

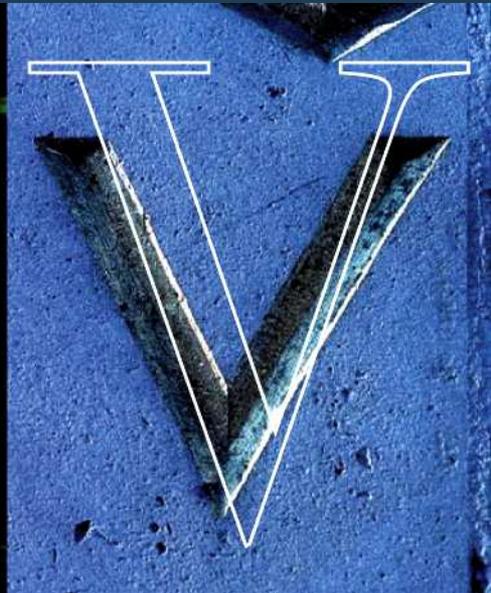
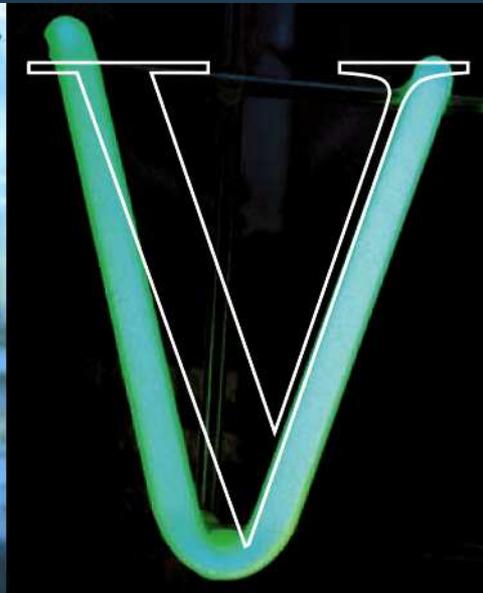
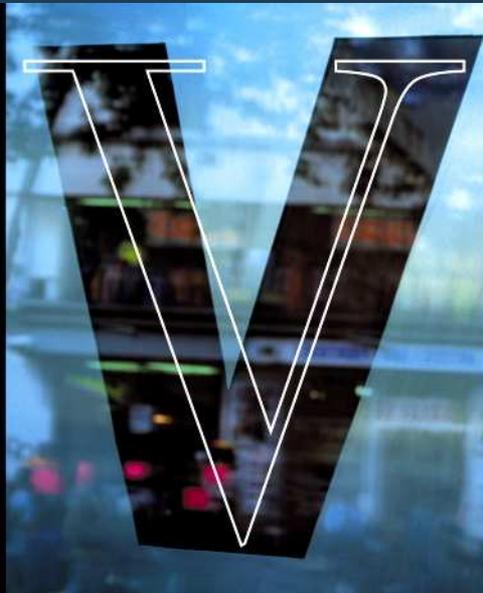
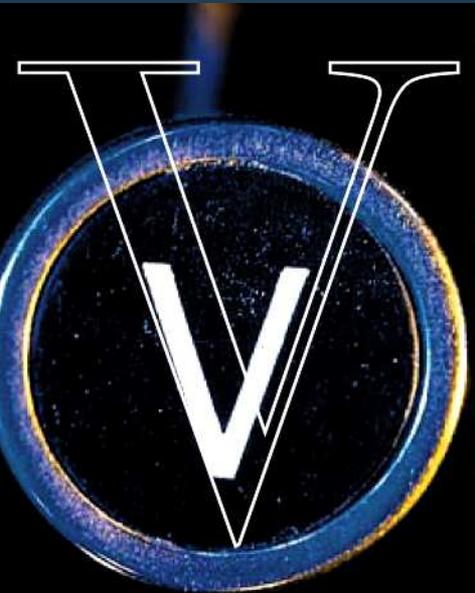
**The Venable Brand IP Seminar (New York)**  
***Strategies to Leverage & Protect Brands and Content***

Marilyn Kelly  
Widge Devaney

Aaron Sawchuk  
Justin Pierce

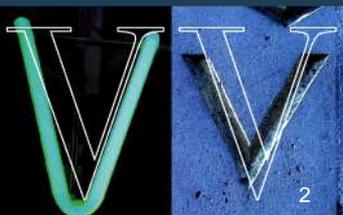
Marcella Ballard (Moderator)

**February 27, 2014**



# Agenda

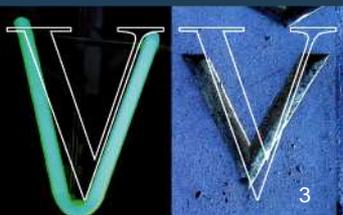
- Welcome to the Brand IP Series
- A Note on CLE
- Introduction of the Panelists
- Developing an Integrated Brand Strategy
- Brand IP in the Pharmaceutical Industry
- FCPA Considerations for Brand Protection Professionals
- New Brand IP Trends & Threats
- Q & A



