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- ✓ **UNDERSTAND** the **interplay** of the **PTO** and **FDA** in the patenting of drugs and biologics
- ✓ **LEARN** the essentials of the **FDA approval process** and its link to drug patents
- ✓ **DEVELOP** an in-depth and practical knowledge of **Hatch-Waxman** protocols, including **Orange Book listings, exclusivities, bioequivalency, the 30-month stay** and **the safe harbor**
- ✓ **APPRECIATE** the crucial and distinct roles of **in-house** and **outside** counsel relative to **invalidity** and **non-infringement opinions**
- ✓ **NAVIGATE** the intricacies of **patent term adjustment** and **patent term restoration**
- ✓ **FINE TUNE claim drafting skills** within the respective contexts of small molecules, biologics, and other biotech products
- ✓ **SEE** how new **pre-commercialization** concerns relative to **CMS** approval and Medicare/Medicaid formulary selection are **influencing** the **patenting** of innovative drugs and biological products

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Edwards Angell Palmer & Dodge LLP
(Boston, MA)

Agenda at a Glance

Thursday, June 21, 2007

7:30 Registration & Continental Breakfast
8:45 Co-Chairs' Opening Remarks
9:00 Key Agencies Overview: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics
10:30 Morning Coffee Break
10:45 Life Sciences Patents: What is Patentable?
11:30 The Nature of the Approval Process for Drugs and Biologics: What Every Life Sciences Patent Attorney Should Know
12:30 Networking Luncheon
1:45 Pre-Patent Considerations: Product Development, Commercialization and Life Cycle Management
2:45 Afternoon Refreshment Break
3:00 Freedom to Operate: Review of Analysis and Opinions for Pharma and Biotech Patents
4:00 Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More
5:30 Conference Adjourns to Day Two

Friday, June 22, 2007

7:30 Continental Breakfast
8:45 Co-Chairs' Opening Remarks
9:00 Patent and Non-Patent Exclusivity
9:45 Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability
10:30 Morning Coffee Break
10:45 Exploring Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration
12:15 Networking Luncheon
1:30 Perfecting Claims in Life Sciences Patent Applications
3:00 Afternoon Refreshment Break
3:15 Understanding the Doctrines of Accidental and Inherent Anticipation and their Impact on Life Sciences Patents
4:00 The Safe Harbor: Assessing Protections and Identifying Infringing Activities Relative to Life Science Patents
4:45 Conference Ends

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Understand the interplay of IP and FDA regulation relative to pharma/biotech patents.

Master the intricacies of life sciences patenting.

The FDA…the PTO…product life cycles…freedom to operate…the Hatch-Waxman Act…exclusivity… pre-commercialization v. commercialization and claims drafting. All represent critical IP and regulatory aspects of pharmaceutical and biotech patents. The highly regulated nature of the products which the pharmaceutical and biotechnology industries manufacture dictates that the patenting of these products be closely tied to regulatory approval by the FDA. Moreover, certain principles and doctrines in patent law that may seem irrelevant or of little consequence to other industries are of tremendous significance in pharmaceutical and biotech patents. In short, these patents hold a unique place in the world of IP. Anyone who works in the life sciences industries — and who even remotely deals with its IP — must be well versed in the regulatory components and IP subtleties that play such an integral role in the patenting of its products.

You cannot afford to be left in the dark regarding the interconnection of IP and FDA regulation in these industries. Get the winning edge — boost your life sciences IP and regulatory IQ.

ACI's Pharmaceutical/Biotech Patent Boot Camp has been designed to give new patent attorneys and patent attorneys who are new to the life sciences industries — as well as business executives in pharma and biotech companies — a strong working knowledge of essential IP and regulatory competencies relative to life sciences patents.

A faculty of top-notch IP and regulatory counsel — all having a wealth of experience in pharmaceutical and biotech patents — will share their knowledge and provide critical insights on:

- The organization and jurisdiction of the FDA and the PTO and their interplay in the approval and patenting of drugs and biologics
- Pre-patent considerations relative to R&D and patent portfolio and patent life cycle management
- The critical role of freedom to operate studies in seeking a life sciences patent
- How the doctrines of accidental and inherent anticipation factor into the drafting of claims for life sciences patents
- How the Hatch-Waxman Act established the paradigm for market entry of generic small molecule drugs — and now possibly follow-on biological products
- The relationship between patent and non-patent exclusivity
- The importance of patenting bioequivalence characteristics in certain drug products
- The ins and outs of patent term extension under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791

