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National Cancer Institute, and National Institute of Diabetes, Digestive, & Kidney Diseases: SBIR-Technology Transfer Contract Topics 310, 311, and 075

Public Briefing/Webinar

NIH Campus
Natcher Building, Room A, Basement Level
Bethesda, MD

Friday October 7, 2011, 10 AM- 1 PM

http://sbir.cancer.gov/funding/contracts/

U.S. Department of Health and Human Services
National Institutes of Health

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NCI and NIDDK SBIR-TT

Dr. Greg Evans (NCI SBIR Development Center) Welcome and Introduction	10:00 AM
Dr. Stephen M. Hewitt (NCI Laboratory of Pathology) Technical Background, Topic 310 (Manual Tissue Microarray Instrument)	10:10
Dr. Greg Evans Phase I Contract Deliverables, Q&A for NCI Topic 310	10:20
Dr. Udai S. Kammula (NCI Surgery Branch) Technical Background, Topic 311 (T Cell Isolation Cancer Immunotherapy)	10:35
Dr. Greg Evans Phase I Contract Deliverables, Q&A for NCI Topic 311	10:45
Dr. Marvin Gershengorn (NIDDK Laboratory of Endocrinology/Receptor Biology) Technical Background, Topic 075 (TSH Receptor Agonist, Thyroid Cancer)	11:00
Dr. Greg Evans Phase I Contract Deliverables, Q&A for NIDDK/NCI Topic 075	11:10
Dr. Tara Kirby (NIH Office of Technology Transfer) Overview of License Application Process	11:25
Q&A Licensing	11:35
Dr. John Hewes (NCI Technology Transfer Center) Technology Transfer at the National Cancer Institute	11:50
Q&A on NCI/NIDDK Technology Transfer, then Open Q&A	12:00
Closing Remarks	Before 1:00 PM

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Welcome and Introduction

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

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Welcome and Introduction

- The National Cancer Institute (NCI), the National Institute of Diabetes, Digestive & Kidney Diseases (NIDDK), and the NIH Office of Technology Transfer (OTT) are continuing to pilot in fiscal year 2012 the SBIR-Technology Transfer (TT) contract concept

- This concept involves coupling out-licensing with SBIR funding in order to move inventions from intramural NIH out into the marketplace (***MOVING SCIENCE TO THE MARKET***)

- This NIH pilot is based on the successful program that another federal agency- The National Institute of Standards and Technology (NIST)- has been running for the last 3 years

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Welcome and Introduction II

- The pilot began last year in NCI, and we just funded our first SBIR-TT contract (preclinical device for noninvasive imaging of oxygen in animal tissues)

-We in NCI are very pleased to be joined in the pilot this year by another NIH Institute- NIDDK- that has an interest in commercializing one of its in-house inventions.

- If this pilot is successful, we hope to continue this SBIR-TT program using some of the several hundred other existing NCI and NIH employee inventions backed by intellectual property filings.

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Welcome and Introduction III

- Purpose of today's event: briefing on technical and licensing aspects of NCI SBIR-TT contract topics 310 & 311, and NIDDK/NCI topic 075

- Short technical summaries for each topic can be found at: http://sbir.cancer.gov/funding/contracts/

- Full NIH SBIR Contract solicitation can be found at: http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf

- Proposal receipt deadline is **Monday November 7, 2011, 5 PM EST**

- Frequently asked questions (FAQ) for SBIR-TT topics are on the web: http://sbir.cancer.gov/funding/contracts/faq.asp

- Q&A from this event will be transcribed and added, along with the slides, to those FAQ already online

http://sbir.cancer.gov/funding/contracts/

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To Ask a Question During this Event

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2- for audience members participating remotely, send your question in writing via e-mail to Elicia Rothschild at: **Elicia.rothschild@nih.gov**

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Topic 310
Simplified Tissue Microarray Instrument For Clinical And Research Settings

Stephen M. Hewitt, MD, PhD
Tissue Array Research Program
Laboratory of Pathology
CCR, NCI, NIH

http://sbir.cancer.gov/funding/contracts/

U.S. Department of Health and Human Services
National Institutes of Health

Need

- TMAs Have Revolutionized Translational Pathology
- Current Instruments
  - Withdrawn From Market
  - Beyond The Budget Of Most Laboratories
- Expansion Into Clinical Market
  - Use Of TMAs For
    - Controls
    - Assay Validation
  - Endorsed In Recent CLSI IHC Guidelines

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Goal

- Low Cost
- Ease Of Use
- Modular

- Low Volume, Focused TMAs
  - 25 to 500 Samples, Fixed Number Of Targets
  - Not Core Labs
- Clinical Labs
  - Controls (10-50 cores)
  - Assay Validation (50-100 cores)

http://sbir.cancer.gov/funding/contracts/

Current Marketplace

- Original TMA Instrumentation Is Not On Market At This Time
- Limited Distribution Of NIH-Licensed Instruments Starting At Over $25,000 Each

http://sbir.cancer.gov/funding/contracts/

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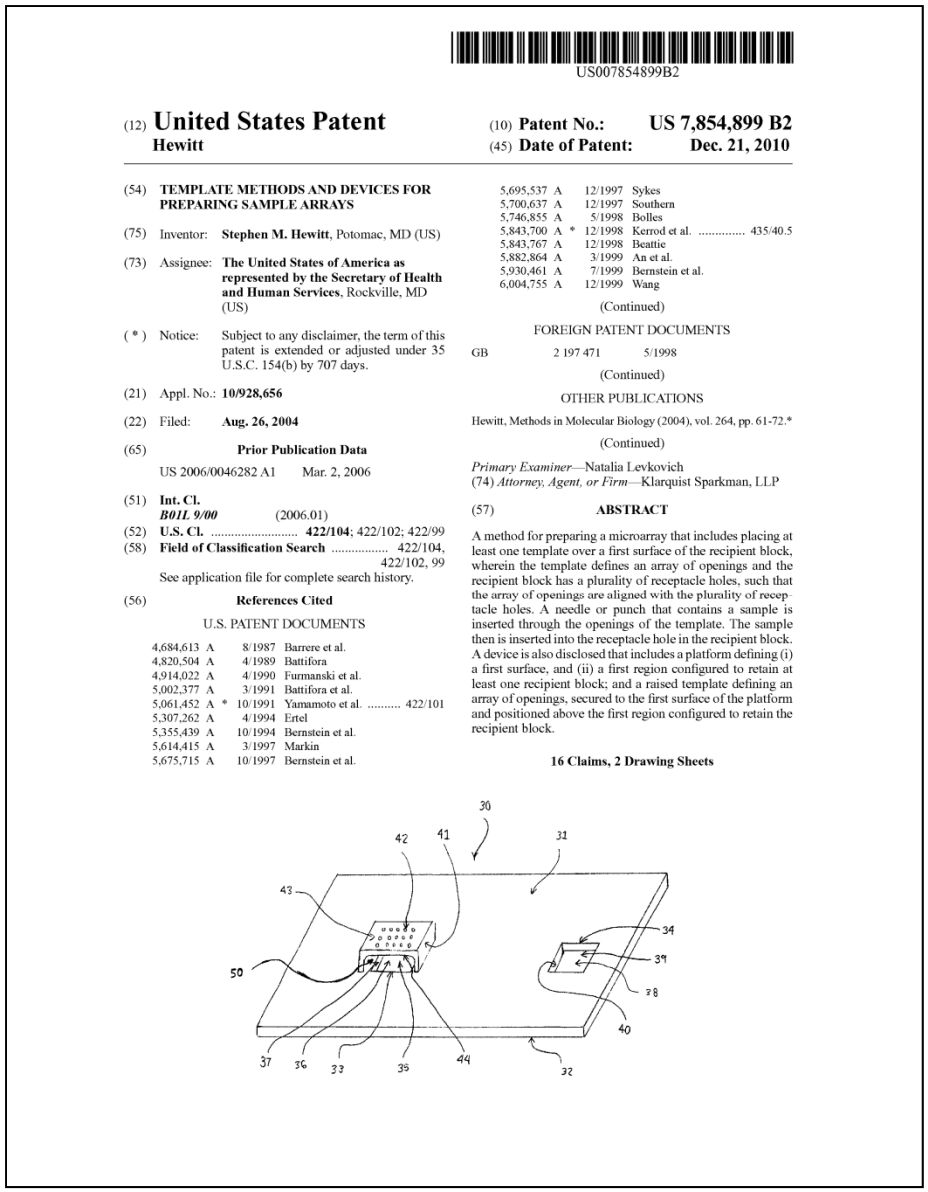
Intellectual Property



