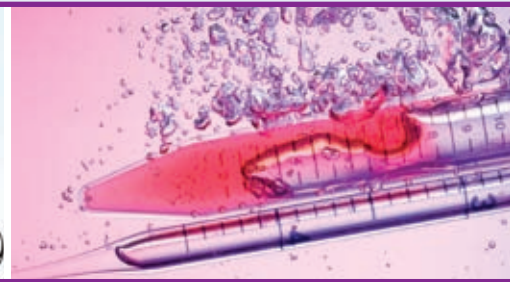
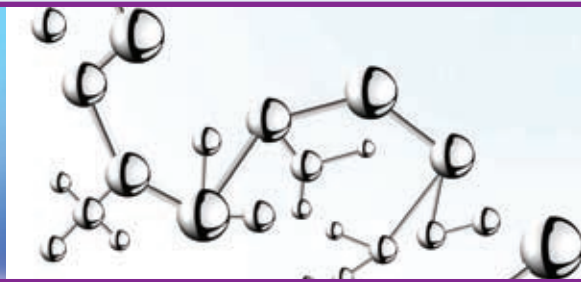


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Basic Training for Products Liability and Patent Lawyers



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Patent Track

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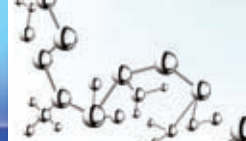
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 - BLAs
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- The role of the Hatch-Waxman Act in the patenting of drugs and biologics
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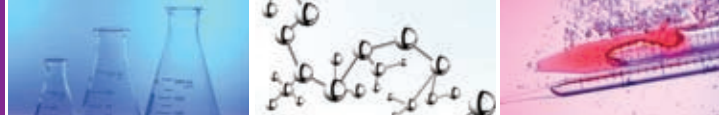
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& Dodge LLP (Boston, MA)



Day One: Monday, September 27, 2010

8:30 Registration and Continental Breakfast

9:00 Chair's Opening Remarks



Howard L. Dorfman

Counsel

Ropes & Gray LLP (New York, NY)

9:15 The Basics: Understanding and Working with the FDA — Jurisdiction, Functions, Organization, and Operations



Daniel A. Kracov

Partner

Arnold & Porter LLP (Washington, DC)

- FDA Overview
- How the FDA is organized
 - Department of Health and Human Services and the Commissioner
 - The 5 FDA Centers and the Office of Regulatory Affairs and their functions
- The 3 major centers and their roles
 - CDER (Drug)
 - CBER (Biologic)
 - CDRH (Device)
- Understanding how CDER and CBER intersect
 - intersection with CDRH
- Defining the scope of the FDA's jurisdiction
- Examining how the FDA exercises its jurisdiction:
 - rule making
 - product decisions
 - enforcement
 - informal mechanisms
- Reviewing the laws that the FDA enforces
- Defining drugs, biologics, and medical devices
- Emerging and expanding technologies
 - cell and tissue-based products
 - nanotechnology
- Labeling: when is a drug a drug and not a medical device or cosmetic, and the consequences
- Defining combination products
- Working with the FDA
 - Administrative Procedures Act
 - formal and informal dispute resolution mechanisms
- FDA's policies and procedures

10:20 Morning Coffee Break

Preapproval and Approval

10:30 The Nature of the Approval Process



Kurt R. Karst

Director

Hyman, Phelps & McNamara, P.C. (Washington, DC)

Rx Drugs

- Understanding the difference between “new drugs” and other drugs
- Overview of the research, development, and approval process for new drugs
- The investigational new drug application (IND)
 - when you need to file one
 - what it needs to contain
 - what it entitles you to do
- The new drug application (NDA)
 - when you need to file one
 - what it needs to contain
 - FDA review process and timing
 - advisory committees
- Accelerated approval (fast track)

