American Conference Institute's 9th Annual

Maximizing Pharmaceutical Patent Life Cycles

The *definitive* Hatch-Waxman event for brand names and generics

OCTOBER 15-16, 2008 • The Helmsley Park Lane • New York City

Distinguished Co-Chairs:

George W. Johnston
VP & Chief Patent Counsel
Hoffmann-La Roche

John C. Vassil
Of Counsel
Morgan & Finnegan LLP

Government Keynote Speakers

Saralisa Brau
Attorney, Health Care Services and Products Division
Bureau of Competition, FTC

Elizabeth H. Dickinson (invited)
Associate Chief Counsel for Drugs
Office of Chief Counsel, FDA

Industry Insights From

Apotex
Boehringer Ingleheim Pharmaceuticals
Cephalon
Concentrx BioSciences
Eli Lilly
GlaxoSmithKline
Hoffmann-La Roche
Merck
PDL BioPharma
Pfizer
Procter & Gamble
Ranbaxy Laboratories
Salix Pharmaceuticals
Sandoz
Schering-Plough
Teva North America
VGX Pharmaceuticals

Leading members of the patent bar reveal how to:

- **PIERCE** the complexity of creating patent settlement options
- **GENERATE** viable action points for innovators to add value to the patent portfolio and for generics to penetrate the innovators' strategies
- **EVALUATE** the thundering change for patent life cycles triggered by *Medimmune, In re Seagate, eBay, KSR* and their progeny
- **MASTER** the intricacies of the 180-day generic market exclusivity period
- **UNCOVER** critical information in the Orange Book
- **FACILITATE** a framework concerning non-patent exclusivity

Master Classes for Brand Names and Generics: October 17, 2008

A The Brand Name Master Class: Overpowering the Challenges in Increasing the Pharmaceutical Patent Life Cycle Through Patent Extensions

B Adding Value to Paragraph IV Certifications and Notice Letters

Sponsored By:

KELLEY DRYE

FISH & RICHARDSON
Intellectual Property | Litigation | Corporate

EARN CLE CREDITS

AMERICAN CONFERENCE INSTITUTE

Register Now • 888-224-2480 • AmericanConference.com/lifecycles

By 2011, branded drugs worth $60 billion will lose their patent status.[1] The time is now to adapt your pharmaceutical patent life cycle plan to confront the massive challenges facing the industry.

Branded and generic pharmaceutical companies are in a mission critical phase where every decision has terrific consequences.

What kind of language should the parties include in a settlement agreement to avoid FTC rejection? How can pharma companies prepare a viable covenant not to sue in a post-*Medimmune* world? What actions will set off forfeiture of 180-day generic market exclusivity?

Increasing competition requires innovators to constantly reevaluate strategies for fully realizing a patented drug's value during the life cycle. In turn, generics trigger formidable competition upon patent expiration.

The tasks on both sides of this complex equation are easy to identify, intricate to analyze, and difficult to execute.

FTC enforcement, FDA rulings, and differing court decisions add to the innovators' already extensive demands of competition in the pharmaceutical industry. Pharmaceutical patent counsel at innovators are entrusted with the massive obligation of looking beyond the patent term and mastering these other complex factors in defining, strengthening, and extending a pharmaceutical patent's life cycle.

Generic pharma must incorporate the same factors in measuring their risk, developing a business plan, and mounting a competitive campaign against a patented drug already emboldened with years of exclusivity, name recognition, and success.

Branded and generic pharma companies must continually sharpen, refine, and evolve their patent life cycle strategies in the wake of constant, challenging, and sometimes volatile change – economic, political, and legal.

ACI is proud to present the hallmark event for the pharmaceutical industry – **9th Annual Maximizing Pharmaceutical Patent Life Cycles Conference**. This definitive Hatch-Waxman event provides the crucial information for pharmaceutical patent counsel to cultivate, modify, and enhance a foundation for their life cycle strategies. Industry leaders will guide attendees on analyzing the complex issues, evaluating options, and benchmarking strategies against competitors on either side of the progressively heated branded-generic battle.

