

## Starting your Company

**Bruce Doeg**

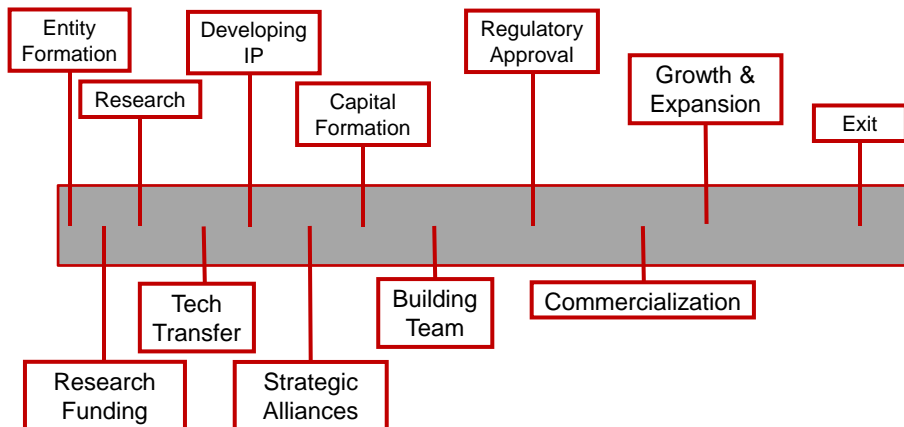
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC  
211 Commerce Street, Suite 800  
Nashville, TN 37201  
615.726.5722  
[bdoeg@bakerdonelson.com](mailto:bdoeg@bakerdonelson.com)

**Chris Sloan**

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC  
211 Commerce Street, Suite 800  
Nashville, TN 37201  
615-726-5783  
[csloan@bakerdonelson.com](mailto:csloan@bakerdonelson.com)

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## Life Sciences Company Life Cycle



## Choice of Entity

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- LLC, C-corporation, or S-corporation (ignore the rest)
- C-corporation
  - Board managed
  - Multiple classes of stock
  - Double taxation
- LLC
  - Extremely flexible management and equity structures
  - No double tax (but pass-through has its own challenges)
- S-corporation (usually ignore this one too)
  - Same as C-corp except...
  - One class of stock; only individuals (and some trusts) can own
  - No double tax

## Choice of Entity (cont.)

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- DE is most familiar and comfortable state for investors
- Recommendations
  - For VC-backed, DE C-corp is "gold standard"
  - LLC possible if unsure of VC path, or not necessarily growing to exit (can always convert later)
  - Usually no reason to use S-corp over an LLC

## Shareholder / Operating Agreements

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- Transfer restrictions (ROFR, no pledging or assignment)
- Repurchase rights/obligations (death, disability, divorce, bankruptcy, bad acts, resignation or termination)
- Governance / Voting agreements
- Deadlock
- Drag-along / Tag-along
- Confidentiality / IP (if not separately addressed)

## Keeping Your House in Order

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- A COMMON, AVOIDABLE PROBLEM – if you don't know who owns what, how do you expect an investor to know??
- Cap Table
  - Keep accurate, current info on equity ownership
  - Both issued and fully-diluted
  - Vesting and forfeiture restrictions
- Transfer Ledger
  - Track each individual stock certificate and equity transaction
  - Keep the paperwork documenting each one
- Minute Book
  - Minutes of all meetings (including actions on written consent)
  - Copies of relevant corporate documents (e.g. certificate of incorporation, bylaws, shareholders agreement, option plan, etc.)

## Securities Law Basics

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- “Security” includes stock, options, LLC membership interests, promissory notes, bonds, investment contracts, etc.
- General Framework – registration is required unless an exemption applies
  - Must have both state and federal exemption
  - Fortunately, there are lots of exemptions
- Private Placements
  - Generally, an offer and sale not involving a public offering
  - Reg D – certain offerings to “accredited investors” are exempt from both state and federal registration
- Unlicensed Broker/Dealers

## Equity Incentives

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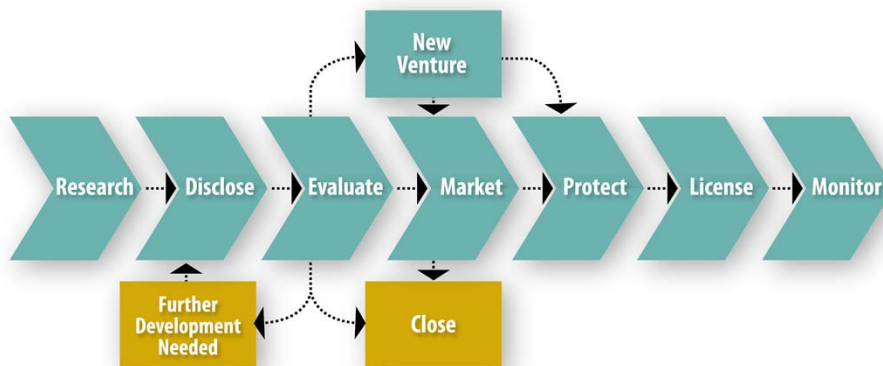
- Restricted Stock vs. Options
  - 409A
  - 83(b)
- ISOs vs. NQSOs
- Vesting Considerations
  - Standard = 4 years with first year cliff then quarterly/monthly
- LLC Profits Interests

# Starting Your Company

Baker Donelson Life Sciences  
Emerging Company Boot Camp

Nov. 14, 2012

## Commercialization Process



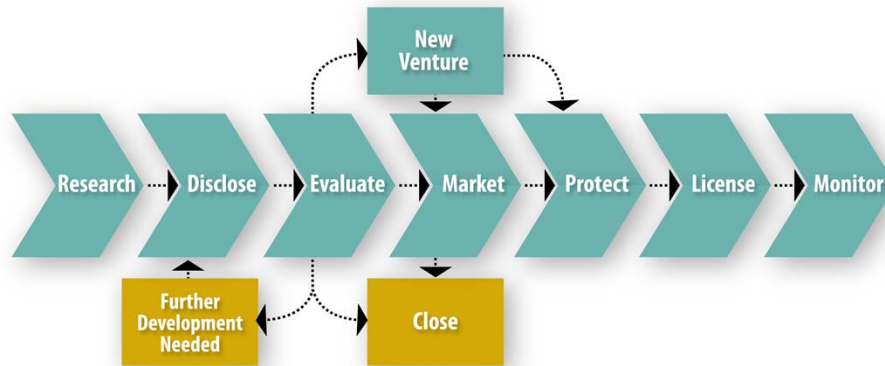
## Evaluation Phase

- Stage of Development
  - Concept
  - Proof of concept
    - Prototype developed
    - Therapeutic molecule identified
  - Validation
- Market
  - Addressable market
  - Size (e.g. affected patient pop.)
  - Penetration

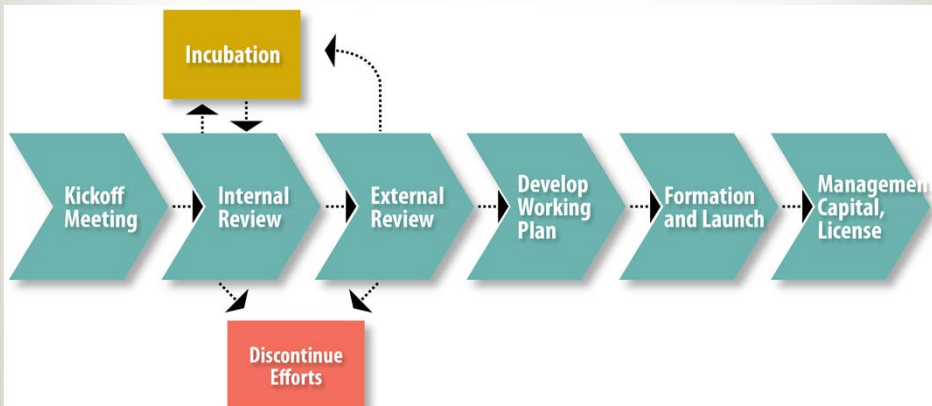
## Evaluation Phase

- Competitive Environment
  - Products & companies
  - Strategic partners
  - Techs in development
- Regulatory Impact
  - OTC/DTC, 510k, PMA, CBER, CDER, EPA
- Pricing
  - Payor reimbursement
    - Established CPT code?
  - Direct-to-consumer