US007854899B2

(12) **United States Patent**
Hewitt

(10) **Patent No.: US 7,854,899 B2**
(45) **Date of Patent: Dec. 21, 2010**

(54) **TEMPLATE METHODS AND DEVICES FOR PREPARING SAMPLE ARRAYS**

(75) Inventor: **Stephen M. Hewitt**, Potomac, MD (US)

(73) Assignee: **The United States of America as represented by the Secretary of Health and Human Services**, Rockville, MD (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 707 days.

(21) Appl. No.: **10/928,656**

(22) Filed: **Aug. 26, 2004**

(65) **Prior Publication Data**

US 2006/0046282 A1 Mar. 2, 2006

(51) **Int. Cl.**
B01L 9/00 (2006.01)

(52) **U.S. Cl.** **422/104**; 422/102; 422/99

(58) **Field of Classification Search** 422/104, 422/102, 99

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,684,613	A		8/1987	Barrere et al.
4,820,504	A		4/1989	Battifora
4,914,022	A		4/1990	Furmanski et al.
5,002,377	A		3/1991	Battifora et al.
5,061,452	A	*	10/1991	Yamamoto et al. 422/101
5,307,262	A		4/1994	Ertel
5,355,439	A		10/1994	Bernstein et al.
5,614,415	A		3/1997	Markin
5,675,715	A		10/1997	Bernstein et al.
5,695,537	A		12/1997	Sykes
5,700,637	A		12/1997	Southern
5,746,855	A		5/1998	Bolles
5,843,700	A	*	12/1998	Kerrod et al. 435/40.5
5,843,767	A		12/1998	Beattie
5,882,864	A		3/1999	An et al.
5,930,461	A		7/1999	Bernstein et al.
6,004,755	A		12/1999	Wang

(Continued)

FOREIGN PATENT DOCUMENTS

GB 2 197 471 5/1998

(Continued)

OTHER PUBLICATIONS

Hewitt, Methods in Molecular Biology (2004), vol. 264, pp. 61-72.*

(Continued)

Primary Examiner—Natalia Levkovich
(74) *Attorney, Agent, or Firm*—Klarquist Sparkman, LLP

(57) **ABSTRACT**

A method for preparing a microarray that includes placing at least one template over a first surface of the recipient block, wherein the template defines an array of openings and the recipient block has a plurality of receptacle holes, such that the array of openings are aligned with the plurality of receptacle holes. A needle or punch that contains a sample is inserted through the openings of the template. The sample then is inserted into the receptacle hole in the recipient block. A device is also disclosed that includes a platform defining (i) a first surface, and (ii) a first region configured to retain at least one recipient block; and a raised template defining an array of openings, secured to the first surface of the platform and positioned above the first region configured to retain the recipient block.

16 Claims, 2 Drawing Sheets

http://sbir.cancer.gov/funding/contracts/

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Additional Background

- Inventor – Chief Of The Tissue Array Research Program
- Technology Is Not Dependent On Other Tissue Array Patents

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NCI Expectations and Deliverables, Topic 310 (Manual Tissue Microarray Instrument)

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

- Goal: perform commercially directed research and development with this manual tissue microarray technology developed in intramural NCI, and independently, to seek a commercialization license from the NIH Office of Technology Transfer
- Fast-Track proposals allowed: No
- Budget: $200,000 Phase I; $1,500,000 Phase II; 1 award only
- Duration: Phase I, 9 months; Phase II, 2 years

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Deliverables for Topic 310 Phase I SBIR Contract

- Develop an instrument as instructed in US Patent 7,854,899 with:
  - Capacity of 100 samples on a single microscope slide for immunohistochemical analysis
  - Controls for immunohistochemistry, as well as clinical assay validation
  - Capability of fabricating replicate arrays
- Develop improved prototype with component parts, including:
  - Optimized needle(s) material and design
  - Optimized templates design and features
  - A donor block holder
  - A recipient block holder/alignment device
  - A recipient block-recipient-holes template
  - A recipient block core-placement alignment template
  - A needle holder/plunger device
- Process and cost estimates for manufacture of the minimum number of tissue arrayers to accommodate 10% of current market
- Provide NCI with all data resulting from Phase I Activities and Deliverables

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Licensing, and Follow-On Phase II SBIR Contract

- The awarded Phase I contractor will automatically be granted a royalty-free, non-exclusive license to use NIH-owned and patented background inventions only within the scope and term of the award. However, an SBIR offeror (pre-award) or SBIR contractor (after award) must negotiate an exclusive or non-exclusive commercialization license to make, use, and sell products or services incorporating the NIH background invention.

- An SBIR contract proposal will be accepted as the INITIAL (unofficial) application for a commercialization license to such background inventions.

- Timing of official license application (coordination of funding/licensing)

- Phase I contract period will be approx Sept 30, 2012 thru June 30, 2013 (9 months)

http://sbir.cancer.gov/funding/contracts/

Licensing, and Follow-On Phase II SBIR Contract cont

- A follow-on Phase II contract can only be submitted by invitation from NCI, and an invitation can in principle be issued within 2 months of the successful completion of Phase I work
- An invitation will generally only be issued if NIH has granted the Phase I SBIR contractor a commercialization license by that time (exceptions)
- Anticipated Phase II deliverables as listed in published solicitation

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Q&A for Topic 310

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Topic 311
High Throughput Isolation of Antigen Specific T-Cells For Cancer Therapy

Udai S. Kammula, M.D.