A distinguished faculty of leading pharmaceutical patent counsel will break down the complexities of developing, strengthening, and countering life cycle strategies and give critical insights on:

- Assessing the viability of the company's patent life cycle strategy to uncover weaknesses, change tactics, and enhance power
- Competing with innovators in the market place with generic design around drugs
- Defining the FTC's role in pharmaceutical patents to compare the company's life cycle plan against the FTC's potential enforcement actions
- Forecasting the courts' future trends in pharmaceutical patent cases

Attend this conference and learn to navigate your way through the regulatory maze that plays a critical role to your practice areas. Don't delay — register now by calling **1-888-224-2480**, faxing your registration form to **1-877-927-1563**, or registering online at **www.AmericanConference.com/lifecycles**.

[1]Arnst, Catherine, *Big Pharma's Patent Headache*, Business Week, February 6, 2008, citing pharmaceutical consultancy IMS Health

Distinguished Faculty - Featuring an Unprecedented 18 In-House Industry Representatives!

Co-Chairs:

George W. Johnston
Vice President & Chief Patent Counsel
Hoffmann-La Roche

John C. Vassil
Of Counsel
Morgan & Finnegan LLP

Speakers:

Hollie L. Baker
Partner
Wilmer Hale LLP

Richard J. Berman
Partner
Arent Fox LLP

James Bauersmith
Director, Legal Affairs
Teva North America

Mark I. Bowditch
Patent Attorney
Sandoz Inc.

Saralisa Brau
Attorney, Health Care Services
and Products Division, Bureau of Competition
Federal Trade Commission

Brian D. Coggio
Senior Counsel
Fish & Richardson P.C.

Philip Datlow
Senior Associate Director
and Senior Counsel Intellectual Property
Boehringer Ingelheim Pharmaceuticals, Inc.

Michael A. Davitz
Partner
Axinn Veltrop & Harkrider LLP

Jay R. Deshmukh
Senior Vice President, Global IP
Ranbaxy Laboratories, Ltd.

Elizabeth Dickinson (invited)
Associate Chief Counsel for Drugs
Office of Chief Counsel
U.S. Food and Drug Administration

Michael P. Dougherty
Special Counsel
Cadwalader, Wickersham & Taft LLP

Eric Fischer
Senior Counsel
Schering-Plough Corporation

William J. Golden, Jr.
Chair, IP and Technology Litigation
Kelley Drye & Warren LLP

William D. Hare
Legal Director
Concentrx BioSciences, Inc.

Thomas D. Hoffman
Patent Counsel - Consultant
Sandoz Inc.

Duane-David Hough
Principal
Fish & Richardson P.C.

Stu Kim
Former Regulatory Counsel
Cephalon, Inc.

Thomas S. Kim
Senior Director of Intellectual Property
VGX Pharmaceuticals, Inc.

Renee Kosslak, Ph.D.
General Patent Counsel
PDL BioPharma, Inc.

Steven J. Lee, Ph.D.
Partner
Kenyon & Kenyon LLP

James P. Leeds
Associate General Patent Counsel
Eli Lilly and Company

Denise L. Loring
Partner
Ropes & Gray LLP

Steven J. Moore
Partner
Kelley Drye & Warren LLP

Richard S. Parr
Assistant Counsel
Merck & Co., Inc.

Stephana E. Patton, Ph.D.
Senior Attorney, Intellectual Property
and Licensing
Salix Pharmaceuticals, Inc.

Andrew A. Paul
Senior Counsel
Procter & Gamble Company

Ann M. Caviani Pease
Partner
Dechert LLP

Bruce A. Pokras
Senior Corporate Counsel
Pfizer Inc.

Mark Rachlin
Senior Patent Counsel, Litigation
GlaxoSmithKline

Charles J. Raubicheck
Partner
Frommer Lawrence & Haug LLP

Mark E. Waddell
Partner
Loeb & Loeb LLP

Shashank Upadhye
Vice President & Global Head of IP
Apotex, Inc.

ACI would like to thank the following media partners for their support.