## Commercialization Process



## Entrepreneurial Support



## Inventor Involvement

- Role of the inventor in the newco
  - Advisory vs. management
- Right to consult and receive equity
- COI process
- Future invention issues
- Sharing of revenue

## Forms of Investment

- Direct
  - Pre-seed funding (\$100k-250k)
    - Purdue, Cleveland Clinic, Partners Healthcare
  - Seed funding (>\$500k-\$2M)
    - OH, IN, MI, CT, NY, SBIR Ph2
- Indirect
  - Proof of concept funding (e.g. VU, UChicago, Children's Hospital Boston, Purdue, CCF)
  - Patent expenses deferment
  - Market research & business planning



## License Structures

- Standstill Agreement
  - 1-3 months
  - No fee
  - Allows analysis of the business opportunity
- Option Agreement
  - 3-12 months
  - Option fee
  - Patent expense reimbursement
  - Allows PoC or validation of the technology

## License Structures

- License Agreement
  - Upfront Fee
    - Equity
    - Cash
  - Patent expenses
  - Diligence events
  - Royalty on net sales
- Sponsored Research



# Running Your Company

*Practical Advice from Start to Sell*

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**BAKER DONELSON**  
**BEARMAN, CALDWELL & BERKOWITZ, PC**

Michael Hess

Who We Are

Emily Brackstone

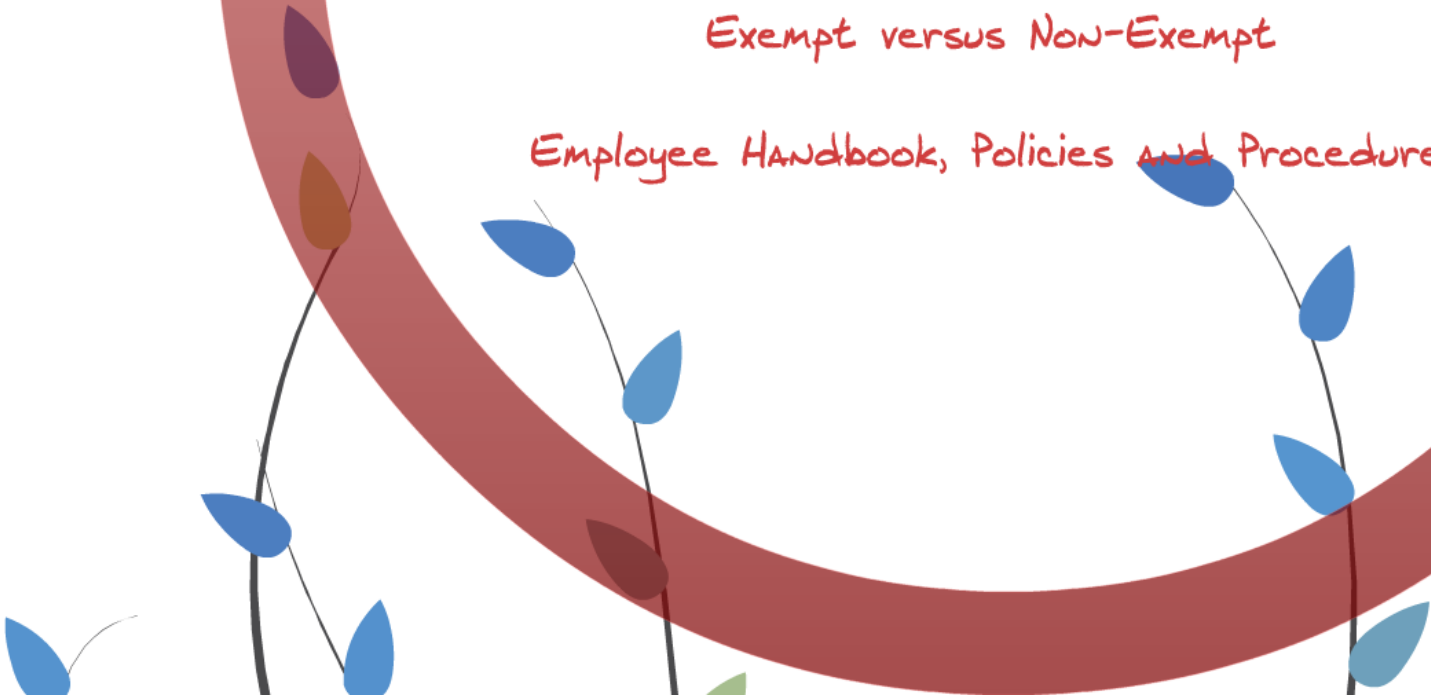
# Employment and Human Resources

Assignment of Rights, NDAs and Non-Competes

Employees versus Independent Contractors

Exempt versus Non-Exempt

Employee Handbook, Policies and Procedures



# Customer and Vendor Contracts

Importance of Good Form Agreements  
Keep it Simple to Speed Sales Cycle  
Well Drafted Agreements Lend Credibility  
Create Effective Filing and Tracking Mechanisms



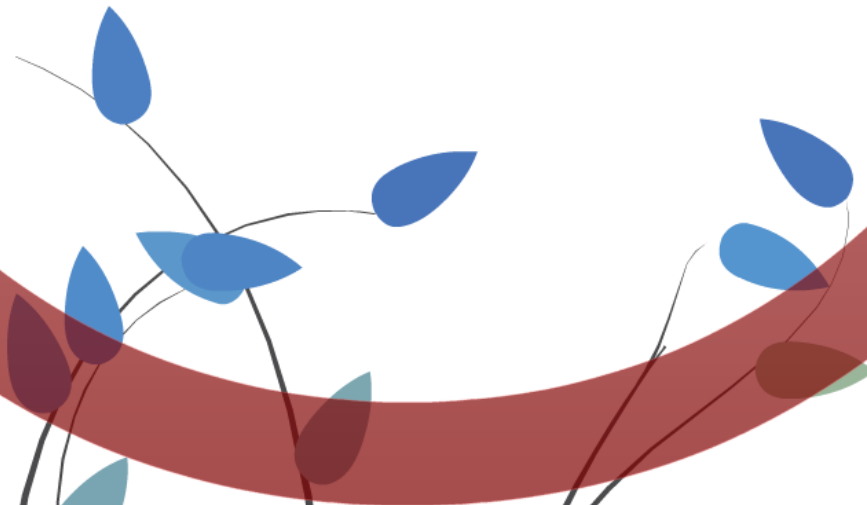
# Working with Suppliers

Read Carefully  
Check Invoices for Terms and Conditions  
Even When on Supplier's Paper, Terms May be Negotiable  
Pick the Terms that Matter



## Regulatory Compliance

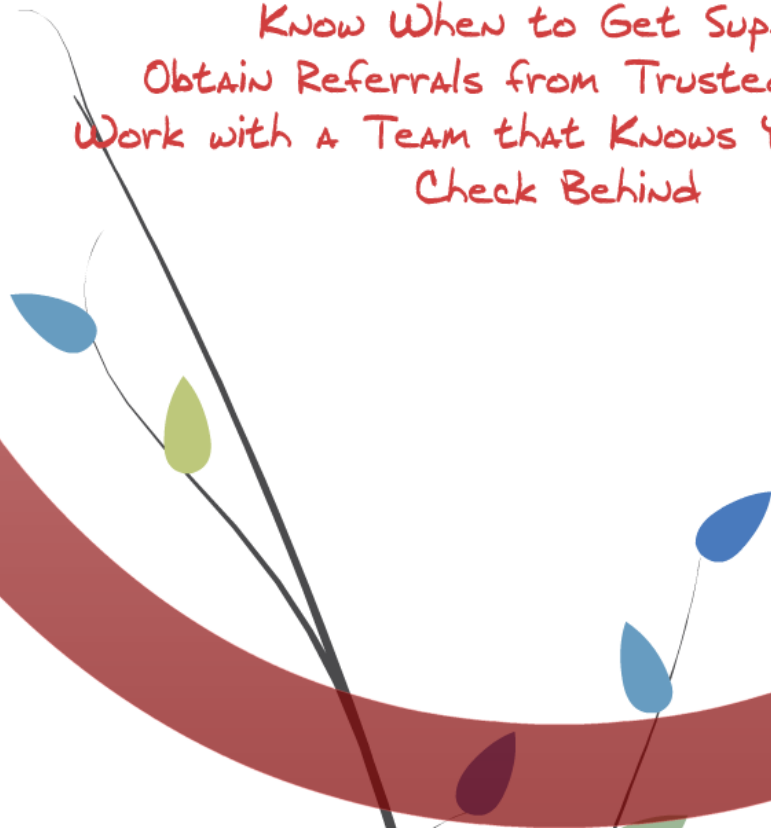
Identify your primary regulator (FDA, DEA, state licensing agency, etc.) and become familiar with the law  
If in a regulated industry, designate a compliance officer  
Privacy and security of data; HIPAA  
Conduct routine internal audits to check how you are doing





