

Ausbiotech 2011

Intellectual Property: An Element of Success of a Technology Company's Life Cycle

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D. Benjamin Borson, M.A., J.D., Ph.D.
Borson Law Group, PC
Lafayette, California USA

Introduction

Commercialization of inventions requires understanding of:

- Different markets during a company's life cycle
- What you bring to the markets
- Alternatives available in the markets
- Competitors
- Collaborators
- Intellectual property protections

First Phase: Start-Up

Corporate formation “To be or not to be”

- A new idea with some rationale
 - »What is the story?
- Alternative start up technologies: competitors
- Intellectual property position
 - »Patent applications (fully prepared)
 - »Non-disclosure non-use agreements
 - »Trade secret protection (“hub and spoke”)
- Freedom to operate/Non-Infringement
 - »Licenses needed?
- Interests of collaborators
 - »Collaboration agreements

Start-Up Phase

During the start-up phase, an innovator should:

- identify possible end user markets (the “big win”)
- educate the working group to generate collaborations and “buy-in”
- begin to develop a first commercial approach
 - (first step business case for first investor)
- Identify seed funding sources
 - Grants
 - Angels
 - “Friends and family”

Start-Up Phase

- First-round investors want to know:
 - How much investment is needed and when
 - How their investment can be repaid (with net profit)
 - Exclusive licenses
 - Key initial milestones
 - Timelines for initial milestones
 - How intimately they can be involved
 - Keep burn rate low
 - Leverage grant funding if possible

Initial IP Protection

- **First patent application:** identify
 - Broadest scope:
 - What is the “universe” of commercial inventions?
 - Subject matter
 - Compounds, methods of manufacture, methods of use, devices
 - What is most rapidly granted?
 - What have the inventors already done?
 - Disunity strategy?
 - Follow-on projects
 - First draft prepared completely, to provide basis for the entire portfolio (except**)
 - File priority application (provisional?)
 - After filing, ok to disclose contents to potential partners: ND-NUAs

Initial IP Protection

- **Employment/consultant agreements**
 - Binds personnel to disclose and assign IP rights
 - Include “I hereby assign” language
 - Be sensitive to “non-compete” provisions
- **Non-disclosure non-use agreements**
 - Mutual vs one way?
 - Bind all parties
- **Trade secrets**
 - Divide into discrete subject areas
 - Assign limited #s of persons to know one
 - Assign one individual to know how the pieces fit together
 - Keep detailed records

Second Phase

- **Identify Follow-on Investors**
 - Same as first investors?
 - Venture capital firm?
 - Banks
 - Institutional investors

- These may have different timelines and payout requirements

Second Phase IP

- Proof of concept
- Prototype(s)
- Intellectual property position
 - »Identify key jurisdictions
 - » sales, manufacturing, distribution
 - »Further patent applications (utility, international)
 - »Narrower, focus on protecting prototypes
 - »Operating/co-development agreements
- Freedom to operate/non-infringement
 - »Licenses obtained?
- Mutuality of interest of collaborators

Third Phase

- **First Commercialization**

- Lead product
- Agreements with suppliers
- Manufacturing
- Testing (clinical trials)
- Intellectual property position of lead product
 - »Further patent applications
 - »Granted patents
 - » Patent enforcement
 - » Licensing out
 - »Additional licenses obtained?

Third Phase

- This phase requires skills at identifying:
- Suitable or best collaborators to produce a lead product
- Consider avoiding early partnering with a “Big-Co.”
 - Because of superior market power, time and funds, Big-Cos may negotiate terms unfavorable to a small company.
- Consider approaching “Mid-Co.”
 - Mid-Co might find your innovation useful in increasing their market penetration, and may be more agreeable to more “balanced” terms than Big-Co and may do an earlier deal..

Third Phase IP

- Identify and refine key products/services based on commercial activity
- Use divisional or continuation applications to “fine tune” patent portfolio
 - applications to focus on narrow “picture claims”
- For products that are not commercially viable, consider abandoning patents or:
- Create “licensing claims” to spin-out or license out.
- File new applications on improvements for specific markets
- Develop portfolios of patents for possible sale, merger or IPO.
- Consolidate trade secrets for potential disclosure to partners

Fourth Phase

- **End-User Commercialization**

- Regulatory approval

- Intellectual property position

- »Further patent applications

- »Divisionals

- »New applications

- »Granted patents

- »Label claims covered by patent claims?

- »Cross-licensing

- Distribution

Fourth Phase

- **IP Enforcement**

- Does your product infringe another's patent?
 - Reexamination of their patent
 - Ex parte
 - Inter partes
 - Cross licensing
 - Litigatino
- Does another infringe your patent?
 - How strong is your patent?
 - Reexamination?
 - Reissue?

Fourth Phase

- **Trade Secret Enforcement**
 - Employees leaving
 - Breaching non-disclosure agreements
 - Local court actions

Patenting Strategies

Where?

- »End user markets
- »Manufacturers
- »Distribution channels

When?

- »As soon as invention is made?
- »Just in time''

–Different standards

- »US: Enablement/written description/best mode
- »EPO: Antecedent basis/enablement
- »Asia: Definite (narrow)

Patenting Strategies

- **Patent Eligible Subject Matter**

- Compounds, compositions
- Devices
- Methods of manufacture
- Methods of use (processes)
- Applications of abstract ideas, natural phenonma etc.

- **Patent Ineligible Subject Matter**

- Software per se
- Abstract ideas
- Purely mental steps
- Natural phenomena
- Products of nature (in natural state)
- Electronic signals per se

Patenting Standards

- **Novelty** over prior art
 - Publications, public use, disclosure
 - 1-year grace period (US only)
- **Not obvious**
 - To person of ordinary skill in the art
 - Difficult to modify prior art
 - No motive to combine prior art references
 - Unexpected results

Patenting Standards

- **Written Description / Sufficiency**
 - Demonstrate “possession” of full scope
 - Antecedent basis
 - “Enough” disclosure
- **Enablement**
 - Teach how to make and use the full scope
 - “Enough” examples (working and prophetic)
- **Best mode (US)**
 - *Quid pro quo* for obtaining a patent is full disclosure
 - Can’t keep both Trade Secret and Patent the same invention

Patenting Standards

- **Definiteness/ clarity**
 - Definitions of key terms
 - Ranges
 - Vague language (e.g., “about”)
 - Alternative Claiming (Markush)
 - Compounds
 - Combinations (not of compounds)

America Invents Act of 2011

- Enacted 16 September 2011
- Major changes in patent law of US
- **Initial provisions**
 - Elimination of “Tax” and “Human o
 - Organism” patents
 - USPTO funding
 - 15% increase in all fees
 - Fee setting authority
- **Later provisions** (16 September 2012 & 16 March 2013)
 - First Inventor to File (FITF)
 - Loss of grace period for commercialization
 - Post-grant oppositions
 - Rulemaking needed
 - Public input will be important

Thank You

- D. Benjamin Borson, M.A., J.D., Ph.D.
- Borson Law Group, PC
- Tel: 001 925 310 2060
- Fax: 001 925 310 2061
- E: bborson@borsonlaw.com
- E: benjamin.borson@USPTO.gov
- Web: www.borsonlaw.com