

July 30 – 31, 2012 | The Union League | Philadelphia, PA

American Conference Institute's 6th National

Tactical and Practical Guide to

Freedom to Operate

Search Analysis, Opinion Writing, and Strategies for Minimizing Risks in the Pharmaceutical, Biotech, and Chemical Industries

Leading patent practitioners and experienced in-house counsel will demystify the complexities of freedom to operate search and analysis and share best practices on how to:

- **Preserve** privilege and confidentiality in freedom to operate opinions
- **License** your way out of trouble
- **Analyze** smart freedom to operate game plans post-America Invents Act
- **Evaluate** the effects of the recent *Mayo v. Prometheus* decision and determine its impact on protecting diagnostic methods
- **Utilize** new procedures like post-grant review to challenge troubling patents
- **Create** a "living" freedom to operate strategy conducted in tandem with the R&D process
- **Tailor** search strategies to the requirements of different products to maximize search effectiveness
- **Overcome** international freedom to operate search challenges
- **Examine** the broadening obviousness standard and its effects on freedom to operate analysis

Network with an outstanding faculty of industry experts including professionals from:

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Cubist Pharmaceuticals
Emergent Biosolutions, Inc.
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Medicis Pharmaceuticals Corporation
Meril Limited
PATH
The Procter and Gamble Company
Pfizer, Inc.

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July 31, 2012:

A The Master Class on Creating and Implementing an Iterative "Living" FTO Strategy: Utilizing FTO to Inform Product Development and Minimize IP Risks

August 1, 2012:

B The Complete Guide to Maintaining Market Exclusivity for Diagnostic Methods Post-*Prometheus*

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Can Your Company Afford to Make the Wrong Freedom to Operate Determination?

Freedom to operate searching and analysis, always a critical component of any patent counsel's profession, is undergoing its biggest shake-up in a generation. Expansion of the obviousness standard, the America Invents Act provisions now requiring a truly global search, and other developments have left patent attorneys and business development professionals perplexed as they try to protect valuable IP in an increasingly competitive global environment. As a result, it is vital that you have the "know-how" to make early, sound, and competent business determinations as to whether you truly have freedom to operate in a given area.

There is one place you can equip yourself with the tools needed to overcome these uncertainties – **American Conference Institute's 6th Tactical and Practical Guide to Freedom to Operate**. This exclusive event will bring you targeted, thoughtful commentary on the mechanics of making sound and competent freedom to operate determinations. ACI has gathered an outstanding faculty of leading in-house counsel and expert attorneys from the biotech, pharmaceutical, and chemical sectors who will share first-hand, practical, and comprehensive best practices on freedom to operate search and analysis. This event will provide attendees with:

- Access to the thought processes and best practices of in-house counsel and executives from biotech, pharmaceutical, and chemical sectors
- Strategic plans of action from leading private practice attorneys specializing in patent prosecution, litigation, and licensing at major law firms
- Key insights on freedom to operate search strategies and the latest legislation and case law impacting analysis
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Further enhance your learning by attending the post-conference **Master Class on Creating and Implementing an Iterative "Living" FTO Strategy: Utilizing FTO to Inform Product Development and Minimize IP Risks** and the **Complete Guide to Maintaining Market Exclusivity for Diagnostic Methods Post-Prometheus**.

You will not find this combination of talent and expertise focusing specifically on freedom to operate anywhere else.

Register today by calling 888.224.2480; by faxing your registration form to 877.927.1563; or register online at www.americanconference.com/fto.

8:15 Registration and Continental Breakfast

9:00 Co-Chairs' Opening Remarks

Judy Jarecki-Black, Ph.D

Head, Intellectual Property
Merial, Ltd. (Duluth, GA)

Anita Varma

Partner
Ropes & Gray, L.L.P. (Boston, MA)

9:15 Strengthen the Value of your Future IP:
Reinventing FTO Procedures in Light of the
Game-Changing Provisions in the America
Invents Act

Scott McBride

Shareholder
McAndrews, Held, & Malloy, Ltd. (Chicago, IL)

Justin Oliver

Partner
Fitzpatrick, Cella, Harper, & Scinto, L.L.P.
(Washington, DC)

- Detailing the relevant changes between the old and new laws that will take effect on March 16, 2013
 - Considering how a patent may be "pinched" by errors in prosecution that impact a patent filed prior to the AIA taking effect by exposing it to the strictures of the new law
 - Incorporating the changes wrought by the AIA into an FTO system to catch patents that have been carelessly prosecuted
- Assessing the AIA's statutory elimination of failure to get an FTO opinion as evidence of willful infringement
 - How might willful infringement still be found in cases where good faith opinions are nevertheless obtained?
 - Investigating whether offering an FTO opinion constitutes a useful defense to a willful infringement charge
- Utilizing the changes in AIA prior art standards strategically
 - Submitting prior art as a 3rd party to force an applicant to make certain admissions to widen your own FTO window
 - Using admissions by applicants to narrow their claims in order to carve out room for a patent on similar art

