



From Start Up to Scale Up

Session 1: IP Fundamentals

October 11, 2023



General Information

■ CLE:

- A recording of today's presentation will be circulated following the event with a copy of the slides and any necessary CLE documents
- A CLE Code will be provided later in the presentation
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■ QUESTIONS:

- Add your questions to the Q+A Section

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Growth, Sales, and Success

- Life sciences companies have many pathways to success based on technological discovery:
 - Seeking progressive stages of investment as the company technology development progresses
 - Licensing or selling the technology to a larger company, or co-developing it
 - Developing a marketed product directly
- Your IP strategy will need to be sensitive to these ultimate goals, and adapted to your technology. Today we will discuss:
 - Patent Strategy
 - Trademark Strategy
 - Partnering and Licensing



- **Patent Basics:**
 - What is a Patent?
 - Ownership, internal disclosures, and filing timelines
 - Prosecution
 - Strategies for pharma / biologics / device / med-tech
 - Competition considerations
- Trademark Basics
- Partnering

What Makes a Patent Useful?

- A limited time monopoly to make, use, sell, or import your invention
 - Scope is determined by specific claims
 - 20-Year Term (with caveats)
 - Rights are per-country
 - A patent does not give you the right to do what is claimed – we will come back to freedom-to-operate searches
- Patents can be Licensed or Sold
 - e.g., Licensing to Different Companies to Enter Different Markets
- Patent can be Enforced in Court, or Through Customs
 - Damages, Injunction, Seizure
- Contributes to Valuation of Company
 - Why buy your company or your product when I can just make my own?

What is in a Patent?

Claims

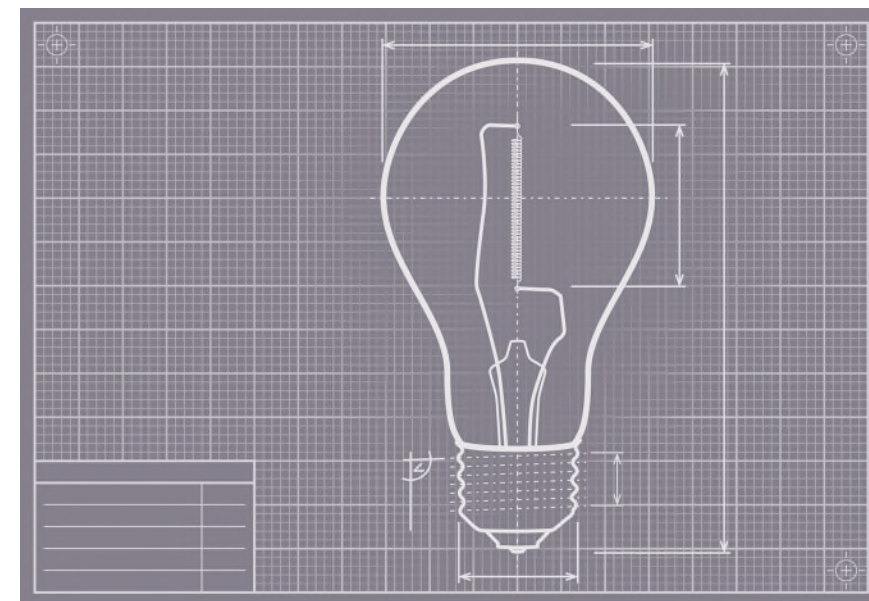
- Main claims:
 - Major qualitative features that distinguish you from the prior art
 - ◆ Product components, method steps
 - ◆ Think broadly; anticipate work-arounds
 - Compositions of Matter + Methods of Manufacture and Use
- Backup claims:
 - Dependent on main claims
 - Additional qualitative features
 - Quantitative features
 - ◆ Material characteristics, process conditions

Disclosure

- Detailed description of important prototypes
- Why does each feature matter and how do the features work together?
- Examples showing how you make and use the technology
- Comparisons to the known prior art (if possible)
- Don't have to disclose *everything*, but enough to enable others to make and use

When is an Idea Patentable?