Surgery Branch,

Center for Cancer Research, NCI

http://sbir.cancer.gov/funding/contracts/

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Personalized Cancer Therapy

The National Cancer Institute is striving to help create a future in which cancer prevention, diagnosis, treatment, and survivorship can be personalized - that is, tailored to the biology of individual patients and their cancers.

http://www.cancer.gov

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Adoptive Cell Therapy (ACT)

ACT is a personalized cancer treatment approach that involves:

1.) Identification from the cancer patient of autologous lymphocytes with antitumor activity

2.) In vitro expansion of these cells to large numbers

3.) Infusion of the expanded cells into the cancer-bearing host

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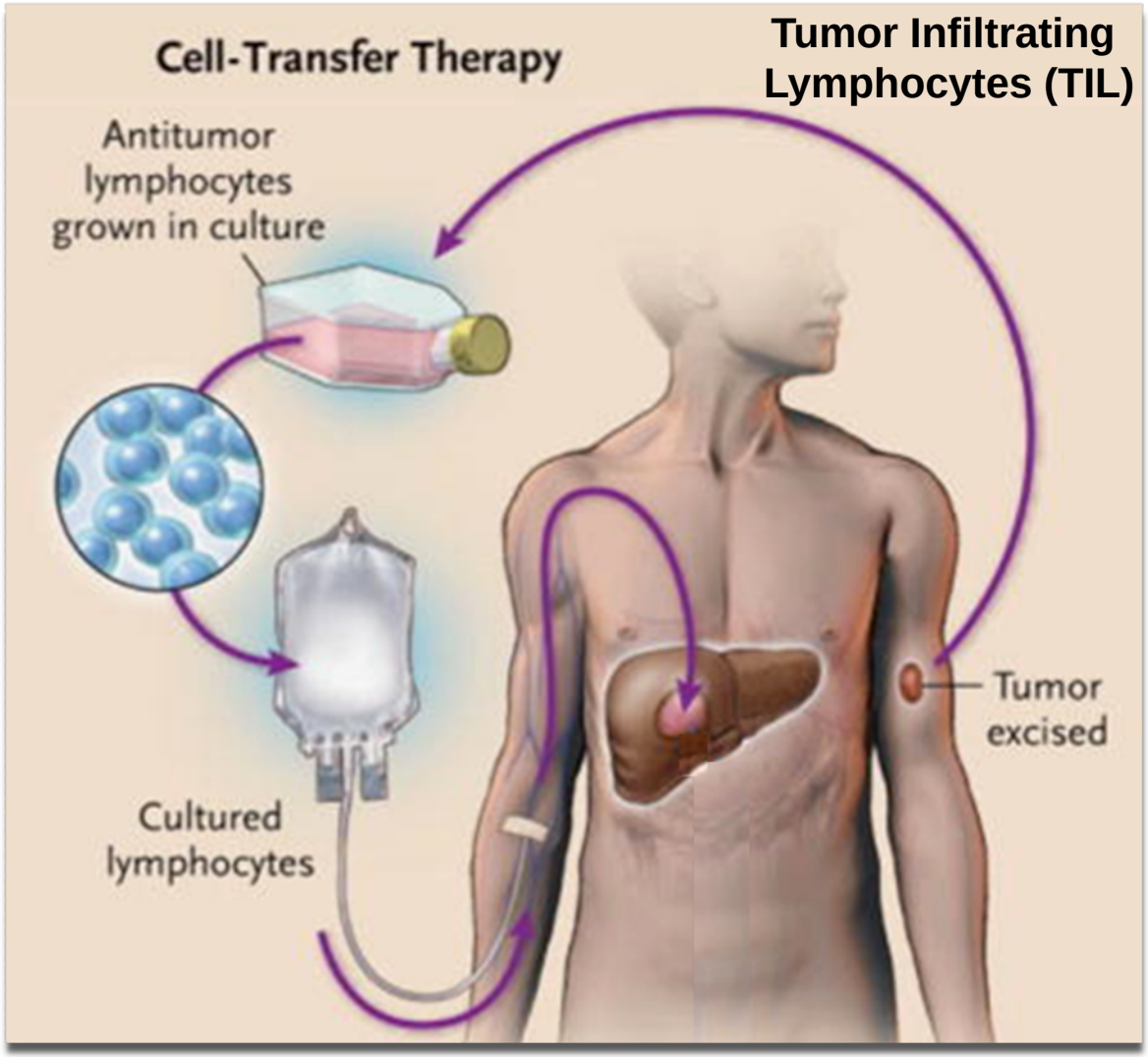
Adoptive Cell Therapy (ACT)



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NCI Surgery Branch Experience

Durable Complete Responses in Heavily Pretreated Patients with Metastatic Melanoma Using T-Cell Transfer Immunotherapy

Rosenberg SA et al.,
Clin Cancer Res. 2011

Treated Patients	Complete Regression	Partial Regression	Overall Response Rate
93	20(22%)	32(34%)	52(56%)

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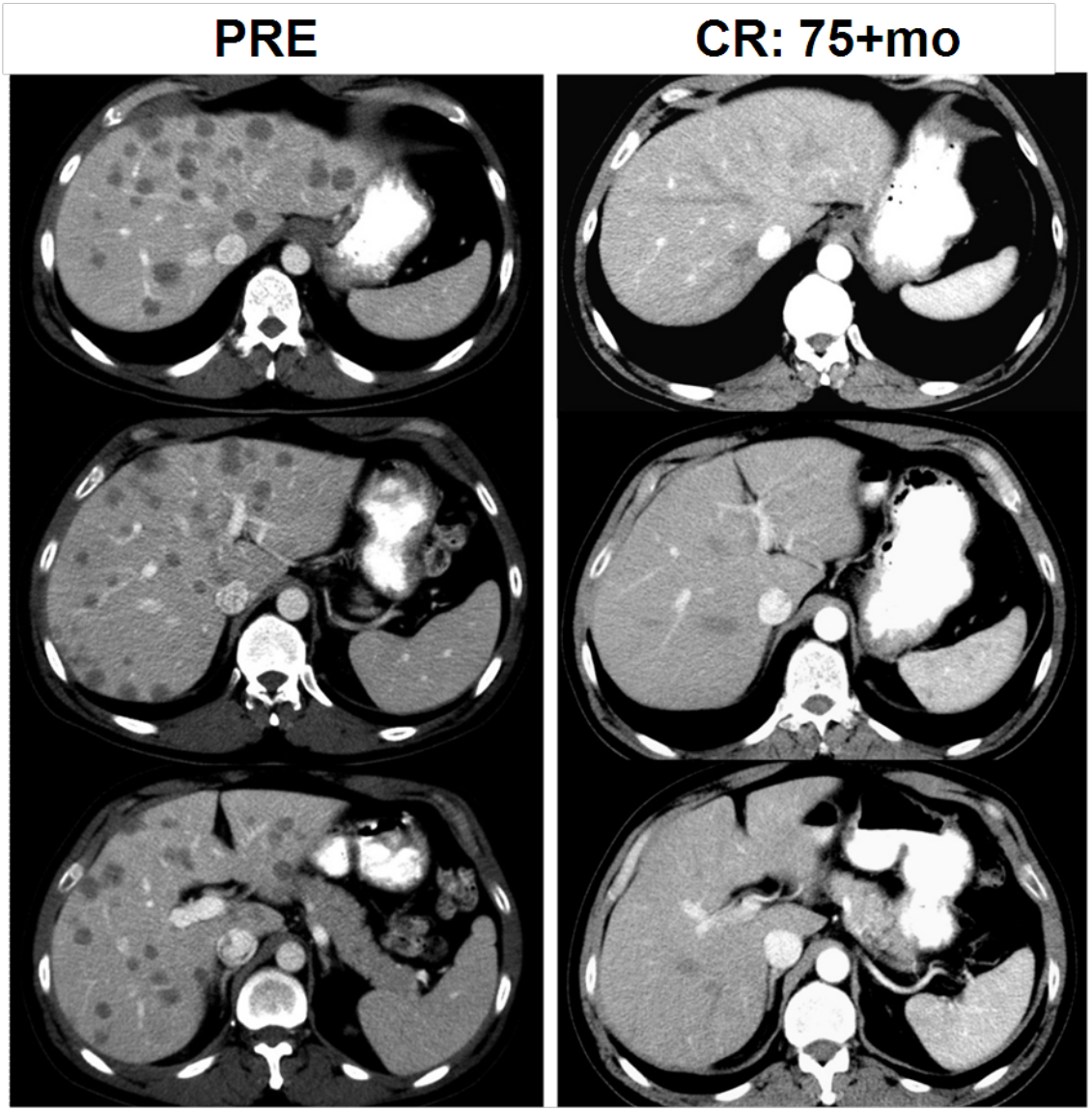
NCI Surgery Branch Experience



