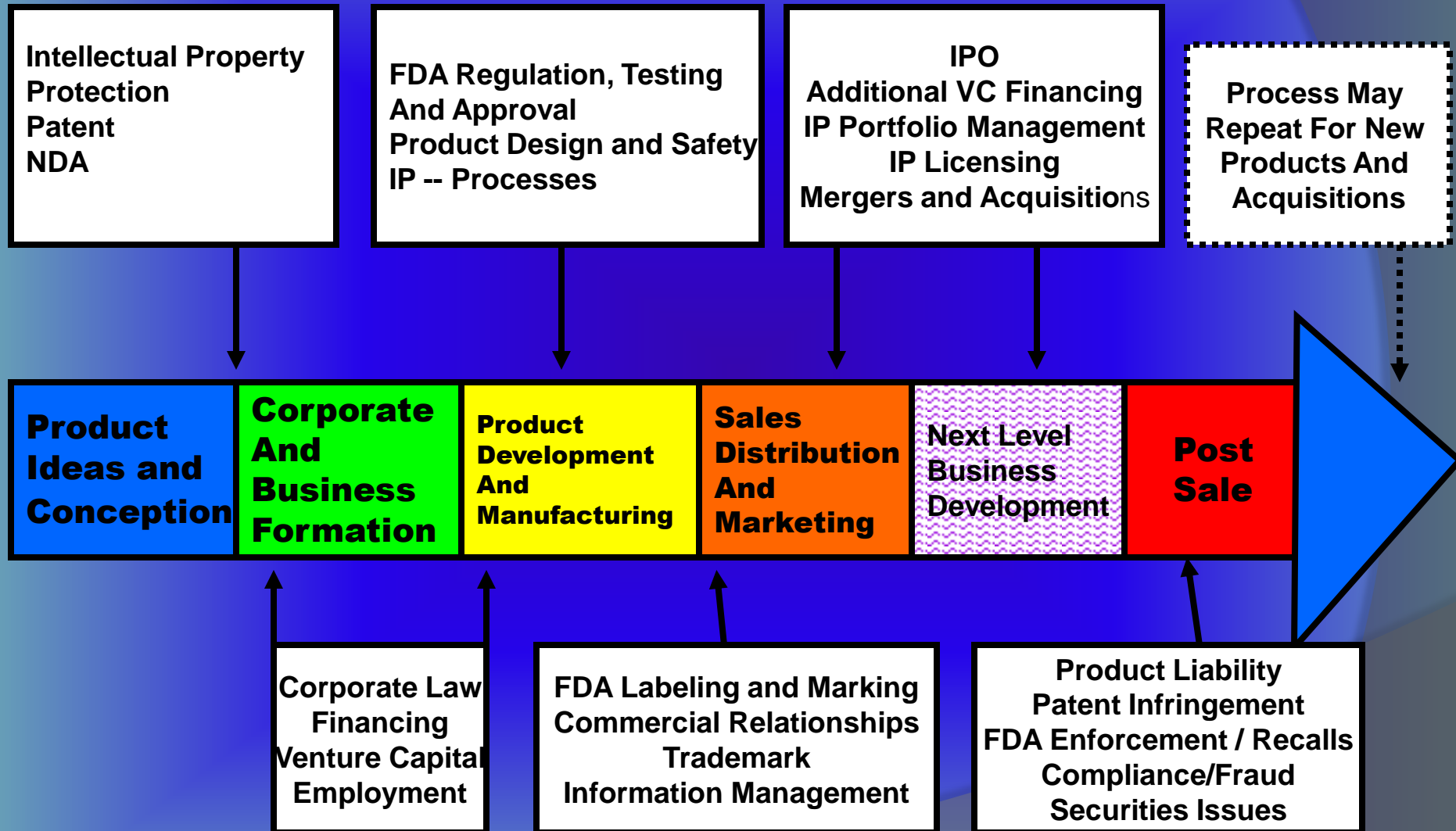


The Biotech Business Life Cycle and The Lawyer's Role as Counselor and Advisor

BIOTECH BUSINESS CYCLE

AN INTERDISCIPLINARY APPROACH TO LEGAL REPRESENTATION



Biotech Life Cycle
ASU February 3, 2011

A Working Definition of Biotechnology?

- **Traditional v. Modern Industrial**
- **Types:**
 - **Tools and Devices / Analysis, Manufacturing, Diagnostics**
 - **Therapeutic Interface**
 - **Pharmaceuticals**
- **Applications:**
 - **Medical / Cosmetic**
 - **Agricultural**
 - **Environmental**
 - **Industrial**

A Working Definition of Biotechnology

- “Before going any further, it is necessary to attempt to come up with a working definition of “biotechnology.” In its narrowest and most traditional sense, “biotech” is a term of art that encompasses the alteration and application of living matter, for example the genetic manipulation of microbes, for a human use. With growth of the industry and the integration of many different technologies, however, a working definition becomes more elusive. As the field has grown, the term has evolved to include research, development, and application of medicines, devices, analytical aids, and therapies intended to contribute to the health and physical wellbeing of humans. The working definition must also include fields, activities, and subject matter that indirectly impact or contribute to wellness or lifestyle. For example, the broader definition of biotech includes activities such the development of pesticides, altered or improved agricultural plants and animals intended for food or other uses, microbes engineered to perform specific tasks such as the breakdown wastes and hazardous substance or the creation of chemical compounds, and even veterinary science aimed at the wellbeing of the family pet. It is this definition of biotech that is exemplified by the broad based membership of many biotech industry groups. This is also the definition applied in this Primer.”

