



PATENT OPINION WRITING BOOT CAMP

Essential Basic Training for Practical and Tactical Opinion Writing for the Pharmaceutical and Biotechnology Industries

October 28-29, 2009 • The Union League • Philadelphia, PA

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Robin N. Silva
Partner
Morgan, Lewis, & Bockius LLP

Joyce Morrison
Director, Intellectual Property
VetMedica

FEATURING 5 INTERACTIVE DRAFTING & STRATEGY WORKSHOPS

“Excellent – the speakers had clear mastery over the subject matter”

Aiyaz Alibhai, prior delegate
Pharma/Biotech Patent Opinion Writing

“Very good topics and presentations... Very relevant to day to day practice.”

Mitchell Bernstein, prior delegate
Pharma/Biotech Patent Opinion Writing

Expert opinion writing faculty will drill you in the basics of opinion writing and show you how to:

- IDENTIFY how *Seagate* has altered opinion practice and the new standard for willful infringement
- CLARIFY business objectives to determine the ultimate purpose of the opinion and the anticipated audiences
- FORMULATE a pre-drafting strategy which accounts for preparation, timing, scope of the opinion
- UNDERSTAND how the letter fits into the overall IP strategy
- INCORPORATE new invalidity opinion strategies from evolving legal standards concerning written description and enablement
- MINIMIZE exposure to liability by taking proactive measures to protect attorney-client privilege
- UNCOVER the newest search strategies and develop cost-effective and time saving ways for both biotech and chemical searches
- GAIN strategies to integrate litigation considerations into your opinion letters

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Master the art of opinion writing at the only event dedicated to providing you with the practical skills and tactics essential to excel in lucrative opinion practice.

Invalidity and non-infringement opinions are the invaluable tools in a company's arsenal. They provide certainty by measuring the company's market position and affording pharmaceutical and biotechnology leaders the security necessary to strategically utilize the IP to increase market power. As a vital member of this process, you must gain an in-depth understanding of the strategic and technical elements essential to writing a comprehensive patent opinion able to withstand intense scrutiny.

Your expert faculty will not tell you how to write outstanding opinions – THEY'LL SHOW YOU

Bringing together decades of opinion writing experience, your faculty of opinion writing experts will pool their collective knowledge into two days of intensive hands-on workshop training.

Through 5 strategy-packed workshops integrated into the program, you will develop skills you can immediately incorporate into your practice. From strategically planning the timing, scope, and cost of the opinion to developing new search techniques, your faculty will walk you through real-life scenarios encountered over years of opinion practice during the hands-on workshop sessions.

Walk away with templates for your next invalidity and non-infringement opinion letter

The event will culminate with the coveted invalidity and non-infringement opinion letter template workshops where you'll gain an unprecedented step by step look at how experienced opinion counsel formulate their validity and non-infringement letters, integrating the latest case law on written description and enablement, anticipating multiple audiences, and carefully considering the client's ultimate objective.

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Wendy Tyler

Group Leader & Business Development Executive
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8:00 **Registration and Continental Breakfast** 🍴

9:00 **Co-Chairs' Opening Remarks**

Robin N. Silva

Partner

Morgan, Lewis, & Bockius LLP

Joyce Morrison

Director, Intellectual Property

VetMedica

9:10 **Reevaluating the Current Use and Demand for Patent Opinions After *In Re Seagate***

Kathleen Madden Williams, Ph.D.

Partner, Co-Chair, Bio-Medical and Patent Practices

Edwards, Angell, Palmer & Dodge LLP

(Boston, MA)

- Understanding how *Seagate* altered patent opinion practice
- Defining the new standards for willful infringement
- Identifying reasons for obtaining an opinion after *Seagate*
- Examining the standard for “objective recklessness”
- Developing a policy that demonstrates operating in a commercially reasonable fashion
- Reconciling *Broadcom* and *Seagate* and the implications for patent opinion writing

10:00 **From the In House Counsel's Desk: Clarifying the Business Objectives and Understanding How Companies Use the Opinion**

Valeta Gregg, Ph.D.

Vice President and Assistant General Counsel, Patents

Regeneron Pharmaceuticals, Inc.

(Tarrytown, NY)

Steven A. Bossone, Ph.D., J.D.

Senior Director, Intellectual Property

Shire Human Genetic Therapies

(Lexington, MA)

Andrew A. Paul

Senior Counsel

The Procter & Gamble Company

(Cincinnati, OH)

Matthew Beaudet, Ph.D.

Patent Attorney

Novartis Institutes for Biomedical Research, Inc.