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Obstacles to Current ACT

Requires potentially invasive surgery to harvest tumor

Post-operative complications may lead to a delay in administering systemic treatment

The composition of bulk TIL is largely unknown, making it difficult to develop improved products

Difficulty in developing this personalized cancer therapy into a feasible and cost effective paradigm for commercialization

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Invention Overview

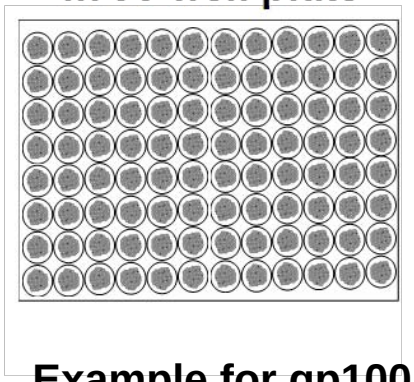
To overcome the current obstacles, we invented a rapid high throughput platform to isolate a variety of tumor specific CD8+ T cells in a non-invasive manner from the peripheral blood of cancer patients, and thus avoid the need for surgical tumor harvest.

(U.S. Patent App No. 61/027,623)

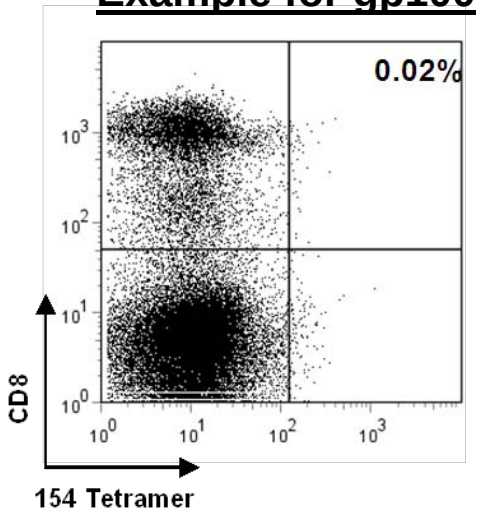
We have combined this method with tumor antigen profiling to develop a well defined personalized T cell product. We believe this therapeutic approach can be commercialized in a cost effective manufacturing strategy.

Invention Specifics

Day 0
Plating of PBMC in 96 well plate



Example for gp100



- Utilize peripheral blood to establish T cell cultures
- Avoid invasive surgical harvest
- Basic in vitro peptide sensitization (Platform is versatile to isolate a variety of ag specific T cells)
- Easily performed under GMP conditions

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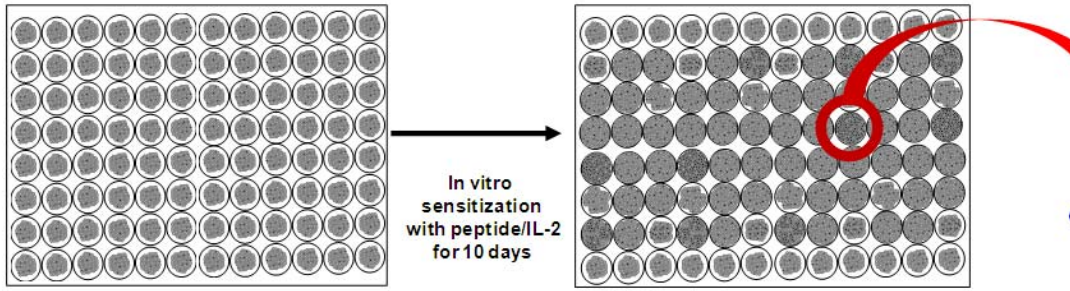
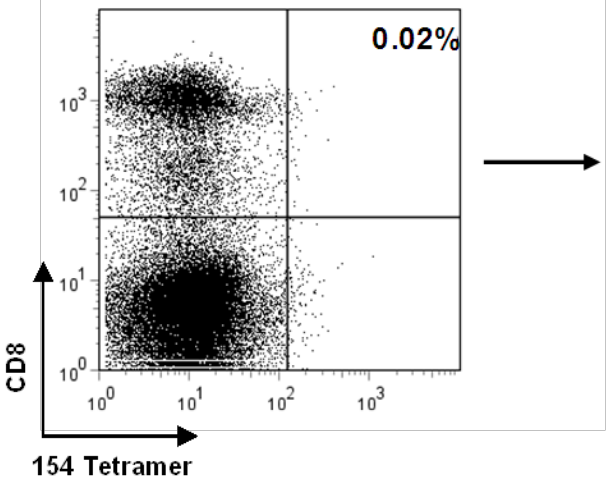
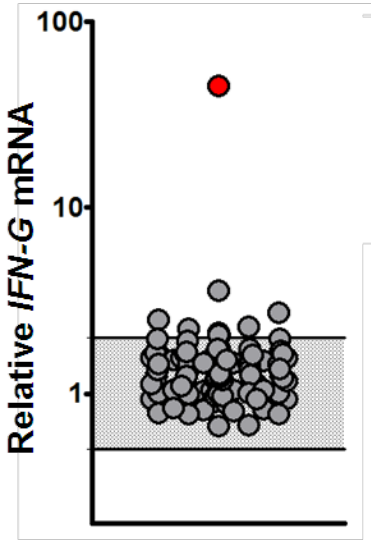
Invention Specifics

Day 0
Plating of PBMC in 96 well plate

Day 10
Detection of Reactive Bulk Cultures By High Throughput qPCR Screening







- Rapid (3 hour) assay adaptable for automation
- Sensitive for the isolation of low frequency T cells (1/100,000)

