Commercialization of Academic Research

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Michael Moore, Ph.D.
Invention Manager, INVO
Topics for Today

I. Introduction to INVO
II. Invention Disclosures
III. Invention Assessment/Patentability
IV. Outreach to Companies
V. Licensing
Commercialization of Academic Research
Bridging the Gap

Basic Discovery Research

Proof of concept & relevance

Early stage Gap Funding

Commercial Development

The Valley of Death
Culture Clash

**Entrepreneurs**
- Teamwork is Vital
- Hoard Knowledge
- Fear Reproduction of Work
- Customers Matter
- Economics Paramount
- Profits are the Currency
- Publishing Has to Justified
- Technology is the Beginning

**Academics**
- Reputation as an Individual
- Give Away Knowledge
- Enable Reproduction
- Customers Don’t Matter
- Economics Don’t Matter
- Publication is the Currency
- Publish over Patent
- Technology is Everything
I. INVO’s Activities

- **Faculty Outreach**
  - Educate faculty about protecting IP and scouting for invention

- **Business Development and New Ventures**
  - Coordinate entrepreneurial and innovation initiatives across NU
  - Provide resources for start up company formation

- **Intellectual Property Protection**
  - Evaluate inventions for patentability.
  - Work with law firms to seek and obtain patent protection when needed

- **License Negotiations**
  - Negotiate agreements with startup or established companies granting rights to NU material or intellectual property
II. Disclosing Inventions

- This is the first step
- Information needed in a disclosure
- Types of inventions disclosed by FSM
Inventors

• What makes a person an inventor?
• Inventorship is a legal determination
• An inventor is one who contributes to the conception of the invention
• Inventors may be from multiple institutions

Sponsors

• Government, foundation, or corporate funding
• Inventions are reported to funding entity
Public Disclosures

- Grants (when awarded)
- Manuscripts when published (online or in print)
- Posters
- Abstracts
- Thesis/Dissertation
- Disclosure to industry
- Presentations*

Impact of Public Disclosure

-Loss of foreign patent rights.
-A US patent is still possible if a patent application is filed within 12 months of the disclosure.
Description of the Invention

• Clearly spell out applications, advantages, and the inventive aspects of the invention
• Background material can be manuscript draft, excerpt from a grant, poster, PowerPoint presentation
• Helpful to know where you see the commercial applications
Life Science Inventions

• Therapeutic compositions
• Novel methods of use of known compounds
• Biomarkers/diagnostics
• Devices
• Research tools
  – Antibodies, animal models, cell lines
III. Assessing Inventions & Patentability

- Questions to ask
- Requirements for patentability
- What’s in a patent
- Important factors outside of patentability
Uh, gee, that's wonderful

Woo Hoo!
Evaluating an Invention

- Can it be patented?
- Would the patent be strong or weak.
- Is there freedom to operate?
- Is it enforceable?
- Is it licensable?
So... what is a patent?

- A patent for an invention is the grant of a property right to the assignee, issued by the USPTO.
- The right is “to exclude others from making, using, offering for sale, or selling” the invention in the US or “importing” the invention into the US.
How do you get a patent?

Deceptively simple requirements:

- Novel
- Non-obvious
- Useful

• The invention must be enabled
• Patent is defined by the claims
• Patents exclude others from using/practicing
• Not all patents are equal
Enabled v Non-enabled*

**Enabled**
- Potential for claims 2B allowed
- Exclude competitors

**Non-Enabled**
- Claims unlikely
- Can’t exclude competitors
- Potentially block others from patenting that space

*Can depend on field of invention*
If Your Not Enabled...

- The specification and claims generically describes activating an unknown and undefined, generic heat shock response comprising increasing the activity of an unknown, undefined and generic HSR signaling factor, which requires administration of nothing; including a ligand of the TGF-B signaling pathway, which is further undefined and generically recited. Although claim 9, for example, does recite administration of a generic "pharmacologic agent", this generic "agent" is also unknown and undefined. Although the instant specification describes use of a C. elegans model system, how this extrapolates to treating a laundry list of unrelated neurodegenerative disease states, including ALS, Huntington's, Alzheimer's and Parkinson's, etc., which are diseases of humans and not C. elegans, is unknown.
How do we get there?

Patent application must be filed within 12 months of a public disclosure for US patent protection.
Foreign Patents

- Application must be filed before disclosure
- World Intellectual Property Organization (WIPO)
- The Patent Cooperation Treaty (PCT)
- PCT application holds foreign rights.
- Enter individual countries 30 months after priority date. ☢️ $$$$$$
MELTABLE FORM OF SUCRALOSE

Inventors: Carolyn M. Merkel, North Haledon, NJ (US); Ning Wang, Plainsboro, NJ (US); Joan Lee, Bridgewater, NJ (US)

Assignee: Tate & Lyle Public Limited Company, London (GB)

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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U.S. Cl. 426/548, 426/471; 426/660
Field of Classification Search 426/548, 426/89, 103, 237, 438, 471, 660
See application file for complete search history.