(Cambridge, MA)

- Establishing effective communication between client and counsel to determine when an opinion is needed
- What elements are clients looking for in an opinion?
- Uncovering why an opinion is being sought – what is the ultimate business objective?
- Ensuring the opinion fits into the client's overall IP strategy
- Strategizing with the client to uncover methods for using opinion letters as leverage to overcome challenges by competitors

- Balancing the costs with the clients objectives and understanding budget constraints
- Thinking like a GC: accomplishing the business objective vs. an explanation of the issues

11:00 **Morning Refreshment Break** 🍴

11:15 **Developing a Cohesive Strategy Prior to Drafting the Opinion: Preparation, Timing, and Determining the Type of Opinion Needed**

Mark S. Cohen

Senior Partner, Chair of Life Science Group

Pearl Cohen Zedek Latzer LLP

(New York, NY)

- Determining the purpose of the opinion: M&A, licensing agreement, financing, litigation
- What factors determine whether you should prepare a written opinion or a verbal opinion?
- Strategically deciding what to document and what not to put in writing
- Examining and utilizing in-house opinions
- Timing the opinion: weighing the costs of delaying product launches vs. future litigation considerations
- Identifying your audience and anticipating multiple audiences as a precursor for litigation
 - Judge
 - Jury
 - Third Party Business Partners
 - Shareholders
 - Scientists
 - CEO/Business Manager
 - Attorney
- Deciding on reasonable deadlines that meet the client's need
- Setting the boundaries of a clearance search and communicating with the client to keep costs down
- Proactively anticipating utilizing the opinion as leverage to strategically position your client
- Expanding the scope of a freedom to operate analysis into an infringement and/or invalidity opinion: distinguishing the product from close patents vs. neutralizing claims
- Determining when to include an invalidity and infringement analysis together
- Establishing the level of certainty of the opinion and setting expectations with the client

Workshop

12:15 **Networking Lunch** 🧑🏫

1:30 **Case Law and Congressional Update: Factoring Patent Reform and Evolving Legal Standards into Your Opinion**

Teresa Stanek Rea

Partner

Crowell & Moring LLP

(Washington, D.C.)

(President, American Intellectual Property Law Association)

- The current status of international patent harmonization and appreciating how it will alter your clearance searches
- Discussing the current status of patent reform and analysis of proposed legislation

- The potential use of post-grant oppositions as an alternative to opinions
- The continuing impact of *KSR* and the interplay between *KSR* and *Kubin* on changing §103 obviousness requirements
- Addressing the standard for obviousness for patenting gene sequences in *Kubin* and incorporating it into your claim construction analysis
- Evaluating the standard for patentability under *Bilski* and the implication on the biotech industry
- Addressing the impact of *Prometheus*, *Classen*, and *Lab Corp* on patentability of diagnostics
- Written Description and Enablement: *Ariad* and the new frontiers of invalidity opinions
- Analysis of the current position of the court on claims of inequitable conduct
 - *McKesson v. Bridge Medical*
 - *Aventis v. Amphaster*
 - *Larson Mfg Co. v. Aluminart Products Ltd.*

3:15 Afternoon Refreshment Break

3:30 Critical Ethics Considerations: Protecting Attorney-Client Privilege and Minimizing Exposure to Liability

Adda C. Gogoris

Partner

Darby & Darby P.C.
(New York, NY)

- Identifying actions that create a waiver of privilege and deem patent opinions discoverable
- Appreciating what documents and work product is discoverable beyond the scope of the opinion
- Addressing the affirmative duty of care standard that arises in composing patent opinion letters
- Uncovering which business transactions trigger duties to third parties
- Tactics to avoid waiving privilege and minimizing exposure
- Limiting the scope of the waiver in advance of pending actions
- Practical application of retaining separate counsel
- Addressing multiple party privilege issues pertaining to collaborations and joint defense agreements
- Anticipating the use of expert testimony by opinion counsel to explain the proffered opinion

4:30 Conference Adjourns for the Day

THURSDAY, OCTOBER 29, 2009

8:30 Continental Breakfast

9:00 CoChairs' Opening Remarks

9:10 Optimizing Biotech and Chemical Search Strategies

Donald L. Zubn, Jr. Ph.D.