## Working with Professionals

Understand Your Limitations  
Know When to Get Support  
Obtain Referrals from Trusted Sources  
Work with a Team that Knows Your Industry  
Check Behind





## Know and Understand How You Get Paid

Reimbursement Schemes  
Government Payors and Requirements  
Commercial Payors and Requirements  
Keeping Track of Your Accounts Receivable  
Collecting from Your Accounts



# Grow Your Business from Start to Sale

*Your Buyer will Assume the Worst, Build  
Your Business so They Find the Best*

Michael R. Hess

Direct: 901.577.8275  
mhess@bakerdonelson.com

Emily T. Brackstone

Direct: 901-577-8274  
ebrackstone@bakerdonelson.com

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BEARMAN, CALDWELL & BERKOWITZ, PC

## Patents to maximize Investment and protect Invention

**David L. Vanik, Ph.D., J.D.**

Baker, Donelson, Bearman,  
Caldwell & Berkowitz, PC  
920 Massachusetts Avenue  
Washington, DC  
202.508.3406  
[dvanik@bakerdonelson.com](mailto:dvanik@bakerdonelson.com)



@Baker\_Donelson  
#BakerHR

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### Overview

- Brief Overview of U.S. Patent System
  - Provisional vs. Non-Provisional Applications
- Patent Cooperation Treaty (PCT)
- Basic Patent Principles
- Getting to Allowance and Navigating the USPTO Hierarchy
- New U.S. Patent Laws
  - September 16, 2012 – Prosecution and Post-Grant Changes
  - March 16, 2013 – “First to File” regime

## Big Picture Considerations

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- Allocation of resources – financial and timing considerations
- What you hope to achieve
  - Patent application as a placeholder
  - Patent as a marketing tool
  - Patent as a mechanism to protect a product
- Thinking globally and taking advantage of changes in the world-wide patent system



## Why pursue a patent?

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What is a Patent?

- Set of exclusive rights granted to an inventor for a fixed period of time in exchange for the public disclosure of the invention
- Limited property right
- Right to exclude others from making, using, selling, offering to sell the invention within the U.S., or importing into the U.S.

## Types of U.S. Patents

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- Utility – protects a useful device or method, e.g. the way it works or is used; functional and structural features
- Design – protects the ornamental (non-functional) appearance of an article, e.g. the way it looks
- Plant – protects certain types of asexually reproducible plant varieties

## U.S. Patent filing system overview

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### Provisional Patent Application

- Serves as a relatively cost-effective placeholder
- No specific format
- Can file multiple provisional applications
- Must file nonprovisional utility application within 12 months

### Non-Provisional Patent Application

- Must file 12 months from earliest priority date
- Claims are included
- Expedited prosecution and other mechanisms



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## Patent Cooperation Treaty Patents (PCT)

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- Gives the right to file applications in countries that are party to the PCT convention 30 months from the earliest filing date (usually from the first provisional patent)
- Includes a Preliminary Examination and Written Opinion by the International Searching Authority
- The selection of the Searching Authority can be made based on a variety of considerations such as cost and comprehensiveness of examination and search

## Non-PCT Filings

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- In many non-PCT countries must file 12 months from the earliest filing date
- Some Representative Non-PCT countries include
  - Argentina
  - Bangladesh
  - Iran
  - Iraq
  - Pakistan
  - Uruguay, and
  - Paraguay





## Strategies regarding when to file a U.S. Non-Provisional Application

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- Filing U.S. Non-Provisional application as a first filed application
  - Commercial Product
- Filing the Non-Provisional Application before the 12 month deadline of the earliest priority application (Provisional Application or foreign application)
- Filing National stage of U.S. Application at the 30 month deadline of the earliest priority application

## Basic Patent Principals – Novelty and Obviousness

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### Novelty

- 35 U.S.C. 102
- U.S. vs. International Differences

### Obviousness

- 35 U.S.C. 103
  - "...differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."
- Obviousness vs. Invention Step (many international countries)

## Written Description, Enablement, and Utility

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- 35 U.S.C. 112, first paragraph – Written Description and Enablement
  - “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. ”
- 35 U.S.C. 101 – Utility
  - “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

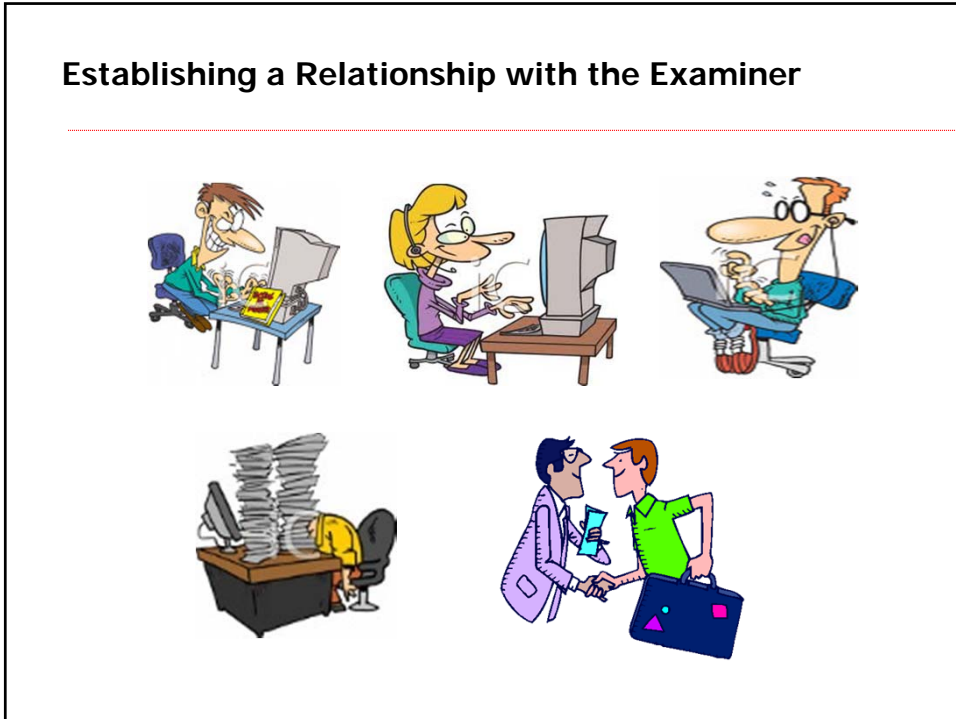
## Getting Applications Through the USPTO

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- Establishing a Relationship with the Examiner
- Navigating the Hierarchy of the USPTO
- Interview-based strategy
- Taking the application out of the Examiner’s hands - Pre-Appeals and Appeals

