password, Inc.
Pathogen Removal and Diagnostic Technologies, Inc.
Peptide Therapeutics, Ltd., and Medeva, PLC (Acambis)
Pfizer, Inc.
Pharmacia & Upjohn Company
Phytera
ProBiotix, Inc.
Protein Research, Inc.
Prowess, Inc.
Response Healthcare Information Management, Inc. (HCIA/RHIM); now Solucient
Santa Cruz
Sequella, Inc.
Sigma RBI (RBI)
Sigma-Tau Research, Inc.
SpectRx, Inc.
Stellar Biosystems, Inc.
Sterilex, Inc.
Tissue Engineering Science, Inc.
Trophogen
Univax Biologics, Inc.
Universal Health Research and Development, Inc.
University Pharmaceuticals of Maryland, Inc.
Upstate USA, Inc.
US Biomaterials, Inc.; now NovaMin, Inc.
U.S. Therapeutics, Inc.
Xenoport

Revenues and Expenses

Although the reimbursement of patent expenses declined ($170,257), royalties and fees increased by 40%, reaching $161,535 in FY03, resulting in $331,792 in gross revenue. In FY02 revenues were more robust, though they were attributable to a single license fee of $415,000 as well as significant improvements in our compliance and payment recovery efforts for pre-existing licenses.

Expenses for FY03 totaled $601,064. Of this amount, $518,354 was spent on patent expenses and another $66,629 was disbursed to UMB inventors and departments, in accordance with the UMB patent policy, on the basis of revenue received during FY02. The disbursements of FY02 include a significant contribution from ORD's successful compliance and recovery efforts, returning to faculty royalties owed from previous years.

ORD also recorded expenses of $16,081 in FY03 for investments and loans provided to specific technologies. The major portion of this amount, $15,000, was invested in new equipment used for Dr. Alan Shuldiner and Dr. Dai Wei Gong's ongoing research related to novel genes important in obesity and metabolic disease. The equipment, a protein purification system, is being used to purify large quantities of omentin and ALTs (or monoclonal antibodies) to set up blood enzyme-linked immunosorbent assays.

See table for details:

REVENUE AND EXPENSES FOR FY03

Revenue	**FY 2002**	**FY 2003**
MTAs	$5,000	$0
Option Fees	$5,000	$5,000
License Fees	$54,454	$123,125
Royalties	$50,609	$33,410
Income Subtotal	**$115,063**	**$161,535**
Patent Expense Reimbursement	$715,079	$170,257
Total Revenue	**$830,142**	**$331,792**
Expenses		
Patent Expenses	$570,084	$518,354
Disbursements to Inventors/Departments	$352,286	$66,629
Investment/Loan	$5,574	$16,081
Total Expenses	**$927,944**	**$601,064**
Net Expenses	**$97,802**	**$269,272**

Agreement Compliance Monitoring Activity

An important but often overlooked aspect of intellectual property asset management is monitoring agreements to ensure compliance with contractual terms and conditions. ORD's Technology Commercialization Group works intensively to ensure that licensees and option holders are in compliance with the obligations in their agreements for license execution costs, option fees, back-patent expenses, or money from workout agreements.

Appendix A - Issued Patents

OFFICE OF RESEARCH & DEVELOPMENT-ISSUED PATENTS FOR FY03

Patent Number	Title	Inventor(s)	Brief Description
6,413,768	Expression Plasmids	James E. Galen	The invention optimizes the maintenance of expression plasmids at two independent levels by removing sole dependence on balanced lethal maintenance systems and incorporating a plasmid partition system to prevent random segregation of expression vector plasmids, thereby enhancing their inheritance and stability
6,444,683	17-Azolyl Steroids Useful as Androgen Synthesis Inhibitors	Angela Brodie Vincent C.O. Njar	Novel 17-azolyl steroids, which are useful as androgen synthesis inhibitors, as well as methods for the use of the same to reduce plasma levels of testosterone and/or dyhydrotestosterone, and to treat prostrate cancer and benign rostatic hypertrophy
6,455,249	Method of Amplifying DNA and RNA Mismatch Cleavage Products	Ih-Chang Hsu William E. Highsmith Jr. James Shih	This invention generally relates to detection of nucleic acid sequence mutations, and more specifically to a new and useful method for signal amplification of mismatch cleavage
6,458,925	Peptide Antagonists of Zonulin and Methods for Use of the Same	Alessio Fasano	Relates to peptide antagonists of zonulin, where the antagonists bind to the zonula occludens receptor, yet do not physiologically modulate the opening of mammalian tight junctions
6,472,221	Lifetime-Based Sensing of Sodium and Potassium	Joseph R. Lakowicz Henryk Szmacinski	A system and method of optically measuring sodium and potassium in a sample such as blood which contains high concentrations of sodium and potassium using a photoluminescent probe having intrinsic analyte-induced lifetime changes
6,479,466	Compositions for Treating Viral Infections, and Methods Therefor	Robert R. Redfield Charles E. Davis Jr. Alonso Heredia	Methods and combinations of an agent that promotes DNA synthesis in a virally targeted cell and a nucleoside analogue having antiviral activity are provided for treating a viral infection
6,548,287	Non-Pyrogenic Bacterial Strains and Use of the Same	Robert J. Powell David M. Hone	Invention relates to gram-negative bacterial strains that stably produce substantially pure non-pyrogenic lipopolysaccharide or lipid A, which may be used for the preparation of non-pyrogenic live and inactive bacterial vaccines and vaccine vectors