Partner

McDonnell Boehnen Hulbert & Berghoff LLP
(Chicago, IL)

Workshop

- Developing search strategies for biotechnology inventions and chemical compounds incorporating budget and time constraints
- Distinguishing the differences between the two types of searches and how your strategies will change depending on what you're looking for
- Identifying the newest databases, developments, and strategies for searching biotech, chemical compounds
- Utilizing the best search terms for the biotechnology inventions including potential keywords, inventors, citations, and international classifications
- What to look for in the claims, file wrapper, and communications
- Biotech specific searches:
 - Recombinant DNA/DNA based patent applications
 - Gene sequences
 - Fragment searches
- Utilizing the best technical and abbreviated search terms for chemical searches
- Uncovering the most cost-effective databases for both domestic and international searches
- Determining how broadly or narrowly to search based on the client's current and anticipated needs
- Searching non-patent literature
- Thoroughly searching the client's existing patents
- Methods for conducting international searches and employing local counsel when searching foreign jurisdictions to interpret the results
- Deciding when to update your search and perform routine checks to newly entered information
- Effectively using the search results to uncover and identify lucrative business ventures and opportunities
- Adjusting the search based on new information
- Establishing and implementing a strategy to end the search

10:30 Morning Refreshment Break

10:40 Playing Devil's Advocate: Honing Your Search Analyses

Robin N. Silva

Partner

Morgan, Lewis, & Bockius LLP
(San Francisco, CA)

Joyce Morrison

Director, Intellectual Property

VetMedica
(St. Joseph, MO)

In this interactive workshop session, Ms. Silva and Ms. Morrison will explore hypotheticals based on real-life scenarios to sharpen analytical skills and develop in-depth and comprehensive analysis of search results to determine all the implications for the client when writing opinions, and gain insight into when to stop analyzing and start writing.

Workshop

Ethics Credits

11:40 **Identifying Ways to Strategically Incorporate Litigation Considerations into Your Opinion Writing**

Chad A. Landmon

Partner

Axinn Veltrop & Harkrider LLP
(Hartford, CT & Washington, D.C.)

- Examining how opinion letters are utilized by litigation counsel in Paragraph IV disputes
- Attacking notice letters after litigation commences
- Gaining insight into how litigators formulate preliminary theories founded on opinions of counsel
- Tailoring the opinion to multiple audiences for use with juries and judges
- Interplay between opinion counsel and litigation counsel and the use of expert witness testimony by opinion counsel
- Incorporating the lessons learned from *Takeda v. Mylan* and *Alphapharm* and how to implement best practices
- Anticipating how Paragraph IV litigation may be modeled into follow-on biologics litigation

12:30 **Networking Luncheon** 

2:00 **Essential Elements of Drafting a Legally Sound Non-Infringement Opinion**

Jonathan A. Harris

Partner

Axinn Veltrop & Harkrider LLP
(Hartford, CT)

- Establishing the purpose of the opinion: M&A, licensing agreement, anticipation of litigation, financing
- Determining whether an opinion can be drafted
- Conducting an in-depth claim construction analysis
- Determining what level of analysis needs to be performed based on the client's needs and the information obtained in the search, including the geographic scope of the investigation
- Analyzing the clearance investigation results
- Identifying close patents and independently addressing each claim including claims belonging to the client
- Evaluating the patent's prosecution history to determine whether a claim is invalid or unenforceable including examining the file wrapper and the prior art cited against the patent
- Incorporating the Doctrine of Equivalents into your analysis and employing design-around work to overcome infringement
- Creating a sound legal argument by appreciating which arguments to include and which to leave out
- Anticipating your audience and carefully drafting the opinion for multiple audiences including a jury, CEO/manger, shareholders, third party business partners, judge, scientist, attorney
- Distinguishing the client's product from close patents
- Determining the level of certainty and avoiding conclusory statements
- Identifying the proper case law to include that may post-date issuance of the patent

Drafting Workshop

- Introducing disclosures into the opinion to protect both you and the client
- Utilizing safe harbor to avoid infringement

3:15 **Afternoon Refreshment Break**

3:30 **Assumption of Infringement and the Elements of an Invalidity Opinion**

Scott A. Chambers, Ph. D.

Partner, Chair of Intellectual Property

Patton Boggs LLP
(McLean, VA)

- Determining whether an opinion can be drafted
- Conducting an in-depth claim construction analysis to identify all possible opposing arguments
- Overcoming claims that are determined to be invalid by first construing the claims and analyzing the prior art
- Using a broad interpretation to argue the claim is invalid for failure to distinguish the prior art
- Advantageously incorporating a narrow claim interpretation
- Strategically incorporating evolving standards of obviousness, written description, enablement, novelty, and utility
- Determining when to employ both an invalidity and infringement analysis
- Carefully considering the client's ultimate objective
- Implications of inequitable conduct claims in your opinion
- Considering the audience of the opinion and tailoring the letter accordingly
- Identifying the proper case law to include that may post-date issuance of the patent
- Introducing disclosures into the opinion to protect both you and the client
- Determining what exhibits to include in the opinion

Drafting Workshop

4:45 **Conference Adjourns**



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for the Pharmaceutical and Biotechnology Industries

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- Patent attorneys
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