Patently patent law blog

ORANGE BOOK BLOG

www.PharmCast.com – Pharmaceutical Internet –

Patent Docs
Biotech & Pharma Patent Law & News Blog

pharmalicensing.com
Open Innovation for the life sciences

PharmaVOICE

CanBiotech
R&D Outsourcing
Capital Sourcing
Competitive Intelligence

patent baristas .com

pharmiweb.com

BENTHAM SCIENCE

piribo

patentCAFE

Pharmaceutical Manufacturing NEWS

Report Buyer

Wednesday, October 15, 2008

8:00 Registration and Continental Breakfast

9:00 Co-Chairs' Opening Remarks

George W. Johnston
Vice President & Chief Patent Counsel
Hoffmann-La Roche (Nutley, NJ)

John C. Vassil
Of Counsel
Morgan & Finnegan LLP (New York, NY)

9:15 Clarifying The Evolving Meaning Of 'Patent Life Cycle' For The Pharmaceutical Business

George W. Johnston
Vice President & Chief Patent Counsel
Hoffmann-La Roche (Nutley, NJ)

John C. Vassil
Of Counsel
Morgan & Finnegan LLP (New York, NY)

- How does the pharma industry view life cycle planning?
  - Where exactly does patent counsel fit into the planning, modifying, and executing of a patent life cycle strategy?
- Why a 'life cycle' plan is a necessity and not a luxury for branded and generic pharma
- Analyzing the original intentions of Hatch-Waxman
  - How have varying interpretations of the Act challenged, surprised, and benefited the pharma industry?
- Allocating the required investment of money, resources, and time to constantly adjust a pharma patent life cycle strategy in the wake of legal, regulatory, and legislative shifts
- Incorporating the legal vulnerability of a patented drug into the life cycle strategy

10:15 Morning Coffee Break

10:30 Constructing, Adjusting, And Executing A Pharmaceutical Patent Life Cycle Management Plan

Steven J. Moore (Moderator)
Partner
Kelley Drye & Warren LLP (Stamford, CT)

James Bauersmith
Director, Legal Affairs
Teva North America (Horsham, PA)

Philip Datlow
Senior Associate Director and Senior Counsel
Intellectual Property
Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT)

Renee Kosslak, Ph.D.
General Patent Counsel
PDL BioPharma, Inc. (Redwood City, CA)

Andrew A. Paul
Senior Counsel
Procter & Gamble Company (Cincinnati, OH)

Branded

- Generating viable action points for branded pharma throughout the patent life cycle to add value to the patent portfolio
  - Assessing the strength of your patent life cycle strategy to uncover weaknesses, change tactics, and enhance power
  - Mitigating against the competitive danger of generics when the patent life cycle terminates
- Evaluating patent filing options and their potential effect on a patent's value
  - When is the optimum time to file a patent application?
  - Considering the option of not filing a patent application
  - Defining the types of patent applications to file
  - What is the risk of publicizing your patent plan to the competition when you file?
    - Classifying the level of competition in the field
- Protecting the company's investment by developing viable strategy to explain patents to judges
  - Guarding against the danger of judges misreading patents
- Ensuring the patents are knowingly filed with supporting information
  - Balancing the need for disclosure in the original filing versus providing data supplements when filing internationally
- Determining the consequences of research uncovering one indication during a development for another indication
  - When should you file the NDA?
  - How will it affect your patent term extension?
  - Do you abandon the patent term extension?
- Ensuring an international patent prosecution strategy is in place

Generic

- Penetrating the branded pharma's strategy in enhancing, extending, and maximizing the patent's life cycle
- Countering branded pharma in the market place with generic design around drugs
  - Deciding which patented drugs may be legally vulnerable
  - Allocating legal risk in challenging a branded pharma patent
- Incorporating the dangers of patent reissues into the pharmaceutical patent life cycle strategy
  - How does a patent reissue affect generic pharma companies?
  - Ensuring that double patenting or misinformation does not exist
- Considering the impact of counterclaims filed by the generic companies on the brand name patent strategy
  - How are the courts dealing with the generic companies' counterclaims?
  - Assessing the probability of a court dismissing the counterclaim outright, dismissing on summary judgment, or letting the case go to trial
- How and when to pursue an 'authorized generic' status

12:00 Networking Luncheon

1:15 View from the FTC

Saralisa Brau
Attorney, Health Care Services and Products Division
Bureau of Competition, Federal Trade Commission
(Washington, D.C.)