- An idea alone isn't enough
 - Although you need not have built the invention yet, you need to have enough information to do so.
 - Identifying an interesting avenue of research isn't enough.
- A new, non-obvious solution to a technical problem
 - Compared to the prior art: publications from before your filing date
 - Whether something is new is easy to determine; whether it's non-obvious is hard
 - Would someone of ordinary skill have come up with the idea?
 - How much experimentation would it take to make the idea work?
 - “Obvious” ideas can include: predictable optimizations, substitution of known materials and techniques

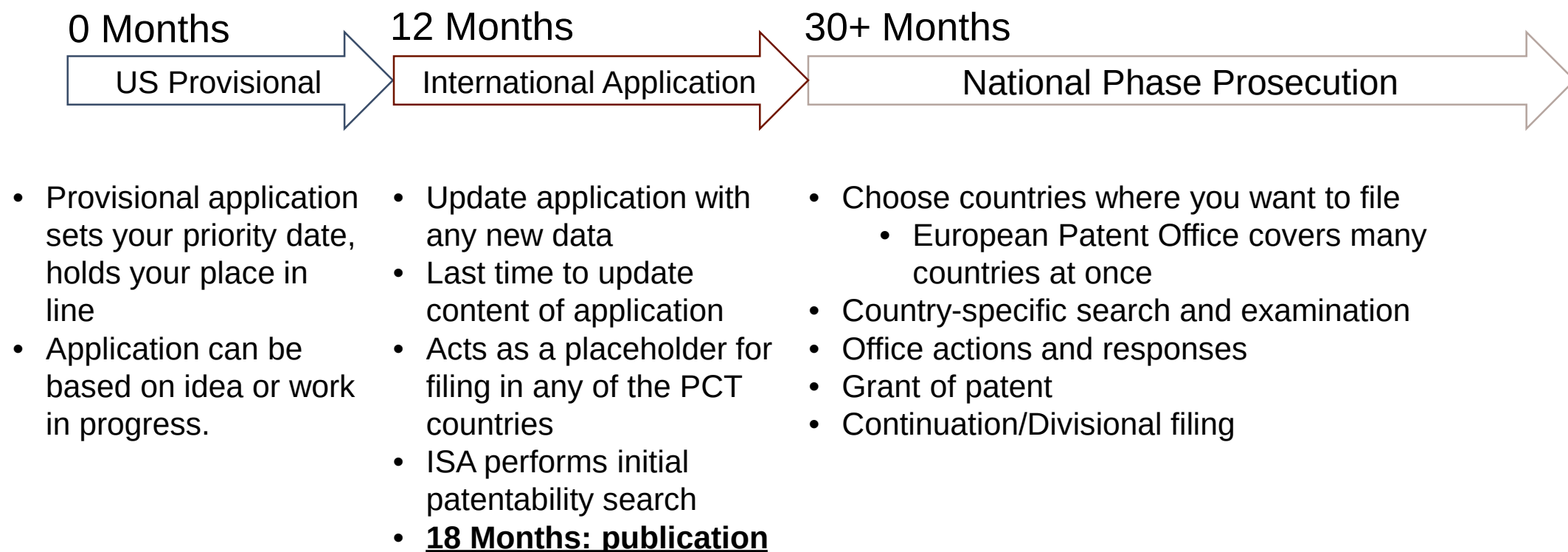


Timing

- An invention is only patentable if the application is filed prior to public disclosure (in Europe)
 - or within a one-year grace period thereafter (in the U.S. and a few other places)
- Academic papers, conference presentations, poster sessions, etc., all can count as public disclosure
 - Public disclosure is broadly construed
 - An offer for sale may also start the clock running in the U.S.
- Once public, if no patent is pursued within the appropriate time limit, the invention is committed to the public domain.
 - Copyright and other IP rights may remain



