

# Biotechnology and the Law

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## Patent Developments and Licensing Trends

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## Licensing Trends

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# Current Trends Influence License Terms

- Trend toward narrower scope of patent claims
- Trend toward creative proprietary positions in the human genome
- Trend toward increased post-genomic research tool licensing deals and massive compound screening deals
- Trend toward license terms that reflect specialized technology in order to maximize value

# Ownership and Control

- Trend toward detailed technical definitions
- “Field” definitions are highly refined
  - may be limited to specified indications
  - therapeutic, preventative or diagnostic use
  - human, veterinary or agricultural use
- “Technology” definitions are increasingly specific
  - patents and patent applications
  - know-how, methods, information, processes
- Trend toward identifying solely owned technology and program technology

# Exploitation and Participation

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- Rights to use “Technology” outside of the “Field”
- Research program
- Technology transfer
- Co-development
- Downstream product development opportunities often are flexible

# Financial Components

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- Up-front fees
- FTE support during research program
- Milestone payments and trigger events
- Equity investments
- Special situations
  - universities
  - research institutes
  - non-profits
  - foreign entities



Example:

How These Trends Are  
Manifested in Database Deals

# Structuring the Database or Research Tool Deal

- Maximize exploitation of the database or research tool with maximum number of licensees with access for different applications
- Do not make the deal so complicated that it is impossible to administer
- Compliance with applicable rules and regulations governing use of technology

# License Grant v. "Licensed Product"

- Maximize access to the technology to create commercial value, but limit rights to the commercial value created
  - create a broader grant at the research stage and narrower rights at the commercial stage
  - force the licensee to return for additional licenses if necessary to practice the technology
- Maximize revenue from technology
  - capture all products or services that would infringe a patent or patent application
  - and all that are "derived from" the technology

# Use Precise Technical and Field Definitions

- The same tool may have multiple applications, i.e., for therapeutic and research purposes
  - use precise technical definitions to identify which products you are encumbering at each stage
  - use the field definition to identify areas of use, e.g., therapeutic, prophylactic or diagnostic; human or animal; and specific indications

# Use Picking or Gating Mechanisms

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- A process must be identified to govern ownership and maintain clarity in the disposition of rights
  - provide a precise mechanism to identify what the licensee will exploit and return the remainder to the “pool”
  - create “gates” throughout the agreement that allow data and materials to be culled from the agreement and returned to either party for alternative exploitation

# Essential to Create Specific "Gates" to Deal with

- Disposition of improvements
- Disposition of data produced during the course of the collaboration
- Disposition of compounds and targets developed or used during the course of the collaboration

# Improvements

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- Precise technical definitions help identify improvements vs. new products
- Division by technical area or coverage
- Patented or unpatented?

# Data

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- Who owns the data?
- Can the data be used outside the field?
- Can the data be provided to third parties?

# Targets and Compound Libraries

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- What returns to the library and who owns what?
- Who owns the target for additional applications?
- Is exclusivity possible?
  - shift exclusivity to the Product
  - identify particular Fields
  - creation of product families

# Picking Mechanisms

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- Timing
  - stage of development determines the risk
- Nature
  - is the pick a target or a drug candidate? Or some combination of the two?
- Frequency
  - pick options and possibilities could vary at different stages of the collaboration

# Potential Pick Structures

- First pick type arrangement
  - take pick from pool, remainder are rejected; pool is either "drained" each time or the rejected candidates are returned to the pool and may be picked the next round. [HGS and TRANSGENE] [BAYER and MILLENNIUM (target picking deal)]
- Alternating type arrangement
  - the picks alternate between parties, each party picking a certain number until the pool is gone. Can vary the number each party gets to pick (e.g., A 1, M 1, A 2, M 2, A 3, M 3).

# Potential Pick Structures (cont'd)

- Indication type arrangement
  - the picks are divided based on therapeutic area; this arrangement is subject to the ability to differentiate any resulting products produced from the same compound as commercially distinct. [AHP and MILLENNIUM] [ROCHE and MILLENNIUM]
- Subscription type arrangement
  - each party subscribes for a certain number of picks from the pool with varying specificity as to required characteristics and stage of development, order is based on when the party subscribed, pool is constantly refreshing. [HGS and SKB]

# Potential Pick Structures (cont'd)

## ■ Diligence arrangement

- both parties may access the entire pool, the first party to obtain some discernable milestone, for example, proof of concept for a candidate, entitles a party to stake a claim to that candidate.

## ■ Alternative diligence arrangement

- pool is randomly divided but if a party fails to achieve a discernable milestone, for example proof of concept, within a specific time frame, the candidates for which no milestones have been achieved are returned to the pool.

## ■ Random division

- pool is randomly divided between the parties at predetermined times. A bias free method of picking and refreshing the pool.

# Integrate into the Licensee's Business Model

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- Greatest value may in the database interface
- Maintain control over the information, i.e., extranet access to server at your facility
- Integrates with the licensee's existing technology
- Allow for meaningful, but limited, access and differentiation

# Financial Terms

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- Royalties
  - target
  - product
- Subscription/user fees
- Target or compound development fee
- Research fee
- Commercialization Rights
- Rights to Identified Field
- License fee
- Milestones
- Revenue Sharing

# Summary of Key Points

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- Trend toward narrower patent claims
- Trend toward creative proprietary positions in the extensive genetic data in the public domain
- Trend toward increased research tool and massive screening deals
- Trend toward detailed and technical licensing terms to grant narrow rights and permit multiple or myriad use