## Establishing a Relationship with the Examiner

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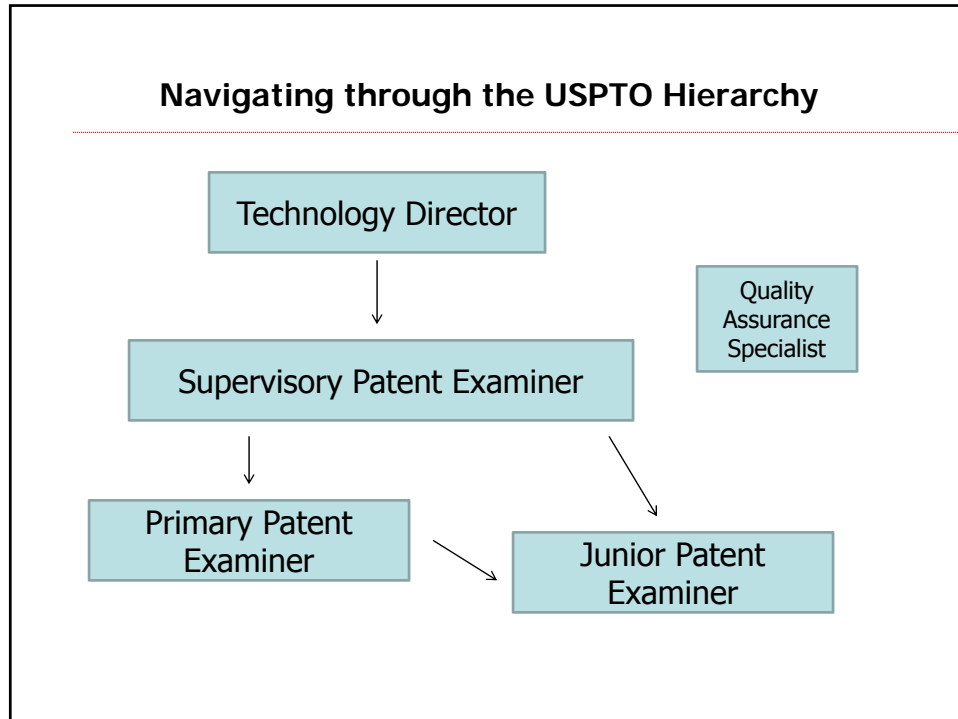
## Establishing a Relationship with the Examiner - Interviews

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- Some advantages of a USPTO interview
  - Placing a “face” with an application
  - Accountability of a junior Examiner with a Primary Examiner/SPE
  - Helping to foster the Examiner/Applicant relationship

## Navigating through the USPTO Hierarchy

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## Examiner Performance Appraisal Plan (PAP)

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- **Production:**
  - Examiners are required to achieve a certain number of “counts” per bi-week.
- **Work Flow:**
  - Revamping the workflow element to provide examiners more opportunities to use their professional discretion to manage their own workflow.
- **Quality:**
  - Revising the performance standards to include a single quality element for all examiners—increasing the focus on examination quality and improving the transparency of how quality is measured; and
  - Establishing a “Stakeholder Interaction” element that emphasizes routine use of interviews to facilitate compact prosecution and timely responsiveness to requests for personal interviews.

## Pre-Appeal vs. Appeal - Factors to consider

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### Pre-Appeal

- quick turnaround time
- can quickly dispose of clearly incorrect rejections
- helps to sharpen arguments for appeal
- pre-appeal conference

### Appeal

- usually about 15 - 30 months for BPAI to consider
- potentially a more comprehensive avenue for legal arguments
- can comprehensively argue each claim separately
- patentability conference

## Preparing for the new U.S. Patent Law Regime

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- “First to File” effective March 16, 2013
  - "first to invent" system to a "first inventor to file" system
  - “Novelty” (35 USC 102) and “Obvious” (35 USC 103) are amended
- Derivation Hearing Replaces Interference Proceeding
- New Rules eliminate the requirement that a “prior public use” or sale be "in this country" to be a prior art activity

### Practical Example: "First-to file" vs. "First-to-invent"

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- Example: An employee at Company X conceives of an invention in April, 2012 and works diligently to reduce it to practice. The corresponding application is filed in October, 2012.
- Suppose that an employee at Company Y independently conceives of the same invention in June, 2012 and files for a patent in September, 2012.
- Who gets the patent? Under the pre-AIA first-to-invent rules, Company X can get the patent because its employee invented first. However, under the new first-to-file system, things will be more complicated.

### Practical advice regarding the First-to-File regime

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- File as soon as possible with as many staggered provisional applications as possible
- File an application before presenting or publishing the subject matter
  - Trade shows
  - Websites
  - Social Networking
- Self-disclosure may buy another 12 months in the U.S., but can destroy international rights
- Competing factors - Marketing a product verses patent protection

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Questions/Comments?



# Financing Your Company

*A Panel Discussion Focused on Early-Stage Life Science Companies*

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MODERATED BY:

Glenn Perdue, Kraft Analytics

PANELISTS:

Joe Cook, Mountain Group Capital

Ken Woody, Innova

Gary Stevenson, MB Ventures



# 1. Company Valuation: Mechanics and Terminology

The highly simplified math with a highly simplified example ...

Year	Actual		Projected					
	1	2	3	4	5	6	7	8
Sales	0.00	0.50	1.00	3.00	7.00	11.00	16.00	20.00
EBITDA	-0.25	-0.50	-1.00	-0.50	0.00	0.00	0.00	0.00
Investment		2.00						

Expected Return ( $r$ ) = 40%  
Holding Period ( $n$ ) = 6 years

Expected Exit Value (FV)  
2.5x Revenues  
\$50 million

$$PV = \frac{FV}{(1 + r)^n}$$

$$PV = \$50m / 7.53$$

$$PV = \$6.64m$$

$$\$2.00m / \$6.64m = .30$$

Post-Money Value: \$6.64 million  
Investors Require: 30% Interest  
Pre-Money Value: \$4.64 million

## 2. Key Questions Asked By Investors When Considering a Life Science Investment?

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### COMMERCIAL VIABILITY ?

#### MARKET NEED ?

- Market Size
- Market Growth
- Standard of Care
- Direct Competitors
- Substitute Offerings
- Other New Entrants

#### PATH TO MARKET ?

- FDA Approval?
- Reimbursement Approval?
- Develop and Operate
- Joint Venture
- License Technology/IP
- Sell Technology/IP

Can Scale Be Reasonably Attained ?

#### FUNDING IMPEDIMENTS ?

- Valuation Expectations
- Too Risky
- Too Much Money
- Too Long To Wait
- No Clear Path to Exit

#### MANAGEMENT ?

- Track Record
- In Place
- Need to Recruit
- Egos

#### PATH TO EXIT ?

- Sale
- IPO
- Long-Term Hold

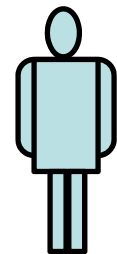
### PROTECTION ?

- Patents
- Copyrights
- Trade Secrets
- Proprietary Know-How

### SCIENTIFIC MERIT ?

# 3. The Funding Lifecycle

**MARKET  
USE**



**EXIT – LIQUIDITY EVENT**  
*Sale / IPO / Buy-Out*

**Outside Capital – Series A - ???**  
*Angels / Seed Funds / VC's / Corporate*

*Founders / Friends / Family / University*

**COMMERCIALIZATION:**  
Small Business  
Corporate

**DEVELOPMENT:**  
Small Business  
Corporate  
University

**RESEARCH:**  
University Research  
Government Research / Grants  
Non-Profit Research / Grants  
Corporate Research  
Corporate-Sponsored Research  
Individual Research