Common Patent Application Timeline



Invention Review Procedures

■ Invention Disclosure Forms

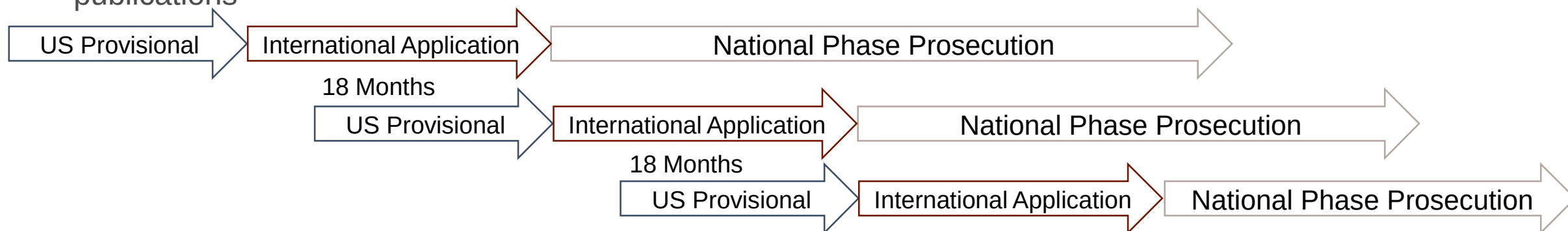
- Who, what, when?
- What problem is being solved?
- How does the solution compare to prior solutions?
- Creating a Paper Trail
- Having a process in place is valuable even if you don't expect any near-term filings

■ High-level group within the company should evaluate disclosures:

- Align timing with development cycle
- Is this important to the business?
- Are you likely to obtain a useful scope of protection?
 - ◆ Consider state of prior art
- Do your investors, partners, or licensees demand filing?
 - ◆ Depends on long-term company strategy, perspectives might differ
- Can the invention reasonably be kept secret?
 - ◆ Might others make the same discovery?

Assembling a Portfolio

- Goal: Obtain numerous patents with overlapping claims and cascading expiration dates that approach your technology from different perspectives
- Advancements relating to similar components: file on refinements in advance of patent application publications



- Obtain separate patents on major features
 - But can combine into one family to save fees, if other timing considerations align



Ownership of Inventions



- By default, an inventor owns their own inventions (in the US).
 - In many foreign jurisdictions an employer owns inventions that originate within the scope of employment.
- Employment agreements almost always assign inventions to the employer.
- Your own employment and consulting agreements should provide for intellectual property ownership (among other things).
- Consider implications of conflicting invention assignment agreements.

Confidentiality and Disclosures

- Anyone with access to innovations should be under confidentiality obligations.
 - Non-Disclosure Agreements for Contractors, Vendors, etc.
 - Employment Agreement for Employees
- Obligation to Assign and Assist
 - Well-defined scope of covered inventions, if applicable
 - Consider scope of other applicable invention assignment agreements.
- Trade Secret Protection Hinges on Reasonable Measures to Protect
 - Both Legal and Operational Measures (InfoSec)

Prosecution

- After Filing, Examiner Searches Prior Art
 - Examiner Issues Office Actions
 - Addressing Formal Issues
 - Assessing Novelty and Non-obviousness
- Applicant Responds
 - Argument for Patentability
 - Claim Amendments
 - Interviews
- USPTO Averages
 - 16.9 Months from Filing to First Office Action
 - 28.1 Months from Filing to Allowance or Abandonment



Allowance and Marking

- After Allowance and Payment of Issue Fees, Patent Issues
 - Prior to Issuance, you can file additional applications that have priority to the original filing date: “continuations” or “divisionals”
 - If someone ever talks to you about a “continuation in part”, be very wary
- Patent Term is 20 years from earliest non-provisional filing date
 - with various adjustments
- Marking
 - “Patent Pending”
 - “Pat. No. US11,111,111”

Freedom to Operate Searching

- For when you are finalizing a design choice
 - Detailed searching is not always practical when in research mode
- Does your technology infringe anyone else's patent rights?
 - What jurisdictions?
 - Who would infringe?
- Complex Products Involve Many Patents
 - e.g., Apple filed ~1,310 patent applications in 2018, and was granted ~2,147. For the period 2007-2016, it has been estimated that 1,291 applications related directly to mobile devices.
- Which Features do I Need to Clear?
 - What is critical to success of product?
- Invalidity or Non-Infringement
 - Proactive Challenges