How does the FTC see its role in the world of pharmaceutical patents? How will the FTC's actions, policies, and history affect your pharmaceutical patent life cycle strategies? What do you need to know from the FTC to craft a viable, flexible, and successful patent life cycle plan?

Get the inside view on the FTC's vigorous enforcement policy against anticompetitive business practices in the pharmaceutical industry and benchmark your strategies against the FTC's potential enforcement actions.

2:15 Navigating The Complexity Of Structuring Patent Settlement Options Between Brand Name And Generic Pharmaceutical Companies

Jay R. Deshmukh
Senior Vice President, Global IP
Ranbaxy Laboratories, Ltd. (Princeton, NJ)

Stephana E. Patton, Ph.D.
Senior Attorney, Intellectual Property and Licensing
Salix Pharmaceuticals, Inc. (Palo Alto, CA)

Shashank Upadhye
Vice President & Global Head of IP
Apotex, Inc. (Toronto, Ontario)

Mark E. Waddell
Partner
Loeb & Loeb LLP (New York, NY)

- Exploring settlement options from the brand name and generic pharma perspectives with sample contract language
  - What types of settlements receive approval?
  - Creating, developing, and implementing strategies pending the FTC's completion of review
  - Assessing the legal restrictions on pharmaceutical patent settlements
- Uncovering the potential for antitrust violations in a patent settlement
- Classifying the precise consideration in exchange for payment by the innovator
  - Assessing the unresolved problem of 'reverse payments' in pharmaceutical patent settlements
  - Clarifying the role of an authorized generic and 'reverse payments' in settlement agreements
- Deconstructing the FTC's recent view on pharmaceutical patent settlements to forecast probability of FTC rejecting a proposed settlement
  - Defining the FTC's role, power, and limitations as a gatekeeper for pharma patent settlements
    - When is the FTC required to review settlements in patent litigation?
  - Factoring the FTC's stake in pharmaceutical patent settlements in concrete terms
  - Piercing the meaning of *FTC v. Cephalon, Inc.* and its effect on settlements between branded and generic pharma
  - Examining settlements submitted to the FTC to select appropriate language for your settlement
  - Determining the FTC's rationale for expanding Hatch-Waxman to prohibit certain settlements
- Understanding the implications of *Tamoxifen* and its sister cases on future settlement options in pharmaceutical patent disputes
- Anticipating potential shifts in the FTC view because of a new presidential administration
- Analyzing key bills and legislation to evaluate their potential consequences on patent settlements
- Defining the authority, scope, and limitations of the International Trade Commission
  - Navigating the complexities of integrating potential ramifications of ITC decisions into life cycle strategizing
  - How does ITC impact Paragraph IV litigation?

3:30 Refreshment Break

3:45 Eye On The Bench: Identifying Judicial Trends In Pharmaceutical Patent Cases

Denise L. Loring (Moderator)
Partner
Ropes & Gray LLP (New York, NY)

Hollie L. Baker
Partner
Wilmer Hale LLP (Boston, MA)

Michael A. Davitz
Partner
Axinn Veltrop & Harkrider LLP (New York, NY)

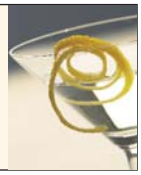
Duane-David Hough
Principal
Fish & Richardson P.C. (New York, NY)

