

TECHNOLOGY TRANSFER UNIVERSITY OUTLINE Spring 2008

**6610 Rockledge Drive, Room 4033
Wednesdays, 9am – 12pm and 1pm - 4pm**

Day One (May 7)

Basic Principles of Intellectual Property Law

Morning -- Patents

Bruce Goldstein, OTT

What is “IP,” and briefly identify differences between the four types

Patents

What is a patent, determining ownership, and rights of patent owners

What kinds of inventions are patentable

Criteria for patentability

Statutory subject matter

Utility

Novelty

Non-obviousness

Written description (incl: “constructive reduction to practice”)

PHS policy on patenting and licensing

Exercise: cases involving inventions

Afternoon -- Other Types of IP

Bruce Goldstein, OTT

Copyrights

What items can be copyrighted

Determining ownership

Rights of © owners

Trademarks

What marks are eligible to be trademarks

Rights of TM owners

Trade Secrets

What information can be protected as a trade secret

Rights of T/S owners

PHS policy on each type of non-patent IP

Day Two: (May 14)

Morning -- Patent Process

Mojdeh Bahar, OTT

- Process for acquiring a patent in the United States
 - Anatomy of a patent
 - What is a “claim” (independent, dependent, Markush)
 - Reading the front page of a patent
 - Provisional applications
 - Original application
 - Prosecution and Issuance
 - Applicant’s choices after final rejection
 - RCEs, CIPs, Divisionals
 - Interferences
 - Reissue, Reexamination, and Litigation
- General process for acquiring a patent in other countries (Patent Cooperation Treaty)
 - Chapter I and Chapter II
 - EPO
- OTT process for prosecuting patent applications
- IC-specific processes (NCI as example)

Afternoon -- Pertinent Laws

Dale Berkley, OGC

- Bayh-Dole Act
 - Funding agreement
 - “Contractor”
 - Grants and Cooperative Agreement Act
 - March-in provision
 - Perfecting rights in contractor-owned inventions
 - Protection of federally-owned inventions
 - Executive Order 10096 and 37 C.F.R. 501
 - Licensing federally-owned inventions
 - Notice for exclusive licenses
 - Employee ownership rights (15 U.S.C. 3710d)
- Stevenson-Wydler Act (as amended by the Federal Technology Transfer Act of 1986)
 - CRADA money
 - CRADA licenses—options
 - CRADA confidentiality
- 28 U.S.C. 1498
 - Contractors
 - Grantees

Day Three (May 21)

Morning – Tech. Transfer Agreements

Patrick Twomey, NCI

Overview of the types of agreements; when to use each type

Confidential Disclosures and Material Transfers

- Definition of “confidential information” and exclusions

- (In)appropriate restrictions on disclosure

- PHS policy on publication

- Duration of obligations

- Issues raised by category of materials being transferred

- Ownership vs mere possession

- Transfers of materials vs transfers of IP embodied by materials

- (In)appropriate uses of materials

- Redistribution and disposal

- Reach-through and other IP issues

Afternoon -- CRADAs

Kathleen Carroll, NCI

- Key components and organization of CRADAs

- Conflict of interest

- NIH review/approval process

- Research plans

- Contribution of resources

- Statutory licenses

- Key clauses

Day Four (May 28)

All Day -- Addressing Human Subject Use in Technology Transfer Agreements

Suzanne Frisbie, NCI

Where to go for more information

Types of research

Laws and regulations

Protection of Human Subjects

 Assurances

 Informed Consent

Clinical trial “phases”

Interacting with the FDA

 INDs

 IDEs

 PMAs

 510K

 NDAs

 Sponsors

 Adverse Events

Orphan drugs

Hatch-Waxman

Clinical trial jargon

Agreement issues

 Types of agreements

 Intramural versus extramural

 Information needed

Examples of different scenarios

Day Five (June 4)

Morning -- Licenses to Patentable Technology

Sue Ano, OTT

Overview – Licensing at the Office of Technology Transfer (OTT)

Authorities for Licensing

Types of PHS licenses, and procedures for each type of license

Case Studies:

Royalty types

License scope, development plans, and key milestones

Sublicensing and license-transfer issues

Retained rights/licenses

Collection, termination, & enforcement/litigation

Marketing strategies

NIH royalty administration

Afternoon – Software, Contract and Grant Related Issues in Technology Transfer

Jeff Thomas, NCI and John Salzman, OER

Software Concerns

Contract related issues

Grant related issues

Impact of using a grant or cooperative agreement versus a contract

Consortia

Day Six (June 11)

Morning – Marketing in Technology Transfer

Ajoy Prabhu, OTT

Basics of Marketing
Principles of Technology Valuation
 Examples
 Case studies
Marketing-oriented Writing
 Examples
 Case studies

Afternoon – Customer Service and Negotiation Techniques

Karen Maurey, NCI

Tools for improving communications
How to handle common situations in negotiations
Wrap-up negotiation exercise – synthesize and apply course material