



**® Intellectual property as an economic asset:
key issues in valuation and exploitation**

IP Management & Exploitation
Practices across Industries

Licensing Strategies & Practices in the Biotech & Pharma Industries

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**® Licensing Strategies and Practices
in the Biotech & Pharma Industries**

Representative Industries

- Pharmaceuticals Industry
- Industrial Enzymes Industry
- Animal Health Industry
- AgroBio Industry
- Diagnostics Industry

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**Representative Concerns:
Large/Medium Enterprises**

- Product Life Cycles
- Patent Issues (Term, FTO)
- Pipeline
- Competition/Generics
- Regulatory Matters

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**Representative Concerns:
SMEs**

- Survival (Funding & Cash Flow)
- Delivering Tools/Candidates
- Patent Issues (FTO)
- Relationship Management
- Pipeline

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Primary Goals

- Facilitate Achievement of Business Objectives
- Value Creation
- Value Extraction

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Various Current Practices

- Market Segmentation
- Grant-Backs
- Options To Future IPR
- Tying Royalties to Market Exclusivity/Competition

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Recent Challenges

- Europe Union :
 - Technology Transfer Block Exemption
- United States :
 - *Integra v. Merck KGaA*
- International :
 - UN Convention on Biological Diversity
 - OECD Best Practices Guidelines

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Recent Challenges

Technology Transfer Block Exemption

- Continual Assessment of Application
- Avoidance of Prohibited Clauses
- Market Contingency Clauses
- “Intended Benefits/Effects” Clauses

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Recent Challenges

Integra v. Merck KGaA

- Timing and Price of License
- Research Tools



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Recent Challenges

UN Convention on Biological Diversity

- DD on “ID of Source” & “Informed Consent”
- Representations and Warranties on
“ID of Source” and “Informed Consent”
- Structuring of Compensation for Source
 - (Early) Sharing of Research Results
 - Monetary Compensation
 - Licensing of IPR



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Recent Challenges

OECD Best Practices Guidelines

- Patient Privacy v. Patient Information
- Broad Availability of Licensed IPR v. Need of SME to Maximize Financial Return
- Providing Local HCPs with Broad Access to IPR
- Control of Transaction Costs/Up-Front Payments
- Broad Licensing for Research, Investigation & Clinical Diagnostic Purposes

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Conclusions

- Increased Importance of Due Diligence
- Increased Reliance on Contractual Representations and Warranties
- Better Planning For Future Contingencies
- Providing for and Structuring of 3rd Party Compensation in Contract
- Premium on Creative Thinking

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