Kammula et al. J Trans Med 2008

http://sbir.cancer.gov/funding/contracts/

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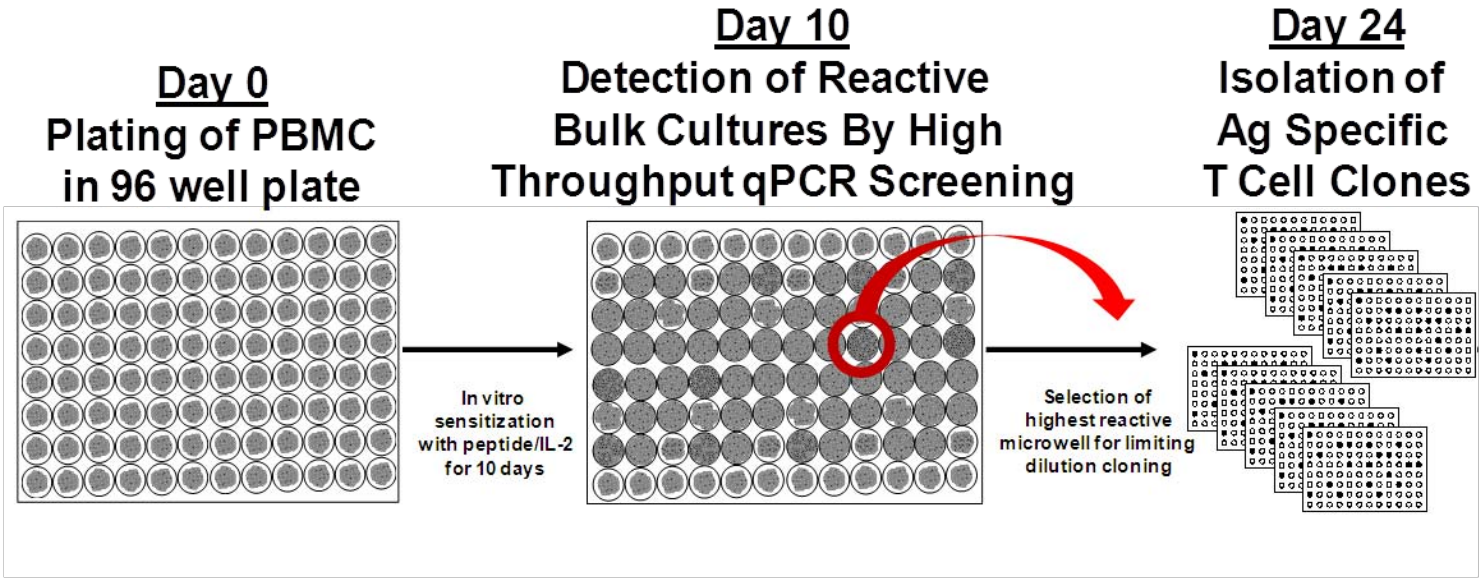
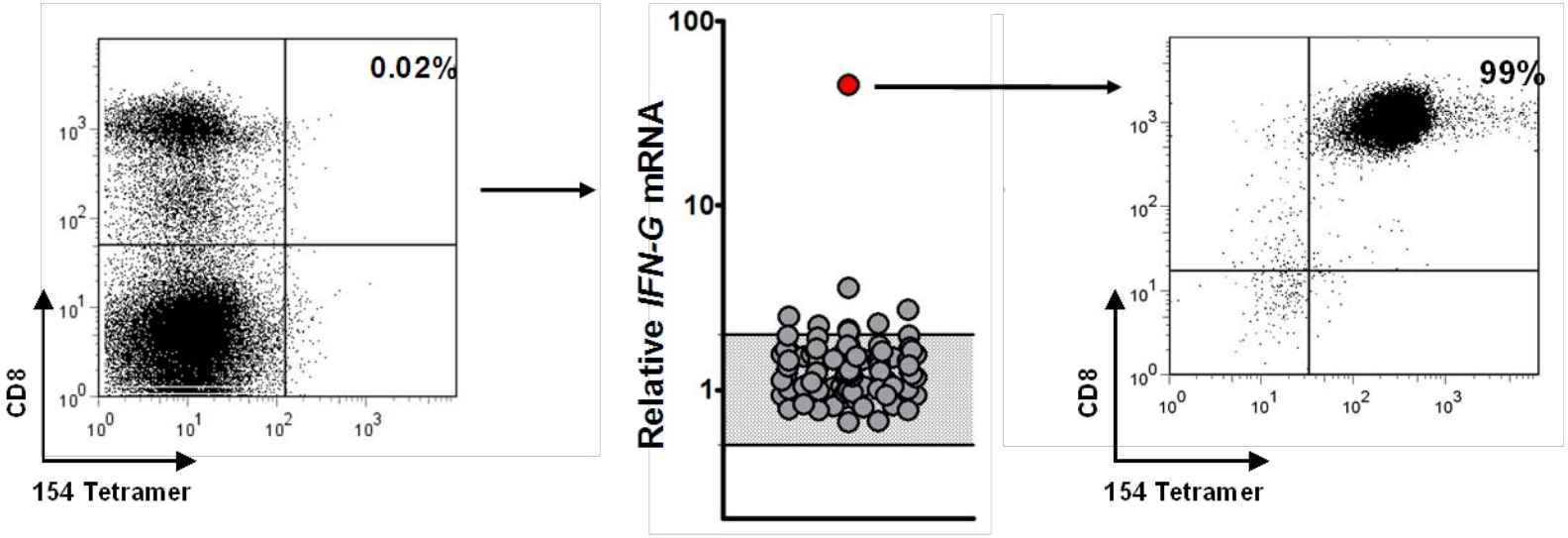
Invention Specifics





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Invention Performance

Examples of Isolated Tumor and Viral Specific CD8+ T Cell Clones

- gp100(154-162) → Clinical Trial NCI-08-C-0104
- gp100(209-217)
- MART(27-35) → Planned for Clinical Trial 2011
- NY-ESO(157-165)
- Tyrosinase(369-377)
- Mesothelin(18-26)
- Mesothelin(21-29)
- Flu M1(58-66)

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Future Plans

Assess the clinical efficacy of current T cell products

Isolate additional tumor and viral specific CD8+ T cells for clinical use

Further refine and develop this platform into a standardized manufacturing operating procedure that could be commercialized for public and private use

Large scale epitope screening to identify novel T cell targets

Expand the application to the identification of novel T cell populations (ie. Central Memory T cells)

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Staff and Collaborators

Biman Paria
Melissa Alvarez-Downing
Syed Shah
Sanmeet Singh
Vishant Ramadorai

Surgery Branch Cell Production Facility
Mark E. Dudley

Surgery Branch Immunotherapy Clinical Service

Steven A. Rosenberg

National Cancer Institute

NCI Expectations and Deliverables Topic 311 (T Cells for Cancer Therapy)

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

- Goal: perform commercially directed research and development with this high-throughput T cell identification and isolation technology from intramural NCI, and independently, to seek a commercialization license from the NIH Office of Tech Transfer
- Fast-Track proposals allowed: No
- Budget: $200,000 Phase I; $1,000,000 Phase II; 1 award only
- Duration: Phase I, 9 months; Phase II, 2 years

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Deliverables for Topic 311 Phase I SBIR Contract

Development of a High Throughput Platform

- Develop protocol for T cell stimulation and growth in 384-well plate format to increase current throughput
- Develop protocol for RNA isolation in 384-well format to increase current throughput
- Develop 384-well multiplex quantitative PCR assay for cytokine profiling
- Apply automated liquid handling technology to facilitate high throughput screening
- Apply automated liquid handling technology to facilitate T cell cloning

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Licensing, and Follow-On Phase II SBIR Contract

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Q&A for Topic 311

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NIDDK

TSH Receptor Small Molecule Agonist for Adjunct Diagnosis/Treatment of Thyroid Cancer

Marvin C. Gershengorn, MD

Laboratory of Endocrinology & Receptor Biology

National Institute of Diabetes & Digestive & Kidney Diseases
National Institutes of Health

Thyroid Cancer Background:

- A near-total or total thyroidectomy is usually performed as initial treatment.