- The Four Horsemen of the Apocalypse: Delineating the thundering change for patent life cycles triggered by *Medimmune, In re Seagate, eBay, KSR* and their progeny
- Deconstructing the effect, value, and challenges of the covenant not to sue in a post-*MedImmune* world
  - What types of covenants have the courts embraced?
  - What language will trigger rejections by the courts?
  - Factoring the risk in pursuing a covenant not to sue
- Defining the influence of *In re Seagate* on the concept of 'reckless disregard'
  - How does *In re Seagate* change the need to get a patent opinion?
  - Scrutinizing the courts' opinions on the issue of willful infringement in pharma patent cases to project their bearing on present cases
- Factoring the *eBay* decision concerning 'compulsory licensing' into your life cycle analysis
  - Forming a strategy to argue for or defend against an injunction
  - Examining the different rationales behind preliminary and permanent injunctions
  - Investigating the decreasing ability to get a preliminary injunction in the initial phase of a patent trial
- Adjusting your pharmaceutical patent life cycle strategy to consider the impact of *KSR* on the obviousness standard
  - Does *KSR* eliminate secondary patent protection?
- Analyzing court opinions on inequitable conduct to further examine the risks in pharma patent challenges
- Determining the latest judicial trends and their consequent impact on a patent life cycle strategy
  - Forecasting the courts' future trends in pharma patent cases
  - What is the Roberts Court's view of patent cases?

5:25 Conference Adjourns to Day Two

5:30 Cocktail Reception

Hosted by: Fish & Richardson — Intellectual Property | Litigation | Corporate



Thursday, October 16, 2008

7:45 Continental Breakfast

8:30 Co-Chairs' Opening Remarks

8:45 Mastering The Intricacies Of The 180-Day Generic Market Exclusivity

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

Mark I. Bowditch
Patent Counsel, **Sandoz Inc.** (Princeton, NJ)

William D. Hare
Legal Director
Concentrx BioSciences, Inc. (Princeton, NJ)

Thomas D. Hoffman
Patent Counsel - Consultant
Sandoz Inc. (East Hanover, NJ)

- Identifying the qualifying criteria for generic market exclusivity
- Classifying the triggers that start and remove 180-day exclusivity
- Exploiting the 180-day exclusivity as part of the generic's strategy
  - Developing a post-exclusivity strategy
- Determining how a 180-day exclusivity period can be transferred to another ANDA applicant
- Examining the ANDA applicant's power to determine who is 'first-to-file'
- Gauging the results of the interplay between the 30-month stay and 180-day exclusivity
- Revealing the circumstances that activate forfeiture of the 180-day exclusivity
- Relinquishing the 180-day exclusivity period
  - When can you relinquish exclusivity?

10:00 Morning Coffee Break

10:15 Penetrating The Complexities Of Non-Patent/FDA Exclusivities

Stu Kim
Former Regulatory Counsel, Cephalon, Inc. (Frazer, PA)

Charles J. Raubicheck
Partner
Frommer Lawrence & Haug LLP (New York, NY)

- Gauging the impact of developments affecting non-patent exclusivities
- Facilitating a strategy to analyze, adjust, and implement a life cycle strategy concerning non-patent exclusivity
  - NDA exclusivity
  - Pediatric exclusivity
  - Orphan drug exclusivity
  - Citizens' Petitions
- Mastering the complexities, challenges, and consequences of follow-on biologics legislation in a pharmaceutical patent life cycle plan

11:15 Plotting A Course Into Safe Harbor For Branded Pharma

Brian D. Coggio
Senior Counsel
Fish & Richardson P.C. (New York, NY)

Eric Fischer
Senior Counsel, Schering-Plough Corporation (Kenilworth, NJ)

Thomas S. Kim
Senior Director of Intellectual Property
VGX Pharmaceuticals, Inc. (Blue Bell, PA)

- Ensuring that safe harbor applies to the pharma patent situation in question
  - Measuring options when safe harbor does not apply
    - What actions are viable when an injunction stops sales of the drugs?
  - Determining when safe harbor applies to the optimization of more than one compound
  - What are the strategies for negating safe harbor?
- Gauging the import of the Federal Circuit's *Merck v. Integra* decision on remand
- Clarifying the difference between unprotected basic research and protected R&D
  - Identifying the types of pre-clinical studies that fall under safe harbor protection
- Extrapolating the impact of *Proveris v. Innovasystems* on safe harbor strategies involving research tool patents
- Anticipating damages for infringing actions
  - Lost profits
  - Reasonably expected royalties
  - Defining reach-through royalties and the scenarios under which courts award them

