IP Considerations During the Product Development Process including Associated Agreements

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Lab to Market Series
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And!!

Due Diligence IP Searches
WAIT!! What are Searches?

- Patentability
- Landscape
- Freedom to Operate (FTO) / Clearance
Product Development Process

IP Review & Filing Strategy
Product Development Process

(1) Concept/ Disclosure/ Initial Assessment
(2) Research & Development
(3) Prototype – Proof of Concept
(4) Field Review & Assessment
(5) Product Refinement
(6) Design Freeze and Test Market Release
(7) Commercial Launch
Product Development Process

Single-Gate® System (Robert G. Cooper)

Source: Product Development Institute, Inc., http://www.prod-dev.com
Each Gate Consists of:

1. Deliverable – Visible
2. Criteria – Test & Meet
3. Outputs – Decision (Go/ Kill/ Hold/ Recycle)
Deep Dive on the Product Development Process
Product Development Process

(1) Concept/Disclose/Initial Assessment

• Agreements
  – Non Disclosure Agreement (NDA) (one way or mutual)
  – Consulting and Assignment Agreement (CAA)
  – Product Development Agreement (PDA)
  – Employment agreement
  – If University is involved, University Sponsored Research Agreement or License Agreement
Product Development Process

(1) Concept/Disclose/Initial Assessment

- NDA
  - Covers technology and who is disclosing
  - Term & tail
  - No obligation to move forward
Product Development Process

(1) Concept/Disclose/Initial Assessment

• Consulting & Assignment Agreement and PDA
  – Duty to (and does) assign IP
  – Non-compete (with tail and right of first refusal)
  – Royalties?
  – MedImmune language
  – Commercialization improvements

• Employment Agreement
  – Assignment
  – Non-compete
  – Confidentiality

• University Sponsored Research Agreement
  – Who owns it?
Product Development Process

(1) Concept/Disclose/Initial Assessment

Searches

- Landscape – Lay of the Land
- Patentability – Protectable or Not?
Product Development Process

(2) Research & Development

• Agreements
  – CAA and PDA → Improvements and additional discoveries
  – Employment Agreements?
    Still an employee or left company?

Other Items

• Searches
  – Use Landscape or refresh
  – Patentability

• File provisional application
Product Development Process

(3) Prototype – Proof of Concept

• Agreement
  – NDA with anyone who reviews → How long?
  – Be careful on suggestions/input

Other Items

• File provisional application (serial and adequate coverage)
  – Get assignments if needed
• Perform FTO Search
Product Development Process

(4) Field Review & Assessment

• Agreement
  – NDA (from anyone who reviews invention)
  – Be careful on suggestions (may need assignment or pay royalties)

Other Items

• Confirm provisional application covers product being developed
• File additional provisional applications and get assignments (if necessary)
• Institute branding due diligence
• Trademark searches
Product Development Process

(5) Product Refinement

- Agreement
  - NDA

Other Items

- File additional provisional applications and get assignments (check for correct inventors)
- FTO Search – Still OK?
Product Development Process

(6) Design Freeze & Test Market Release

**Agreements**
- Royalty Agreement and/or Combo Agreement (Product Development & Royalty Agreement)

**Other Items**
- Review all provisional applications for coverage
- Update FTO search
- Update Knockout Trademark search
- Develop filing strategy for all IP (utility, design – PCT vs. U.S. Only) (trademark – U.S. vs. Madrid/CTM)
Royalty Agreement

• Key Terms
  – How to pay? (Royalty % or units)
  – Term
  – Net or gross sales
  – Sublicense or not
  – *MedImmune* clause
  – Non-compete
  – Milestones / Anti-shelving
  – Commercialization or not – Who decides?
  – Reports & Audits
  – Improvements – Obligation to disclose?
Combo Agreement

- Covers Product Development Activities & Assignment of IP
- If Key IP Developed, Morphs into Royalty Agreement
- If no IP Developed, Terminate with non-compete
Product Development Process

(7) Commercial Launch

• File trademark applications prior to launch and start watch service
• Monitor the competition
  – Update Landscape Search (How often)?
• Monitor non-compete compliance
• If Agreements cover product improvements
  – May need to start again with Stage 1
  – Watch for new inventors and developers
Summary

• Key Agreements
  – NDA
  – PDA (or Consulting Agreement)
  – Royalty Agreement (or Combo Agreement)
  – Employment Agreement
  – If University is included, Sponsored Research Agreement or License Agreement

• Key Searches
  – Patentability
  – Landscape
  – FTO / Clearance

• Filings
  – Provisional / non-provisional / PCT / Design
  – Trademarks (US / Madrid / CTM)
Questions?

Thanks!!

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