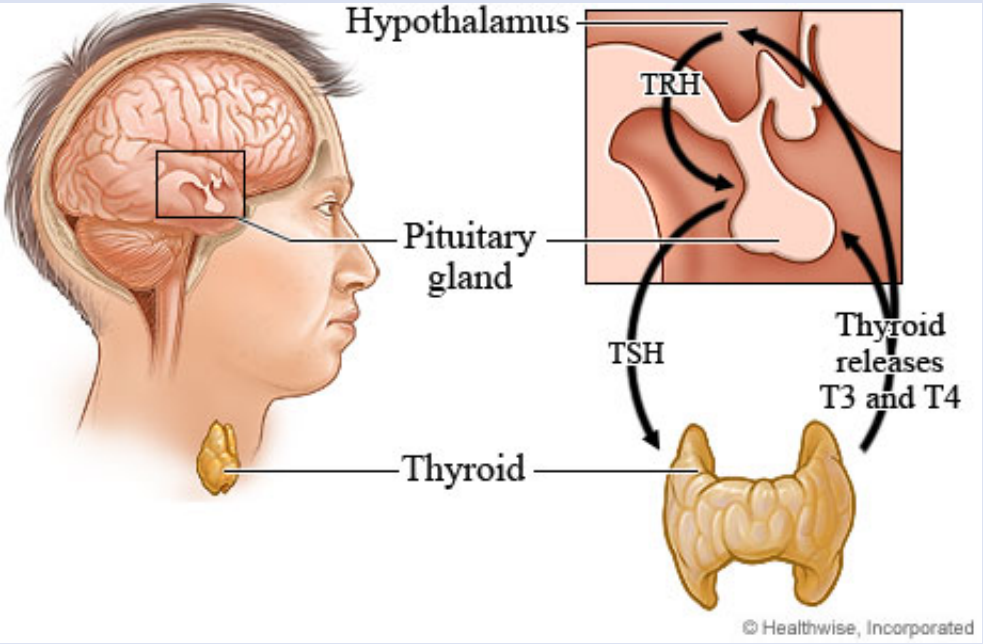
- Post-thyroidectomy, radioiodine treatment to destroy residual normal thyroid tissue and microscopic residues of malignant tissue may follow.

- Prior to radioiodine treatment, serum TSH must be raised to promote uptake of radioiodine by thyroid cells or thyroid cancer cells.

Thyroid Cancer Background:

- For the initial treatment –and later re-evaluations- elevation of TSH is usually achieved by withholding thyroid hormone medication that is necessary after thyroidectomy.

- However, withdrawal of thyroid hormones leads to hypothyroid symptoms including weight gain, fatigue, depression, mood swings, dry hair and skin, and constipation.

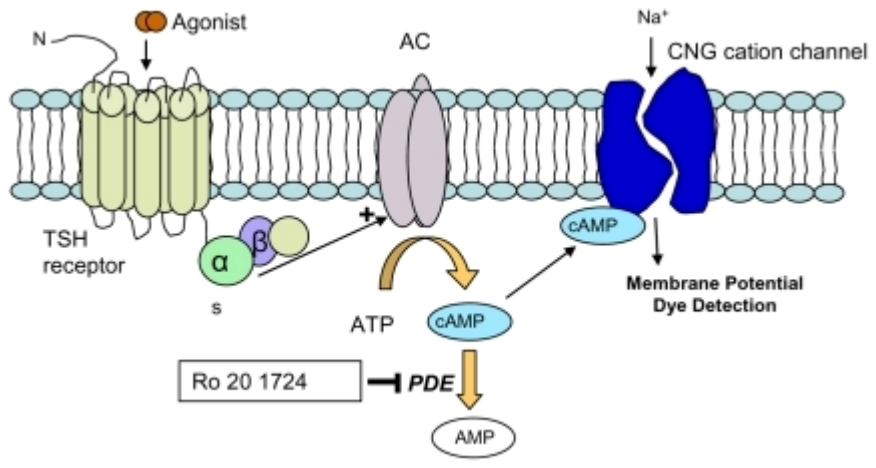


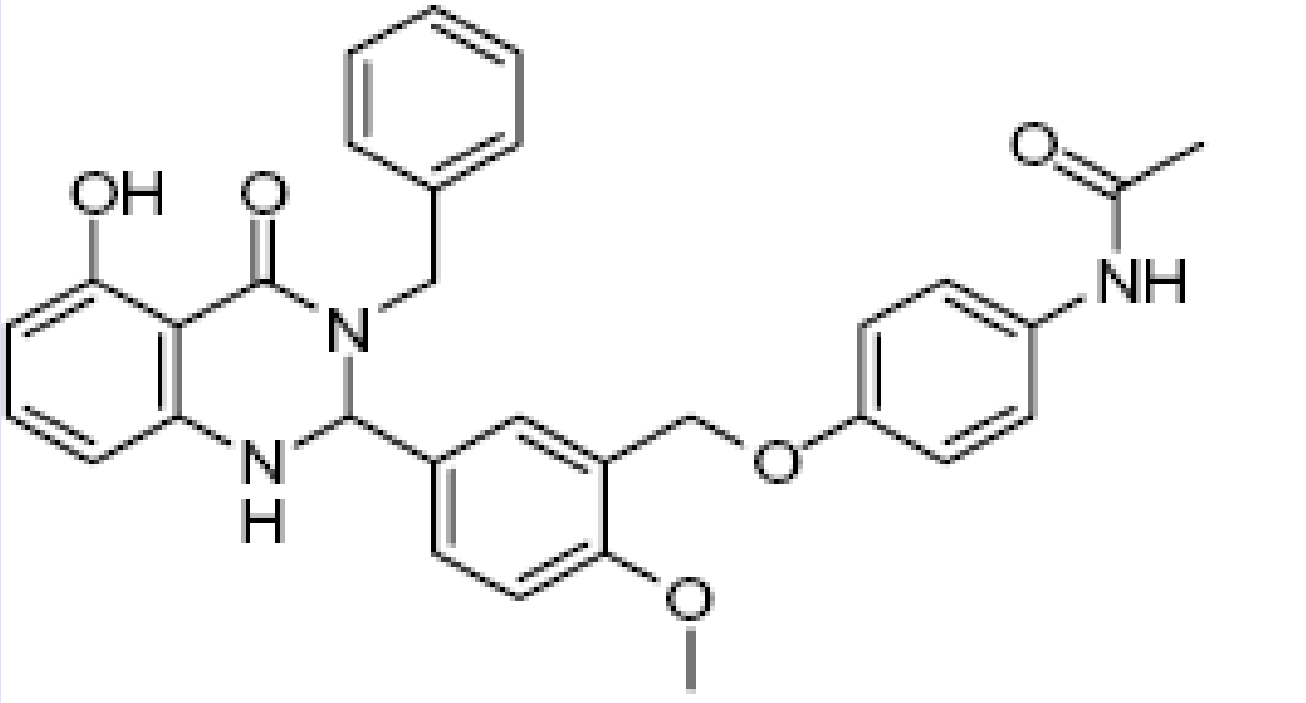
Therapeutic Treatment:

Recombinant human thyrotropin alfa, the natural agonist of the human Thyroid-Stimulating Hormone (TSH) receptor is administered via intramuscular (buttocks) injections.

