

# The Importance of Devices in Outcomes: Experiences of an Anesthesiologist and Entrepreneur

Mark J. Rice, MD

Professor

Associate Vice Chair of Clinical Affairs

Vanderbilt University

# Conflicts of Interest

***Served on several Roche Diabetes Care  
Advisory Boards***

***Co-Founder  
Cataract Innovations***

Do I know of what I speak?

# Da Vinci Surgical System

- Late 1990s
- Call from a friend
- What do I think of this robot surgery technology?



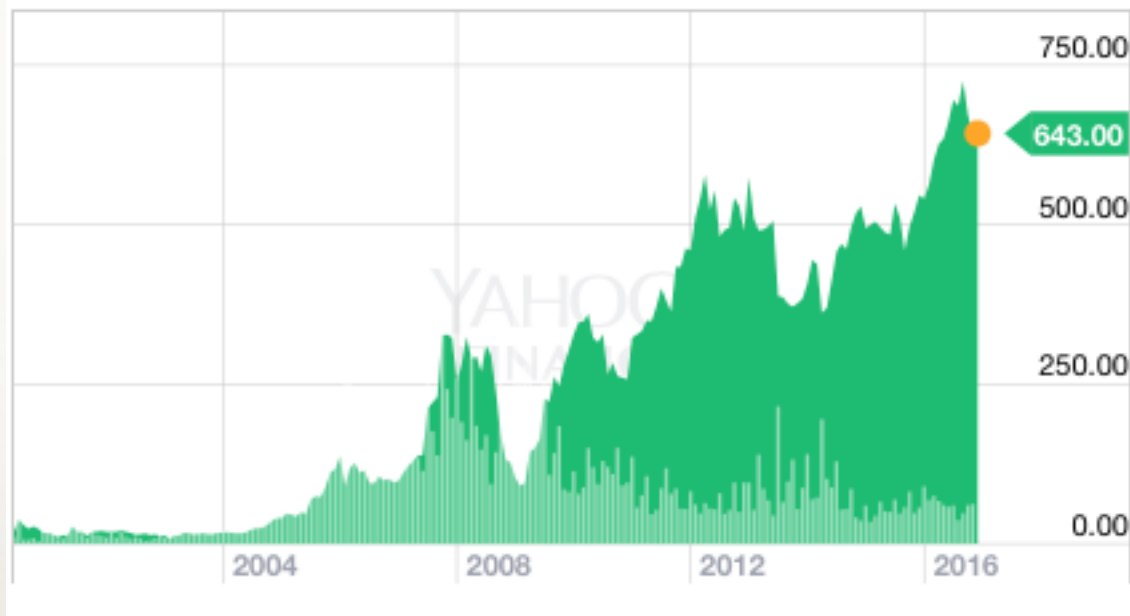


# My thoughts

- Super expensive – capital and recurrent
- Slow surgery
- Hard pressed to show a difference
- Steep learning curve
- Limited number of applications
- How could this possibly be successful?



Successful IPO in 2000  
Market cap = \$24.91 B



# Vanderbilt University Medical Center





# Nashville



# Goal

Tell you my story and hope to:

- Inspire
- Learn from some mistakes
- Give you a few clues in you want to stray away from the traditional path