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Thursday, June 21, 2007

7:30 Registration & Continental Breakfast

8:45 Co-Chairs' Opening Remarks

Thomas J. Kowalski
Partner
Frommer Lawrence & Haug LLP
(New York)

Robert B. Nicholas
Partner
McDermott Will & Emery LLP
(Washington, DC)

9:00 Key Agencies Overview: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics

On the FDA:

William Vodra
Partner
Arnold & Porter LLP
(Washington, DC)

On the PTO:

Thomas J. Kowalski
Partner
Frommer Lawrence & Haug LLP
(New York)

- Understanding the respective roles and interplay of the FDA and PTO in the patenting of drugs and biological products

FDA

- FDA overview and organization
  - Department of Health and Human Services and the Commissioner
  - The 5 FDA Centers and the Office of Regulatory Affairs and their functions
- CDER (Drug) and CBER (Biologic) overview
- Defining the scope of the FDA's jurisdiction with respect to drugs and biologics
- Examining how the FDA exercises its jurisdiction:
  - rule making
  - product decisions
  - enforcement
  - informal mechanisms
- Reviewing the laws that the FDA enforces relative to the patenting of drug and biological products
  - Food Drug & Cosmetic Act
  - Prescription Drug Marketing Act
  - Public Health Services Act
  - Hatch-Waxman Act
  - other applicable laws
- Defining drugs and biologics
- Labeling: when is a drug a drug and not a biologic
- Working with the FDA
  - Administrative Procedures Act
  - formal and informal dispute resolution mechanisms

The PTO

- Review of the organizational structure of the PTO
- Patents: overview of drug and biological products that may be patented
- Who may apply for a patent?
  - agency and inventorship
- What is the PTO's jurisdiction in the patenting of drugs and biologics?
- What laws and regulations does the PTO enforce relative to the patenting of drugs and biologics?
- PTO Rule Making
- Patent Reform Legislation
- Trademark and copyrights vis-à-vis drugs and biologics

10:30 Morning Coffee Break

10:45 Life Sciences Patents: What is Patentable?

Deborah L. Lu, Ph.D.
Patent Attorney
Frommer Lawrence & Haug LLP
(New York)

- Identifying drug and biological products that may be patented
  - small molecules
  - biologics
  - research tools
  - methods
  - genes
  - gene sequences
  - gene therapies
  - purified genes
  - SNPs
  - fragments
  - proteins
  - small peptides
  - DNA
  - stem cells

11:30 The Nature of the Approval Process for Drugs and Biologics: What Every Life Sciences Patent Attorney Should Know

Robert B. Nicholas
Partner
McDermott Will & Emery LLP
(Washington, DC)

- Understanding the link between the FDA approval process and the patenting of drugs and biologics

Rx Drugs (new drugs)

- Identifying the application process for the approval of a new drug, *i.e.*, small molecule, new chemical entities, etc.
- NDA (New Drug Application)
  - what information does it contain?
  - labeling, patent information, trade name issues
  - when is it filed?
  - who is it filed with?
  - how does the FDA review it?
- INDA (Investigational New Drug Application) aka "IND"
  - how does it differ from an NDA?
  - when is it filed?

- who is it filed with?
- what does it entitle you to do?

- Accelerated approvals
  - defining eligibility criteria for accelerated approval and priority reviews
  - what portions of approval submissions might FDA release?
  - when?
- Using advisory committees in the approval process
  - when are they used and what happens there?

Biologics

- Understanding the approval process for a biologic
  - how does the approval process for a biologic differ from that of a drug?
- BLA (Biological Licensing Application)
  - how does a biologic differ from a drug?
  - what application needs to be filed and with whom is it filed?
  - which products require BLAs instead of NDAs?
  - what does a BLA look like?
- Why is it a "license," rather than an "approved application"?