Alternative Treatment with NIDDK Product:

An orally administered, small molecule agonist that activates the human TSH receptor to be used in place of synthetic thyrotropin alfa.

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Market Overview:

Parameter	U.S.	US & EU	Global
New Cases/Yr.	44,670*	65,000	123,000
Current Survivors	400,000	650,000 Est.	1,230,000 Est.
Incidence trend	Increasing	Increasing	Increasing
Thyrotropin Alfa Sales: Est. 2010 patients Est. Avg. Selling Price		$182 Million 107,000 $1700	
5-Year Cancer survival	80-90%		
Potential Recipients	70% of survivors to receive 2 or more courses of treatment		

* NCI estimate

Features and Benefits	
Small Molecule Synthesis	Less complicated manufacturing than the biological thyrotropin alfa*
Targets a GPCR	Many approved drugs target GPCRs
Oral Formulation	Better patient compliance
Niche market	Possible Orphan Drug Status

*$7.1 Million of product scrapped, 2010

- **Stage of Development:** Preclinical
- **Patent Status**: PCT/US2008/011958; National Stage filed 4/20/2011 (US, EU, AU, CA, JP, IN)

Next Steps

1) PK/ADME/stability studies in mice – ongoing
2) GPCR selectivity screen
3) Genetic toxicity studies
4) Safety pharmacology in rats & dogs
5) Toxicology in rats and dogs

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NCI and NIDDK Expectations and Deliverables Topic 075 (TSH Receptor Agonist)

Greg Evans, Ph.D.
Project Officer
NCI SBIR Development Center

- Collaborative NCI and NIDDK effort. Funding to be provided by NIDDK. Contract proposal receipt and technical review to be performed by NCI. Contract award and oversight to be a joint NCI-NIDDK effort.

- Goal: perform commercially directed drug development research with this TSH receptor agonist from intramural NIDDK, and independently, to seek a commercialization license from the NIH Office of Tech Transfer

http://sbir.cancer.gov/funding/contracts/

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NCI and NIDDK Expectations and Deliverables, cont
Topic 075 (TSH Receptor Agonist)

- Fast-Track proposals allowed: No

- Budget: $200,000 Phase I; $1,000,000 (per year for 2 years)

  Phase II; 1 award only

- Duration: Phase I, 9 months; Phase II, 2 years

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Deliverables for Topic 075 Phase I SBIR Contract

- Synthesize and evaluate activity of non-GMP drug in HEK293 TSH receptor cells and in primary cultures of retro-orbital fibroblasts provided by investigator
  [clarification- inventor will provide non-GMP drug, but contractor must synthesize GLP drug for studies below]

- Conduct tests* in rats and dogs to determine pharmacokinetics and bioavailability

- Conduct dose range finding* in rats and dogs with serum measurements of T3 and T4 thyroid hormones, and of thyroidal radioiodine uptake

- Conduct genetic toxicology* in rats

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Deliverables for Topic 075 Phase I SBIR Contract cont

- Conduct safety pharmacology* in rats.
- Conduct toxicology* studies in rats for 5 days.
- Conduct histology/pathology* assessments in rats.
- Conduct Pre-IND meeting with FDA.
  *Note: Conduct as non-GLP or GLP as appropriate.
  [FDA requires GLP for all preclinical safety studies in support of an IND filing]
- Provide results of all studies.

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Licensing, and Follow-On Phase II SBIR Contract

- The awarded Phase I contractor will automatically be granted a royalty-free, non-exclusive license to use NIH-owned and patented background inventions only within the scope and term of the award. However, an SBIR offeror (pre-award) or SBIR contractor (after award) must negotiate an exclusive or non-exclusive commercialization license to make, use, and sell products or services incorporating the NIH background invention.

- An SBIR contract proposal will be accepted as the INITIAL (unofficial) application for a commercialization license to such background inventions.

- Timing of official license application (coordination of funding/licensing)

- Phase I contract period will be approx Sept 30, 2012 thru June 30, 2013 (9 months)

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Licensing, and Follow-On Phase II SBIR Contract cont

- A follow-on Phase II contract can only be submitted by invitation from NCI, and an invitation can in principle be issued within 2 months of the successful completion of Phase I work
- An invitation will generally only be issued if NIH has granted the Phase I SBIR contractor a commercialization license by that time (exceptions)
- Anticipated Phase II deliverables as listed in published solicitation

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Q&A for Topic 075

We will take questions in two ways:

1- for audience members in the room, raise your hand

2- for audience members participating remotely, send your question in writing via e-mail to Elicia Rothschild at: **Elicia.rothschild@nih.gov**

During the designated Q&A time slots, we will alternate taking questions from local versus remote participants

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Overview of License Application Process

Tara L. Kirby, Ph.D.

Senior Licensing and Patenting Manager
Division of Technology Development and Transfer

Office of Technology Transfer
National Institutes of Health

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Important NIH Offices for an SBIR-TT Contractor

1) NCI Office of Acquisitions
   - Awards SBIR-TT Contracts.

2) NCI Technology Transfer Center or
   NIDDK Office of Technology Transfer and Development
   - Coordinates collaborative interactions with the Topic inventor(s).

3) NIH Office of Technology Transfer
   - Coordinates the Topic licenses.

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The NIH Office of Technology Transfer (NIH OTT)

- The NIH OTT is the centralized office that manages inventions that arise from intramural NIH and FDA research.
  - The NIH OTT serves as the bridge that connects these discoveries to commercial partners that develop these technologies into products and services to benefit public health.
  - In FY10
    - Managed ~1,300 active agreements
    - $91.6M in royalties
    - $6B total licensee sales

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Patents and Licenses

- Q: Why are licenses relevant to an SBIR-TT contractor?
- A: Because issued and pending patents exist for the SBIR-TT Topic background inventions.
  - For development and commercialization of these inventions, licenses must be in place.

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The Internal Use License

- The SBIR-TT contractor is automatically awarded a "royalty-free, non-exclusive" internal use license concurrent with the SBIR-TT contract.
  - This internal use license allows the SBIR-TT contractor to complete its research without worrying about possibly infringing any existing NIH patents.
  - This internal use license is automatic and royalty-free.

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The Commercialization License (Part 1)

- The internal use license allows the SBIR-TT contractor to complete internal research and development using the invention, but it does not allow an SBIR-TT contractor to actually make, use, or sell the final commercial product.

