Maximizing Pharmaceutical Patent Life Cycles

The definitive Hatch-Waxman event for brand names and generics

October 7-8, 2009 | The Helmsley Park Lane Hotel | New York, New York

Industry Insights from:

Hoffmann-LaRoche  AIPLA
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Sandoz, Inc.

Preeminent patent counsel and advisors to leading brand name and generic pharmaceutical companies, as well as representatives from key government agencies and industry associations will provide insights on the latest Hatch-Waxman challenges and help you:

» SEE how a new global legal paradigm for pharmaceutical patent life cycles is being shaped by forces in the US and abroad

» UNDERSTAND the interplay between Patent Reform and Follow-On Biologics legislation and how these pending laws will dramatically alter pharmaceutical patent life cycle strategies

» DETERMINE when secondary patents should be pursued in light of KSR’s progeny and Kubin

» LEARN to properly calculate PTA via Wyeth v. Dudas and avoid A and B period overlap dilemmas

» EXAMINE how Bilski may affect pharmaceutical method claims

» INCORPORATE precedents from leading Paragraph IV cases involving declaratory judgments, inequitable conduct and double patenting into your life cycle strategies

» ASSESS the impact of skinny labeling and carve-outs on Orange Book listing determinations

» DECIPHER FDA’s new interpretations of pre- and post- MMA exclusivity and make sense of new rulings on forfeiture determinations

» NAVIGATE the new boundaries of the safe harbor as set by Proveris

» EXPLORE pharmaceutical patent life cycle strategies for emerging markets

Antitrust Spotlight

Hear from the:

• FTC’s Bureau of Competition’s Health Care Division on Promoting Competition in the Pharmaceutical Industry

• EC’s DG Competition’s Pharmaceuticals Task Force on The Pharmaceutical Sector Inquiry

October 6, 2009: Pre-Conference Workshop

A. Hatch-Waxman Boot Camp — A Primer on IP Basics and Regulatory Fundamentals

October 9, 2009: Master Classes for Brand Names and Generics

B. Brand Name Master Class — New Strategies for Obtaining Pharmaceutical Patent Extensions in a Post-KSR World

C. Generic Master Class — Updated Drafting Guidelines for Paragraph IV Certifications and Notice Letters

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Co-Chairs:

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Vice President & Chief Patent Counsel  
Hoffmann-La Roche (Nutley, NJ)

John C. Vassil  
Patent Attorney (formerly Of Counsel to Morgan & Finnegan LLP) (New York)

Speakers:

Edward John Allera  
Shareholder, Buchanan Ingersoll & Rooney PC (Washington, DC)

Stephen R. Auten  
Vice President, Intellectual Property  
Sandoz, Inc. (Princeton, NJ)

Aaron F. Barkoff, Ph.D.  
Partner, McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

Margaret “Peg” M. Buck, MLS, JD  
Patent Attorney  
Lundbeck Research USA, Inc (Paramus, NJ)

Patricia Carson  
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Brian D. Coggio  
Senior Principal  
Fish & Richardson, P.C. (New York)

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

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

Guy Donatiello  
Vice President, Intellectual Property  
Endo Pharmaceuticals (Chadds Ford, PA)

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

Lila Feisee  
Managing Director for Intellectual Property  
Biotechnology Industry Organization (Washington DC)

Bob Filippone, Ph.D.  
Vice President, Federal Affairs  
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Of Counsel, Womble Carlyle Sandridge & Rice, PLLC (Research Triangle Park, NC)

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Patent Attorney (New Lisbon, NY)

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Director  
Sterne, Kessler, Goldstein & Fox P.L.L.C (Washington, DC)

Markus H. Meier  
Assistant Director of the Health Care Division, Bureau of Competition  
Federal Trade Commission (Washington, DC)

Monica Alfaro Murcia  
European Commission  
DG Competition, Pharmaceuticals  
Task Force (Brussels, Belgium)

Brian P. Murphy  
Partner & Deputy Practice Group Leader, Patent Litigation Group  
Morgan Lewis & Bockius LLP (New York)

Bert Oosting  
Partner, Lovells (Amsterdam, NE)

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

Tedd W. Van Buskirk  
Partner, K&L Gates LLP (New York)

Martin A. Voet  
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity (former Senior Vice President, Chief IP Counsel, Allergan)
The Pharmaceutical Patent Endgame is in the midst of a radical metamorphoses being shaped by forces here and abroad.