12:15 Networking Luncheon

1:30 View from the FDA

Elizabeth Dickinson (invited)
Associate Chief Counsel for Drugs, Office of Chief Counsel
U.S. Food and Drug Administration (Rockville, MD)

With tremendous power over the listing and de-listing of patents in the Orange Book comes terrific responsibility in ensuring the public good. A complete understanding of the FDA's policies, actions, and authority in the pharmaceutical patent world is critical to success in maximizing pharmaceutical patent life cycles. Hear from a veteran FDA attorney who will share invaluable insights concerning the FDA's role in Orange Book listings and other vital matters related to Hatch-Waxman.

2:30 Slicing Through The Complex Spectrum Of Declaratory Judgment Actions In Pharmaceutical Patent Cases

Michael P. Dougherty
Special Counsel
Cadwalader, Wickersham & Taft LLP (New York, NY)

Steven J. Lee, Ph.D.
Partner, Kenyon & Kenyon LLP (New York, NY)

James P. Leeds
Associate General Patent Counsel
Eli Lilly and Company (Indianapolis, IN)

- Gauging the potential effects of DJ actions on a pharmaceutical life cycle plan
  - Allocating financial resources, personnel, and time to address potential DJ actions as part of the life cycle strategy
- Ascertaining the generic pharmaceutical strategies in bringing a case against a brand name pharmaceutical company
- Appraising the benefit and cost of suing a second generic company that wants to bust the brand name's patent
  - Determining whether to bring the case against other generics in one district
  - Classifying whether the generic companies successfully achieved a design around to evaluate the brand name company's chance of success
- Incorporating the analysis of landmark cases into the life cycle strategy
- Assessing the implications of a covenant not to sue on removing a court's jurisdiction
  - How strong is the covenant not to sue?
- Defining the case or controversy once a court's jurisdiction is removed
  - Who has standing to sue?

3:45 Refreshment Break

4:00 Factoring The Role, Challenges, And Impact Of Orange Book Listings And De-Listings In Patent Portfolio Management

Ann M. Caviani Pease, Ph.D.
Partner, Dechert LLP (Silicon Valley, CA)

Bruce A. Pokras
Senior Corporate Counsel, Pfizer Inc. (New York, NY)

- Penetrating the massive wall of information in the Orange Book to uncover the critical information for the life cycle strategy
- Unlocking the new challenges posed by the Orange Book
- Drafting patent applications in consideration of Orange Book listings and subsequent ANDA litigation
- Probing the effects of de-listing a patent on 180-day exclusivity
- Evaluating the benefits and disadvantages of listing, de-listing, and holding in reserve
- Assessing the import of antitrust considerations in listing
- Scrutinizing the competition to reveal its strategies for dealing with Orange Book concerns and measure your strategies accordingly

5:00 Conference Ends

Who You Will Meet

Patent attorneys (in-house and outside counsel) who represent:

- brand name pharmaceutical companies
- generic pharmaceutical companies
- biopharmaceutical companies

FRIDAY, OCTOBER 17, 2008

A BRANDED MASTER CLASS
9:00 –12:30 *(Registration begins at 8:30)*

Overpowering The Challenges In Increasing The Pharmaceutical Patent Life Cycle Through Patent Extensions

Denise L. Loring
Partner
Ropes & Gray LLP (New York, NY)

Richard S. Parr
Assistant Counsel
Merck & Co., Inc. (Rahway, NJ)

Mark Rachlin
Senior Patent Counsel – Litigation
GlaxoSmithKline (King of Prussia, PA)

The heat is on branded pharma. Their patented drugs are headed for a cooling off period thanks to imminent expiration of patent rights. And the generics are ready, willing, and able to exploit the lucrative opportunities created when patented drugs lose their exclusivity because of patent expiration.

