Freedom to Operate: Identifying a Clear Field and Keeping it

A small-company perspective

Barbara A. Niksch, BS, MBA
Vice President, Regulatory, Quality & Clinical Affairs
Visiogen, Inc., Irvine, CA

April 5, 2005
About Visiogen...

- Founded in 2001
- ~ 25 Employees
- Venture Capital Funded
- Focused on the development of an accommodative intraocular lens (permanent implant)
- Currently conducting clinical studies
Getting Started. . .

- Forming the company

  - Ideas evaluated and researched before company is funded by Venture Capitalists
  - Outside legal counsel conducts FTO analysis (review of IP potential or IP that may already exist)
  - Goal is to secure freedom to operate

Validity of idea and assessment of patent protection
Importance of Freedom to Operate

- Without this a start-up may never get funding from VC’s
- Minimizes future risks
- Develop strategies (product scope, filing of future patents, possibly cross-license or work-around, etc.)
The process in a small-company

- Maintenance Phase
  - Continuous review of all related patents and potential for filling gaps (scientists, engineering, business development)
  - Information sharing within the company
  - Ongoing protection of technology

- Some companies are focused while others are looking to add technologies and look for gaps in the industry.

Company focus dictates scope of Patent activities
The process in a small-company

- Need to budget for legal expenses $$$
  - Continuous counsel on freedom to operate and obtaining freedom to operate letters
  - Filing of patent applications for continued protection

- Ahead of competition
  - This is key in a small company with limited funding and aggressive timelines
  - Without patent protection, regulatory approvals could be meaningless

Patent protection is vital to the small company
The results . . .

- Proudly present on wall ("wall of fame")
- Increases valuation of company
- Investigators more willing to work with company in clinical phases – inquisitive about patent protection
- Increases acquisitions or IPO possibilities
- Ability to continue to develop, manufacture, and commercialize product(s)