# The engine that drives our economy



# A Tale of Two Businesses

1. Blue Ridge Medical, Inc.

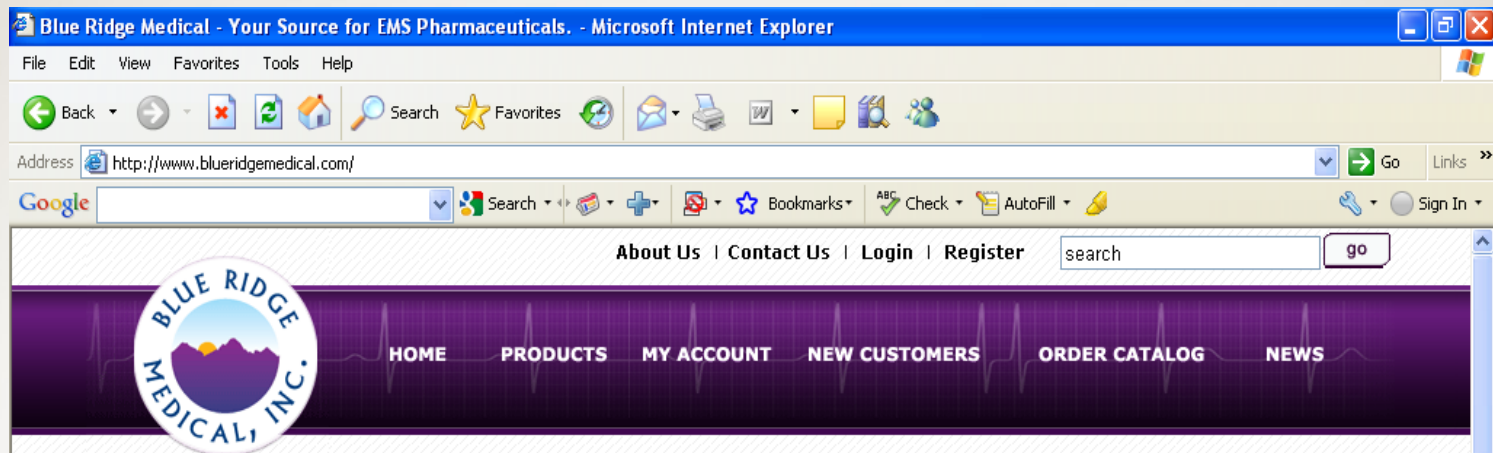


2. FoviOptics, Inc.



We made a little money with the first one

I am going to talk about the other one



- Started 1993
- Co-founded w my pharmacist brother
- Sold pre-hospital drugs



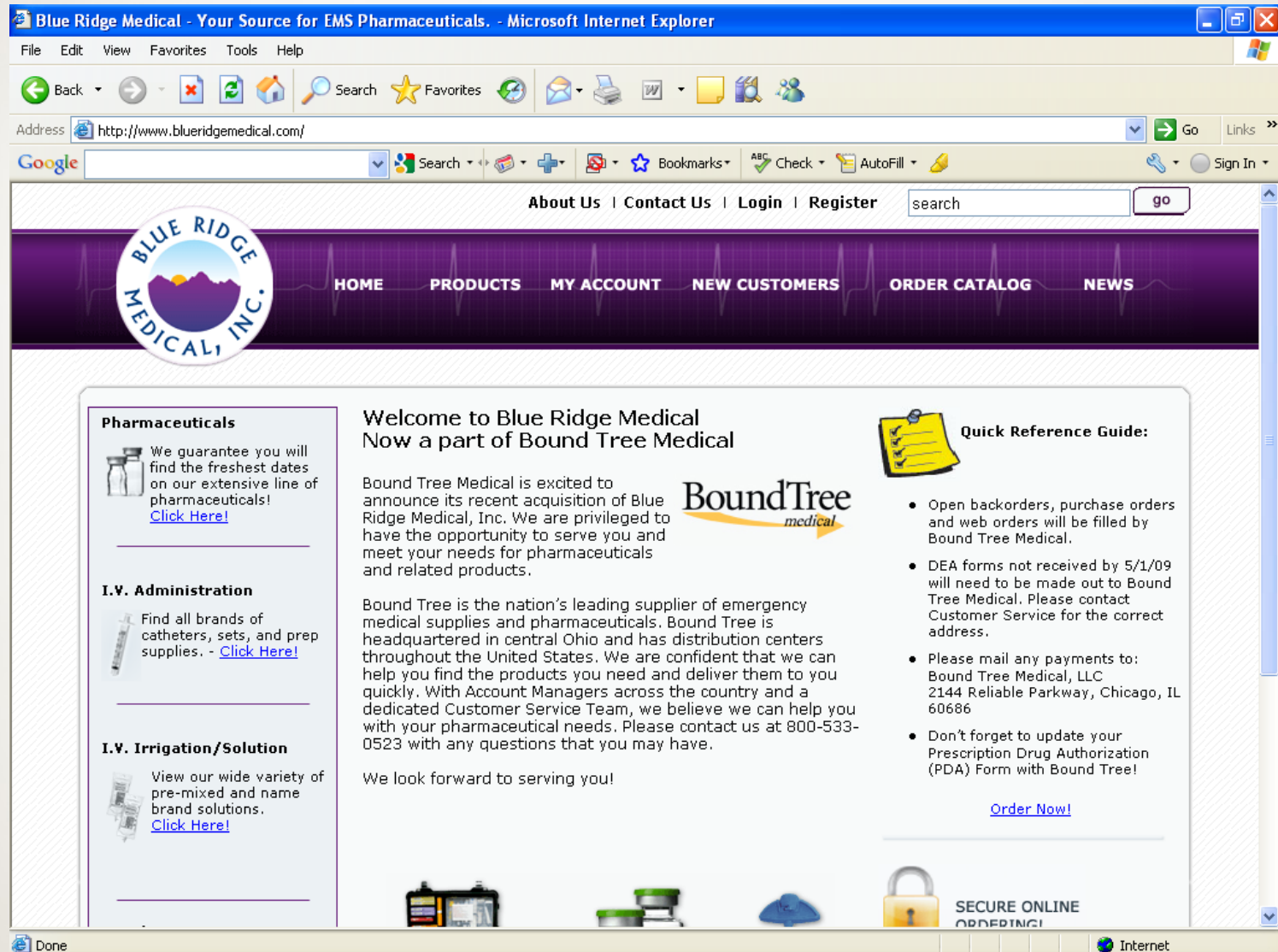




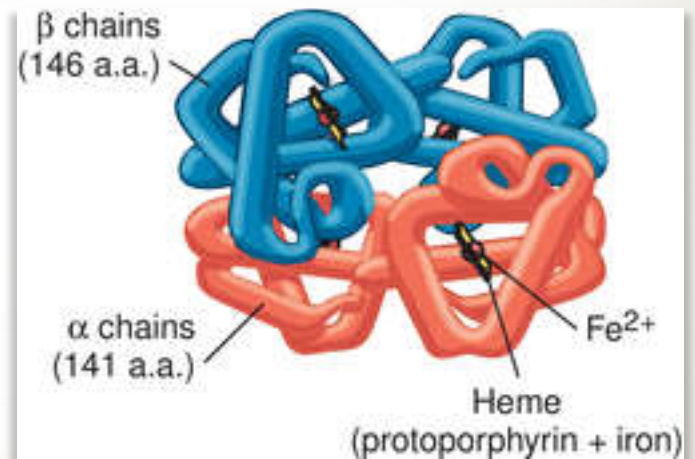
- EMS equipment
- Respiratory supplies
- Airway tools