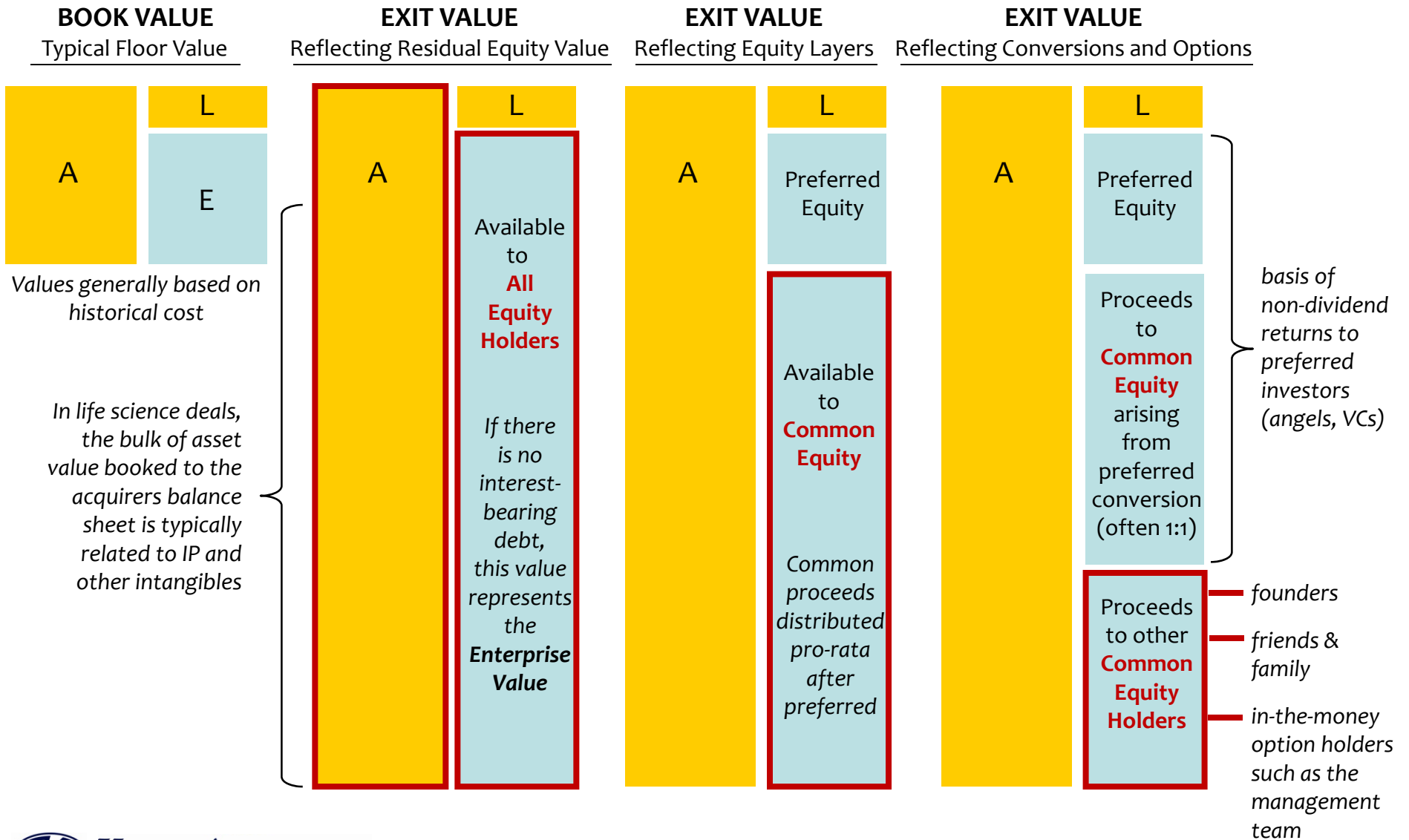
**IDEA**



**Outside Capital – Key Questions:**

1. When should you look?
2. How do you increasing your chances of funding?
3. How do you optimize your relationship with investors after funding?

# 4. Capital Structure and Value Allocation





**Bruce C. Doeg**

Shareholder  
Nashville  
Phone: 615.726.5722  
Fax: 615.744.5722  
bdoeg@bakerdonelson.com

Bruce C. Doeg, chair of Baker Donelson's Business Department, concentrates his practice in the area of business law with an emphasis on technology. He previously served as the Nashville office managing shareholder and chaired both the Mergers & Acquisitions Group and the Business Technology Group for the Firm. His experience includes public and private capital formation, mergers and acquisitions, technology agreements, strategic alliances, Web site and eCommerce agreements, health care information technology, executive and employee compensation issues, corporate governance and business law advice. He has worked extensively with technology and traditional companies, integrating technology into their business plans. Mr. Doeg also has formed and represented venture and seed capital funds. Mr. Doeg started his legal career as a corporate litigator in Wilmington, Delaware. He has authored numerous articles and is a frequent speaker on business and technology law topics.

### **Recent Representative Transactions**

- Represented acquiror of assets of Elvis Presley Enterprises.
- Represented NYSE company in purchase of consumer brand company.
- Represented leading website development company for automobile dealers in sale of the company to a publicly traded purchaser.
- Represented Fortune 50 company in the divestiture of technology subsidiary.
- Represented hospital system in outsourcing its IT department.
- Represented Fortune 50 company in outsourcing of software development and implementation project to Indian company.
- Represented nationally known consumer products company in sale of the assets of a subsidiary containing key brands.
- Represented acquiror of British technology company.
- Represented U.S. manufacturing subsidiary of Malaysian company in sale of company.
- Capital formation for manufacturing, technology, health care technology, biotech, oil and gas and other companies.
- Represented technology company in dealings with the Federal Trade Commission arising out of computer hacking incident leading to possible dissemination of personal information.
- Represented technology company in developing open source software strategy.

- Corporate counsel for leading emerging company in electronic health records field.
- Corporate counsel for independent oil and gas company.
- Corporate counsel for emerging biotechnology firm.
- Corporate counsel for fiber optics company.
- Corporate and board counsel to non-profit foundation focused on education and protection of First Amendment principles.

### **Recent Publications & Speaking Engagements**

- Co-Chair/Author – "Selling Products and Services and Licensing Software Online: An Interactive Guide with Legal Forms and Commentary to Privacy, Security and Consumer Law issues," ABA Section of Business Law Publication (2007)
- Co-Chair/Author – "Model Web Site: A Knowledge Management Approach to E-Business," ABA Section of Business Law Publication (2005)
- "Effects of Sarbanes-Oxley in Private Companies and Not-For-Profit Organizations," Lorman Seminars: Nashville, Memphis and Knoxville, TN; Wilmington, DE; Orlando, FL
- "Sarbanes-Oxley: Why You Should Care!" Nashville Bar Association
- "Board and Committee Structure and Function After the Sarbanes-Oxley Act," Lorman Seminars, Wilmington, DE
- "Document Management Policies and The Impact of Sarbanes-Oxley," Lorman Seminars: Nashville, Memphis and Knoxville, TN; Wilmington, DE; Orlando, FL
- "Ten Potential Pitfalls of an Outsourcing Deal: A Lawyer's Perspective," Chicago, IL
- "The 'What' of the Agreement: Defining and Managing Scope of Service and Service Levels," Outsourcing Seminar, Nashville, TN
- "Whistleblower and Criminal Provisions of the Sarbanes-Oxley Act of 2002," Wilmington, DE
- "Organizing the New Venture," Musculoskeletal New Ventures Conference, Memphis, TN
- "eBusiness and Information Technology Legal Assessment," Presentation to the GE Legal Department

### **Professional Honors & Activities**

- Named – "Power Leaders in Technology for 2011" by the *Nashville Business Journal* (August 2011)
- Listed – *Nashville Post* "In Charge" list - Technology (2010 – 2012)
- Listed in *The Best Lawyers in America*®; Cyber Law from 2003 – 2005 (category changed); Information Technology Law (new category) since 2006; Technology Law (new category) since 2006; Corporate Law since 2005; Venture Capital Law since 2010
- Board member of the Nashville Technology Council (2005 – present); Secretary (present)

- Board member of the International Business Council of the Nashville Chamber of Commerce (present)
- Board member of the Tennessee Technology Development Council (2008 – present)
- Board member of the Tennessee Capital Formation Board (2008 – present)
- Board member of Life Sciences Tennessee (2011 – present)
- Board member of the American Heart Association/Middle Tennessee Chapter (2011 – present)
- Adjunct Professor – University of Tennessee School of Law (Contract Drafting)
- Adjunct Professor – Vanderbilt University School of Law (Corporate and Securities Transactions)
- Guest Lecturer – University of Tennessee (Technology law)
- Guest Lecturer – Owen School of Management at Vanderbilt University (Technology law)
- Taught Tennessee State and Federal Judges in the area of technology law
- Drafted and helped enact amendments to Tennessee Securities law creating an accredited investor exemption and an exemption for employee stock option plans
- Co-Chair – "Technology Outsourcing in the Healthcare Industry," national seminar on legal issues associated with healthcare technology
- Co-Chair – American Bar Association Model Website Project
- Co-Chair – Tennessee Bar Association CLE Seminar “Legal Issues in Computer and Internet Law” (2000 – present)
- Member – American (Business Law – Cyberspace Committee), Tennessee, Knoxville, Nashville and Delaware Bar Associations
- Named to the Lawdragon 3000 (2010)

### **Admissions**

- Tennessee, 1995
- Delaware, 1991

### **Education**

- University of Virginia, J.D., 1990
- Duke University, B.A., 1987, cum laude



## **Chris Sloan**

Shareholder  
Nashville  
Phone: 615.726.5783  
Fax: 615.744.5783  
csloan@bakerdonelson.com

Mr. Sloan is a corporate and intellectual property lawyer who represents entrepreneurs, start-ups and other emerging businesses, handling complex software and other IT transactions for both small and large companies alike. He helps many early-stage, high-growth businesses with business planning and formation, venture capital funding, drafting and negotiating vendor and customer agreements, strategic contract negotiations, mergers and acquisitions, intellectual property protection and other general business law and intellectual property law issues. He often serves as outside general counsel for these types of companies.

