The IP Based Start of A Life Science Company

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Why Do We Do What We Do?

Because Life Science Companies Can Change The World!

In health care, law gives you a chance to have a real impact on getting new health care technologies from the lab bench to the patient to improve lives.
Venture Capital Reaction Process

+ $\rightarrow$ Patents
Some Things We Do As Attorneys To Start a Company

• Company Formation
• Licensing
  – Obtaining rights to practice patented inventions, usually for a royalty
• Patent Prosecution
  – Drafting new patent applications and guiding patents through the Patent Office to get a patent
• Due Diligence
  – Confirming a company’s rights to IP
  – Determining whether another party has IP that would block the company from the market
Some of the companies we are helping
• Genetically engineering microorganisms to make drugs, such as Artemisinin, and biofuels
• Technology from University of California
• Originally financed by funding from the Gates Foundation ($35M) and now from VCs ($20M – Khosla Ventures)
Nodality

- Mapping of protein phosphorylation responses in cell signaling pathways
- Reveals personalized information about, e.g., cancer cells for treatment
- Technology from Stanford
• Single Molecule DNA sequencing
• Technology developed at Cornell
• Patents have issued this recently
• Raised over $200M in financing
• The hundred dollar genome???
• Fast acting proton pump inhibitors
  – For treatment of upper GI disorders
• Technology licensed from the University of Missouri
• Recently went public
Taiji Biomedical, Inc.

- Neurodegenerative Diseases- licensed from UCSF
  - Amyotrophic Lateral Sclerosis
- Technology licensed from the Parkinson’s Institute- Reduction of dyskinasia

**United States Patent**

**Inventor:** Michael S. McGrath, Burlingame, CA (US)

**Assignee:** The Regents of the University of California, Oakland, CA (US)

**Filed:** Jan. 24, 2005

**Application No.:** 11/042,816

**Patent No.:** US 7,105,183 B2

**Date of Patent:** Sep. 12, 2006

**Title:** CHLORITE IN THE TREATMENT OF NEURODEGENERATIVE DISEASE


Medline Abstract, accession No. 20031076 (2003).*


So, A Typical Scenario: A Day In Our Life

- A clever scientist at Stanford comes up with a great new drug, diagnostic, or research tool
- A few people see the vision, and come to WSGR to start a company
- What do we do:
  - License in the IP from Stanford
  - Help pitch them to our VC friends
  - Identify and license in technology from other universities that may be needed
  - Help in company formation
  - Defend in the due diligence of the VCs
  - Push their patents through the Patent office
  - Engage in reducing/eliminating IP that may be detrimental
  - Get the company GREAT patents throughout the world
  - Help partner the technology to move it rapidly to the market
Strategic Alliances
A Conceptual Framework

Michael J. O’Donnell
Wilson Sonsini Goodrich & Rosati
Strategic Alliances
A Conceptual Framework

- Who does what?
- Who pays what?
- Who gets what?
Who does what?

- General description of what each party is to do
- Scope of project often expressed in FTE’s
- Who controls research/development?
  - Role of Joint Research Committee
  - Often equal number of representatives
  - Issue of deadlocks
- Who controls manufacturing/commercialization?
- Who controls patent prosecution/infringement?
Who pays what?

- Typically partner pays:
  - *Upfront payment/equity investment*
  - *Funded R&D*
  - *Milestones*
  - *Royalties*
Who pays what? (Cont.)

- **Upfront payments**
  - *Nice to get*
  - *Tough to get back more than you put in*

- **Equity**
  - *Can be in addition to upfront payment*
  - *Pro – easier to get than upfront payment, promotes “partnership” concept*
  - *Con – dilution to stockholders, can be seen as “captive”*
  - *Premium – Easier for private companies to get*
  - *IPO participation*
Funded R&D

- **Typically Partner funds research and development**
  - *Partner committed resources versus funding*
  - *Reimbursement at FTE rate versus actual cost basis*

- **Partner’s ability to terminate**
  - *Limited to “scientific failure”?*
  - *Notice/wind down provisions*
Milestones

- **Typically based on regulatory progress**
  - *Tend to be back end loaded*

- **Interesting issues to consider**
  - *Domestic versus international*
  - *Back-up compound for same indication*
  - *Same compound for different indication*
Royalties

- “Where the rubber meets the road”
  - Key term – important to valuation
  - Ability to “buy in” to increase royalties

- Issues
  - Only if covered by “valid” patent claim
  - Offset for other royalties
What do you want to maximize?

- Up front payment?
- Funded R&D?
- Royalties?
Who gets what?

- Typically exclusive right to market and sell in Field
  - “Field” definition is key
  - Geographic restrictions?
  - Limited to specific compounds?
  - Who gets leftovers?
  - Rights to use developed technology inside and outside Field
Other Issues

- Due diligence obligations on the partner
- Rights of first offer/negotiation
- Rights to co-promote
- How about a Quid?
Some Real World Examples

- Early stage deal – Cytokinetics/GSK
- Later stage deal – Pain Therapeutics/King
Cytokinetics/GSK

- **Earlier Stage Deal**
  - *Broad platform technology applicable across multiple cancers and potentially other diseases*
  - *$14 million cash upfront and $14 million equity investment*
  - *5 year significant funded research*
  - *GSK pays milestones ($30-50 million pre-commercialization for each target) and royalties*
  - *GSK funds and controls development and commercialization*
Cytokineti cs/GSK, contd.

- **Interesting Features**
  - Option for Cytokinetics to select certain targets for independent research and development and subsequent commercialization (subject to a royalty to GSK), subject to GSK’s right to buy back for premium plus increased royalty
  - Option for Cytokinetics to co-fund later stage development costs in exchange for higher royalty from GSK
  - Further option for Cytokinetics to co-promote products and receive reimbursement for certain sales force costs
  - Enables Cytokinetics to potentially establish specialty sales force
Pain Therapeutics/King Pharmaceuticals

- Remoxy – Later stage compound
  - Compelling Phase II data
  - Multiple potential partners
  - Resulted in attractive deal terms
    - Big upfront – $150 million
    - Significant milestones – up to $150 million
    - Royalties 15-20%
    - King to fund, but PTI to control development through Phase II, joint control through Phase III
Complications

- **PTI license to Durect Technology**
  - *King to meet all PTI obligations to Durect (due diligence, etc.)*

- **Field Definition Critical**
  - *Limited to Durect technology applied to certain opioids*
  - *Possible competition from other Pain non-Durect products*
  - *Considered limited Right of First Offer*
Commercialization Due Diligence

- Agreed on detailed initial budget for King
- Couldn’t agree on detailed full budget at time of signing, so agreed on minimum and maximum level of spending over several years with JDC to determine specifics
Take Away Messages

- Deals are complex, need to think through issues
- Takes a long time to negotiate
- You need leverage and patience to get what you want (and having a good lawyer doesn’t hurt!)