12:30 Networking Luncheon

1:45 Pre-Patent Considerations: Product Development, Commercialization and Life Cycle Management

Christopher Stomberg, Ph.D.
Principal
Bates White, LLC
(Washington, DC)

Questions to ask now:

- What types of products are drug and biotech companies now seeking to develop and patent?
- Is there any impediment through patent or regulatory restraint that prevents these companies from pursuing the development of the desired product?
- Even if all patent and IP hurdles are met, are there FDA hurdles that cannot be cleared?
- Patent portfolio considerations vis-à-vis patent life cycle management
  - pharma (small molecule) v. biotech

New considerations:

- The new role of the Center for Medicare and Medicaid Services (CMS) in the approval process
  - how does this affect drug patents?
- Understanding the connection between CMS approval and commercial viability via government payor systems and rebates
- Techniques for analyzing the value the product adds to the company's product and patent portfolios, and methods for proving value
- Assessing the competition and analyzing potential therapeutic interchange considerations

2:45 Afternoon Refreshment Break

3:00 Freedom to Operate: Review of Analysis and Opinions for Pharma and Biotech Patents

Teresa Bittenbender
Senior Patent Attorney
Wyeth
(Collegeville, PA)

Kathleen Madden Williams, Ph.D.
Partner
Edwards Angell Palmer & Dodge LLP
(Boston, MA)

The crucial first step — the precursor to the start of R&D — for a patentable pharmaceutical or biotechnology invention is a freedom to operate analysis. A critical competency for every life sciences patent practitioner is the ability to correctly determine whether there truly is freedom to operate in a particular field.

- Knowing when you should undertake a freedom to operate analysis
  - unique factors in making this determination in the life sciences industries
- Goals of freedom to operate evaluations in pharma and biotech
  - guiding research away from third party IP
  - defining landscape
- Searching strategies
  - finding and mining the best and most accurate sources of information
  - effectively dealing with search providers
  - addressing unique biotech search concerns
    - recombinant DNA /DNA based patent applications
    - gene sequences: nuances and questions of variation
    - fragment sequences
- Deciding if an opinion is needed
  - when? what? who?
  - *Knorr-Bremse v. Dana Corp*
- In-house versus outside counsel opinions
  - when is an in-house opinion appropriate?
  - when is an outside counsel opinion appropriate?
  - when is the opinion of outside counsel prudent?
- Elements of a soundly reasoned opinion
  - what factors must be considered?
  - what issues must be addressed?
- Non-infringement opinions
  - *Integra, Housey,* and *Madey* and their effect on opinions
  - claim construction cases: use of dictionaries; *Festo*
- Invalidity opinions
  - prior art; enablement
  - the strength of written description opinions: *Rochester, Enzo*, and claim construction issues (dictionaries)
- Understanding the complexities of privilege and discovery issues relative to opinions
  - what do you put in writing and what do you leave unsaid?
  - is privilege afforded to documentation used in an opinion letter?
    - findings in *Knorr-Bremse v. Dana Corp.* on this issue
  - should communications with your outside counsel regarding an opinion letter be memorialized?
  - what communications and documentation will be ultimately discoverable?

4:00 Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More

Jason Lief
Partner
McDermott Will & Emery LLP
(Washington, DC)

Steven H. Sklar
Partner
Leydig, Voit & Mayer, Ltd.
(Chicago, IL)

Gary L. Veron
Attorney
Sidley Austin LLP
(Washington, DC)

IP Protection for Drugs and Biologics

- Analyzing the patenting process for drugs and biologics
- 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 role of Orange Book under Hatch-Waxman vis-à-vis the MMA
  - 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
  - why are other biologics outside of the Hatch-Waxman rubric?
- The rationale for concerns regarding the safety and efficacy of second generation biologics
- Examining the FDA's current position on an abbreviated application process for "generic" biologics
  - proposed white paper
  - Sandoz "omnitrope" case
- Status of proposed legislation

Trademark Issues

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

5:30 Conference Adjourns to Day Two

Friday, June 22, 2007

7:30 Continental Breakfast

8:45 Co-Chairs' Opening Remarks

9:00 Patent and Non-Patent Exclusivity

Erika King Lietzan
Partner
Covington & Burling LLP
(Washington, DC)

- Patent exclusivity v. non-patent, *i.e.*, regulatory exclusivity
- The concept of market exclusivity under the Hatch-Waxman Act
- Understanding which drug products are eligible for regulatory exclusivity
  - small biologics v. biologics
- The different modes and methods of regulatory exclusivity (non-patent)
  - NCE (new chemical entity)
    - 5 years marketing exclusivity
    - 5 years data exclusivity
  - Indication (new indication or use)
    - 3 years marketing exclusivity
  - NDF (new dosage formulation)
  - ODE (orphan drug exclusivity)
  - PED (pediatric exclusivity)
- FD&C 505b2 (alternate pathway to ANDA) a/k/a paper NDA
- What role does the FDA play in regulating these modes of exclusivity?
- When are each of these methods sought?
- Using trade dress as means of exclusivity

