Principles of IP Strategy

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Building and Optimizing an IP Strategy for a Life Sciences Innovator Company

• Starting point - Corporate Strategy
  • Understand goals, objectives, time frame, and risks
  • Understand how company will make money from its businesses

• Ask: What can Intellectual Property do to advance Corporate Strategy?
  • IP is one of many available tools…
Fundamental IP Concepts

• Which type of IP is most fit for each specific purpose?
  • **Patent** – time-bound exclusionary right in return for technology disclosure
  • **Trade Secret** – potentially indefinite exclusionary right if kept secret
  • **Trademark** – renewable rights in names, branding as source of goods/services
  • **Copyright** – long term exclusionary right in original works of authorship
  • Other exclusionary rights / barriers to competitive entry
    • Data Exclusivity (FDA; Hatch Waxman)
    • Orphan Drug, Pediatric Exclusivity (FDA)
    • Contractual Rights / Covenants (Exclusive Supply, Exclusive License, ROFN, etc.)
    • Sole Control of unique resources, raw materials, know-how…
Life Sciences products embody multiple types of IP - example

Product
- Patents on biologically active components, formulation, indications for use, etc.
- Trademark & Trade Dress in Packaging
- Copyright in Product Insert / Literature
- Data Exclusivity arising from FDA Label

Support Services
- Branded website and customer support help line

Manufacturing
- Patents on unique manufacturing processes, assays etc.
- Know-how & Trade Secrets

Supply Chain
- Contractual exclusivities / preferred terms
- Unique Raw Materials

R&D
- Patents on upstream inventions
- Exclusive Licenses from technology innovators
Developing an IP Portfolio for a New Product

Three fundamental considerations

• Asset Development and Management
  First to File / Timing Constraints
  Foreign Filing (Cost; Market)

• FTO and Risk Management
  Align with Development Stage Gates
  Risk Mitigation Strategies

• Business Utility / Value Extraction
  Attract Investment
  Licensing & other transactions

$\infty \infty \infty 30$ months after filing


Prepare for Due Diligence
Developing an IP Portfolio for a New Product

Additional factors to consider

- Position in Development Pipeline and Position in Product Portfolio
  - Key value driver?
    - Foundational or secondary IP?
- Timeline to Launch
  - Building Patent Term Ladders
  - Time to execute IP Risk Mitigations
- Resources available for investing in IP
- Market / Competitive Position
- NPV ~ COGs and Royalty Burden
Framing your IP Approach: The Strategy Canvas

- **Partner for Learning & Development**
- **Invest, Develop & Leverage Assets**
- **Divest or Discard**
- **Partner for Income**
Developing an IP Strategy for a Company

Align all Product Portfolio Strategies to Company’s overall needs, resource constraints, stage of development and preferred / forecast exit strategy (Aspects 1-3 of 6):

- Markets
  - Commercial IP rights: trademarks, reputation
  - Commercialization Risks: FTO
  - Competitive Surveillance
- Products & Technologies
  - Pipeline product candidates
  - Due Diligence (in-bound and out-bound)
  - M&A and partnering, collaborations
- Resources
  - Expertise (in house staff and outside counsels)
  - Financial resources
  - IT systems/subscriptions

Pre-Launch Clearance Searches; Risk Mitigation Activities
Invest in Personnel Development
Docketing, Annuities, Search & Analytics
Developing an IP Strategy for a Company

Align all Product Portfolio Strategies to Company’s overall needs, resource constraints, stage of development and preferred / forecast exit strategy (Aspects 4-6 of 6):

- Operational Systems
  - Guidelines for IP Asset & IP Risk management
  - IP Disclosures Portal
  - Review of Scientific Publications
- Governance Systems
  - Oversight ~ Steering Committee
  - Policy & Procedures Framework
  - Training & Compliance Programs
- Culture
  - Employee engagement in IP generation
  - Employees knowledgeable about IP risks
  - Risk Appetite / Risk Tolerance

- Additional IT Systems
- Regular Training Campaigns; Employee outreach

Clear Communication and Understanding of Risk is Essential
Preparation for an IP-driven transaction:

- **Hosting In-bound Due Diligence**
  - Formalities compliance, including chain of title
  - Portfolio overview (Patents, Trademarks)
  - VDR, ease of navigation
  - Preserving Attorney-Client Privilege

- **Conducting Out-bound Due Diligence**
  - Assessing upstream rights, defects in title
  - Collaborative & other legal agreements
  - Staged & targeted searches
  - Target’s IP portfolios
  - Target’s culture toward IP matters

Opinions, Advice of Counsel
*Cf. Trade Secrets*

Align to Deal Stage and Technology Stage of Development
Types of IP-driven Transactions:

- Leveraging IP Assets
  - Collaborations
  - Licenses & cross-licenses
  - Attracting funding for development
- Extracting Value from IP Assets
  - M&A
  - Asset dispositions
  - Services agreements
- Exclusivity versus Access
  - What’s really necessary for commercial success?
  - What creates relevant barriers to competitors?
The IP Strategy Life Cycle – Adaptation and Renewal

• IP Strategy needs to be as dynamic as the Corporate Strategy
  • Revisit & update regularly to maintain alignment with Corporate Strategy
  • Consider impact of external events / changes in environment

• Success should be measured by Effective Implementation
  • IP Strategy should be applied to an Operational Master Plan
    • Success Criteria
    • Key Performance Indicators
    • Owners Assigned to Specific Performance Goals

Alignment enhances Individual Motivation
Thank you!

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