# Developing Integrated Brand Strategy

Three Key Pillars:

- Enforcement
- Licensing & Standards
- Prosecution, Registration & Compliance



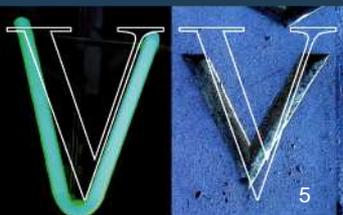
# Pillar One: Enforcement

- Online
  - Internet and Ecommerce sites
  - Social Media
- Offline
  - Brick & Mortar
  - Customs
- Litigation
  - Administrative Proceedings
  - Court Proceedings



## Pillar Two: Licensing & Standards

- Key Provisions in Contracts
- Importance of Brand Guidelines and Public Use Guidelines
- Settling Disputes: Closing the Loop and Moving Forward



# Pillar Three: Prosecution, Registration & Compliance

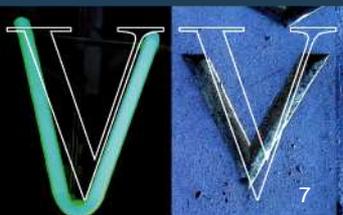
- Respecting the IP of Others: Clearing Brands and Marketing Activities
- Developing and Maintaining a Streamlined and Robust Trademark Portfolio
- Creative Ways to Avoid or Minimize Disputes
- Practical Tips (“Do’s and Don’ts”) for Outside Counsel



# Brand IP in the Pharmaceutical Industry

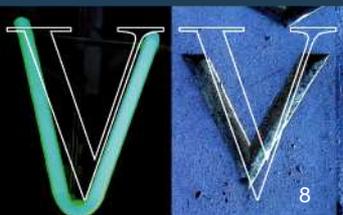
Three Key Pillars:

- Pharmaceutical Brand Lifecycle
- Enforcement
- Divestitures



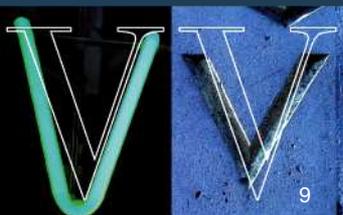
# Pillar One: Pharmaceutical Brand Lifecycle

- Copyrights considerations
  - Scientists sharing journal articles
    - What rights do authors of journal articles retain after submission
    - What can we give out at sales meetings
    - What can salespeople give to Health Care Providers (HCPs)
- Brand Names
- Generic Names (clearance and domain issues)
- Local Language Names<sup>1</sup>
- Clinical Trial Names



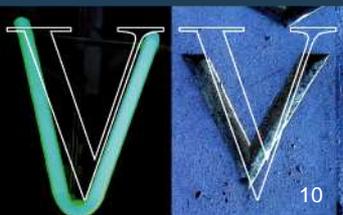
## Pillar Two: Enforcement

- History of Brand IP Enforcement in the Pharmaceutical Industry
- How and why practices have changed
- [The Partnership for Safe Medicines “Counterfeit Drugs: A Dangerous Threat to American Patients”](#)
- Working with Customs
- The FDA Secure Supply Chain Pilot Program (SSCPP) – enhancing the security of imported drugs



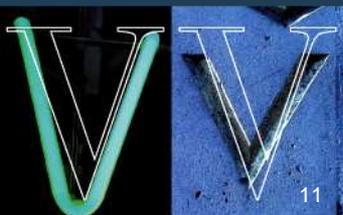
# Pillar Three: M & A and Divestiture Considerations

- Merger & Acquisition Implications
- Divestiture Implications
  - What to do with trademarks when only selling one form of the product<sup>2</sup>



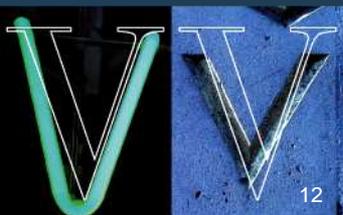
# The U.S. Foreign Corrupt Practices Act (“FCPA”) and Brand Protection

- In the brand protection arena, you may encounter FCPA risks in a variety of contexts
- Most likely to encounter FCPA risks when:
  - Conducting a field investigation
  - Working with foreign intellectual property offices
    - Applying to register a foreign mark
    - Opposing/cancelling a confusingly similar mark
  - Working with customs/border patrol
    - Seizures of counterfeit goods
    - Training seminars



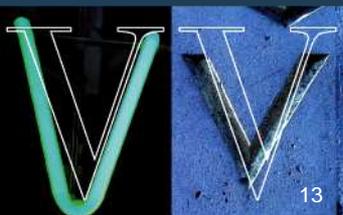
# What is the FCPA?