# Sold in 2009

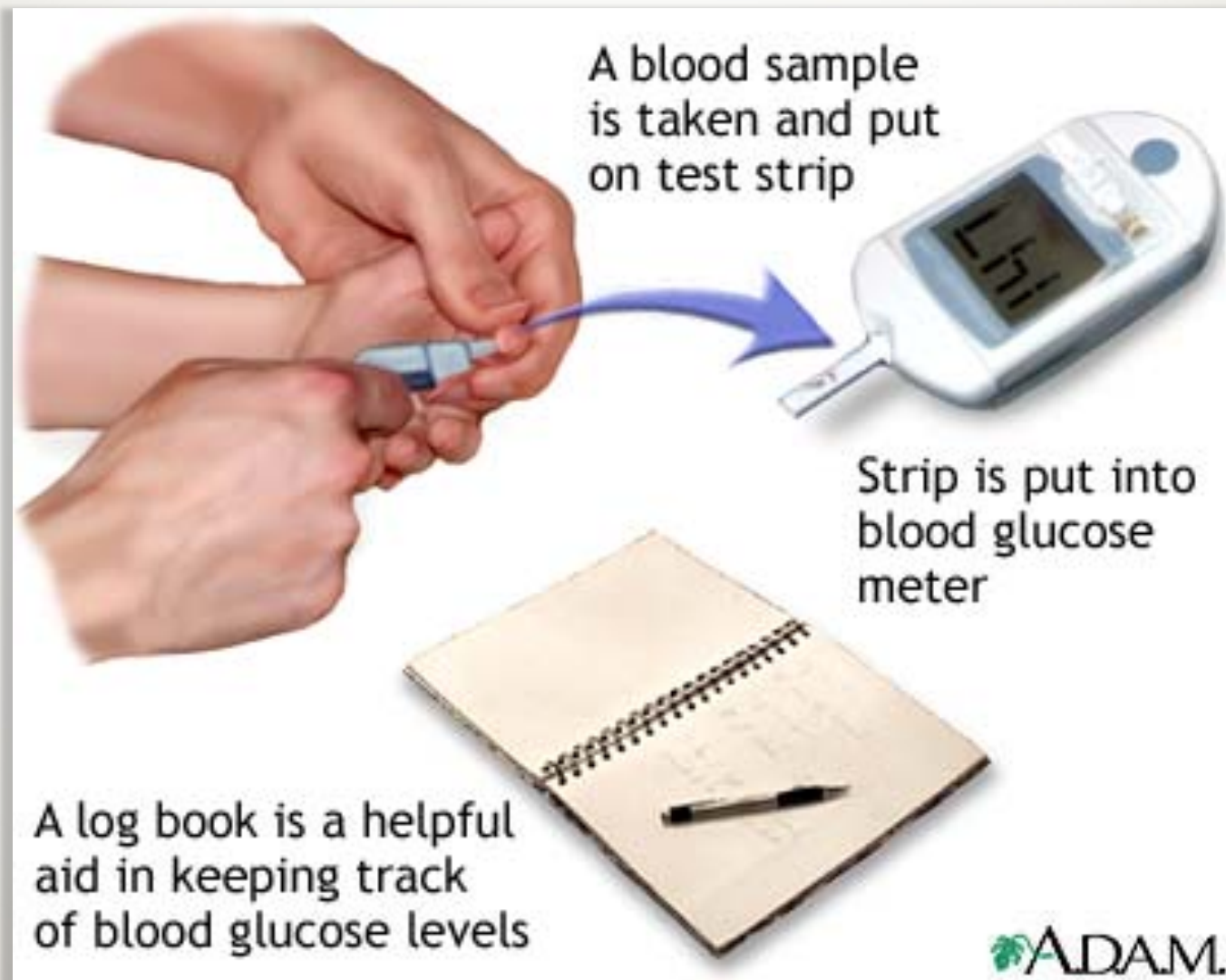


# LEXMARK<sup>TM</sup>



An opportunity arises

# \$4-5 B market



# Noninvasive measurement of glucose

- Over 200 companies have attempted to solve this problem
- Over \$1B has been spent pursuing this
- The “holy grail” of medical diagnostics

Although I had run a distribution business,  
I had no idea what was ahead



# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$



# Noninvasive glucose has been tried:

With:

- Near Infrared
- Mid Infrared
- Raman
- Photoacoustic
- Light scattering
- Optical rotation

In the:

- Skin
- Ant Chamber
- Tympanic membrane
- Tongue
- Saliva
- Tears
- Breath
- You name it

# The Idea

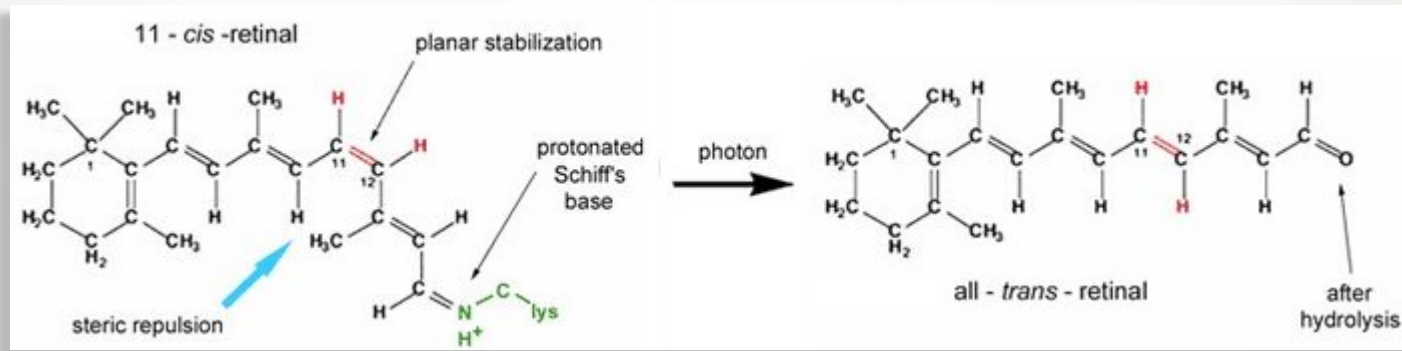
- Big markets that are growing:  
Venture guys like >\$1B markets
- What's the competitive advantage?:  
No needles  
Increase the testing
- Disruptive technologies:  
Doesn't get better than this
  - Go to Market:  
How are you going to sell it?

# What was our big idea?

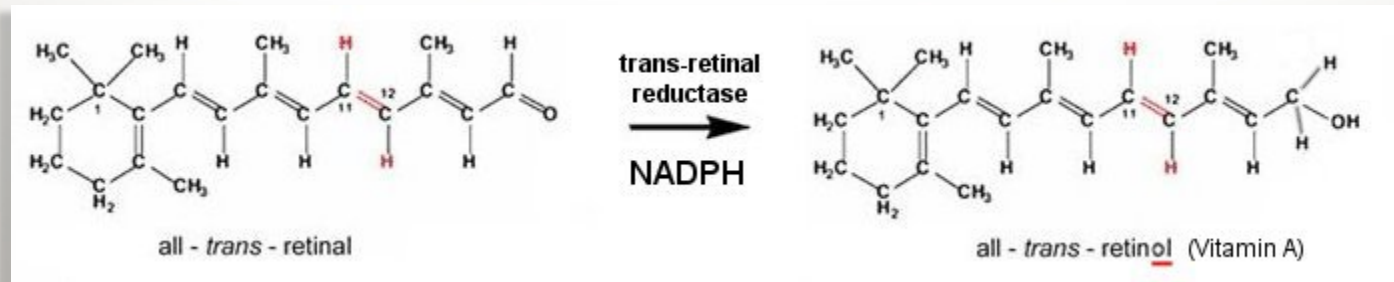
Regeneration of visual pigment is  
proportional to glucose concentration