Regulatory review, marketing challenges, and Hatch-Waxman cases combine with pending patent legislation to create massive challenges for branded pharma. This critical session will drill deeply into these intricate problems to reveal the proven solutions, strategies, and tactics for extending the patent's life.

The panelists will guide you through the maze of obtaining patent extensions, tailoring a strategy to fit your particular scenario, and provide the necessary tools to achieve your patent life cycle objectives.

- Defining the benchmarks in the drug's development
- Determining eligibility for patent term extension
- Mastering the regulatory review period determinations
- Calculating the patent term restoration
  - Researching, preparing, and submitting an application for patent term restoration
- Adjusting the patent term because of delays, glitches, and obstacles in prosecuting patents at the USPTO
- Calculating the effect of patent term extensions outside the U.S.
- Obtaining extensions through FDA Pediatric Exclusivity and Orphan Drug Exclusivity
  - Identifying the criteria for eligibility
  - Gauging the impact of regulatory, legislative, and case law development
- Measuring the import of second-generation patents
  - Incorporating approaches by branded pharma in obtaining second-generation patents
  - Enforcing second-generation patents
- Incorporating non-US filing strategies into the life cycle plan for pharmaceutical patents
  - How does a non-US jurisdiction affect market share, compulsory licensing, and resulting protection?
  - What mechanisms are available for protecting a drug if that patent is not granted?
  - Defining a viable SPC strategy

B GENERIC MASTER CLASS
9:00 – 12:30 *(Registration begins at 8:30)*

Adding Value To Paragraph IV Certifications And Notice Letters

Mark I. Bowditch
Patent Attorney, Sandoz Inc. (Princeton, NJ)

William D. Hare
Legal Director, Concentrx Biosciences, Inc. (Princeton, NJ)

ANDA applicants can greatly enhance their power by filing a Paragraph IV Certification. However, with great power comes great responsibility. If an ANDA applicant errs in its certification, it can face a willful infringement charge. To withstand attacks from patentees seeking attorneys' fees or other relief, ANDA applicants must exercise extreme care in preparing its Paragraph IV Certification, notice letter, and related legal opinions.

This critical session will provide pharmaceutical patent counsel with the tools required to successfully fulfill Paragraph IV Certification requirements and will also cover the impact of the FDA Orange Book Rule and the MMA.

- Defining the four types of patent certifications
- Clarifying the obligations of the ANDA applicant
- Probing the impact of the declaratory judgment and counterclaim provisions
- Applying the 30-month stay effectively
- Incorporating the benefits, costs, and impact of the 180-day exclusivity
- When will forfeiture of exclusivity be triggered?
- Forecasting consequences of inadequate notice letters
- When should disclosure of technical information about the ANDA and proposed generic product occur?
- Identifying exceptional cases where attorney's fees may be awarded
- Illuminating the procedural and substantive requirements of Paragraph IV letters

Global Sponsorship Opportunities

ACI, along with our sister organization based in London, **C5** Conferences, works closely with sponsors in order to create the perfect business development solution catered exclusively to the needs of any practice group, business line or corporation. With over 350 conferences in the United States, Europe, the Commonwealth of Independent States (CIS) and China, **ACI/C5** Conferences provide a diverse portfolio of first-class events tailored to the senior level executive spanning multiple industries and geographies.

For more information about this program or our global portfolio of events, please contact:

Wendy Tyler
Group Leader & Business Development Executive
American Conference Institute

Tel: 212-352-3220 x242 • Fax: 212-220-4281
w.tyler@AmericanConference.com

Continuing Legal Education Credits

CLE CREDITS

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as **nontransitional** for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board in the amount of 15.5 hours. An additional 4.0 credit hours will apply to workshop participation.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California in the amount of 12.75 hours. An additional 3.5 credit hours will apply to workshop participation.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and **ACI** will make every effort to process your request.