- The goal of the SBIR-TT funding mechanism is to enable an SBIR-TT contractor to develop an NIH invention into a commercial product that benefits the public.

  – For commercialization rights, we require (issued claims) and/or request (pending claims) that an SBIR-TT contractor obtain a commercialization license.

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The Commercialization License (Part 2)

- Because commercialization is a critical component of SBIR-TT, we have included a commercialization license requirement into each Topic.
  - "A Phase II proposal will typically/generally only be invited by NCI if the Phase I contractor has been granted a commercialization license" via the NIH license application process.

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The Timing of the Commercialization License

- Because the time required to obtain a commercialization license can vary, SBIR-TT offerors are strongly encouraged to apply for a commercialization license at the same time that they submit an SBIR-TT contract proposal.
  - We want to help you to obtain a commercialization license before the SBIR-TT Phase II proposals are invited.

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The Negotiation of the Commercialization License

- Q: Can we negotiate the terms of the commercialization license?

- A: Yes. Many of the terms within the license are negotiable.
  - We will help you to design the license that will best fit your commercialization plans.

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Start-Up License Agreements

- Offered during FY 2012 (Oct.1, 2011-Sept.30, 2012)
- Goal: facilitate licensing of NIH/FDA intramural inventions to start-up companies
  - Vaccines, drugs and therapeutics
- Applicant eligibility:
  - Less than 5 years old
  - Less than $5M funding
  - Less than 50 employees
- More information at http://www.ott.nih.gov/startup/

http://sbir.cancer.gov/funding/contracts/

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How Do I Obtain a Commercialization License?

- Contact the responsible Licensing and Patenting Manager (LPM) in the NIH OTT.
  - For Topic 075, the responsible LPM is Tara Kirby, tarak@od.nih.gov
  - For Topic 310, the responsible LPM is Cristina Thalhammer-Reyero, thalhamc@mail.nih.gov
  - For Topic 311, the responsible LPM is Sam Bish, bishse@mail.nih.gov
- Tara, Cristina, and Sam will walk you through the licensing process.

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For Further Questions

- Please see the SBIR-TT FAQ at:

http://sbir.cancer.gov/funding/contracts/faq.asp

- For licensing questions, please contact the Licensing and Patenting Manager responsible for the Topic that interests you.

- For all other SBIR-TT questions, please contact Anita Hughes, Contract Specialist, NCI Office of Acquisitions, anita.hughes@nih.gov.

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Q&A for Licensing

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Technology Transfer at the NCI

John Hewes, Ph.D.
NCI Technology Transfer Center

http://sbir.cancer.gov/funding/contracts/

U.S. Department of Health and Human Services
National Institutes of Health

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How to Partner with NIH

- Grants (http://www.grants.gov)
- Contracts (https://www.fbo.gov)
- Public Private Partnership
- Research Collaboration / Co-development
- Licensing
- Materials/Services
- **SBIR-TT**

http://sbir.cancer.gov/funding/contracts/

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Many ways to collaborate

- Confidential Disclosure Agreement
  - *Initial discussions with researcher(s)*
- Material Transfer Agreement
  - *transfer of tangible research materials between two or more organizations*
- Collaboration Agreement
  - *Basic, pre-clinical or clinical research collaboration*
- Clinical Trial Agreement
  - *NCI clinical trial of company agent or device*
- Cooperative Research and Development Agreement (CRADA)
  - *License option on forward IP*
  - *NCI's efforts compensated by company*

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NCI Collaboration Agreement

- Defined research project
- No license option
- Data and material sharing
- Confidentiality
- Publications
- No funding exchange
- Anticipated to be the agreement of choice for the SBIR-TT program initially.
- Can expand into CRADA as project dictates

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CRADAs: Legal Requirements and NIH Policies

- Law:
  - Provide option to exclusive license in specified field of use
  - Government can receive (but not provide) funding*
  - Consistent with missions of the Federal laboratory

- NIH CRADA policies
  - Intellectual contribution by NIH and Collaborator
  - Dissemination of research results
  - Conflict of interest review
  - Focused CRADA research plan
  - License option balanced with research tools policy

* Except when funds are provided by the same Federal Lab.

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CRADA Inventions

- Reported in about 10% of CRADAs
- Collaborator may exercise option and license (royalty-bearing) NIH inventions made solely or jointly with Collaborator
- If Collaborator declines option for exclusive license, NIH may license to others
- NIH does not provide assignment (ownership) of government inventions made under the CRADA to the company
- NIH does not provide royalty-free commercial sales licenses (except for combination study inventions)

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Negotiation of CRADAs

- Determine if CRADA is best agreement type
- Appendix A: Research Plan
  - Focused
  - Responsibilities of each party
- Appendix B: Financial/Materials
- Appendix C: Modifications to NIH model
- Route for clearance
- Review by NIH CRADA subcommittee
- Agreement execution

The structure of the collaboration is flexible

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How much does it cost?

- Most collaborations involve in-kind exchange
  - Each party responsible for its own costs
- CRADAs only permit NCI to receive funds to offset NCI costs for CRADA research. However, in the context of SBIR recipients. NCI cannot receive funding that was provided to the Collaborator from an NCI grant or contract. <u>However, funding from other non-NCI sources is acceptable if needed</u>
- NCI cannot provide funding to Company under any of these agreements

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Collaboration on SBIR-TT Contracts

- ✓ NIH labs can co-develop under many different formats, depending on the need;
- ✓ Company can exchange knowledge with the NCI researcher;
- ✓ Company can utilize fixed asset resources at NCI and NCI-Frederick;
- ✘ Company cannot contact NCI researchers prior to contact award;
- ✘ Company cannot rely on the NCI lab to perform the majority of the effort being proposed for the SBIR contract;
- ✘ Company cannot fund work in NCI lab using SBIR money under a CRADA.

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Q&A for NCI Tech Transfer, Then for Any Topic

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Closing Remarks

Greg Evans, Ph.D.
NCI SBIR Development Center

- Thanks to the presenters and audience (remote and local)

- Content from this event (slides and Q&A) to be posted on the NCI SBIR website (linked to the 3 SBIR-TT topics) within 1 week (proposal receipt date is 4 weeks away)

http://sbir.cancer.gov/funding/contracts/

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Important Information for Proposal Submission

PROPOSAL RECEIPT DEADLINE IS MONDAY NOVEMBER 7, 5 PM EASTERN TIME

http://sbir.cancer.gov/funding/contracts/
- **Technical, budget, and project duration summaries for topics 310, 311, and 075**
http://grants.nih.gov/grants/funding/SBIRContract/PHS2012-1.pdf
- **Full NIH SBIR Contract Solicitation Document, with instructions, forms, review criteria, contact names/info, and topic summaries in the NCI and NIDDK sections**

All technical inquiries from companies must be sent to:
Ms. Anita Hughes
Phone: (301) 435-3805
Fax: (301) 480-0309
Email: anita.hughes@nih.gov

Proposals to the NCI, if mailed through the U.S. Postal Service, must be addressed as follows:
Ms. Anita Hughes
Contract Specialist
Office of Acquisitions
National Cancer Institute
6120 Executive Blvd., EPS, Room 6038
Bethesda, MD 20892-7193

http://sbir.cancer.gov/funding/contracts/