# Simplified Biochemistry

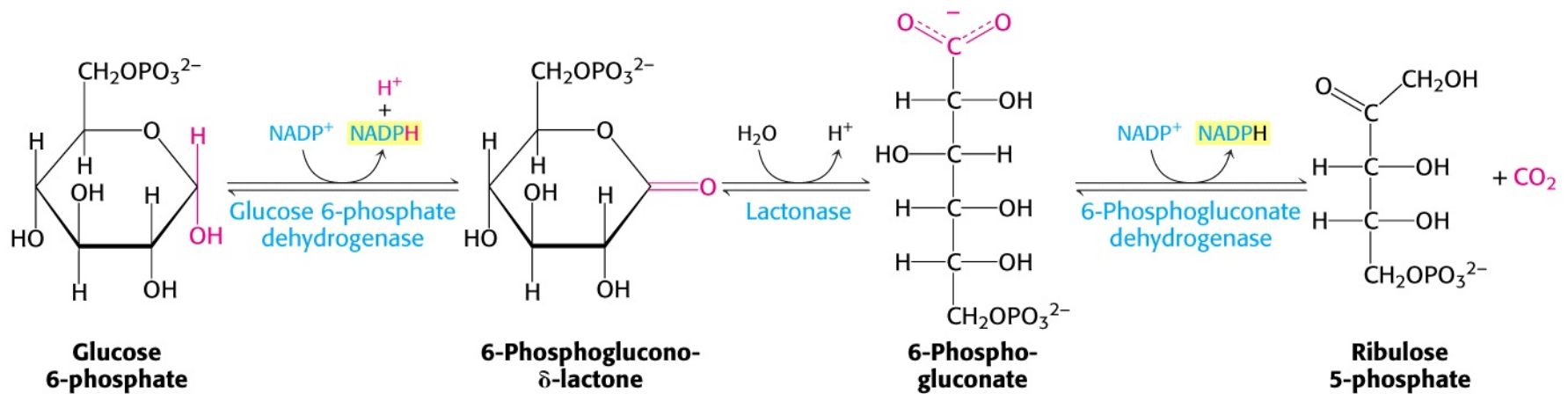
The Initial step in vision is the absorption of a photon by cis-retinal, followed by isomerization to trans-retinal:



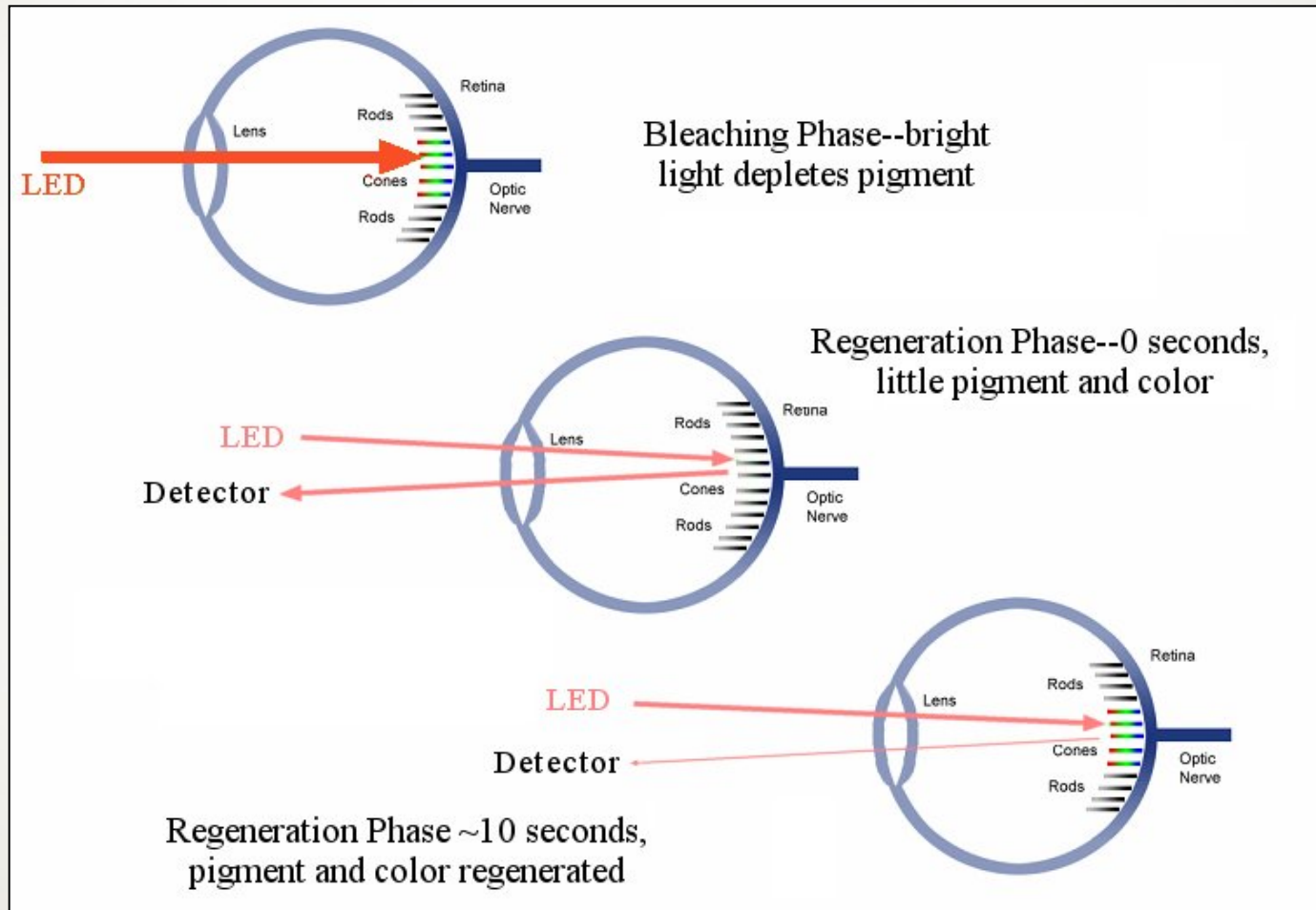
The Rate-determining step in pigment regeneration is reduction to retinol, using NADPH produced exclusively from glucose:



# The Pentose Shunt



# Instrumentation Principle



# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- **Market: Who will buy this?**
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$



# Rare instance

- No one argues the market
- Diabetes incidence keeps increasing
- No one wants to prick their finger

# Go To Market

How are you going to sell your product?

