Startups – Tips for Navigating Your Company to Success

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Presented by:
Shawn P. Foley. Esq
My Background

30 years of IP experience in personal care/pharma/ life sciences

• U.S. Patent Office
• Ag Bio (In-House, a real “hybrid” situation)
• Private Practice

Viewed the patent system from many perspectives
Representation of Startups

- Personal Care (Skin Care)
- Pharma (e.g., Small Molecules)
- Life Sciences
  - Immunotherapy
    - mAbs
    - ADCs
    - CAR-T
    - Macrophages
Entrepreneurs Must Wear Many Hats!

• Be honest with yourself – Assess what you are best at doing
• Consider delegating other tasks
• Technologist/Engineer/Researcher
• CEO/President
• Manager
• Accountant
• Marketer
Not the least of your duties -- Salesmanship

• Not innate but can be acquired
• Raise Capital – several rounds of financing in increasing amounts
  • Don’t be afraid to ask for money!!
• Pitch your company to interested parties
  • Understand your audiences
  • Develop a clean and concise presentation
  • Dress rehearsal
  • Refine presentation
• Fundamentally you are selling yourself!
Selecting IP Counsel

• Sometimes the selection is out of your hands!
  • In-licensed university originated technology

• Find an IP Counsel “who you trust”!
  • Be wary of IP Counsel who promise too much too soon!
  • Can the attorney provide you with a realistic cost-effective plan customized to YOUR needs?

• Can the attorney manage your expectations?
Selecting IP Counsel

CLIENT EXPECTATION

CLIENT BUDGET
IP Protection

• “Quality over quantity”
  • Some ‘reasonable’ amount of IP coverage
  • Robust coverage is not always available

• Bear in mind the primary objective:
  • Investors/VCs – early and more cursory review
  • Larger Pharma – later, critical and sophisticated review by in-house BD experts
Patent Filing Considerations

• Be practical and work within your budget!
• Understand and plan for likelihood that the Patent Office is a zealous gatekeeper of the public domain
• Courts continue to interpret patent statutes more narrowly, especially with respect to antibodies (Abs)
• Don’t jeopardize 2nd generation IP – could be of vital importance
Patent Filing Considerations (Continued)

• Provisional

• PCT

• What if investors want to see an issued patent
  • Consider filing a narrow patent application in the U.S. with request for accelerated examinations.
  • ‘Track 1’ application filing fee at time of filing: $2,000 (small entity)
Global IP Considerations

• Where to file?
  • US – major market for therapeutics
  • Europe, Asia, South America?

• Risk vs Reward – is it worth investing in a given country?
Global IP Considerations (Continued)

- How much of the global market can I cover for X dollars?
**FDA Drug Development Pathway**

**Drug attrition rates through the phases**

- Phase I: 59.5%
- Phase II: 35.5%
- Phase III: 61.9%
- NDA: 90.4%

11.8% of drugs that enter Phase I


More IP Considerations

A patent bestows upon the owner a negative right – it does not grant an affirmative right to commercialize the invention covered by the patent

- Should I spend the money to conduct a freedom to operate (FTO) analysis?
- Would the commercialization of your product infringe non-expired 3rd party patents?
More IP Considerations (Continued)

• Not until you are reasonably sure what your product will look like

• Understand that FTOs come in all shapes & sizes: “looking under the hood and kicking the tires” (e.g., $5-10k) versus more exhaustive and expensive studies which might be premature
Burns & Levinson LLP

What we offer start-ups?

• Customized legal services
  • Innovation Program
  • Dress Rehearsals
THANK YOU!

QUESTIONS?
Shawn Foley
Of Counsel

“Successfully practicing law requires dedication, composure and juggling. Every client expects and deserves nothing less than your very best.”

At this point in a solid legal career, a lawyer should have a litany of success stories. What Shawn is especially proud of, however, are the versatility he has gained and the ability to listen, all of which enables him to effectively represent clients who have diverse technologies, business and legal goals and personalities.

With more than 30 years of experience in the field, Shawn brings refined legal and advocacy skills and technical versatility. His approach to patent procurement is practical, cost effective, distinctly business-oriented and personable.

Prior to joining Burns & Levinson, Shawn played an integral role in developing his previous firm’s practice in life sciences and pharmaceuticals. A wide spectrum of clients with diverse technologies and business needs have sought his counsel, including major pharmaceutical and personal care companies, medium-sized brand and generic drug companies, start-ups, universities, and entrepreneurs, both in the U.S. and abroad.

Shawn began his career as an examiner with the U.S. Patent Office, where he reviewed patent applications during the emergence of the biotechnology field. After an initial 2-year stint with a leading Southeastern IP firm, he gained valuable corporate experience as counsel for Ciba-Geigy. At Ciba, Shawn was co-in house counsel for its agricultural biotechnology research division (now Syngenta Seeds), where he worked on a daily basis with management and scientists to gain patent protection for transgenic crop seed and to bring these first generation products to market. He also collaborated with colleagues in Switzerland and prosecuted patent applications directed to pharmaceuticals. Thus, Shawn has experienced many different aspects of the patent system.

Shawn has particularly enjoyed creating commercially valuable patent estates for a variety of clients. Patent estates that he has created have facilitated many licenses and outright acquisitions (e.g., by big pharma). He also has extensive experience in guiding clients and their products through the maze of third party patents. He prides himself in a communication style that is simple and direct. He is equally experienced and comfortable in making formal presentations to Boards of Directors as he is in dealing with in-house counsel and scientists. Although he has been successful in patent appeals and post-grant matters including European oppositions, Shawn’s familiarity with the inner workings of the Patent Office and his approach to prosecuting patents has enabled him to avoid resort to appeal except in rare situations.

Over the course of his years of practicing law, Shawn has become versatile in a wide spectrum of technologies. He has handled patent work involving chimeric proteins, monoclonal antibodies (including antibody-drug conjugates), industrial enzymes, therapeutic and diagnostic nucleic acids, small molecules and new chemical entities, drug delivery systems (including 505(b) (2) applications), molecular diagnostics, personal care compositions and cosmetics, transgenic plants (including crop plants and use of the plants for production of protein), crop science, dental care and caries detection, and medical devices.

Honors & Awards

Speaking Engagements
• IP and Licensing: Navigating the Landscape, Speaker, 8th Annual World Bispecific Summit, September 2017
• IP and Licensing: Navigating the Landscape, Speaker, CAR-TCR Summit 2017, September 2017

Practices
- Intellectual Property
- IP Litigation
- IP Transactions
- Patent

Education
- J.D., George Mason University School of Law
- B.A., Biochemistry, University of Pennsylvania

Admissions
- New Jersey
- North Carolina