Follow The Money . . .

- ◎ Law School and Legal Studies
 - Liability v. Damages
 - Rights v. Remedies

- ◎ Biotechnology
 - Science v. Business
 - Ideas v. Dollars

The Biotechnology Business Model

- **General Biotech Company Goal:**
 - **Develop And Sell Products That Will Generate A Profit**
- **Additional Startup Goal:**
 - **Develop A Probability Of Success And Become A Target For Acquisition**
- **Science and Technology -- A Means To An End**
- **High Degree Of Failure / Unrealistic Expectations**
 - **Short Term Clients?**
- **Lawyers Are, At Best, A Necessary Evil**
 - **Cost**
 - **Barrier To Success**

Does The Idea Justify Starting A Company?

- **Cost To Develop And Commercialize?**
- **Size Of Market?**
- **Will Customers Buy And For How Much?**
- **Competition / Ease Of Entry**
- **Patent Protection Required And Feasible?**
- **How To Attract The Right Talent?**
- **Will Investors Invest?**
- **Is There Something Better To Do With My Time?**

What Does This Means For The Lawyer?

- **Learn About The Industry**
- **Know Your Client's Business**
 - **Learn About The Business Before Addressing The Legal Issues**
- **Collaboration With Experts And Other Lawyers**
- **Business Partner Or Watchdog**
 - **Approach To Risk**
- **Specialist v. Generalist**
- **Outside Counsel Role**
 - **Develop the Client Relationship**
 - **How Are You Going To Get Paid?**
- **In-House Counsel Role**
 - **Who Is The Client?**
 - **Compliance**

Idea Conception, Research and Products

Which Comes First – The Idea Or The Business?

Sources Of Ideas

- **Large, Established Biotech and Pharma**
 - Internal R&D
 - Startup Acquisition
 - Licensing
 - Subsidiaries And Nurseries
- **University / R&D**
 - Private Startups
 - University Licensing And Tech Transfer
- **Government Institutes**
- **Non Profit Research Institutes**
- **Solo Inventors**
- **Patent Acquisition and Licensing Houses**

Idea Conception, Research and Products

Intellectual Property

○ Patents

- Creating
- Acquisition
- International
- Offensive Use
 - Competitive Weapon
 - Licensing Profits
- Are Biotech Patents Unique?
 - Leash Theory
 - DNA Identification
- Patent Portfolios – Know The Company's Patents

Idea Conception, Research and Products

- ◉ **Trademark**
- ◉ **Copyright**
- ◉ **NDA**
- ◉ **Trade Secrets**

Corporate and Business Formation

- ◎ **Who Runs The Company?**
 - **Scientists and Engineers v. Business People**
 - **Research Approaches v. Business Deadlines**
 - **The Long Road To The Biotech Market**
- ◎ **Make Up Of The Board Of Directors**
- ◎ **Science Advisory**
 - **Research Expertise**
 - **Profile**
 - **Ability To Attract Capital**

Corporate and Business Formation

- **Biotech Development – Time And Cost Intensive**
 - **Multiple Layers Of Funding May Be Required**
- **Funding Sources:**
 - **Friends And Family**
 - **Federal Grants**
 - **Angels – Individual Investors**
 - **Incubators And Hatcheries**
 - **Venture Capital**
 - **Large Company Collaboration Or Acquisition**
 - **Initial Public Offering (IPO)**
- **Impacts**
 - **Founders Loose Control**
 - **Stock Dilution**

Product Development And Manufacturing

- **Federal Regulation – Multiple Agency Involvement**
 - FDA, USDA, EPA, NIH, FTC, CDC, etc.
- **FDA Process**
 - Pre Clinical and Clinical Trials
 - Time and Cost Intensive
 - The Lawyer's Role
 - Representative or Advisor
- **Agency Relationships 101**

Product Development And Manufacturing

The Company's Employees

- ◎ **Protect the IP Assets – Set Up Defenses**
 - Confidentiality
 - Noncompete Agreements
 - Ownership of IP
 - Trade Secrets

- ◎ **Foundry Agreements**

Product Development And Manufacturing

● Product Safety

- Establish a Record of Compliance with Agency Rules
- Warranties, Disclaimers, Warnings
- Respond Early to Complaints and Claims

● In General, . . .

- Train Employees in Proper Use of Email and Composition of Internal Documents
 - “Someone is going to die”
- Develop Data Security and Document Retention Policy
- Customer / Consumer Complaints

● Strategic Use of the Attorney / Client Privilege

Next Level Business Development

- **IPO**
- **Additional VC Financing**
- **IP Portfolio Management**
- **IP Licensing**
- **Mergers and Acquisitions**

Post Sale Issues

● Patent Litigation

- Origin of the Sport of Kings
- “It’s Technical”
- Competitive Barrier or Profit Center
- Offensive or Defensive
- Escalating Costs

Post Sale Issues

● **Product Safety and Liability**

- **Record of Care and Compliance**
- **Accurate Advertising and Agency Reporting**

● **Fraud, Compliance and Security Issues**

- **Many types of fraud**
- **Medicare / Medicaid / State Programs**

● **Alternative Dispute Resolution**

Biotech Life Cycle

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Reoccurring Issues

- ① **Investment and Acquisition**
- ① **Cycle May Reoccur With Each New Product**

The End

- **Many Issues We Haven't Discussed**