- Reimbursement a huge issue for medical devices
- VC's like recurring revenue
  - Razor/Razor Blade : Glucose meter/Test Strip

# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/  
engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

# The Technical Guy

- John Smith “Hunting the Deceitful Turkey”
- PhD analytical chemistry
- CSO LifeScan
- Spent years with J&J pursuing noninvasive glucose

# Getting John signed: *The* key

The Pursuit of Noninvasive Glucose:

“Hunting the Deceitful Turkey”

By John L. Smith

# The Finance Guy

- A “must have”
- Set up the financing plan right from the start
- Vital for future raises
- Plan for the exit
- Make sure handicap > 10

# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

# We raised a few bucks

- \$2.4M raised from angel investors; F and F
- Started in Lexington, Ky with Lexmark group
- Hired a few technical people



# What financing partners look for:

- Unmet need – is there a market?
- Can you make it?
- Can you sell it?
- Can you protect it?
- Can you make a profit?

# Types of financing partners

- F and F
- Angel – e.g., EGF II
- Venture
- Corporate partners (J&J Capital)

# Financing Macro Environment

- Healthcare cost management
- Focus on outcomes, not volume
- Shifting to low cost sites
- Higher patient expectations
- Prevention and wellness

# Venture capital:

## Subsectors of interest

- Medical devices
- Biotech
- Services
- Health IT
- Diagnostics

# Venture health care funding

- 2007 -> \$10B
- 2103 -> \$7B
- Venture % in healthcare
  - 2007 -> 31%
  - 2013 -> 24%

# Venture health care funding

- Between 2005 – 2008, 99 VC firms doing healthcare funding
- Between 2009 – 2012, 65 VC firms doing healthcare funding (down 34%)

# Why the decrease in VC healthcare activity?

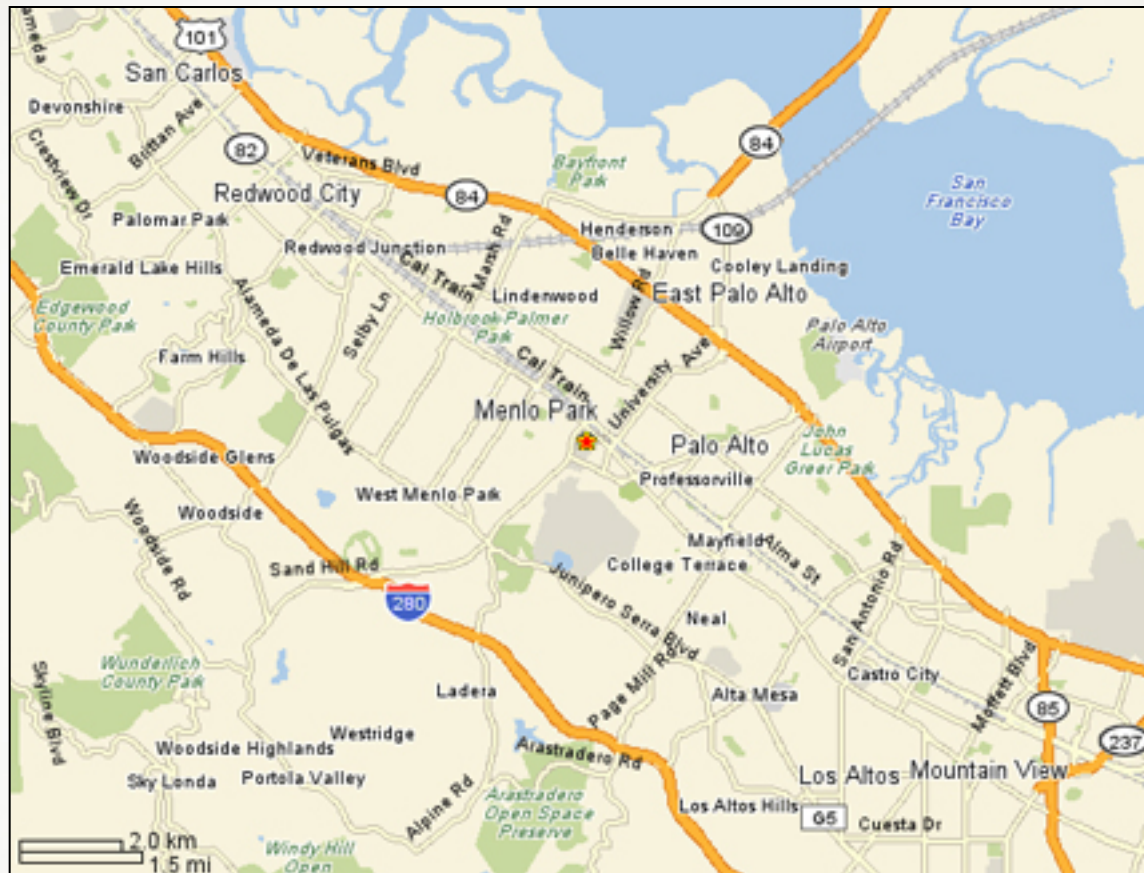
- Difficult FDA climate
- Related to FDA, high risk of a “no”
- Cost pressures (opportunity?)
- Generic Rx on the market

# Financing

- Two kinds of money:
  1. Yours
  2. OPM (the best kind)
- F and F
- Angels
- Venture



# Sand Hill Road



80% of total private investment  
in medical devices

# What do the financial partners want?

- A big market
- A way to sell into it
- An idea that can be protected
- A sound regulatory path
- An experienced management team that can build the business
- A reasonable financial model with a ROI of at least 10x
- An exit

# Lesson

No one will write a big check if you are not  
100% committed



# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

# The Corporate Attorneys

- Get good corporate counsel
- Spend the money
- Painful, but necessary
- Make sure they have done lots of start-ups
- Find an attorney you can deal with rough spots



# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

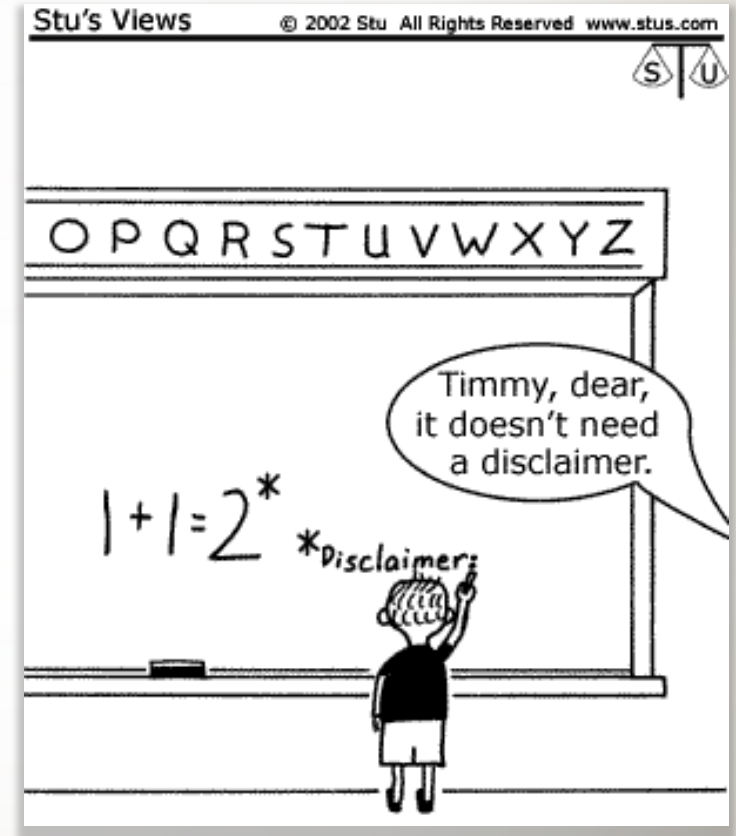
So far, so good:

Let's protect the  
idea



# Intellectual property

- Spend the money
- Painful, but necessary
- Get good IP counsel





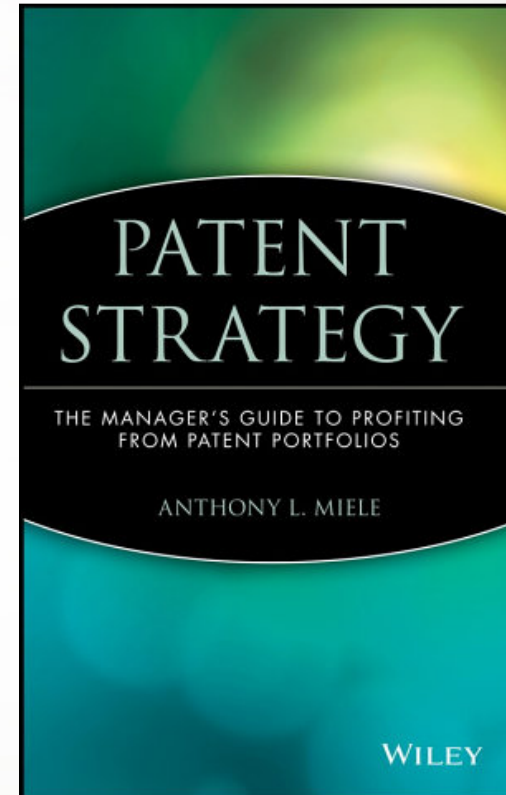
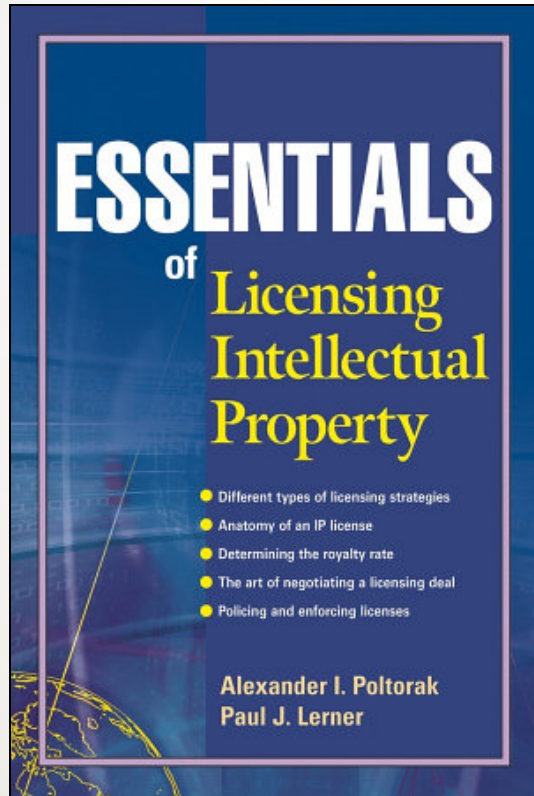
# A patent must meet the following criteria:

- Novel
- Useful
- Not obvious

There is no requirement that it must work!

# IP advice & education

# Spend some time → learn this



(54) **NON-INVASIVE MEASUREMENT OF BLOOD ANALYTES USING PHOTODYNAMICS**

(75) Inventors: **Wilson Routt**, Lexington, KY (US);  
**Mark J. Rice**, Johnson City, TN (US)

(73) Assignee: **Fovioptics, Inc.**, Lexington, KY (US)

(10) **Patent No.:** **US 6,650,915 B2**

(45) **Date of Patent:** **Nov. 18, 2003**

What is claimed is:

1. A method for use in the determination of blood glucose in an individual comprising:

- (a) projecting illuminating light into an eye of the individual to illuminate the retina in the eye, the light illuminating wavelengths that are absorbed by rhodopsin with the intensity of the illuminating light varying in a selected temporal manner;
- (b) detecting light reflected from the retina of the eye to provide a detected light signal corresponding to the intensity of the detected light; and
- (c) analyzing the detected light signal to determine the frequency content of the variation in the intensity of the detected light relative to the illuminating light.

# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$



# Regulation

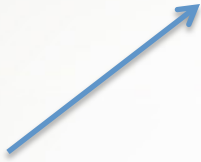
- Huge issue, not frequently thought through
- One of the biggest questions from VCs: “What’s the regulatory path?”
- 510(k): quick, cheaper, no protection
- PMA: very, very expensive, some protection

# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

Out of  
Lexington



Off to the  
Bay





# The Bay

- I fought the VC and the VC won
- Good move
- Everything within a few miles

# Location:

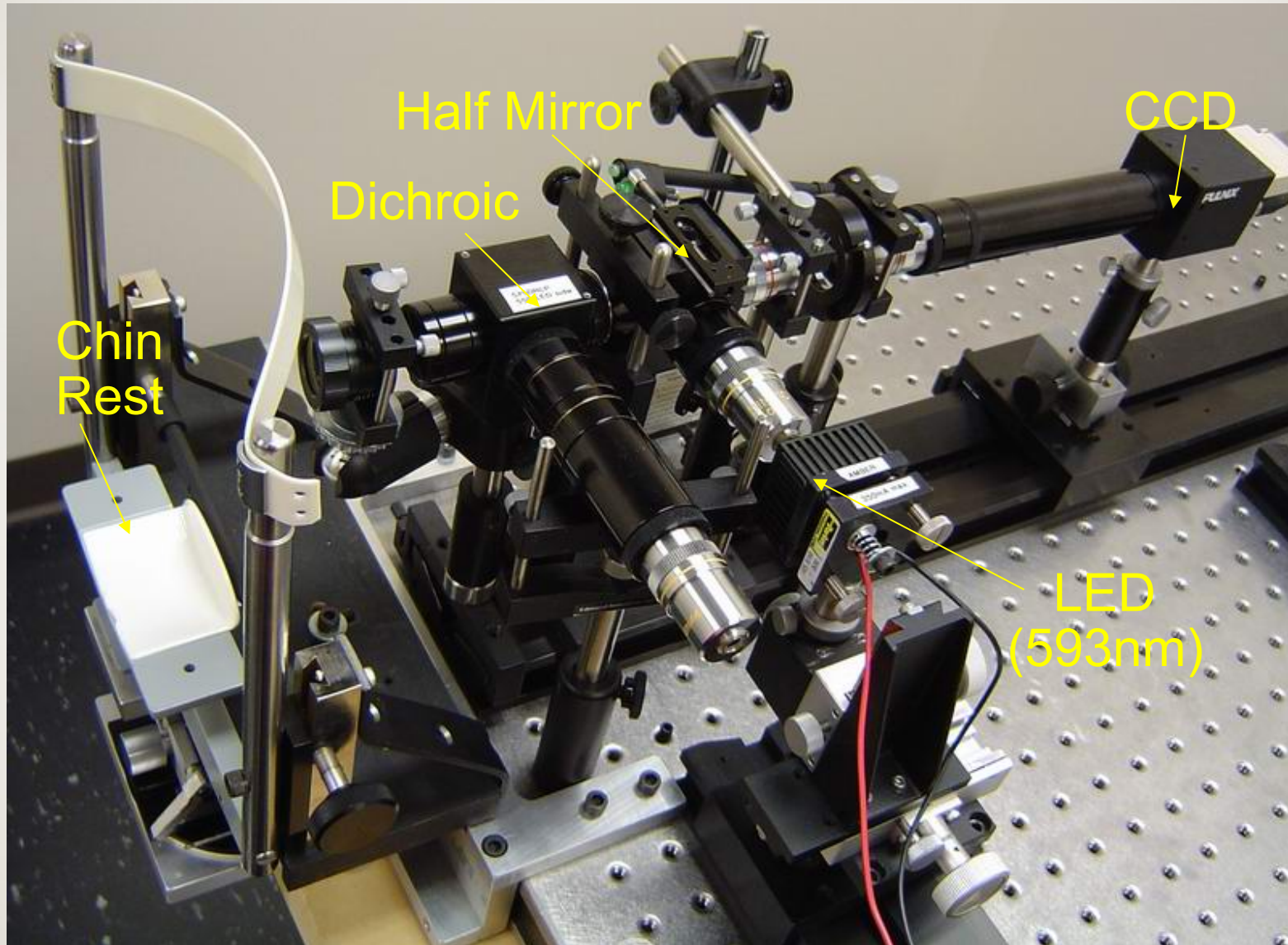
Put all the pieces together in one place

- Management
- IP attorneys
- Corporate attorneys
- Banking
- Industrial design
- Outside engineering groups
- The address on the letterhead matters

# Elements of a High Tech Business: Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$

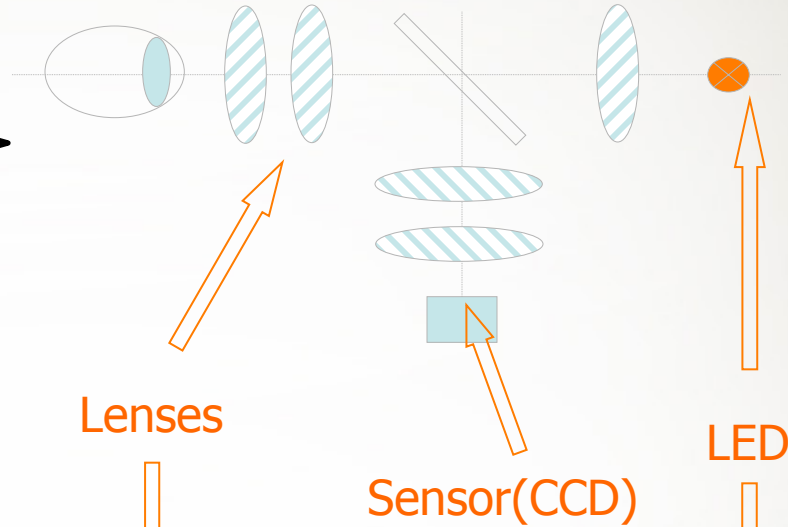
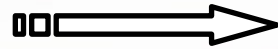
# Optical Bench Breadboard



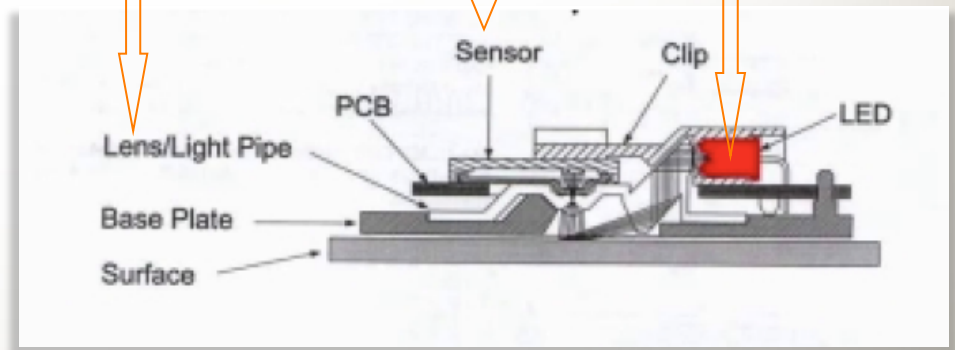
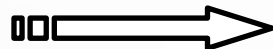
Let's make this thing



