

Technology Transfer: a tool to advance scientific research for IMAT researchers

Kevin Brand
Technology Transfer Center
National Cancer Institute
National Institutes of Health
brandk@mail.nih.gov



NCI's Goals for IMAT

Develop and carry out pilot applications of novel technologies that will enable the molecular analysis of cancer and their host environment

The IMAT Program

The IMAT Program was designed with three objectives:

- ❖ To focus innovative technology development efforts on the field of cancer
- ❖ To solicit highly innovative technology development projects from the scientific and medical communities
- ❖ To accelerate the maturation of meritorious technologies from feasibility through to development and/or commercialization

Therefore, proper attention to technology transfer (by the NCI and by IMAT grantees) is paramount in order for the IMAT program to meet these objectives.

Technology transfer to advance the IMAT mission

Publishing of research findings is at its core the most common modality for transferring technology; other ways include:

- ❖ Patent protection
- ❖ Exchanges of information by way of Confidentiality Agreements (CDAs)
- ❖ Exchanges of materials by way of Material Transfer Agreements (MTAs)
- ❖ Collaborations with academic/industry partners (sponsored research agreements)

What is the Output?

- ❖ Information
- ❖ Research tools
- ❖ Platforms with many potential applications
- ❖ Commercial products for research use
- ❖ Commercial products with clinical applications, e.g., diagnostic/prognostic

Potential challenges encountered by IMAT investigators

- ❖ Problems with patenting due to poor documentation or public disclosure
- ❖ Coordination among multiple collaborating institutions
- ❖ Investigator concerns about licensing of invention to company:
 - Loss of control/participation in development
 - Freedom to operate for future projects
- ❖ Licensee “sits” on technology and fails to meet critical milestones
- ❖ Early stage technology will require the interaction of multiple players (academic & commercial) to advance the technology to a useable platform for commercial development
- ❖ Financial and regulatory (product development) concerns

NIH Funding Requirements and their relevance to IMAT

- Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts (1994)
- Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts (1999)
- NIH Data Sharing Policy (2003)
- NIH Policy on Sharing of Model Organisms for Biomedical Research (2004)

Research Tool Guidelines

- Unique research resources arising from NIH-funded research community are to be made available to the scientific community
- Obligations to other sources of funding of projects in which NIH funds are co-mingled are to be consistent with the Bayh-Dole Act and NIH funding requirements
- Exclusive licenses for research tools are acceptable for:
 - Diagnostic and therapeutic uses as long as research uses remain available
 - Research uses when licensee agrees to make the research tool widely available to researchers

Intellectual Property and patents

- Patent- the right to exclude others from making, using, offering for sale or selling the invention throughout the United States, or importing the invention into the United States and its territories and possessions
- In most countries, a patent is granted to the first to file; but in the U.S., it is the 'first to invent'

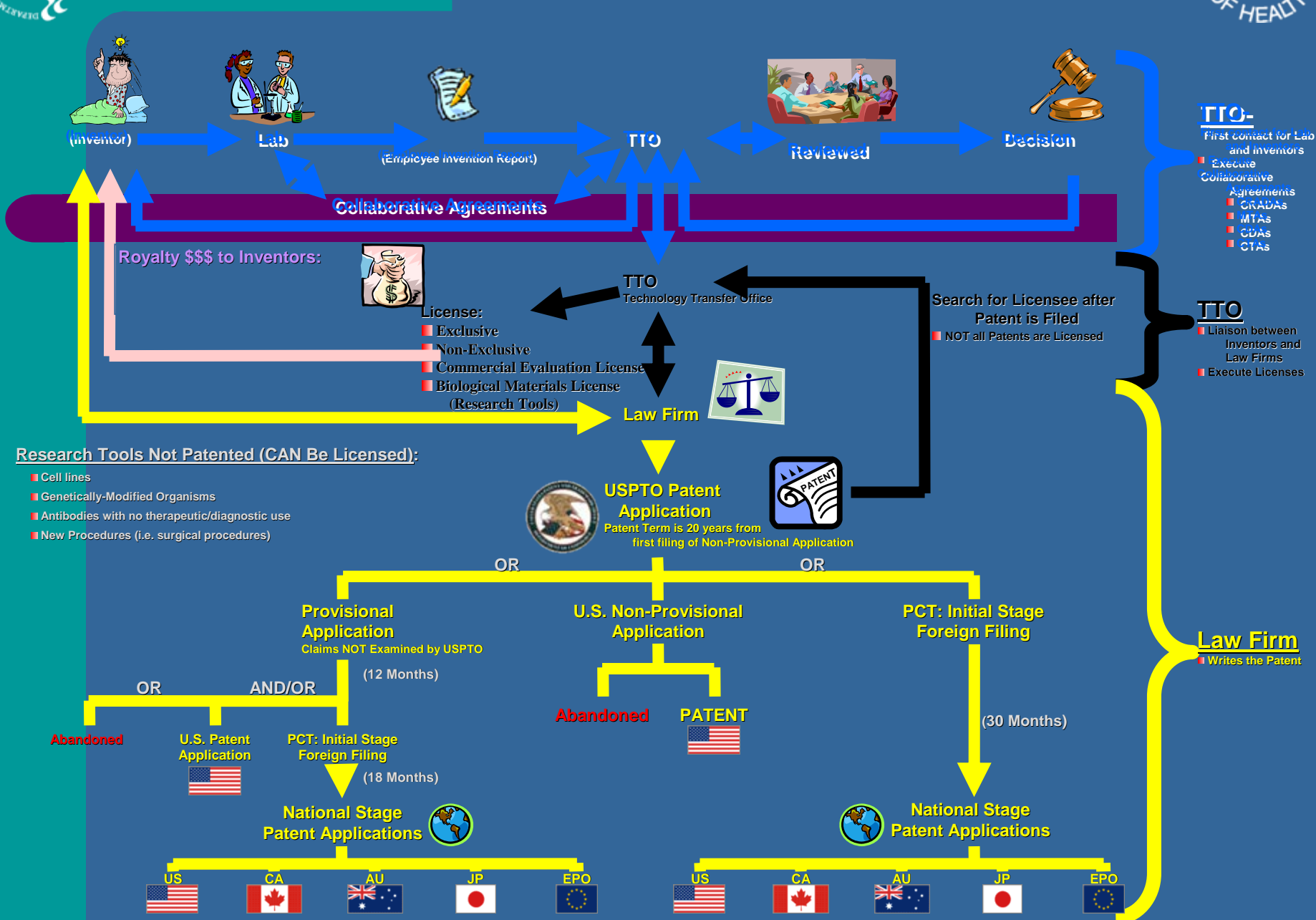
Patents: What is patentable?

