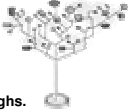


Role of Technology Transfer Office: The NIH Experience

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Technology Transfer Workshops & Symposium
Indo-US Science & Technology Forum
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Science. Ideas. Breakthroughs.

NIH Office of Technology Transfer: Overview

- Division of Technology Development and Transfer (DTDT)
- Division of Administrative Management (DAM)
- Division of Policy
- International Activities

Division of Technology Development and Transfer

- Composed of 5 branches:
 - General Medicine
 - Cancer
 - Infectious Diseases/Medical Engineering
 - Monitoring and Enforcement
 - Technology Transfer Service Center
- Clearinghouse for invention disclosures from all 27 ICs/FDA
- Manages Records

Role of DTDT

- Assess Inventions
- Manage Patent Prosecution
- Market Technologies
- Conduct Out-Licensing
- Monitor and Enforce Agreements

Role of DTDT

- Assess Inventions
 - Seek patent protection or license w/out patent
 - NIH Research Tools Policy
 - Any material or method that can be used to further investigation into biological systems or pathways or which can be used to identify potential new pharmaceutical products
 - NIH Patenting Policy
 - Seek if facilitates availability for preventative, diagnostic, therapeutic or other commercial use
 - Seek if further R&D necessary to realize technology's primary use
 - Seek if commercial or public health value warrants expenditure of funds
 - Seek if research has practical utility or reasonable expectation of future practical utility
 - Do not seek if commercialization/transfer can best be accomplished without
 - Waive rights to inventor
 - Dedicate to public domain

Role of DTDT

- Manage patent prosecution
 - In concert with contract law firms
 - Advise IC's on strategy
 - General patenting model:
 - Invention Disclosure
 - Provisional Patent Application
 - PCT Application
 - National Stage (various countries)

Role of DTD

- Market Technologies
 - Federal Register
 - OTT list serv
 - Commercial databases
 - Present at various national/international venues in concert with ICs and/or inventors
 - Direct marketing

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Role of DTD

- Conduct out-licensing
 - Transfer inventions to private sector for further R&D and potential commercialization to benefit public health
 - Aim to commercialize intramural US Federal technologies with the intent of recouping US taxpayers' dollars
 - Negotiate mutually beneficial terms and language with academia, start-ups, multi-national pharma, biotech, med-device, research reagent companies and other Gov Agencies and private foundations
 - Ensure use, commercialization and public availability
 - Gateway to licensing: NIH License Application
 - Typical agreements
 - Non-exclusive vs. exclusive preference

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Role of DTD

- Monitor and Enforce Agreements
 - Monitor obligations to ensure compliance
 - Coordinate with RAU to enforce payment obligations & intervene if obligations not met
 - Investigate and settle patent infringement cases
 - Initiate and manage 3rd party royalty audits
 - Negotiate and settle disputes involving license obligations or royalty audit findings

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Role of DAM

- Manage royalties
- Conduct operational procurements
- Manage law firm procurements
- Service IT needs of OTT
- Coordinate personnel matters
- Process travel
- Manage facilities

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Role of DAM

- Notify Licensees of financial obligations
- Collect royalties from Licensees
- Recover patent prosecution costs
- Calculate & authorize IIA payouts
- Reconcile monthly receipts with OFM
- Authorize release of (licensed) material

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Typical Royalties in NIH Agreements

- Execution fees
- MAR
- Milestone/Benchmark payments
- Sublicensing consideration
- Patent reimbursement costs
- Earned Royalties

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Royalty Rate Negotiation

- Type of Product
- Stage of Development
- Market Value of Product
- Market Timing
- Scope of Patent Coverage
- Uniqueness of Materials
- NIH "Content"
- Public Health

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Division of Policy

- Provide policy review & development
- Provide CRADA support
- Provide intramural policy support
- Provide legislative feedback
- Provide input to international technology transfer and intellectual property initiatives
- Handle waivers and FOIA requests

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Thank you!

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