- Enacted by Congress in 1977 to halt practice of bribing foreign officials
- Two main provisions
  - Anti-Bribery Provisions
  - Books and Records Provisions
- Increased government resources focused on the FCPA
- DOJ/The SEC interpret key provisions extremely broadly
- You can be held liable for FCPA violations committed by your:
  - Employees
  - Third-party agents (investigators)
  - Licensees/Joint-Venture Partners
  - Subsidiaries



# Think about the FCPA whenever...

- Your investigation/transaction involves a “high corruption risk” country
- A transaction involves unusual contract/payment terms, such as payment “in cash”
- Foreign officials (or their relatives) have been given gifts of any sort
- Shell companies are being used
- There has been a request for a charitable donation
- A foreign counterparty insists that a particular agent be used



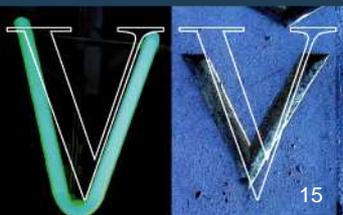
# Think about the FCPA whenever...

- An investigator, sales agent or other third-party representative is involved, and they request an unusually high “commission” or fee
- The role/function of an agent is unclear
- An agent will not complete FCPA certifications
- A foreign official requests a fee/payment, and it is not reflected in the written laws of that country and/or the foreign official refuses to provide a receipt



# Example #1: Field Investigations

- Before retaining private investigators/other field agents:
  - Conduct appropriate due diligence
  - Insist on a written agreement including express FCPA/anti-corruption certifications
- Protect your investigation budget – make sure it is not used as a “slush fund”
  - Restrict who can withdraw funds and authorize expenditures
  - Require investigators/other agents to record all expenditures in detail at the time of the transaction
- Apply for search/arrest warrants – no “grease” or facilitation payments



## Example #2: Local IP Offices

- In foreign countries, trademark prosecution and dispute processes can take a long time
- Beware of requests by IP office officials for “expediting payments” or payments that can speed the processes along
  - “Facilitation payment” exception to the FCPA, but it is interpreted extremely narrowly
  - If payment is requested, at a minimum:
    - Confirm it is a legitimate payment authorized by laws/regulations of country in question
    - Seek advice from local counsel
    - Ensure payment is recorded accurately
  - Require agents (including local counsel) to follow same procedures; prohibit them from making payments to government officials without prior written consent

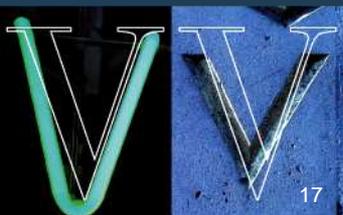


## Example #3: Working with Customs

- Customs/Border Protection can be first line of defense in foreign country; employees, investigators, others can work with them to:
  - Stop shipments of counterfeit goods
  - Facilitate shipments of authorized goods
  - Learn how counterfeit products travel in commerce
- Can you provide product samples to customs?

It depends:

- Inexpensive products to help them differentiate between counterfeit and licensed goods are unlikely to raise FCPA “red flags”
- Expensive items that are incidental or unrelated to training purposes are prohibited



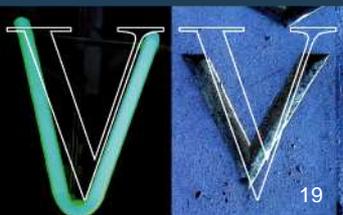
## Example #3: Working with Customs

- For training seminars, always consider:
  - Whether the location is distant/desirable
  - Whether spouses/children are invited
  - Excessive entertainment is offered that appears unrelated to any training purpose
  - Expenses personally paid to officials/attendants
  - The business purpose seems incidental to the training purpose



# FCPA Brand Protection Checklist

- Due Diligence
  - Conduct risk-based FCPA due diligence on all agents, third-party business partners, licensees
  - All agreements should be in writing
  - Require express FCPA/anti-corruption certifications
- Investigation budget does not equal “slush fund”
  - Restrict who has access to the budget
  - Book expenditures accurately and require documentation
- Be careful whenever a payment or fee is requested
  - Is it an official fee or a “grease” payment?
  - Obtain a legal opinion from foreign counsel
- With customs officials, avoid even the appearance of impropriety
  - Providing product samples is okay if it helps officials identify counterfeit goods
  - Training seminars and related activities should be tied to legitimate business purpose



# New Trends & Threats Impacting Your Brands and Content

## Trends

- Trade Dress and Design Protection
- Recent application of DMCA to protect content and streaming media

## Threats

- Corporate indifference to IP
- 3-D Printing



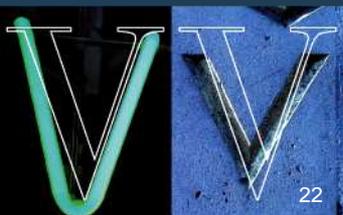
# Trends

- Trade Dress & Design
  - Increased filings and disputes
  - Increased value and use in brand protection
  
- DMCA case law developments – pro-content protection
  - Capitol Records, et al v. Vimeo
  - Disney, et al v. Hotfile



# Threats

- The Implications of Corporate Indifference to IP
- 3-D Printing (On Demand Manufacturing)  
Implications



Thank You