- Can be any new and useful process, or method
- Machines
- Articles that are manufactured
- Compositions of matter
- Any new and useful improvement thereof

Patents: Losing Rights Through Public Disclosure

- Most international rights can be lost by making an enabling public disclosure before filing a patent application. Limitations may include:
- The U.S. and Canada allow a 1-year grace period
- Japan and Australia allow a 6-month grace period for certain circumstances
- Europe requires ‘absolute novelty’; i.e., no grace period

Invention Process and Stages of Patent Filing



The Bayh-Dole Act: Federal Funding Requirements

The Bayh-Dole Act addresses patent rights for a contractor under funding agreements by a federal agency (e.g., grants, contracts, and cooperative agreements) for performance of experimental, developmental, or research work funded in whole or in part by the Federal Government.

The Bayh-Dole Act: Recipient rights & Responsibilities

- Recipient owns rights in discoveries by timely electing title to subject inventions
- May be released to the individual inventor(s) but must seek a waiver from the funding agency to approve such a transfer of title from the non-profit recipient institution
- Recipient has responsibilities to meet reporting requirements

Bayh-Dole- Selected Definitions

- Invention: “Any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).” 35 U.S.C. § 201(d)
- Subject Invention: “Any invention of the contractor **conceived or first actually reduced to practice** in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.” 35 U.S.C. § 201(e)

Bayh Dole Requirements

- Reporting of inventions (via iEdison.gov)
- Election of title
- Move to practical application
- Notice on patent application of federal support

Invention Reporting Requirements of Funding Recipients

- Disclose Each Invention ⇒ **within 60 days**
- Resolve Election or Waive of Title ⇒ **within 2 years**
- File Patent ⇒ **within 1 yr. of election**
- Provide License to the Govt. ⇒ **upon title election**
- Indicate Govt. Support on Patent ⇒ **with patent application**
- Product Manufacturing in U.S. ⇒ **required**
- Report on Invention Utilization ⇒ **annually**
- Final Invention Report ⇒ **at award close out**



Points to consider

- When reporting inventions, please let your university know if your discovery is supported with IMAT funding so that the invention can be reported as appropriate to the NIH
- Careful consideration should be given to the signing and dating of laboratory notebooks to clearly document when the invention came into existence (U.S., “first to invent” patent system)

NCI IP Management Plans

- ❖ To help address some of the IP challenges of NCI-funded research, NCI now requests when appropriate that grant applicants submit IP management plans.
- ❖ Purpose is to ensure that applicant investigators work with tech transfer offices & sponsored research offices to think through potential issues prospectively.
- ❖ <http://ttc.nci.nih.gov/intellectualproperty/sample.php>

NCI IP Management Plans for IMAT

- ❖ Address coordination of patent prosecution and licensing if necessary to enable licensee to access IP to take product to market
- ❖ Suggested strategies provided in RFA
- ❖ Technology transfer official submits
- ❖ Just-in-time requirement

Options for coordinating rights

- ❖ Inter-institutional agreements to bundle technologies
 - **Lead institute manages patents, licenses**
 - **Costs and licensing revenue shared**
- ❖ Assignment of inventions from several institutions to a single invention management firm
- ❖ Formal patent pooling

Suggestions for IMAT Investigators

- ❖ Consider commercial applications of technology
- ❖ Discuss issues with your technology transfer office:
 - to develop IP management plan
 - address issues during collaborations
 - timely report inventions
 - explain context of project for invention
- ❖ Make sure you talk with all appropriate personnel during the process (“cradle to grave”)

Collaborations!

Collaborations with other entities can serve as the vehicle by which an early stage technology is advanced to the point where it is commercial viable. Further, such collaborations can assist the university in justifying the expenditure of costs to maintain patent applications or to seek international patent protection.

Collaborations- what to do?

Advertise!

- ✓ Publications, presentations, etc.
- ✓ Website (tech transfer or your personal lab website)
- ✓ Scientific meetings
- ✓ Colleagues and friends in your same area of research
- ✓ Tech Transfer Annual Meetings

Take home points

- Report new discoveries to your respective tech transfer offices
- Transparency- make sure that tech transfer knows that discovery is supported in whole or in part by IMAT funding
- Tertiary, non-federal funding of IMAT discoveries; ensure that your sponsored research dept is aware of IMAT involvement in your discovery

Other ideas?

- Talk to fellow IMAT investigators on how their universities advance discoveries that originate from IMAT funding
- When engaging discussions with outside groups to advance IMAT discoveries, make sure appropriate protections are put in place (CDAs)
- Encourage tech transfer to involve YOU in outside negotiations when it is appropriate!

Questions for me

Kevin Brand

Technology Transfer Center

National Cancer Institute, NIH, DHHS

301-496-0477

E-mail: brandk@mail.nih.gov