10:15 Case Law Update: Predicting the Patentability
of Diagnostic Patents Post-*Mayo v. Prometheus*

Suzannah Sundby

Partner
Smith, Gambrell & Russell, L.L.P. (Washington, DC)

- Exploring the state of subject matter patentability post-*Prometheus*
 - Does the Machine-or-Transformation test retain any usefulness?
 - How useful is a "common sense" inquiry in patentability?
- What framework does the Court employ for determining what constitutes a "law of nature"?
- Determining what the decision may do to patent valuation
- Placing the *Prometheus* decision in context: Recent trends regarding patentable subject matter

- Evaluating existing diagnostic patents in light of *Prometheus*
- Divining the outcome of the now-remanded *Myriad* case in light of *Prometheus* and other opinions

10:45 Refreshment Break

11:00 Maximizing FTO Effectiveness by Tailoring Search
Strategies to Different Products' Requirements

Daniel Stelter

Vice President, Associate General Counsel
and Chief Counsel, Intellectual Property
Cardinal Health, Inc. (McGaw Park, IL)

Richard Berman

Partner
Arent Fox, L.L.P. (Washington, DC)

- Setting up standard operating procedures based on the type of search needed
 - Validity searches for a closed set of claims
 - Completing an FTO search for the characteristics of a particular thing that might be expressed in numerous ways
 - Addressing the different ways the same invention might be described in different patents
- Utilizing layers of FTO analysis for products with different infringement exposure
 - Engaging in mid-level searching when there's low infringement risk
 - Possessing higher certainty levels when the product has greater exposure
- How to do a search to confirm a desired non-infringement finding

12:00 Networking Lunch

1:15 Confronting and Overcoming Challenges in
International FTO Searches to Ensure Global
Rights for Commercializing Products

Mary Catherine DiNunzio

Head of Global Patent Alliances
H. Lundbeck, A/S (Copenhagen, Denmark)

Anita Varma

Partner
Ropes & Gray, L.L.P. (Boston, MA)

- Designing an international search strategy
 - Addressing international searching cost concerns
 - Recognizing which jurisdictions will present the most troubling patents
 - Ascertaining the jurisdictions in which a product will be manufactured and sold
 - Balancing the burden of searching in a jurisdiction against the expected benefit of operating in that market
 - Evaluating the importance of a market in which your product might be barred
- Identifying common difficulties in obtaining adequate international searches
 - Understanding how to search in order to avoid domineering claims
 - Avoiding overbroad search terms that produce unacceptable levels of "noise"
- Partnering with foreign counsel in order to conduct an adequate search in that jurisdiction
 - Ensuring that counsel with whom you would partner is sufficiently expert

2:15 **Drafting Informative FTO Opinions: Perspectives from In-House and Outside Counsel**

David Marks

Senior Commercialization Officer
PATH (Washington, DC)

Andrew Paul

Senior Counsel
The Procter & Gamble Company (Cincinnati, OH)

Patricia Carson

Partner
Kaye Scholer, L.L.P. (New York, NY)

- Understanding when in-house opinions are sufficient and outside opinions will be necessary
- Ascertaining the value of written FTO opinions
- Identifying the types of opinions requested and their various roles in FTO analysis
 - Patentability opinions
 - FTO clearance opinions
 - Invalidity opinions
 - Validity opinions
- Determining the role of FTO opinions post-AIA reforms
 - How can lawyers advise clients now that opinions are no longer needed to head off claims of willful infringement?
 - Is it possible for failure to obtain an opinion to still be used as evidence of willful infringement in certain circumstances?
 - Using opinions as an affirmative defense against claims of willful infringement
 - Presenting opinions to investors and shareholders to mollify their concerns

3:30 **Refreshment Break**

3:45 **Combating Troubling FTO Results by Conducting Thorough Claim Construction Analysis**

Claire Laporte

Partner
Foley Hoag, L.L.P. (Boston, MA)

Bryan Diner

Partner
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. (Washington, DC)

- Assessing the breadth of a patent's claims when determining likelihood of validity
 - Recognizing the starting point for analyses of patents found in FTO
 - Addressing the risk of a patent claim being interpreted broadly
 - Establishing whether broad claims entitle patent to the widest possible interpretation
- Utilizing specific arguments to undermine a patent claim's scope
 - Determining when an invention is much narrower than what is being claimed
 - What to do when it is a close question between breadth of claims and the invention being patented
 - Getting a separate invalidity opinion involving prior art when over-broad claims are suspected
- Combining written description and claim construction analysis

4:30 **Demystifying the Current Obviousness Standard and its Implications for FTO**

Thomas Kowalski

Shareholder
Vedder Price, P.C. (New York, NY)

Michael Davitz, M.D.