Mr. Sloan regularly represents both technology and brick-and-mortar clients in connection with software, IT and other vendor contract negotiations, including software and health care IT transactions valued as high as \$100 million. He regularly counsels hospitals and other health care providers on IT and intellectual property issues. Mr. Sloan takes pride in providing his clients with practical, cost-effective advice tailored for each client's unique business objectives. He is actively involved in the technology and entrepreneur communities, and he is a frequent author, speaker, board member and leader in that community.

Mr. Sloan routinely advises clients on such intellectual property law issues as trademark selection and protection, copyright protection, nondisclosure agreements, trade secret protection and domain name disputes. He is a recognized authority on intellectual property licensing, and is the author of the licensing chapter of both editions of the American Bar Association's book *Intellectual Property Deskbook for the Business Lawyer*. He has handled a variety of website-related disputes, including privacy policies, terms of use, click-wrap, browsewrap, and similar online agreements, the Digital Millennium Copyright Act and domain name disputes under the Uniform Domain Name Dispute Resolution Policy. In the entertainment law sector, Mr. Sloan regularly represents book publishers in connection with a variety of domestic and foreign publishing and licensing matters.

He is actively involved in the Nashville Technology Council, serving as the chairman of the board of directors, on the executive committee and as general counsel. Mr. Sloan was a member of the Nashville Chamber's Partnership 2010 Entrepreneurship Task Force and serves on the advisory board for the Nashville Entrepreneur Center. Mr. Sloan is a long-standing member of the executive committee of the Tennessee Bar Association's Intellectual Property Law Committee.



Mr. Sloan is a frequent speaker and contributor to CLE seminars, Nashville Area Chamber of Commerce, Nashville Technology Council events and other similar events. Follow him on Twitter [@casloan](#) and LinkedIn [@chrisloanesq](#).

### **Professional Honors & Activities**

- Listed in *The Best Lawyers in America*<sup>®</sup> in Intellectual Property Law (2005 – 2006, 2009 – 2010); Information Technology Law (2007 – 2013); Copyright Law (2012, 2013); Corporate Law (2013)
- Listed as a Rising Star in *Mid-South Super Lawyers* (2011)
- Chairman of the Board, Member of Board of Directors and Executive Committee – Nashville Technology Council
- Board of Directors – Life Science Tennessee
- Advisory Board – Nashville Entrepreneur Center
- Listed – *Nashville Post* "In Charge" list - Technology (2011 – 2012)
- Named – "Power Leaders in Technology" by the *Nashville Business Journal* (2011, 2012)
- Executive Committee and Intellectual Property Committee – Tennessee Bar Association
- Founding Board of Directors – Nashville Preparatory Charter School
- Member – Nashville, Tennessee and American Bar Associations
- Member – Partnership 2010 Entrepreneurship Task Force
- Member – American Health Lawyers Association
- Mentor – JumpStart Foundry
- Member – Startup Tennessee Advisory Board

### **Publications & Recent Speaking Engagements**

- Speaker – "Law of Technology: What You Need to Know," Tennessee Bar Association, September 22, 2011
- Guest – "[Boston Style Bluegrass: Phones, drones, privacy for royals and more](#)," *This Week in Law*, September 21, 2012
- Panelist – "Venture Capital 101," Tennessee Governor's Conference, September 22, 2011
- Judge – TechVenture Challenge, Nashville, Tennessee, April 5, 2011
- Judge – Belmont Business Plan Competition, Nashville, Tennessee, April 1, 2011
- Moderator – "Negotiating a Term Sheet," Nashville Technology Council's Entrepreneurial Series, Nashville, Tennessee, February 15, 2011
- Speaker – Owen Entrepreneurship Center Breakfast, Nashville, Tennessee, September 24, 2010
- Panel member – "Panel Discussion: IT License Agreements," 2010 Mississippi Software Institute, Jackson, Mississippi, February 26, 2010

- Speaker - "Top 10 Issues for Software Companies," 2010 Mississippi Software Institute, Jackson, Mississippi, February 16, 2010
- Speaker - "Capital Formation," Nashville Technology Council's Entrepreneurial Series, Nashville, Tennessee, December 3, 2009
- Speaker - "Doing Business in China," North Alabama International Trade Association, Huntsville, Alabama, September 1, 2009
- Speaker - "IP for Small Businesses," Green Hills Rotary Club, Nashville, Tennessee, August 7, 2009
- Panel Member - "China—Still the Land of Opportunities for U.S. Businesses," Nashville Area Chamber of Commerce's China Business Group, Nashville, Tennessee, January 13, 2009
- Speaker - "Service Level Agreements: Tricks and Traps for the Unwary," Tennessee Bar Association's "The Law of Technology: What You Need to Know" seminar, Nashville, Tennessee, September 26, 2008

### **Admissions**

- Tennessee

### **Education**

- Vanderbilt University Law School, J.D., 1999
- University of Virginia, B.A., 1996

### **Interests**

Mr. Sloan is actively involved in many conservation organizations locally, nationally and internationally. He is one of the more widely recognized regional experts on bird identification and distribution, and he co-authors a quarterly column on birds of Tennessee & Kentucky for *North American Birds*. Several of his papers on birds have been accepted and published in scientific journals. Mr. Sloan is also an avid nature photographer and has sold photos to publications in North America and Europe. Some of his pictures can be found at [www.chrissloanphotography.com](http://www.chrissloanphotography.com).



**Michael R. Hess**

Shareholder  
Memphis  
Phone: 901.577.8275  
Fax: 901.577.4289  
mhess@bakerdonelson.com

Mike Hess is a shareholder in the Memphis office of Baker Donelson. He is focused solely on the pharmaceutical trade and distribution industry, and leads the Firm's Drug, Device & Life Sciences industry service team. Mr. Hess's clients are small and large drug manufacturers, wholesalers, group purchasing organizations, reimbursement hubs, pharmacies and 340B covered entities. He provides them with strategic business advice, transactional and regulatory guidance, and routinely navigates the legal and business maze to get drugs from the manufacturer's warehouse to the patient's door, safely, legally, effectively and efficiently. Mr. Hess also cultivates the relationships needed to grow a pharmacy, build a pharma service business or launch a new product.

Mr. Hess enjoys the challenge of taking small and large drug manufacturers' new products to market and has six years of direct pharmacy and pharma experience relevant to these challenges. He understands the legal, regulatory and business needs that drive the supply chain and its success, and has negotiated hundreds of agreements to move product through the supply chain. These include wholesale distribution, specialty and retail pharmacy direct distribution, fee for service, reimbursement hub services, co-pay and coupon program services, adverse event or clinical hotline services and associated software and program design agreements.

He also works with a number of wholesalers and group purchasing organizations as they move product from the manufacturer to the pharmacy, physician or hospital. His experience in this area includes structuring compliant GPO arrangements and negotiating contracts for administrative service fees and rebates.

Mr. Hess also helps large and small specialty and home infusion pharmacies develop their businesses. With experience growing a large specialty pharmacy, he understands the nuances of a company's contractual, regulatory and operations requirements and how to effectively balance those while maintaining compliance, competitiveness and flexibility.

Mr. Hess also has extensive experience in structuring 340B contract pharmacy arrangements and has advised hospitals, FQHCs, Ryan White Clinics, and hemophilia treatment centers programs accessing 340B discounted drugs for their eligible patients. He works closely with programs as they make major changes to their businesses, including outlining the 340B impact on acquiring medical oncology practices, building contract pharmacy networks, integrating physician practices and accessing limited distribution drugs. Through this work, he has personal relationships within many of the 340B consulting firms and service providers and knows how to get an effective structure in place for covered entities or pharmacies.

