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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

COORDINATE patent filings with FDA strategies

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

DETERMINE when and how to undertake a freedom to operate analysis

NAVIGATE the intricacies of patent term adjustment and patent term restoration

FINE TUNE claim drafting skills and distinguish weak claims from strong claims

AVOID common pitfalls when entering into licensing agreements

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LEARN THE FUNDAMENTALS OF PROTECTING VALUABLE LIFE SCIENCES ASSETS!

Pharmaceutical and biotech companies spend billions of dollars to develop new products with the hope that these products will gain FDA and patent approval. Because of the extensive amounts of time and money invested, it is imperative that patents actually protect the product a company plans to market. In order to accomplish this, patent counsel, patent agents, and R&D and business development executives need to ensure that patent claims are correctly drafted, patent filings coordinate with FDA strategies, and purchased patents are truly valid and enforceable.

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ACI's Pharma/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.

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AGENDA-AT-A-GLANCE

- Key Agencies: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics
- Life Sciences Patents: What is Patentable?
- Tests for Patentability in the Life Sciences
- Perfecting Claims in Life Sciences Patent Applications
- Pre-Patent Considerations Relative to Product Development, Commercialization and Life Cycle Management
- Freedom to Operate: Analysis and Opinions for Pharma and Biotech Patents
- Finding Safe Harbors for Life Sciences IP: Assessing Protections and Identifying Infringing Activities Relative to Third-Party Patents
- The Nature of the Approval Process for Drugs and Biologics: What Every Life Sciences Patent Attorney Should Know
- Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More
- Patent and Non-Patent Exclusivity
- Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability
- Exploring Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration
- Transactional Considerations: The Essentials of Life Sciences Licensing

Tuesday, September 18, 2007

7:30 **Registration and Continental Breakfast**

8:15 **Co-Chairs' Opening Remarks**

MaCharri R. Vorndran-Jones
Patent Counsel
Eli Lilly and Co. (Indianapolis, IN)

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

8:30 **Key Agencies: Understanding the Jurisdiction and Interplay of the FDA and PTO in the Patenting of Drugs and Biologics**

On the FDA:

Donald O. Beers
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 and approval 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

9:30 **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

10:00 **Morning Refreshment Break**

10:15 **Tests for Patentability in the Life Sciences**

Bart W. Wise, Ph.D.
Senior Intellectual Property Counsel
Geron Corporation (Menlo Park, CA)

Matthew W. Siegal
Partner
Stroock & Stroock & Lavan LLP (New York)

- Fundamentals of prosecution with regard to life sciences inventions
  - obviousness
  - novelty
  - utility
- Considerations relative to 35 USC § 112
  - written description and disclosures
  - enablement
  - best mode
- The doctrine of inherent anticipation
  - understanding what this doctrine holds and how the CAFC is applying it
  - what are its unique implications for biotech inventions?
  - for small molecules?
- Defining and understanding the doctrine of accidental anticipation
  - is this still a viable doctrine?
  - can inherent disclosure not anticipate? If so, when?
- Using these doctrines to invalidate a patent
- How to analyze your patent portfolio for vulnerability
  - how to write/re-write your claims

11:15 **Perfecting Claims in Life Sciences Patent Applications**

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

Len S. Smith
Senior Intellectual Property Counsel
Novo Nordisk (Princeton, NJ)

- Crafting claims for drugs and biologics broad claims vs. narrow claims
- Drafting the claims for the patent sought:
  - compound
  - formulation
  - method
- Protecting the invention from every possible angle by using different types of claims
  - composition of matter
  - method of treatment
  - method of use
- Evaluating the strengths and weaknesses of different types of claims
- Ensuring that your claims are supported
  - specifications needed to support claims
    - knowing what should be included in specifications
- The current legal framework and evolving trends in claim construction relative to drugs and biologics
- Specimen deposits relative to claims drafting
- 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?
- Litigation challenges: claim drafting that may prove difficult or impossible to defend
- Harmonizing life sciences patent applications with PTO procedures
  - understanding the PTO classification system
    - writing claims to accommodate the different search methods used by examiners
  - restriction practice and its effect on claim writing
    - using strategic layering to get more claims into an application
  - scheduling in-person or telephonic interviews with examiners
  - making information disclosures
    - what needs to be disclosed to the PTO?
    - what is considered "material?"
    - findings of inequitable conduct

1:00 Networking Luncheon

2:15 Pre-Patent Considerations Relative to Product Development, Commercialization and Life Cycle Management

Jeffrey A. McKinney
VP & Chief Patent Counsel, Altairnano (Reno, NV)

Judy Jarecki-Black, Ph.D.
Head, Intellectual Property, Merial Limited (Duluth, GA)

Questions to ask now:

- What types of products are drug and biotech companies now seeking to develop?
- 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?
- Determining whether patenting an invention affords it the most protection
  - alternatives to patenting
- When to evaluate patent portfolio considerations vis-à-vis patent life cycle management?
  - pharma (small molecule) v. biotech

New considerations:

- The new role of the Centers for Medicare and Medicaid Services (CMS) in the approval process
- 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