Biological Products

- What are biological products?
- What does it mean to say that they are also “drugs”?
 - which “new drugs” require BLAs instead of NDAs?
- How do the research, development, and approval process for biological products differ from the process for new drugs?
- The biologics license application (BLA)
 - when you need to file one
 - what it needs to contain
 - FDA review process and timing
 - advisory committees
- Key similarities and differences between the drug and biological product schemes

OTC Products

- The concept of “OTC” (OTC-ness)
- The OTC Review
 - which drugs are covered?
 - what is a “monograph”?
 - what does a monograph contain?
 - what if you want to deviate from the monograph (innovate)?
- When is a new drug suitable for OTC?
 - when must a drug be Rx only?
 - how do you switch a new drug from Rx to OTC?
 - can a new drug be Rx in some forms/dosages/etc., and OTC in others?
- Overview of how an OTC drug comes to market
 - if it's a new drug
 - if it's not a new drug

11:30 Understanding the Clinical Trial Process for Drugs and Biologics



Natasha Leskovsek

Partner

Cooley Godward Kronish LLP (Washington, DC)

- Overview of the clinical trial process
 - phases of testing (I-IV)
 - which are mandatory?
 - what happens in each phase?
 - who conducts the testing?
 - special considerations for Phase IV testing

- Regulatory requirements
 - informed consent
 - IRBs
 - sponsor obligations
 - investigator obligations
- FDA authority
- Other issues
 - CROs
 - who reviews the data?
 - how do clinical trials for drugs differ from clinical trials for biologics?
- Disclosure of clinical trial information
 - FDA Amendments Act of 2007
 - FDAMA § 113
 - clinicaltrials.gov
 - PhRMA policies
- Global clinical trials: overview of FDA regulation for trials conducted overseas

12:30 Networking Luncheon

1:45 Patent and IP Overview: Hatch-Waxman, Trade Dress, and More



Eric J. Marandett

Partner
Choate Hall & Stewart LLP (Boston, MA)



Thomas C. Meyers

Partner
Brown Rudnick LLP (Boston, MA)



Kathleen Madden Williams, Ph.D.

Partner
Edwards Angell Palmer & Dodge LLP (Boston, MA)

IP Protection for Drugs and Biologics

- Analyzing the patenting process
- Seeking patent protection during the pre-approval process
- Making up for time lost in the patent life cycle during the pre-approval process
 - IP and regulatory redress for lost time
- Distinguishing the patenting process for drugs from that of biologics
 - which biologics are treated as drugs and why?
- Identifying the respective roles of the FDA and the PTO in the patenting of drugs and biological products

Drugs

- NDA v. ANDA (Abbreviated New Drug Application)
 - how do they differ?
- ANDA
 - what does an ANDA require?
- Paragraph IV Certifications and Notice Letters
- Bioequivalence defined
- The Orange Book: what is it and why is it Orange?
 - listings
 - de-listings
- The patent end game (Hatch-Waxman Overview)
 - overview of Hatch-Waxman and reforms under MMA
 - the Orange Book
 - exclusivity (180 day)
 - 30-month stay

- patent extensions
- the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Biologics

- Identifying biologics that fall within the purview of Hatch-Waxman
 - understanding why other biologics fall outside of the Hatch-Waxman rubric
- Examining the FDA's current position on an abbreviated application process for generic biologics

Trademark Issues

- Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product

3:00 Afternoon Refreshment Break

3:15 Spotlight on Follow-On (Comparable or Biosimilar) Biologics and the 2010 Health Care Reform Legislation



Donald R. Ware

Partner
Foley Hoag LLP (Boston, MA)

- What are biologic drugs and why are they different for purposes of generic competition?
- When can FDA approve a follow-on biologic under current law?
- Review of the Omnitrope approval—what does it say about FDA's views on follow-ons?
- Detailed analysis of the provision in the Health Care Reform Bill creating a pathway to enable the FDA to approve biosimilars
 - approval pathway
 - clinical standards
 - safety
 - interchangeability and substitutions
 - postmarket requirements
 - public process
 - exclusivity provisions

4:00 Drugs and Biologics: Labeling



James S. Cohen

Shareholder
Buchanan Ingersoll and Rooney PC (Washington, DC)

The labeling of the drug/biological product is the final stage of the approval process. The labeling affects what you can do post-approval. It is the point of transition between the approval process and post-approval world.