Before returning to the Firm, Mr. Hess was Chief Counsel and VP of Strategic Development for Accredo Health Group, which was at that time the nation's largest specialty pharmacy, and Assistant General Counsel for Accredo's corporate parent, Medco Health Solutions. While at Accredo, Mr. Hess was responsible for the full range of legal services and functions associated with the specialty line of business.

### **Speaking Engagements**

- Panelist – "How to Structure 340B Contract Pharmacy Agreements," American Bar Association webcast, September 6, 2012
- Presenter – "[Specialty Drugs & Limited Distribution Networks](#)," 16th Annual 340B Coalition Conference, July 2012
- Presenter – "[Nuts & Bolts of Contract Pharmacy Implementation and Compliance](#)," 8th Annual 340B Coalition Winter Conference, March 2012
- Presenter – "[Drug Supply Policy, Challenges & Solutions](#)," 8th Annual 340B Coalition Winter Conference, March 2012

### **Professional Honors & Activities**

- AV<sup>®</sup> Preeminent<sup>™</sup> Peer Review Rated by Martindale-Hubbell
- Listed in *Mid-South Super Lawyers* (Health Law, 2009)
- Vice-Chair – American Health Lawyers Association RAP Practice Group
- Member – Make-a-Wish of the Mid-South Board of Directors
- Member – Memphis Leadership Academy Board of Trustees
- Member – Advisory Board, National Infusion Center Association

### **Admissions**

- Alabama, 2005
- Tennessee, 2003
- Mississippi, 1996

### **Education**

- University of Mississippi School of Law, J.D., 1996
- Mississippi State University, M.A., 1993
- Mississippi College, B.A., 1992



## **Emily T. Brackstone**

Associate  
Memphis  
Phone: 901.577.8274  
Fax: 901.577.0791  
ebrackstone@bakerdonelson.com

Emily T. Brackstone is an associate in the Memphis office of Baker Donelson where she concentrates her practice in the areas of corporate law, mergers and acquisitions and health law. Ms. Brackstone has experience structuring and forming business organizations, drafting and negotiating general business contracts and advising clients regarding corporate governance issues. She has represented both buyers and sellers in the acquisition and sale of businesses in a variety of industries. Ms. Brackstone has also counseled health care clients on a wide range of topics, including issues involving the Stark self-referral law, the federal anti-kickback statute, HIPAA, managed care contracting and reimbursement and licensure issues.

### **Publications and Speaking Engagements**

- Author - "Civil Rights—Title IX—An Individual May Maintain a Private Right of Action Under Title IX When the Federal Funding Recipient Retaliates Against the Individual Due to His Complaints About Sex Discrimination," 73 *Tenn. L. Rev.* 115 (2005)
- Author - "S Corps and Child Support: What the Majority Shareholder Needs to Know," 7 *Transactions: Tenn. J. Bus. L.* 203 (2005)

### **Professional Honors & Activities**

- Member – American, Tennessee and Memphis Bar Associations
- Member – American Health Lawyers Association
- Member – Order of the Coif, University of Tennessee chapter
- Associate Member – The Leo Bearman Sr. Chapter of the American Inns of Court
- Member – YMCA Y-CAP Board of Directors
- University of Tennessee Certificates of Academic Excellence in Criminal Law, Torts I, Constitutional Law, Evidence, Commercial Law and Income Taxation of Business Organizations

### **Admissions**

- Tennessee, 2007

### **Education**

- University of Tennessee, J.D., 2007, *summa cum laude*
  - Student Materials Editor, *Tennessee Law Review*, 2006 – 2007

- Executive Editor: Transactions, *Tennessee Journal of Business Law*, 2006 – 2007
- University of Notre Dame, B.A., 2004, *magna cum laude*



## David Louis Vanik

Associate  
Washington, D.C.  
Phone: 202.508.3406  
Fax: 202.220.2206  
dvanik@bakerdonelson.com

David L. Vanik, Ph.D., associate in Baker Donelson's Washington, D.C., office, is a member of the Firm's Intellectual Property Group. As a registered patent attorney, he focuses his practice on patent prosecution and counseling, opinion work, and patent portfolio strategy in the chemical and biotechnology arts. Dr. Vanik has significant experience working with foreign patent associates to help secure foreign patent rights for U.S. clients. Dr. Vanik also has experience prosecuting patent applications related to biotechnology, plants, chemical compounds, small-molecules, pharmaceutical compositions and antibodies ad proteins.

Prior to joining Baker Donelson, Dr. Vanik worked as an associate for several years in a Washington, D.C., law firm and was also a patent examiner at the United States Patent and Trademark Office. As an examiner, Dr. Vanik's docket encompassed a wide range of technologies including small molecules, pharmaceutical compositions, medical device coatings, rapid and extended release drug delivery formulations, liposomes, tissue engineering compositions, nanoparticles, cosmetics, hair care products, and methods of treating cancer. Additionally, in evaluating patent applications, Dr. Vanik participated in patentability interviews and pre-appeal conferences, conducted prior art searches, and drafted Office actions. Dr. Vanik also has experience examining applications filed under the Patent Cooperation Treaty (PCT).

As a graduate student, Dr. Vanik investigated the biophysical properties of the mad cow disease-related prion protein using a multitude of biophysical techniques to study the molecular basis of the propagation and interspecies transmission of prion disorders. In addition to his work in the lab, Dr. Vanik helped to develop a novel chemistry course entitled "Chemistry and the World."

### Admissions

- District of Columbia, 2008
- State of Illinois, 2007
- United State Patent and Trademark Office

### Education

- The George Washington University Law School, J.D., 2007
- Case Western Reserve University, Ph.D., 2004, Protein Chemistry
- Washington & Jefferson College, B.A., 1998, Chemistry and Philosophy



**Steve Wood Jr.**

Shareholder  
Nashville  
Phone: 615.726.5556  
Fax: 615.744.5556  
sfwood@bakerdonelson.com

Steve Wood, Co-chairman of the Business Technology Group at Baker Donelson, counsels tech companies, venture capital funds, and health systems in a broad array of business and corporate transactional matters, from company formation to acquisitions and financing deals. He is well-versed in securities law and taxation and he has particular experience with software licensing and development agreements. His work frequently involves health IT and Mr. Wood has considerable knowledge of HIPAA compliance issues. He serves as the Information Privacy and Security Officer for Baker Donelson.

In addition to his 20 years as a lawyer (including five years as a law professor at Vanderbilt Law School), Mr. Wood draws upon significant real-world business experience in representing his clients. He had a career in banking and commercial real estate finance prior to law school and later co-founded and was CEO of a successful financial services software business, including two years as division executive of the NYSE-listed firm that ultimately acquired his company. He also has served as an advisor and business consultant to several technology-related start-ups. These hands-on business experiences provide a valuable foundation for understanding the client's strategic objectives beyond a purely legal perspective.

### **Other Work Experience**

- Professor, Vanderbilt University Law School, and Adjunct Professor, Vanderbilt Owen Graduate School of Management
- Business consultant and advisor to technology-oriented businesses
- Division Executive, Ocwen Financial Corporation (NYSE:OCN)
- Founder and CEO, Synergy Software, Inc. (financial services software)
- Vice President, Woodmark, Inc. (real estate finance and investment services)
- Real Estate Lending Officer, NCNB National Bank (predecessor to Bank of America)

### **Representative Matters**

- Venture capital and angel financing – both investor and company representation
- Health information technology – development, licensing, and hosting agreements
- Information privacy and security – Business Associate Agreements, HIPAA compliance issues, data breaches
- IT aspects of hospital acquisitions – complicated transition services agreements



- Mobile apps (iPhone and Android) – development and hosting/content management system agreements
- Online social networks – click-through Terms of Service and Privacy Policies
- Music industry technology agreements
- Software license agreements – both installed and hosted applications, including SaaS and cloud computing
- Software application development agreements
- Source code license and escrow agreements
- Large-scale IT outsourcing agreements
- Outside general counsel – broad business-legal counsel to start-up and emerging companies

### **Professional Honors and Activities**

- Board of Directors, Nashville Capital Network (angel investing and entrepreneurial guidance organization)
- Board of Directors, Nashville Entrepreneur Center (initiative of Nashville Area Chamber of Commerce and Nashville Technology Council)
- Health Information and Management Systems Society (HIMSS)
- American Health Lawyers Association
- American Bar Association, Section on Science and Technology

### **Admissions**

- Tennessee, 1991

### **Education**

- Vanderbilt University Law School, J.D., 1991 (Associate Editor, *Vanderbilt Law Review*)
- Indiana University School of Business, B.S. in Business Economics with high distinction, 1983 (Beta Gamma Sigma)



## **Glenn Perdue**

MBA, AVA, CFFA, CLP

Managing Member

Kraft Analytics

[gperdue@kraftcpas.com](mailto:gperdue@kraftcpas.com)

Glenn Perdue is the managing member of Kraft Analytics, LLC, which focuses upon valuation, forensic and transaction advisory services.