Leading members of the patent bar will steer you through the intricate maze of Hatch-Waxman challenges, cases, and strategies. Learn from the experts at:

American Conference Institute's 9th Annual

Maximizing Pharmaceutical Patent Life Cycles

The *definitive* Hatch-Waxman event for brand names and generics

OCTOBER 15-16, 2008 • The Helmsley Park Lane • New York City

Master Classes:
Friday, October 17, 2008

A. Overpowering The Challenges In Increasing The Pharmaceutical Patent Life Cycle Through Patent Extensions

B. Adding Value To Paragraph IV Certifications And Notice Letters

REGISTRATION FORM

PRIORITY SERVICE CODE:
641L09.WEB

ATTENTION MAILROOM: If undeliverable to addressee, please forward to:
PATENT COUNSEL, INTELLECTUAL PROPERTY COUNSEL, IP COUNSEL

CONFERENCE CODE: 641L09-NYC

❑ YES! Please register the following delegate for the
9TH ANNUAL MAXIMIZING PHARMACEUTICAL PATENT LIFE CYCLES

NAME _____ POSITION _____

APPROVING MANAGER _____ POSITION _____

ORGANIZATION _____

ADDRESS _____

CITY _____ STATE _____ ZIP CODE _____

TELEPHONE _____ FAX _____

EMAIL _____ TYPE OF BUSINESS _____

FEE PER DELEGATE	Register & Pay by Aug 13, 2008	Register & Pay by Sept 17, 2008	Register after Sept 17, 2008
❑ Conference Only	$1895	$1995	$2195
❑ Conference & Master Class ❑ A or ❑ B	$2495	$2595	$2795
❑ I would like to add __ copies of the conference materials on CD–ROM to my order – $299 each			
❑ I cannot attend but would like information regarding conference publications			
❑ Please send me information about related conferences			

PAYMENT
Please charge my ❑ VISA ❑ MasterCard ❑ AMEX ❑ Please invoice me

Number _____ Exp. Date _____

Signature _____
(for credit card authorization and opt-in marketing)

❑ I have enclosed my check for $_____ made payable to
American Conference Institute (T.I.N.—98-0116207)

Can be recycled

5 Easy Ways to Register

MAIL **American Conference Institute**
41 West 25th Street
New York, NY 10010

PHONE 888–224–2480

FAX 877–927–1563

ONLINE
AmericanConference.com/lifecycles

EMAIL
CustomerService
@AmericanConference.com

Hotel Information

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a preferential rate. Please contact the hotel directly and mention the "ACI – Pharma Patent Life Cycles" conference to receive this rate:

VENUE: The Helmsley Park Lane
ADDRESS: 36 Central Park South, New York, NY 10019
RESERVATIONS: (212) 521-6640

Registration Fee

The fee includes the conference, all program materials, continental breakfasts, lunches, refreshments and complimentary membership of the ACI Alumni program

Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add–ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

Cancellation and Refund Policy

You must notify us by email at least 48 hrs in advance if you wish to send a substitute participant. Delegates may not "share" a pass between multiple attendees without prior authorization. If you are unable to find a substitute, please notify **American Conference Institute (ACI)** in writing up to 10 days prior to the conference date and a credit voucher valid for 1 year will be issued to you for the full amount paid, redeemable against any other **ACI** conference. If you prefer, you may request a refund of fees paid less a 25% service charge. No credits or refunds will be given for cancellations received after 10 days prior to the conference date. **ACI reserves the right to cancel any conference it deems necessary or remove/restrict access to the ACI Alumni program and will not be responsible for airfare, hotel or other costs incurred by registrants. No liability is assumed by ACI for changes in program date, content, speakers, venue or arising from the use or unavailability of the ACI Alumni program**

Incorrect Mailing Information

If you would like us to change any of your details please fax the label on this brochure to our Database Administrator at 1–877–927–1563, or email data@AmericanConference.com.

CONFERENCE PUBLICATIONS

To reserve your copy or to receive a catalog of ACI titles go to **www.aciresources.com** or call **1-888-224-2480.**

SPECIAL DISCOUNT

We offer special pricing for groups and government employees. Please email or call for details.
Promotional Discounts May Not Be Combined. **ACI** offers financial scholarships for government employees, judges, law students, non–profit entities and others. For more information, please email or call customer care.