Competitive Intelligence Searching

- Reviewing competitor patent publications can give you a different look at your industry
- Develop a practical search strategy you can run and review regularly to see new patent grants and publications relevant to your business
 - Keep clean paper trails
- Benefits to patent portfolio
 - Better knowledge of prior art
 - Patent Office disclosures

Align your Patents with your Business Goals

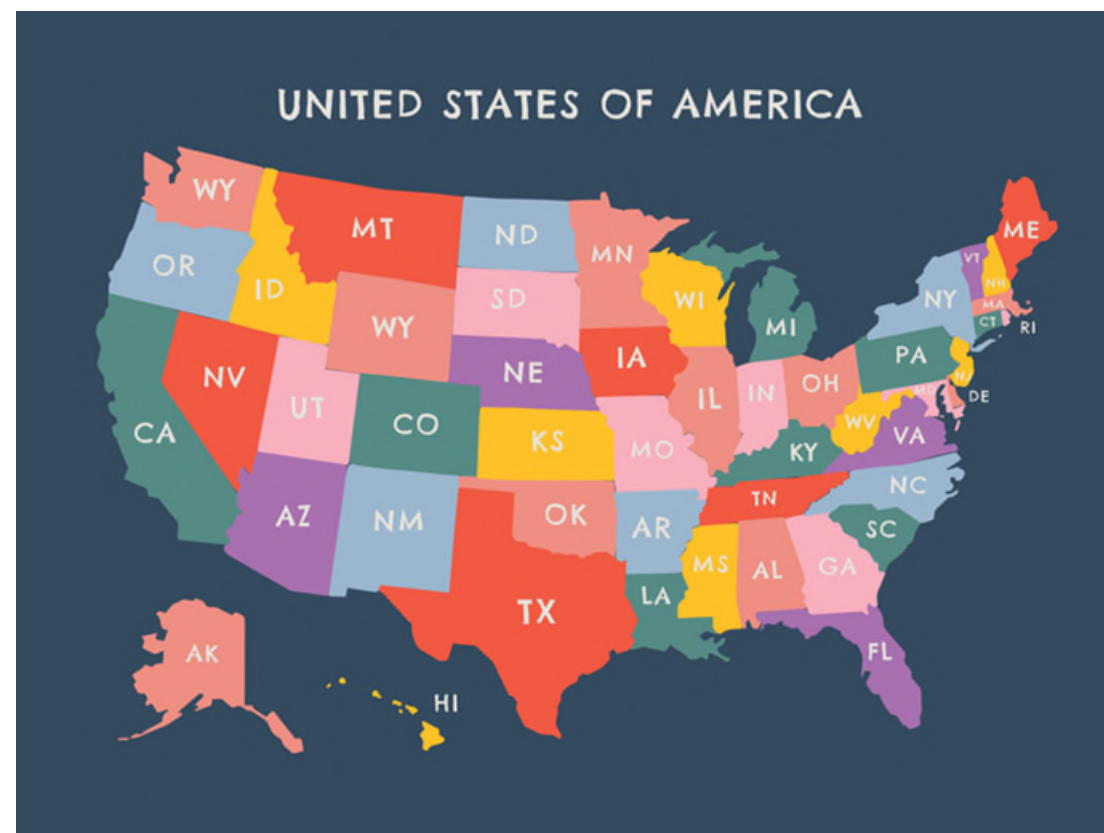
- What is your technology's economic advantage?
 - Better materials
 - ◆ Ideal subject for patents
 - Better processes
 - ◆ Protecting fundamental process steps can still be very valuable
 - ◆ Specific process conditions should usually be kept as trade secrets
- What are your competitors working on?
 - Similar or orthogonal technologies?
- Out-licensing opportunities
 - Patent can drive revenue from a market or country you don't want to be in
 - Licenses can segment a market by field or by geography



- Patent Basics
- **Trademark Basics:**
 - Trademark Overview
 - Trademark Clearance and Approval – PTO v. Regulatory
 - Non-Traditional Trademarks
 - Infringement and Enforcement
 - Strategies for Success
- Partnering

Trademark Overview:

- A trademark can be any word, phrase, symbol, design, or a combination of these things that distinguishes your goods or services from others.
- Trademarks offer legal protection, and safeguard against fraud and counterfeiting.
- Trademark rights vest as soon as you start using your mark with your goods or services, but these rights are geographically limited (“common law rights”).
- To establish broader and more robust trademark rights, federal registration with the United States Patent and Trademark Office (PTO) is necessary.