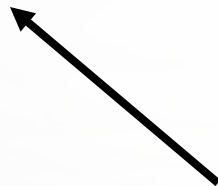
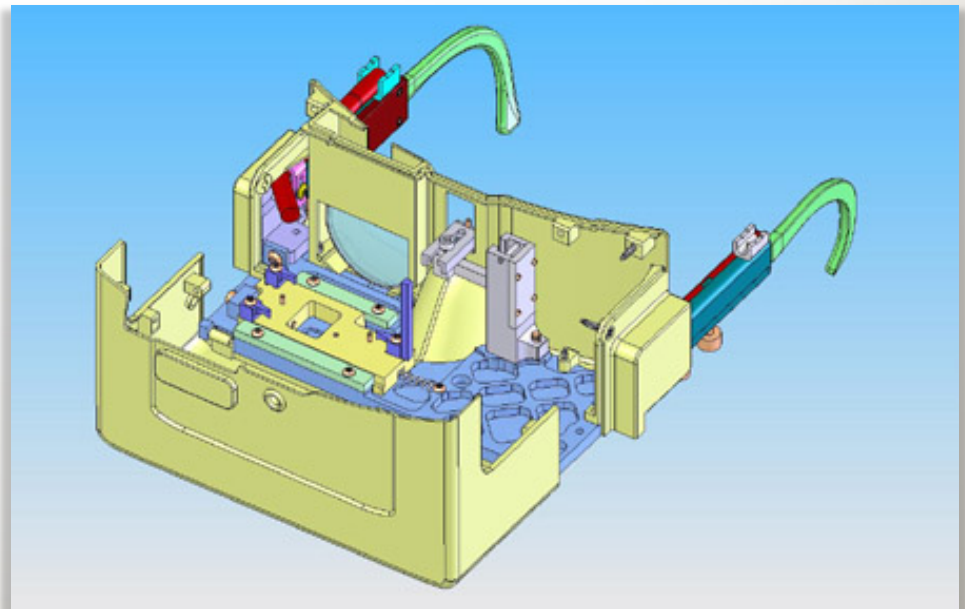
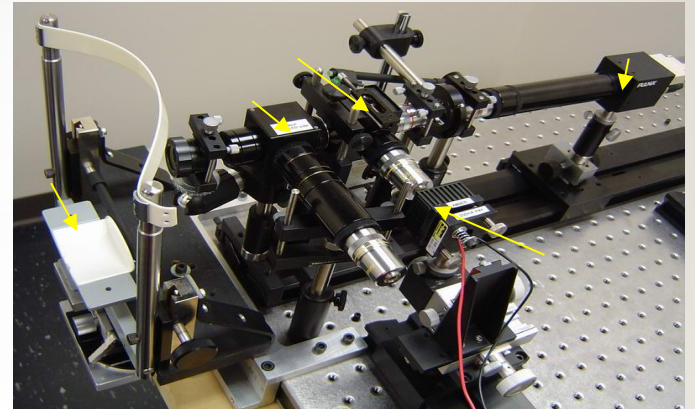
Fovioptics



Logitech Optical Mouse  
(COGS ~\$10)







# Elements of a High Tech Business:

## Steep learning curve

- Idea: Helps if it works
- Market: Who will buy this?
- People: administrative/engineering/etc.
- Financing: Who, how, how much?
- Company: Corporate documents/law
- Protecting the idea: Intellectual property
- Regulation: FDA issues?
- Location: Move; really?
- Exit: Investors actually want to make \$\$



# Exit

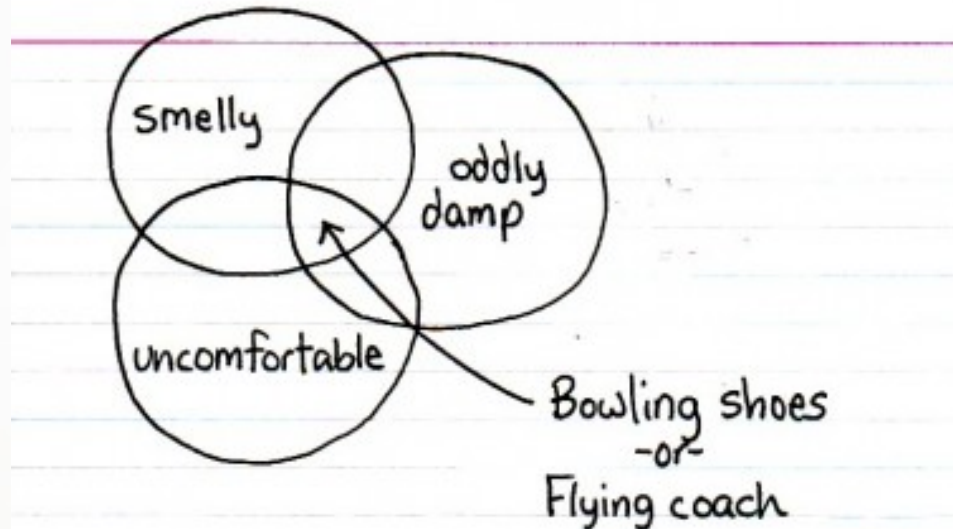
Start setting up your exit from the beginning:

- IPO (not these days)
- Long term business (rare)
- Sale to strategic partner (the best option)

# Oh, what happened to Fovioptics?

- It worked OK in the dark lab
- In light, it didn't work at all
- Gave \$17M back to our investors

# Got on the plane and went back to Florida



# Transition to consulting work and then back to the OR

# Turned experience into academic career



## Timely Hospital Glucose Measurement: Here Today, Gone Tomorrow?

David C. Klonoff, MD, FACP, FRCP (Edin), Fellow AIMBE; Robert A. Vigersky, MD;  
James H. Nichols, PhD; and Mark J. Rice, MD

-Critically ill patients – Can we use these?

# Point of Care Devices Should Not Be Relied Upon for Perioperative Glucose Measurement

Andrew D. Pitkin, MD

Douglas Coursin, MD

Mark J. Rice, MD

Department of Anesthesiology

University of Florida College of Medicine

Gainesville, Florida

University of Wisconsin School of Medicine

and Public Health



# Take home points

- Doctors can have multiple careers
- It has to be fun
- Nothing is forever
- Go for it

Thanks much