Appendix A - Issued Patents (Continued)

ISSUED PATENTS IN FOREIGN COUNTRIES

Patent Number	Title	Inventor(s)	Brief Description
AUSTRALIA			
745,507	Peptide Antagonists of Zonulin and Methods for Use of the Same	Alessio Fasano	Relates to peptide antagonists of zonulin, where the antagonists bind to the zonula occludens receptor, yet do not physiologically modulate the opening of mammalian tight junctions
750,082	Altered DNA Synthesome Components as Biomarkers for Malignancy	Linda H. Malkas Robert J. Hickey Pamela E. Bechtel	Antibodies that specifically bind to components of the DNA synthesome, which are altered in malignant cells. These antibodies can be used, *inter alia*, to diagnose, prognose, and treat malignancy and in assays to screen cells, tissues, and bodily fluids for the presence of a malignant phenotype
752,285	A Method for Diagnosing and Treating Chronic Pelvic Pain Syndrome	Richard B. Alexander Sathibalan Ponniah	A method of diagnosing Chronic Pelvic Pain Syndrome in men comprising measuring levels of cytokines in semen or components or fractions of semen
754,142	Method of Using Zot or Zonulin to Inhibit Lymphocyte Proliferation in an Antigen-Specific Manner	Alessio Fasano, Marcelo B. Sztein Michael K. Tanner	Methods for using Zot or Zonulin as an antigen-specific inhibitor of APC activity and lymphocyte proliferation, being primarily useful in the field of immunoregulation and immunotherapy
754,795	Attenuated Mutants of *Salmonella* which Constitutively Express the Vi Antigen	Fernando R. Noriega Marcelo Sztein Myron M. Levine	Attenuated *Salmonella* mutants that constitutively express the Vi antigen, as well as vaccines against typhoid fever
755,567	Breast Cancer Resistance Protein and the DNA which Encodes it	Douglas D. Ross L. Austin Doyle Lynne Abruzzo	The breast cancer resistance protein is described, as well as the cDNA that encodes it. This protein has been found to confer resistance to cancer chemotherapeutic drugs
NEW ZEALAND			
508,110	Attenuated Mutants of *Salmonella* which Constitutively Express the Vi Antigen	Fernando R. Noriega Marcelo Sztein Myron M. Levine	Attenuated Salmonella mutants that constitutively express the Vi antigen, as well as vaccines against typhoid fever
510,150	Method of Using Zot or Zonulin to Inhibit Lymphocyte Proliferation in an Antigen-Specific Manner	Alessio Fasano Marcelo B. Sztein Michael K. Tanner	Methods for using Zot or Zonulin as an antigen-specific inhibitor of APC activity and lymphocyte proliferation, being primarily useful in the field of immunoregulation and immunotherapy

Appendix A - Issued Patents (Continued)

ISSUED PATENTS IN FOREIGN COUNTRIES (CONTINUED)

Patent Number	Title	Inventor(s)	Brief Description
SINGAPORE			
71624	Methods and Compositions for Whitening Teeth	Gary D. Hack Leonard J. Litkowski David C. Greenspan	A novel silica-based bioactive glass composition that can be used in conjunction with a delivery agent such as a toothpaste, gel, etc., for the immediate and long-term reduction of dentin hypersensitivity and tooth surface remineralization
SRI LANKA			
12036	Methods and Compositions for Whitening Teeth	Gary D. Hack Leonard J. Litkowski David C. Greenspan	A novel silica-based bioactive glass composition that can be used in conjunction with a delivery agent such as a toothpaste, gel, etc., for the immediate and long-term reduction of dentin hypersensitivity and tooth surface remineralization
PEOPLES REPUBLIC OF CHINA			
ZL 97 193,085.6	Methods and Compositions for Whitening Teeth	Gary D. Hack Leonard J. Litkowski David C. Greenspan	A novel silica based bioactive glass composition that can be used in conjunction with a delivery agent such as a toothpaste, gel, etc. for the immediate and long term reduction of dentin hypersensitivity and tooth surface remineralization

TRADEMARKS

Number	Title	Inventor(s)	Brief Description
2,649,922	Castix	Sharon C. Siegel Ronald B. Gunderson	This mark is used in conjunction with dental casts, used or sold in conjunction with dental articulators and components and accessories.

Produced by the Office of External Affairs, 2003