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Primary Examiner—Leslie Wong
(74) Attorney, Agent, or Firm—Martner/Prestia

ABSTRACT
The present invention provides a meltaable sucralose and saccharinum-k sweetener. This sweetener may be incorporated in a wide variety of reduced calorie food products such as cooked and hard candies, microwaveable food products, glazed food products, deep fried food products and as a substitute for sugar in applications that require mol糖 sugar.

21 Claims, 2 Drawing Sheets
The Heart of the Patent

• **Drawings**: required if necessary to understand the invention.

• **Specification**: text of the patent. Should act as a users manual to make/use the invention.

• **Claims**: include “limitations” that define the boundaries of a patent owner’s right to exclude.
What is claimed is:
1. A compound of the formula S-(+)-4-amino-3-(2-methylpropyl) butanoic acid as a single optical isomer.
2. 4-amino-3-(2-methylpropyl) butanoic acid, or a pharmaceutically acceptable salt thereof.
3. A pharmaceutically acceptable salt of S-(+)-(4)-amino-3-(2-methylpropyl) butanoic acid, said salt being present as a single optical isomer.
4. A pharmaceutical composition comprising a compound any one of claims 1 or 3, together with a pharmaceutically acceptable carrier.
Claim Examples

• A method to treat cancer in a mammal, comprising administering to a mammal in need of such therapy an effective amount of a compound with antiangiogenic activity.

• A method to treat cancer in a mammal, comprising administering to a mammal in need of such therapy an effective amount of a Drug X.

• A method to treat a basal cell carcinoma in a mammal, comprising administering to a mammal in need of such therapy an effective amount of a Drug X.

• A method to treat a basal cell carcinoma in a mammal, comprising administering to a mammal in need of such therapy 100mg of a Drug X once per day.
Patent v Patent Application

- **Patent**
  - Issued by the patent office
  - Can enforce rights
  - Defined claims

- **Patent Application**
  - Request for a patent, nothing is issued
  - Generally is broader than what will be allowed.
  - Can file an application on *anything*... it just won’t be granted
  - Can make competitors aware of pending application
Freedom to Operate

If you’ll recall...

• Patent provides assignee with right to exclude others from practicing the claimed invention
• Thus, patentability does NOT mean freedom to operate!
Freedom to Operate: Example

A Knife

A Fancy Knife
Enforceability

• Commercial or Academic
• Would it be known if an infringer was practicing the invention
• Ultimately, what value would our patent provide a licensee.
IV. Outreach to Companies

- By INVO
  - Identify Potential Partners
  - Identify Key Personal
  - Send Invention Abstracts
  - Cultivate Relationships
  - Web Promoting

- By Inventors
  - Publications
  - Scientific Conferences
  - Lab Websites
Profit is not a driver to bring research to the market

It is a numbers game.

Long time lines -- almost impossible to pick winners
Valuation

Value vs. Risk

Time

Risk

Value
V. Licensing

- What is a License
- What Does Northwestern License
- Licensing Considerations
- Anatomy of a License Agreement
What is Licensing?

We own it, but you can use it if...
What is Licensing?

• Licensing is the practice of leasing a legally protected property to another party in conjunction with a product, service or promotion.

• Based on a contractual agreement between the owner of the property (licensor); and normally a manufacturer or retailer (licensee). It grants the licensee permission to use the property subject to specific terms and conditions, which may include the purpose of use, a defined territory and a defined time period.

• In exchange for this usage, the licensor receives financial remuneration - normally in the form of a guaranteed fee and/or royalty on a percentage of sales.
What Does Northwestern License?

- Patent Rights
  - Rights covered under our patents or patent applications.

- Material
  - May not be patented. Often biological (cell lines, animal models, antibodies) or chemicals/materials.

- Software
Licensing Considerations

• Overall goal is to get innovation to the public.
• Financial terms are only one consideration.
• Structure to ensure development of the invention.
• Ensure continued academic use.
• Protect ability to publish.
• Minimize inclusion of future improvements.
• Maintain access to research tools.
Content of a License Agreement

- Recitals
- Definitions
- Grant
- Confidentiality
- Milestones/Diligence
- Payment
- Reports and Records

- Publication
- Patent Prosecution
- Infringement
- Product Liability
- Term and Termination
- Assignment
- Dispute Resolution
- General
Milestones and Due Diligence

- Define activities a licensee must achieve to keep the license in effect.
- Often associated with a time frame.

Examples of milestones:
- Business Plan
- Clinical approval phases
- Launch product in marketplace
- Annual Progress Reports
- Prototype development
- Generate sales

Generally borrowed from licensee’s development plan.
Payments

- Numerous ways to structure payments.
- Payments can be structured to shift cost to later date.
- Payments can include:
  - Upfront fees (cash and/or equity)
  - Maintenance Fees
  - Milestone payments
  - Royalty & Minimum Royalty
  - Patent Expenses
  - Assignment Fee
  - Sublicense Fee
Thank you!

Michael Moore
michaelmoore@northwestern.edu
847-491-4645