- Labeling overview: key regulatory requirements, information, and contents
- Review process for labeling
- How does the final labeling control the scope of post-market activities?
- When should the labeling be amended post-market?
 - what is the process for doing so?
- How is the labeling a defense in products litigation?

4:45 Conference Adjourns to Day Two

Day Two: Tuesday, September 28, 2010

8:30 **Continental Breakfast**

9:00 **Opening Remarks**

Post-Approval

9:15 **Preemption Fundamentals**



Sharon L. Caffrey

Partner

Duane Morris LLP (Philadelphia, PA)

- Defining express and implied preemption
- Recognizing the basis for drug and device preemption
- Uncovering how the presumption against preemption has been applied in drug and device litigation
- Recognizing the interplay between preemption and the FDA regulatory process
- Emerging precedents: *Riegel v. Medtronic* and *Wyeth v. Levine* and *Circuit decisions applying them*
- Understanding the “parallel requirements” exception to preemption

10:00 **Morning Coffee Break**

10:15 **Marketing and Promotion**



Vernessa T. Pollard

Counsel

Arnold & Porter LLP (Washington, DC)

Advertising and Promotion Overview

- Overview of laws and regulations controlling the advertising, marketing, and promotion of prescription drugs and biologics
 - 21 CFR Sections 202.1, 352(n), 314.81(b)(3); Section 352(n) of FD&CA
 - guidance documents
- DDMAC (Division of Drug Marketing, Advertising and Communications)
 - what duties and responsibilities is DDMAC charged with?
 - what are its enforcement capabilities and jurisdiction?
- Identifying the role of the FTC in the advertising and promotion of drugs
 - SEC?
- Advertising requirements for prescription v. nonprescription products
- Reviewing the steps which DDMAC takes for the review of launch campaigns and promotional materials
 - overview of the promotional materials submission and review process
- What constitutes a launch?
- What defines an advertisement?
 - what information must a drug advertisement include?
- Exploring the role of the label in advertising

Special Concerns for DTC Advertising

- How is direct-to-consumer advertising regulated and monitored?
 - how is it different from other pharmaceutical advertising?

- What information must every DTC ad contain?
- How do the PhRMA DTC guidelines interplay with current FDA regulation?
- FDA's DTC Television User Fee Program
- Advertising and new media
 - how is Internet and e-mail advertising regulated?
 - application of FDA guidance to evolving social networking sites

Bifurcated Tracks – Choose One

Patent Track

11:00 **Non-Patent Exclusivity**



Charles J. Raubicheck

Partner

Frommer Lawrence & Haug LLP (New York, NY)

- The different modes and methods of exclusivity (non-patent)
 - data
 - orphan drug
 - pediatric
 - new product
- FD&C 505b2 (alternate pathway to ANDA)
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Exploring the relation and intersection of each of these methods to 180-day exclusivity

12:00 **Bioequivalence: What Patent Lawyers Need to Know**



Chad A. Landmon

Partner

Axinn Veltrop & Harkrider LLP
(Hartford, CT and Washington, DC)

- Defining bioequivalence in drugs and biologics
 - drugs v. biologics
- What an ANDA-filer must demonstrate for bioequivalence
 - bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical
- How does bioequivalence relate to patents?
 - patenting of bioequivalence characteristics – extended-release drug products
 - bioequivalence v. Doctrine of Equivalents – what is the difference?
 - arguments about bioequivalence raised in Paragraph IV patent litigation
 - infringement, copying (non-obviousness)