A new pharmaceutical patent paradigm is emerging.

Be part of the one event which for nearly a decade has shaped industry policies and patent strategies for both brand name and generic drug companies.

The rules of the pharmaceutical patent endgame are being re-written through several pending and potentially iconoclastic measures in Congress, groundbreaking decisions in the courts and the aggressive actions of various agencies including the PTO, FDA and FTC – all of which may drastically alter the Hatch-Waxman rubric and related patent life cycle strategies. This collective activity is causing drug makers – for both brand name and generic pharmaceutical companies – added anxiety as they frantically re-work current strategies to accommodate the potential changes of this emerging patent paradigm and prepare for patent losses which will exceed $40 billion by 2012 alone. Moreover, with the proposed introduction of follow-on biologics and the findings of the EC pharmaceutical sector inquiry, the industry must now think globally – in terms of both product portfolio and international reach.

Now is the time to come to the one and only event that has consistently allowed brand name and generic drug makers to benchmark their companies’ current Hatch-Waxman strategies and tactics against competitors in both camps.

This 10th American Conference Institute event on Maximizing Pharmaceutical Patent Life Cycles will bring you the thoughtful and targeted commentary and in-depth analysis that you have come to expect from this industry leading conference. This year’s conference will help you prepare for the sweeping changes currently underway by providing you with:

- Focused panels on the pending Follow-On Biologics and Patent Reform legislation that will allow you to assess how both legislative proposals will impact pharmaceutical patent life cycle management
- Access to key officials from the FTC’s Bureau of Competition’s Health Care Division and the EC’s DG Competition’s Pharmaceuticals Task Force who will provide you with direct insights into the logic of these agencies on some of the most pressing antitrust matters currently affecting the industry
- An in-depth review of new FDA determinations regarding exclusivity, forfeitures, patent listing and delistings and strategies for incorporating these guidelines into your initial life cycle management plan
- Analyses of key cases that have affected patent life cycle strategies and tips for using these rulings to your advantage

Also, this year, in response to your requests, we have added the following specialized class:

- Hatch-Waxman Boot Camp – A Primer on IP Basics and Regulatory Fundamentals

This Boot Camp, together with our in-depth Master Classes for brand names and generics on:

- New Strategies for Obtaining Pharmaceutical Patent Extensions in a Post-KSR World
- Updated Drafting Guidelines for Paragraph IV Certifications and Notice Letters

will offer hands-on practical advice on core Hatch-Waxman principles as well as some of the most critical day–to–day concerns for both sides of the pharmaceutical industry.

Nearly 2,000 pharmaceutical patent professionals – for both brand names and generics – have made this conference their source of information for the legal issues surrounding life cycle management for nearly the last ten years. This updated event will bring you the latest legal strategies and tactics for successful maneuvering in the evolving patent endgame.

With all that’s at stake, you cannot afford to miss this conference.

Don’t delay – register now by calling 888-224-2480, faxing your registration form to 877-927-1563 or registering on-line at www.americanconference.com/Lifecycles.