Partner
Axinn, Veltrop, Harkrider, L.L.P. (New York, NY)

- Exploring the reaffirmation of *KSR* through *In re Kao* (Fed. Cir. 2011)
- Understanding the impact of *KSR* and its progeny on primary compound and composition claims
- Analyzing the state of the law on obvious-type double patenting
- Evaluating the effects the AIA will have on obviousness and FTO
 - Assessing the elimination of the Hiller Doctrine
 - The expansion of what constitutes prior art
 - Addressing the new global reach of prior art and how it will affect FTO analysis
- Examining questions of secret prior art and inherent anticipation
 - Incorporating secret art into art supporting an obviousness rejection
 - Using unpublished applications to support an obviousness rejection
- Identifying the differences between the AIA's new inclusion prior art for obviousness rejection and the standards employed abroad
 - Understanding how the AIA's move to first to file affects obviousness rejections
- Grasping the implications the shift in the obviousness standard will have for FTO opinions
 - Strategies for evoking and responding to an obviousness challenge in concurrence with current law

5:15 **Conference Adjourns to Day 2**

Tuesday, July 31, 2012

8:15 **Continental Breakfast**

8:45 **Co-Chairs' Opening Remarks**

9:00 **Taking Action to Address Potential Roadblocks with Effective FTO Analysis**

Judy Jarecki-Black, Ph.D

Head, Intellectual Property
Merial, Ltd. (Duluth, GA)

Allen Baum

Shareholder and Chair, Chemical Practice Group
Brinks, Hofer, Gilson, & Lione, P.C. (Durham, NC)

- Identifying search results that may include troubling patents
 - Completing an in-house analysis of results
 - Determining whether there are elements in claim that will be practiced by your invention
- Developing a strategy to address patents likely to cause trouble

- Investigating whether results include patents that have a high likelihood of invalidity
- Approaching the patent owner with an anonymous inquiry regarding his or her willingness to license the patent
 - Evaluating the right time to approach a patent holder about licensing
- Adjusting product parameters in order to reduce the risk of infringement
- Preparing to defend a patent for a product coming to market with high infringement risk
- Identifying the relative risk tolerance of a product developer
 - Measuring risk tolerance against the size of the developer
 - How does the product line's expected market impact affect the infringement risk tolerance for that product?
- Determining how to allocate resources in order to address risks

- Engaging in risk assessment when completing FTO in anticipation of acquisition of a company or product line
 - Reviewing FTO opinions and determining whether it is out of date
 - Adopting an adversarial stance
 - Identifying the actions that should be taken when analyzing FTO search results
 - Understanding the extremely high degree of certainty required in FTO analysis for mergers and acquisitions
- Responding to circumstances where an FTO risk has emerged during due diligence for a merger
 - Approaching patent holder for license
 - Attempting to attack patent validity
 - Recognizing the risks and effects of invalidating a patent for a technology
 - Considering doing nothing

10:00 **Clearing the Underbrush: Utilizing New Procedures to Challenge Troubling Patents**

Gillian Fenton

Vice President of Intellectual Property
Emergent Biosolutions, Inc. (Rockville, MD)

Kevin Laurence

Partner
Stoel Rives, L.L.P. (Salt Lake City, UT)

- Understanding the advantages and disadvantages of using alternative procedures to attack patent validity
- Using inter partes review (IPR) to dispute a patent's validity
 - Comprehending the new IPR process
 - Conforming with the time requirements and bars on other procedures to initiate IPR
 - Avoiding the estoppel risks inherent to IPR
- Employing the new post-grant review (PGR) procedure to contest an issued patent
 - Complying with the time-sensitive strictures of post grant review
 - Identifying the grounds on which validity of a patent can be attacked in PGR
 - Recognizing the estoppel risks associated with challenging a patent in PGR

11:00 **Refreshment Break**

11:15 **Satisfying the Stringent FTO Requirements Demanded in Due Diligence for M&A**

Matthew Bodenstein

Intellectual Property Counsel
Medicis Pharmaceuticals Corporation (Phoenix, AZ)

Matthew Zisk

Partner
Skadden, Arps, Slate, Meagher, & Flomm, L.L.P. (New York, NY)

12:00 **Networking Lunch**

1:15 **Privilege and Confidentiality in FTO Opinions: When are they Preserved and When are They Waived?**

Bruce Weintraub

Senior Corporate Counsel, Intellectual Property
Pfizer, Inc. (New York, NY)