Products Litigator Track

11:00 **Regulation and Dissemination of Off-Label Information**



Allison D. Burroughs

Partner

Nutter McClennen & Fish LLP (Boston, MA)

- Overview of the FDA's regulation of off-label promotion
- How can information on off-label or unapproved uses of drugs and biologics be disseminated?
 - peer review articles v. ghost-writing
 - MSLs v. sales reps
- What are the consequences of inappropriate off-label promotion?
 - the role of the OIG, U.S. Attorney's Office, and states in monitoring off-label promotion
- How allegations of improper off-label activity can become the bases of personal injury actions

11:45 Examination of Regulatory/FDA Experts



Lori B. Leskin

Partner

Kaye Scholer LLP (New York, NY)

Direct Examination

- Making the most of the direct of the FDA expert
 - explaining the extensive regulatory process and the agency's extensive authority
 - explaining the continuing oversight provided by FDA
- Telling the story of your product's development
- Utilizing the expert to describe the label review and approval processes
- Handling problematic FDA evidence

Cross-Examination

- Exploring the basis of the expert's opinions
- Establishing a basis for *Daubert* or other challenges to the expert's opinion
- Using the plaintiff's regulatory/FDA expert to:
 - establish the credibility of the FDA
 - establish the pervasiveness of FDA review/oversight
 - establish yourself as knowledgeable

12:45 Networking Luncheon

2:00 Adverse Events Monitoring, Pharmacovigilance and Risk Management



Howard L. Dorfman

Counsel

Ropes & Gray LLP (New York, NY)

- What is pharmacovigilance?
- How pharmacovigilance uses adverse event reports
 - how ADE reports come to a company
 - solicited direct reports
 - unsolicited direct reports
 - indirect reports
 - how companies investigate, analyze and use ADE reports
 - causality assessments
 - labeling changes
 - requirements for reporting ADEs to regulatory agencies
 - premarket stage
 - post-market stage
 - how regulatory agencies use ADE reports
- Examining other tools for pharmacovigilance

- What is risk management?
 - the new Risk Evaluation and Minimization Strategies (REMS) law
 - Risk evaluation in the approval process
 - Risk minimization tools
 - REMS assessments
- Enforcement of ADE reporting and REMS requirements
- Examining the relevance to product liability risks

3:00 Afternoon Refreshment Break

Medical Devices

3:15 Medical Device Essentials: Premarket and Post-Market Requirements



Pamela Furman Forrest

Partner

King & Spalding LLP (Washington, DC)

FDA's Risk-Based Classification Scheme for Medical Devices

- Understanding the concept of risk-based classification
- Three main classes of medical devices
 - Class I: "low risk"
 - Class II: "moderate risk"
 - Class III: "high risk"
- Device reclassification

The Premarket Review Process for Medical Devices

- 510(k) exemptions for low risk devices
- Premarket notification (510(k)) process
 - understanding the selection of "predicate" devices when 510(k) submissions are made and the consequences of choosing the wrong predicate
- Premarket approval (PMA) process
- The role of the Investigational Device Exemption (IDE)

Post-Market Requirements and Concerns

- What types of facilities must comply with FDA's establishment registration and device listing requirements?
- What is the scope of the Quality System Regulation (QSR)?
- What types of adverse events must be reported?
- What kinds of field actions must be reported?
- What other types of post-market requirements can FDA impose on medical devices, e.g., tracking?

Labeling and Advertising

- What are the differences between labeling and advertising and do they include websites?
- What claims can device manufacturers make regarding cleared/approved devices, devices with pending 510(k) notices, and investigational devices?
- How can device manufacturers convey information about new uses to health care professionals and/or consumers?
- What are the consequences of illegal promotion of a device?

4:30 Conference Ends

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 - Products liability litigation
 - Patent litigation
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 - Patents and IP
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- Examination of Regulatory Experts

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