PTO Considerations

■ Naming:

- Trademarks strength depends on uniqueness.
 - ◆ Suggestive, fanciful or arbitrary v. descriptive or generic
- Avoid confusing similarity with prior trademarks.
 - ◆ Likelihood of Confusion Test: similarities in marks, relatedness of goods and services, relatedness of trade channels, market conditions, and the number and nature of similar marks in use for similar goods.
- Clearance Searches: Trademark clearance searches gather and assess information to evaluate a proposed trademark's availability and protectability.



PTO Considerations

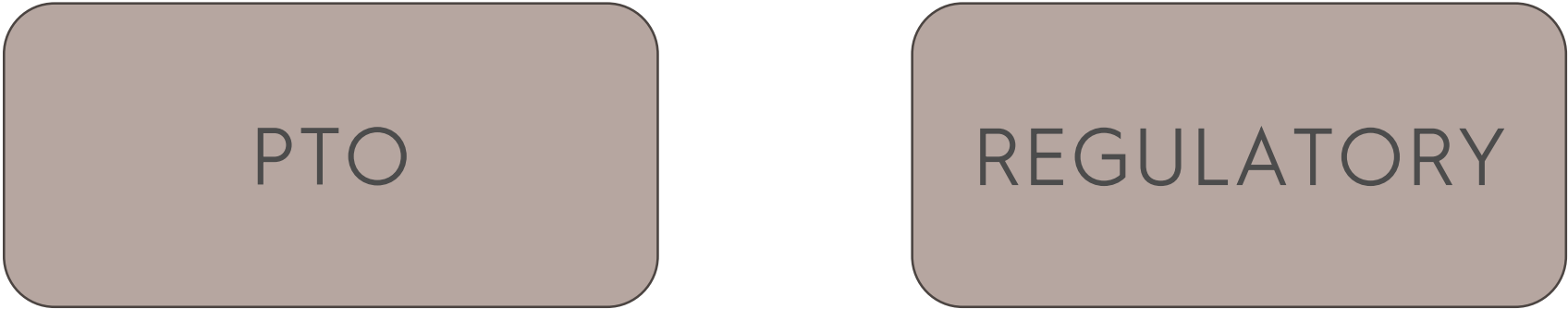
■ Timing:

- In Use: trademark rights vest upon use.
 - ◆ When filing a use-based application, evidence of use of the mark in interstate commerce in connection with the relevant goods/services must be submitted as part of the application.
- Intent-to-Use: if you have not used your mark in commerce yet, but have good faith intention to do so in the future, you can file an application with an intent-to-use basis.
 - ◆ Advantage: Earlier filing date than a possible competitor.

Trademark Clearance and Approval: PTO v. Regulatory

In the life sciences sector, and especially for pharmaceutical products, the convergence of legal, regulatory and scientific considerations create additional hurdles for trademark rights holders.

TWO PATHS



PTO

REGULATORY

Regulatory Considerations

Regulatory bodies such as the FDA have stringent requirements for drug labeling and packaging. Trademarks and proprietary names must comply with these regulations to ensure that crucial information is presented accurately and effectively not only to consumers, but to physicians, pharmacists and nurses.

Trademarks and proprietary names must be reviewed and approved by the FDA before the product may be marketed and sold.



Regulatory Considerations

■ Naming:

- The FDA's main goal is to ensure patient safety by mitigating the potential for medication errors (i.e., confusion between drug names) or misleading patients (e.g., misrepresenting a drug's characteristic or capabilities).
 - ◆ “Look alike, sound alike” errors
 - ▶ E.g. CELEBREX is an oral pain reliever, CEREBYX is an injectable drug to prevent seizures, and CELEXA is an oral antidepressant.
 - ◆ Misleading or misdescriptive
 - ▶ E.g., Rogaine, the brand name for hair-growth drug minoxidil in the U.S., is called Regaine in other countries. The FDA would not approve Regaine, believing it to be misleading as the product does not work for everyone.