1 AP, April 2008
Agenda-at-a-glance

Workshop A
Tuesday, October 6, 2009

7:30  Registration and Continental Breakfast
8:15  Co-Chairs’ Opening Remarks
8:30  The Endgame Re-Invented: Preparing for an Emerging Pharmaceutical Patent Paradigm
9:30  Patent Reform and the Pharmaceutical Industry: Anticipating and Adapting to Change
10:45  Morning Coffee Break
11:00  Follow-On Biologics: Understanding the Role of Patents in Healthcare Reform and Related Consequences for Life Cycle Strategies
12:15  Networking Luncheon
1:30  Wyeth v. Dudas: Revisiting Patent Term Adjustment Calculations
2:00  Overcoming Obviousness: An Analysis of the Post-KSR Treatment of Primary and Secondary Patents and Finding New Ways to Extend Patent Life
3:15  Continental Breakfast
4:15  In Re Bilski: Exploring Its Implications for Pharmaceutical Method Claims
5:15  Conference Ends

Workshop B
Friday, October 9, 2009

7:30  Registration and Continental Breakfast
8:45  Co-Chairs’ Remarks and Recap of Day One
9:00  FTC Keynote: Promoting Competition in the Pharmaceutical Industry
10:00  EC Keynote: The European Commission Pharmaceutical Sector Inquiry - Main Findings and Policy Recommendations
11:00  Morning Coffee Break
11:15  Rethinking Life Cycle Strategies for Established and Emerging International Markets: Focus on Europe and Asia
12:15  Networking Luncheon
1:30  A New Look at Orange Book Listings, Delistings and Related Challenges
2:30  FDA Keynote: Update on FDA Activities Relative to Pharmaceutical Patent Life Cycles
3:30  Exclusivity: Modes, Methods and New Interpretations
4:30  Re-Exploring the Safe Harbor: Learning to Navigate the Potential Limits and Boundaries of Provers
5:15  Conference Ends

Workshop C
Friday, October 9, 2009

7:30  Continental Breakfast
8:30  Registration and Continental Breakfast
9:00  Workshop Begins
12:30  Workshop Ends

Who You Will Meet:

Patent Attorneys (in-house and law firm), Business Executives and Policy Analysts for:
- Brand name pharmaceutical companies
- Generic pharmaceutical companies
- Biopharmaceutical companies

Expand Your Network

The complimentary ACI Alumni Program is designed to provide returning delegates with unique networking and learning opportunities beyond the scope of their conference experience.

Highlights include:
- Instantly access thousands of free presentations, PowerPoint’s and other event resources - Online!
- Make direct contact with fellow conference alumni
- Post a question or look for answers in our Industry Forums
- Join a live Industry Chat in progress
- Earn Forum points towards free conferences & workshops

Expand your Network at www.my-aci.com
October 6, 2009: Workshop A
Hatch-Waxman Boot Camp —
A Primer on IP Basics and Regulatory Fundamentals

This hands-on workshop will provide you with an in-depth review of Hatch-Waxman and other IP and regulatory basics relative to small molecules and biologics, as well as critical insights into commercialization and the pre-approval process for these products. The workshop leaders will lay the necessary foundation for you to comprehend thoroughly the dynamics of patent life cycles as they apply to pharmaceutical and biopharmaceutical products and business development plans. They also will help you fully appreciate the complexities of the Hatch-Waxman challenges presented during the main conference.

9:30 Registration and Continental Breakfast

10:15 Understanding Pre-Commercialization Concerns Relative to Small Molecules and Biologics

Edward John Allera
Shareholder, Buchanan Ingersoll & Rooney PC
(Washington, DC)

The current pre-commercialization landscape:
• Reviewing the types of products that pharmaceutical, biotechnology and biopharmaceutical companies are seeking to develop now
• Identifying impediments – through patent or regulatory restraints – which prevent these companies from pursuing the development of the desired product
  - FDA hurdles that may not clear even if all patent and other IP hurdles are met
• Techniques for analyzing the value the product adds to the company’s portfolio, and methods for proving value

Regulatory considerations:
• Understanding how the introduction of follow-on biologics will change the commercial landscape
• Examining the role of the Center for Medicare and Medicaid Services (CMS) in the approval process
  - the connection between CMS approval and commercial viability via government payor systems and rebates
• Assessing the competition and analyzing potential therapeutic interchangeability considerations