9:45 Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability

Donald O. Beers
Partner
Arnold & Porter LLP
(Washington, DC)

- Defining bioequivalence in drugs and biologics
  - drugs v. biologics
  - same active ingredient
- What an ANDA-filer must demonstrate for bioequivalence?
  - bioequivalence and dosage form – oral tablet/capsule, injection, nasal sprays, topical, nasal sprays
- 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)

10:30 Morning Coffee Break

10:45 Exploring Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration

Denise Loring
Partner
The Fish & Neave IP Group of Ropes & Gray LLP
(New York)

- Extension of patent term under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791
- Exploring the viability of extension applications to:
  - basic compounds
  - secondary patents
  - combination compounds
- Important benchmarks in the drug's development and patent timelines
- Eligibility for patent term extension
- Regulatory review period determinations
- How to calculate the patent term restored
  - respective roles of the FDA and PTO in granting patent extensions
  - third-party challenges --- "diligence"
- Patent term extensions outside the U.S.
- Examining patent term adjustment due to delays in prosecution before the USPTO
  - strategies for:
    - diligence in prosecution by the patent applicant
    - calculating the adjustment period
- Understanding the link between patent extensions and exclusivity
  - extensions obtained through FDA Pediatric Exclusivity and Orphan Drug Exclusivity
- Obtaining patent coverage for pharmaceuticals through the use of second-generation patents, *e.g.*,
  - maintaining patent position for second-generation products
  - approaches taken by pharmaceutical companies in obtaining second-generation patents
  - enforcement of second-generation patents
- Assessing the impact of proposed PTO Rule regarding elimination of continuation practice on pharmaceutical patent extensions

12:15 Networking Luncheon

1:30 Perfecting Claims in Life Sciences Patent Applications

Richard J. Berman
Partner
Arent Fox LLP
(Washington, DC)

- Crafting claims for drugs and biologics
  - broad claims v. narrow claims
- Drafting the claims for the patent sought:
  - compound
  - formulation
  - method
- The current legal framework and evolving trends in claim construction relative to drugs and biologics
- Drafting claims that can withstand potential impact of proposed PTO rule concerning the elimination of continuation practice
- Understanding the roles of specification and prosecution history vis-à-vis claim construction relative to life sciences patents
  - what does it mean to define claims in light of the specification and prosecution history?
- Considerations relative to 35 USC § 112
  - written description and disclosures
  - enablement
  - best mode
- Specimen deposits relative to claims drafting

3:00 Afternoon Refreshment Break

3:15 Understanding the Doctrines of Accidental and Inherent Anticipation and their Impact on Life Sciences Patents

Anne Brown
Senior Director of Intellectual Property
Athersys, Inc.
(Cleveland, OH)

- Defining and understanding the doctrine of inherent anticipation
- Understanding how the doctrine is being applied by the Federal Circuit
  - what are the important recent decisions from the Federal Circuit?
    - compositions
    - methods
  - are these decisions consistent with Supreme Court precedent?
- Defining and understanding the doctrine of accidental anticipation
  - is this still a viable doctrine?
  - can inherent disclosure not anticipate? If so, when?
- How to invalidate a patent using inherency doctrine
- How to analyze your patent portfolio for vulnerability
  - how to write/re-write your claims
- How the inherency doctrine plays out in the field of biotech
  - actual and prophetic examples

4:00 The Safe Harbor: Assessing Protections and Identifying Infringing Activities Relative to Life Science Patents

Brian D. Coggio
Partner
Greenberg Traurig, LLP
(New York)

- Exploring the safe harbor of the Hatch-Waxman Act 35 USC § 271(e)(1)
- The safe harbor and the scope of protection for otherwise infringing activities
- New test for applying the safe harbor in light of *Integra Life Sciences v. Merck KGaA*
  - when is it now safe to discount a competitor's patents in starting research on a new product?
  - when are pre-clinical studies with patented compounds exempt from infringement under the safe harbor?
  - must data from such studies actually be submitted to the FDA for the exemption to apply?
- To which activities will the safe harbor now apply:
  - basic R&D?
  - research tool patents?
  - new product screening?
  - optimization?
  - post-approval testing?
  - supplying materials for FDA-related testing?

4:45 Conference Ends

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