Valuation experience includes the valuation of businesses, equity interests, intellectual property and other intangible assets for investment, lending, managerial planning, compliance, accounting, tax, marital dissolution, restructuring and litigation purposes.

Forensic experience includes work with attorneys related to valuation issues, transactional disputes, economic damages, intellectual property, antitrust analysis, corporate investigations, employee fraud, insurance coverage, computer forensics and e-discovery. Glenn has been retained as an expert in over 80 litigation matters and has provided testimony as an expert witness at depositions, in mediations, in arbitrations and in federal and state courts before judges and juries.

Transaction advisory experience includes valuation, fairness opinions, due diligence and transaction structuring support related to business sales, asset sales, M&A transactions, equity investments, lending transactions, licensing transactions and joint venture arrangements.

Other consulting experience includes market entry studies, industry and competitive analysis, business strategy, technology strategy, technology investment analysis, risk analysis and capital formation support.

Glenn began his professional career in the venture capital industry and later became the president of a technology company which he sold before attending graduate school. Prior to joining Kraft, Glenn was with Crowe Chizek and Company where he led the intellectual property practice. Prior to that, he was with LECCG, an international economics and finance consulting firm.

Glenn has over 20 years of experience working with business owners, executives, attorneys, accountants and other professionals. Industry experience includes work in information technology (software, hardware, internet, telecommunications); life sciences (pharmaceuticals, biotech, medical devices, medical supplies); healthcare services (hospital, long-term care, ASC, dialysis, home health, health insurance, imaging, healthcare IT, EMR, EHR, PBM's); music, media and entertainment; inventory-based businesses (manufacturing, distribution, retail); banking and financial services; construction and transportation; and service-based businesses (professional services, technology services, real estate, advertising, event management, etc.).



**Ken Woody**

President

Innova

[kwoody@innovamemphis.com](mailto:kwoody@innovamemphis.com)

As President of Innova, Ken leads a dedicated staff focused on finding, funding and growing startup technology businesses in Tennessee to help them achieve commercial success. With 23 companies in the Innova portfolio and seats on the Board of 10 of them, Ken's time is spent not only investing, but also mentoring management teams. He provides strategic guidance when portfolio companies are faced with the difficult decisions that startups frequently encounter.

Ken is a U.S. Army Veteran who served honorably as an Infantry Captain and General's Aide. He was also an entrepreneur and a Fortune 500 Executive. He worked for GE for over 16 years, serving as a VP and General Manager in its Healthcare and Capital businesses. He served as VP of Sales for DePuy Spine, a Johnson and Johnson company, before moving his family to the Memphis area in 2004. Ken was Senior Vice-President for Global Sales with Smith and Nephew Orthopedics, in charge of Sales and Operations for this multi-billion dollar global enterprise.

In addition to his portfolio company Board roles, Ken serves as Board Chairman for the ZeroTo510 medical device accelerator. He is also on the Life Science Tennessee Board and the Advisory Board for the FedEx Institute of Technology at the University of Memphis.



**Gary Stevenson**

Co-Founder

MB Venture Partners

[gstevenson@mbventures.com](mailto:gstevenson@mbventures.com)

Gary Stevenson co-founded MB Venture Partners in 2001 after six years in health care investment banking and research. He also spent seven years in a variety of general management roles with Abbott Laboratories, one of the largest and most diversified health care companies in the world. Gary holds an undergraduate degree in accounting from the University of Missouri. He also received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University. He is a certified public accountant and a chartered financial analyst. Gary is a board member or observer for several MBVP portfolio companies including AxiMed Spine, BioSET, Kereos, KFx Medical, Hapten Sciences, S2 Interactive, Spinal Restoration, and Visioneering. Gary is also a Board member of the ZeroTo510 accelerator program.



**Joseph C. Cook, Jr.**

Principal and Co-Founder  
Mountain Group Capital  
jcj@mgcfund.com

Joseph C. Cook, Jr. presently serves as a Principal and Co-Founder, Mountain Group Capital, LLC and The Limestone Fund, LLC, both located in Nashville, TN. Mr. Cook also serves as a director of two publicly traded companies, Ironwood Pharmaceuticals, Inc. in Cambridge, MA and Corcept Therapeutics, Inc. in Palo Alto, CA.

Mr. Cook earned a BS in Engineering from the University of Tennessee in 1965 graduating with High Honors. He was named a Torchbearer, UT's highest student honor given for academic achievement and commitment to others. Cook then began his engineering career at Eli Lilly & Company in Indianapolis, focusing on automated cancer screening research. During his 28+ years with Eli Lilly, he held numerous senior executive positions in manufacturing, engineering, finance, sales and marketing, and general management. In 1993, Cook retired as group vice president for Global Operations.

After retiring from Lilly, he began a new career in biotechnology. He was a founder and Chairman of Ironwood Pharmaceuticals, Inc. a biotech company that recently received FDA approval for a new medicine for people with serious gastro-intestinal disorders. In 1998, he was elected chairman and CEO of Amylin Pharmaceuticals, Inc. a publicly traded company in San Diego. He led Amylin through the development of two new drugs for people with diabetes, BYETTA and BYDUREON, both of which have now been approved by the FDA. Cook retired as CEO Amylin in 2003 but continued to serve as the company's chairman until 2009.

Following retirement from the Amylin CEO role, Cook and partners formed Mountain Group Capital ("MGC"), a Nashville based investment firm dedicated to investing in and actively guiding transformational businesses in the Life Sciences and Technology sectors. In 2009, he and partners formed The Limestone Fund which was subsequently chosen by the State of Tennessee as one of the original six TNInvestco award winners. Through various funds, MGC principals have invested in more than 20 companies in their targeted sectors

Cook also serves as chairman of Mercy Ministries International, a faith-based global ministry headquartered in Nashville and on the national board of the American Diabetes Association. Additionally, Cook has been a member of the College of Engineering's Board of Advisors at the University of Tennessee, Knoxville for over 20 years, previously serving as chairman.

In 1999, Cook was awarded the Nathan W. Dougherty Award by the College of Engineering at the University of Tennessee. The Corporate Directors Forum named Cook its Director of the Year in 2003 and 2006, respectively. He also received the Pinnacle Award for Life Science Leadership from the Rady School of Management at the University of California, San Diego in 2009. In 2011, Cook received the Distinguished Alumni Award from the University of Tennessee, Knoxville.



**Michael Villalobos, PhD**

Manager, Biotech Licensing  
Center for Technology Transfer and Commercialization  
Vanderbilt University  
mike.villalobos@vanderbilt.edu

Dr. Villalobos is a seasoned licensing professional with 10 years of experience bringing early-stage life science technologies to the commercial markets through licensing and start-up company formation. Michael joined Vanderbilt University in September 2011 to head up the Biotech Licensing Team and is responsible for commercializing life science technologies through corporate partnerships. Prior to joining Vanderbilt, Mike managed the commercialization of therapeutic, medical device, diagnostic, and software technologies for The Cleveland Clinic and Purdue University. Prior to his career in licensing, he was a Senior Process Scientist at Abbott Laboratories where he oversaw the manufacturing of diagnostic assays for human blood borne pathogens.

Additionally, Michael has a strong life sciences background, which includes a bachelor's degree in Microbiology from the University of Illinois - Urbana and a doctorate in Molecular Biology from Loyola University Chicago. He is a member of the Association of University Technology Managers and the Licensing Executives Society.