



Legal:GPS

Growth and Protection Strategies to
Help Navigate Your Business Success

The IP Factor for Life Sciences Companies

September 23, 2009





Foley & Lardner LLP

- National law firm (19 domestic; 3 international offices) with over 1,000 attorneys and a full range of corporate legal services including:
 - Intellectual Property
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 - Private Equity & Venture Capital
 - Tax & Employee Benefits – and more!
- Strong commitment to women both internally and externally
- Women Business Owners' Resource Guide
 - Information on legal topics when starting and growing a business
 - Visit: www.womenlegalresource.com





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- Venture-Catalyst **Springboard Enterprises** is the go-to organization for information about and support for emerging growth ventures led by women. Springboard recruits, qualified, coaches, showcases, and supports women entrepreneurs as they seek equity capital and build their businesses.
- The 380 companies selected from 4000 applicants and showcased at Springboard Venture Forum Programs have raised over \$4.5 billion in equity, grants, and corporate investments and provided positive returns for their investors including 7 IPOs.
- For more information about funding your business with investment capital please visit our website's Learning Center www.springboardenterprises.org./learning/





Housekeeping Details

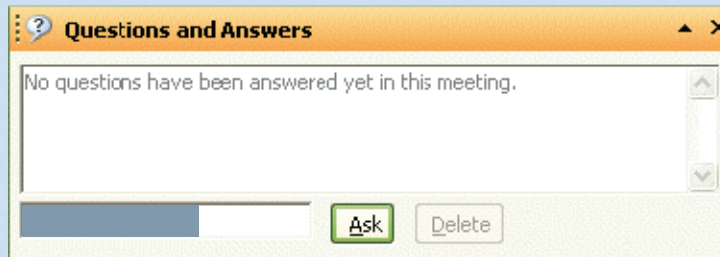
- Today's program will last one hour
- A recording of the program will be available in the next few weeks on Foley.com and via a link on Springboard's Web site
- To view the presentation in full screen mode, please go to View on your Toolbar and select "Full Screen Mode"





To Ask a Question

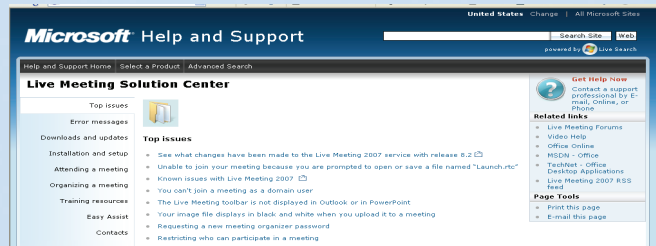
- Enter your question into the text area of the Question Pane, and select Ask
- Time permitting, we will address Questions at the end of the presentation. Please indicate if you would like a particular speaker to address your question.





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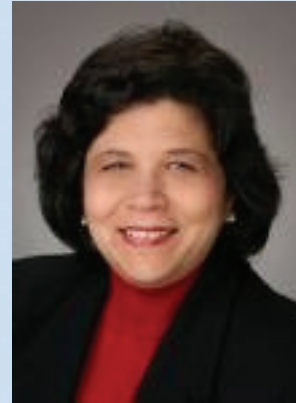




Today's Panelists

Julie Goonewardene

- Director of Business Development, Purdue Research Foundation & Discovery Park
- Currently leading Purdue University's new venture formation effort where she manages the Emerging Innovations Fund
- Former founder and President and CEO of Cantilever Technologies
- Co-author of "The Right Decision for the Right Reason"





Today's Panelists

Michele M. Simkin

- Partner with Foley and chair of the Biotechnology & Pharmaceutical Practice
- Provides strategic business counseling to life sciences clients
- Former patent examiner in the biotech group of the U.S. Patent and Trademark Office
- Has over 19 years of experience in the patent field





IP: It is Never Too Early

- Problems can start very early in the process
- Be thinking about regulatory pathways in the lab
- IP issues can go all the way to lab notebooks
- For most university inventors the thought of IP comes at the time of publication.

That may be too late!





What is the Investor Thinking?

- If the IP is coming from the University, has the inventor played by the rules?
No one wants a rogue inventor
- Does the inventor understand that the IP protections only cover what they disclosed?
If they held back information it won't be in the claims
- Does the inventor understand that inventorship cannot be used to reward and punish people?





IP and the Patent

- Has the company/inventor carefully reviewed the IP landscape?
- Have they paid for a “freedom to operate”?
- Is the freedom to operate “clean”?

“Maybe” is as good as a “no”

- Does the company have a global IP strategy?





Tools to Manage/Develop IP

- Invention Disclosure Forms
- Laboratory Notebooks
 - Both are considered legal documents
 - Need witnessing
 - Written policies for maintaining





Invention Disclosure Forms

- Offensive Use of IDFs; Systematic Invention Harvesting Techniques
 - Quarterly Analysis: What products are in development?
 - What differentiators could be added to current products?
 - Quarterly Prophetic Inventing: Invent your place in the market of the future
 - Competitor Targeting





Invention Disclosure Forms

- Defensive Use
 - Regular documentation of inventions can be used to support declarations to antedate references during prosecution of US applications
 - Can be used to antedate opponent in interference





Laboratory Notebooks

- Notebooks are an original record providing a technical reference and legal evidence
- Can be used to antedate opponent in interference
- Must be witnessed!
 - Recent case held that Inventor's laboratory notebook that was not witnessed provides no independent source of authority for invention (Medichem S.A. v. Rolabo S.L., 77 USPQ 2d 1865 (Fed. Cir. 2006))





Laboratory Notebooks

- What to record:
 - Use new notebook for each new major project and record:
 - A brief statement of the project and problems envisioned
 - A brief outline of the proposed method





Laboratory Notebooks

- Each new experiment should be recorded on a new page and include:
 - Object of that experiment
 - Changes made in the equipment or apparatus used
 - source and physical or chemical characteristics of raw materials used
 - operating parameters - amounts, temperatures, pressures, reaction times, rates of flow, yields etc.
 - Observations and conclusions (minus negative/unnecessary statements)
 - Identification of samples submitted for analysis
 - Calculations made from data





Laboratory Notebooks

- How to Record:
 - Each experimenter must date (in full) and sign (not initial) each page of every notebook he/she uses only after all other entries have been made.
 - “Invented by”/”Recorded by” should be SIGNED and DATED either by the experimenter(s), if the written material results from experimental work, or by the writer if other written matter is entered
 - “Witnessed & Understood by me,” should be SIGNED and DATED by a person other than one of the experimenters, preferably a person technically qualified in the same field.





Laboratory Notebooks

- Abbreviations/tradenames, other than those widely adopted in scientific work, should not be employed unless clear explanations of their meaning are given
- DO NOT ERASE! When an error is recorded, a line should be drawn through it (so that it can still be read) and the correction inserted adjacent thereto.





Invention Process

■ DO:

- Keep accurate notebooks and ensure that they are signed and witnessed
- Complete an Innovation Disclosure form as soon as possible
- Think broadly (in scope and time) when considering the utility of an invention
- Keep up with the patent literature (if possible)





Invention Process

■ DON'T:

- Disclose the invention publicly before a patent application is filed or without an executed Proprietary Information Agreement (non-disclosure agreement)
- Sell or offer for sale a unit containing the invention before a patent application is filed
- Make potentially damaging statements in e-mail or other written correspondence





Summary

- IP protection is a sophisticated and expensive game: PLAY WITH A PRO!
- Without IP you may not have anything
- Global matters!





Questions & Answers





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