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Pharma/Biotech Patent Boot Camp

Basic training in core IP and related regulatory competencies for the life sciences industries


Preeminent members of the nation’s Patent and FDA bars will drill you in the basics of IP and regulation relative to pharmaceutical and biotech patents and help you:

✓ 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, bioequivalence, 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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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
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

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?
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

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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

Attend this conference and learn to navigate your way through the IP and regulatory mazes that play such a crucial role in your practice areas. Register now by calling 1-888-224-2480, faxing your registration form to 1-877-927-1563, or registering online at www.AmericanConference.com/PBPatentBootCamp
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


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?
- IND (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
- Why is it a “license,” rather than an “approved application”?
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

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

- 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

Afternoon Refreshment Break

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

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?
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