3:15 Afternoon Refreshment Break

3:30 Freedom to Operate: Analysis and Opinions for Pharma and Biotech Patents

Teresa Bittenbender
Senior Patent Attorney, Wyeth (Collegeville, PA)

John P. Iwanicki
Partner
Banner & Witcoff, Ltd. (Boston, MA)

Geoffrey M. Karny
Partner
Baker & Daniels LLP (Washington, DC)

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 to 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
  - defining landscape
  - guiding research away from third party IP or knowing what licenses to obtain
- 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
  - what type of opinion should be sought?
  - when should different types of opinions be sought?
  - who should issue the opinion?
    - 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?
  - identifying circumstances where it is acceptable to forego an opinion
  - *Knorr-Bremse v. Dana Corp.*
- 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)
- Dealing with an adverse opinion
- 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?

4:30 Finding Safe Harbors for Life Sciences IP: Assessing Protections and Identifying Infringing Activities Relative to Third-Party Patents

William L. Leschensky
Vice President, Intellectual Property
Alexza Pharmaceuticals, Inc. (Palo Alto, CA)

Raymond S. Parker, III, Ph.D.
Associate Vice-President & Head, Internal Medicine
US Patent Department Operations
sanofi-aventis US L.L.C. (Bridgewater, NJ)

James F. Haly, Jr.
Partner
Ropes & Gray 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?

5:30 Conference Adjourns to Day 2

Wednesday, September 19, 2007

7:30 Continental Breakfast

8:45 Co-Chairs' Opening Remarks

9:00 The Nature of the Approval Process for Drugs and Biologics: What Every Life Sciences Patent Attorney Should Know

Mark Krietzman
Shareholder
Greenberg Traurig, LLP (Santa Monica, CA)

- 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"?

10:00 Morning Refreshment Break

10:15 Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More

Hans Sauer, Ph.D.
Associate General Counsel for Intellectual Property
Biotechnology Industry Organization (Washington, DC)

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

Eric Marandett
Partner
Choate, Hall & Stewart (Boston, MA)

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
  - 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

11:45 Patent and Non-Patent Exclusivity

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

Anthony D. Sabatelli, Ph.D.
Vice President Intellectual Property
Rib-X Pharmaceuticals, Inc. (New Haven, CT)

- Patent exclusivity v. non-patent exclusivity
- The concepts of marketing and regulatory exclusivity under the Hatch-Waxman Act
- Understanding which drug products are eligible for non-patent exclusivity
  - small drug molecules v. biologics
- The different modes and methods of regulatory and marketing exclusivity (non-patent)
  - NCE (new chemical entity)
    - 5 years marketing exclusivity
    - 5 years data exclusivity
    - ANDAs and generic challenges
  - Indication (new indication or use)
    - 3 years marketing exclusivity
  - NDF (new dosage formulation)
  - ODE (orphan drug exclusivity)
  - PED (pediatric exclusivity)
- FD&C § 505(b)(2) (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 a means of exclusivity
- The FDA Orange Book
  - understanding and using it
- Active ingredients (USANs and other chemical names) vs. proprietary names
- International considerations for thinking globally about your docket

12:30 Networking Luncheon

1:45 Bioequivalence and the "Same Active Ingredient" vis-à-vis Patentability

Janet MacLeod, Ph.D.
Partner
Crowell & Moring LLP (New York)

Veronica Mullally
Partner
Orrick, Herrington & Sutcliffe LLP (New York)

- Defining bioequivalence in drugs and biologics
  - drugs v. biologics
- What must an ANDA filer 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)

2:30 Afternoon Refreshment Break

2:45 Exploring Pharmaceutical Patent Extensions: Patent Term Adjustment and Patent Term Restoration

MaCharri R. Vorndran-Jones
Patent Counsel, Eli Lilly and Co. (Indianapolis, IN)

- 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

4:15 Transactional Considerations: The Essentials of Life Sciences Licensing

Peter A. Cicala
Vice President of Intellectual Property
Shire Pharmaceuticals, Inc. (Wayne, PA)

Dolly Vance
Sr. Vice President, General Counsel
Rigel Pharmaceuticals (South San Francisco, CA)

In-Licensing

- Examining the patent stage the technology is in to determine when to take a license
- Understanding the client's intended use in relation to the claims
- Reviewing title and prior technology to determine ownership
- Examining the file history every single time
- Understanding what other technology may need to be licensed along with licensed technology
- Anticipating and planning for licensing issues in view of *Medimmune v. Genentech*
- Assuming third party licenses and sublicenses
- Enforcement of rights and the Hatch-Waxman Act

Collaborations

- Know-how vs. patent rights
- Appreciating the impact of definitions on patent rights
- Examining the license
- Understanding exclusivity vs. license rights
- Carving out something for the licensor
- Milestones and royalties dependent on patent rights
- Joint inventions
- Rights to review, disclosure requirements, and the typical "patent committee"
- Conducting effective due diligence reviews
- Defense of third party claims
- Patent term restoration
- Unwinding a collaboration or joint venture

5:00 Conference Adjourns

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