Mark FitzGerald, Ph.D

Partner
Nixon Peabody, L.L.P. (Boston, MA)

- Determining which communications subject to a freedom to operate opinion remain confidential
 - Communications with outside counsel
 - Communications with R&D
- Identifying when privilege may be considered to be waived
 - Staying on top of recent case law on the scope of waiver
- Structuring communications and document flow so that privilege and confidentiality are preserved
 - When should the other side be allowed to see an opinion?
 - Communicating with a counter-party so that the roadmap outlined in an opinion is not inadvertently revealed
- Remaining aware of multiple-party privilege and confidentiality issues
 - Claiming privilege in collaborations and joint defense agreements
- Devising real-world, practical solutions for preserving privilege and confidentiality
- Handling jurisdictional differences and non-alignment between local rules and actual practice

2:15 **Conference General Session Concludes**

Post-Conference Workshops

Tuesday, July 31, 2012

3:00 – 6:00 (Registration starts at 2:30)

A The Master Class on Creating and Implementing an Iterative “Living” FTO Strategy: Utilizing FTO to Inform Product Development and Minimize IP Risks

Jennifer Camacho

Shareholder

Greenberg Traurig, P.C. (Boston, MA)

Gillian Fenton

Vice President of Intellectual Property

Emergent Biosolutions, Inc. (Rockville, MD)

Heather Boussios

Intellectual Property Counsel

Emergent Biosolutions, Inc. (Rockville, MD)

With biotech and pharmaceutical product development cycles often lasting years and requiring investment of millions of dollars, freedom to operate search and analysis must be conducted in tandem with the R&D process. Smart legal counsel and product development managers already make efforts to ensure that FTO is done conscientiously to keep them abreast of any changes to the IP environment in which they are operating. Nevertheless, FTO efforts often wind up being piecemeal affairs, failing to ensure that product features maintain both a high certainty of patentability and a low risk of infringement. At this exclusive Master Class, you will hear top patent counsel explain how to craft an iterative FTO strategy utilizing search and analysis techniques that track product development and provide more consistent updates on competing patents, applications, and other prior art. Learn how to assist your product developers by:

- Understanding the necessity of an iterative search process
- Applying a continual and systematic updating FTO process
 - Starting with a routing FTO search
 - Knowing when to retain counsel and not just a search firm
- Developing a continual search string to use in-house or by outside counsel
 - Running a reliable search string regularly
- Striking a balance between needs and the administrative burden of running FTO searches
- Combing through FTO results effectively
 - Reading patents and applications closely enough
- Discussing the possibility of intervention when threatening patents are identified
- Completing a final FTO search de novo prior to product launch

Wednesday, August 1, 2012

9:00 – 12:00 (Registration and Continental Breakfast at 8:30)

B The Complete Guide to Maintaining Market Exclusivity for Diagnostic Methods Post-*Prometheus*

Nick Boivin

Director, Intellectual Property Counsel

Cubist Pharmaceuticals, Inc. (Lexington, MA)

Courtenay Brinckerhoff

Partner

Foley & Lardner, L.L.P. (Washington, DC)

The Supreme Court's landmark unanimous decision in *Mayo v. Prometheus* dealt a body blow to the entire diagnostic industry and has created serious doubts among commentators regarding the future viability of personalized medicine. But while the opinion significantly reduced the scope of patentable subject matter, there remain available numerous avenues to maintain market exclusivity for diagnostic methods. During this session, experienced in-house and private practice counsel will cover the fallout from *Prometheus* in detail, share insights on protecting these valuable methods, and enhance your:

- Understanding what the *Prometheus* opinion does and does not consider to be outside the scope of patentable subject matter
 - Determining what the Supreme Court's approach to patentability really means
 - Applying the patentability standard under §101 to life science technologies
- Analyzing your risk exposure under the new patentability standard in *Prometheus* in a life science organization
 - Identifying and assessing possible risks to existing patents
 - Exploring use of 35 U.S.C. §101 as a possible defense to third party patents
 - Evaluating third party patents as business assets after *Prometheus*
- Deciding what to patent and drafting a patent for a method following *Prometheus*
 - Investigating patenting and publication strategy
- Considering alternative ways to protect a diagnostic method
 - Regulatory approaches
 - Improved technology
 - Marketing and publication strategy
 - Having an alternative business plan in case a diagnostic method cannot be protected

Who You Will Meet

- ✓ In-House Patent Counsel at Pharmaceutical, Biotech, and Chemical Companies
- ✓ Corporate Officers
- ✓ Patent Agents Specializing In:
 - Pharmaceuticals
 - Biotechnology
 - Chemicals
- ✓ Patent Attorneys Who Handle:
 - Prosecution
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 - Due Diligence
 - Licensing

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