Regulatory Considerations

- Timing:
 - Trademark applications filed with PTO before filings with FDA; intent-to-use basis.
 - ◆ Use of a mark can be shown through shipment of the drug (bearing the mark) to clinical investigators during the FDA approval process.
 - Pharmaceutical companies submit new proprietary name applications to the FDA for review after certain clinical trials are conducted.



Non-Traditional Marks or Trade Dress

- Refers to marks other than word marks or figurative marks.
 - Colors, shapes or packaging, smell, taste, texture, motion marks, hologram marks, etc.
- Considerations: Functionality & Distinctiveness.
 - Functionality: Trade dress is functional, and cannot serve as a trademark, if a feature of that trade dress is "essential to the use or purpose of the article or if it affects the cost or quality of the article." *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 165, 34 USPQ2d 1161, 1163-64 (1995).
 - Distinctiveness: Trade dress that is not inherently distinctive must also be refused registration.
 - ♦ Acquired distinctiveness or "secondary meaning."

Non-Traditional Marks or Trade Dress

- Pharmaceutical companies have found additional trademark protections for their products using non-traditional marks.
 - Nexium®
 - Viagra®
 - Pepto-Bismol® (*Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959))



Infringement and Enforcement

- Trademark infringement is the unauthorized use of a trademark on or in connection with goods and/or services in a manner that is likely to cause confusion, deception, or mistake as to source.
- USPTO does not “police” the use of marks; trademark owners are responsible for enforcing their rights and bringing legal action to stop a party from using an infringing mark.
 - Monitoring: Google alerts and trademark watch services.

Strategies for Success:

1. Timing
2. Clearance
3. Legal Experts





- Growth, Sales, and Success
- Patent Basics
- Trademark Basics
- **Partnering**

Top 10 Points for Partnering

1

Strategic Goals Dictate Deal Structure



- Define Strategic Goals of the Licensing Deal
- Align Licensing Terms with Business Objectives
 - License vs. Collaboration
 - Fields, Indications, Targets (optionality)
 - Territory
 - Co-Commercialization Right

Top 10 Points for Partnering

2

Economics



- Upstream Payments
 - Upfront Payment
 - Research Support
 - Patent Expenses
 - R&D Milestone Payments
- Downstream Payments
 - Royalties
 - Sales Milestone Payments
- Equity

Top 10 Points for Partnering

3

Who Controls Patents on New Inventions



- Ownership by inventorship, by technology area, other structures
- Consider rights:
 - During Collaboration
 - Upon Termination
- Control of Patent Prosecution

Top 10 Points for Partnering

4

Consider Non-Patent Intellectual Property



- 
- Know-How
 - Trade Secrets
 - Biological Materials
 - Software/Copyrights
 - Data

Top 10 Points for Partnering

5

What are Licensee's Obligations



- 
- Diligence Requirements
 - Sublicensing

Top 10 Points for Partnering

6

Indemnification, Liability and Compliance



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- Intellectual Property Infringement
 - Compliance with Laws
 - Breach of Representations and Warranties
 - Gross Negligence and Willful Misconduct
 - Products/Services

Top 10 Points for Partnering

7

Governance/ Dispute Resolution



- 
- Joint Steering Committee
 - Mediation, Arbitration, and Litigation
 - Dispute Resolution Strategies

Top 10 Points for Partnering

8

Change of Control Considerations



- 
- Impact of Mergers and Acquisitions
 - Change of Control Provisions

Top 10 Points for Partnering

9

Importance of Anticipating Termination Scenarios



- 
- What is Terminating?
 - Termination Reasons
 - Effect of Termination

Top 10 Points for Partnering



- 
- Defining “Confidential Information” and Exceptions
 - Use
 - Permitted Disclosure and Publications

Things to Consider Early in the Transaction

Due Diligence

- Intellectual Property Portfolios
- Regulatory Compliance

Legal and Regulatory Guidance

- Diligence
- Term Sheet
- Definitive Agreement



QUESTIONS?