11:00 Exploring the Link between the FDA Approval Process and the Patenting of Drugs and Biologics

David Fox
Partner, Hogan & Hartson LLP
(Washington, DC)

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): definition, contents and regulatory overview
• IND (Investigational New Drug Application) aka “IND”
  - how does it differ from an NDA?
• Accelerated approvals
  - defining eligibility criteria for accelerated approval and priority reviews
  - what portions of approval submissions might FDA release and when?
• Using advisory committees in the approval process

Biologics
• How does the approval process for a biologic differ from that of a drug?
• BLA (Biological Licensing Application): application and filing
  - how does a biologic differ from a drug?
  - which products require BLAs instead of NDAs?
• Why is it a “license,” rather than an “approved application”?

12:00 Networking Luncheon

1:00 Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More

Tedd W. Van Buskirk
Partner, K&L Gates LLP
(New York)

Martin A. Voet
Consultant in Intellectual Property and Pharmaceutical Product Exclusivity, (Mission Viejo, CA/ Amsterdam, NE)
(former Senior Vice President, Chief IP Counsel, Allergan)

IP Protection for Drugs and Biologics
• Analyzing the patenting process for drugs and biologics
• Seeking patent protection during the pre-approval process
• IP and regulatory redress for time lost during the pre-approval process
• 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
• Exploring the differences between a NDA and an ANDA (Abbreviated New Drug Application)
• ANDA: what does it require?
• Paragraph IV Certifications and Notice Letters
• Bioequivalence defined
• The Orange Book: what is it and why is it Orange?
  - listings and de-listings
• The patent endgame (Hatch-Waxman Overview)
  - overview of Hatch-Waxman and reforms under MMA
  - the role of Orange Book under Hatch-Waxman vis-à-vis the MMA
  - exclusivity (180 day); 30-month stay
  - patent extensions
  - the safe harbor
• FD&C 505b2 (an alternate pathway to an ANDA)

Biologics
• Identifying biologics that fall within the purview of Hatch-Waxman
  - why are other biologics outside of the Hatch-Waxman rubric?
• The rationale for safety and efficacy concerns surrounding second generation biologics
• Examining the FDA’s current position on an abbreviated application process for “generic” biologics
• Status of proposed legislation

Trademark Issues
• Identifying the PTO and FDA clearances necessary for trade name/trademark approval on your product

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2:15 Patent and Non-Patent Exclusivity

Michael A. Siem  
Of Counsel, Fish & Richardson, P.C.  
(New York)

- Patent exclusivity v. non-patent, i.e., regulatory exclusivity
- The concept of market exclusivity under the Hatch-Waxman Act
- Understanding which drug products are eligible for regulatory exclusivity  
  - small molecules v. biologics
- The different modes and methods of regulatory exclusivity (non-patent)  
  - NCE (new chemical entity): 5 years marketing exclusivity/5 years data exclusivity
  - indication (new indication or use): 3 years marketing exclusivity
  - NDF (new dosage formulation)  
  - ODE (orphan drug exclusivity); PED (pediatric exclusivity)
- FD&C 505b2 (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 means of exclusivity

3:00 Afternoon Refreshment Break

3:15 Bioequivalence and the “Same Active Ingredient” vis-à-vis Patentability

Kurt Karst  
Attorney, Hyman, Phelps & McNamara, P.C.  
(Washington, DC)

- Defining bioequivalence in drugs and biologics  
  - drugs v. biologics
  - generic drug “sameness” issues
- What an ANDA-filer must demonstrate for bioequivalence?  
  - bioequivalence and dosage form - oral tablet/capsule, injection, nasal sprays, topical, nasal sprays
  - inactive ingredient changes
- Therapeutic equivalence - what is it?  
  - Orange Book nomenclature
- How does bioequivalence relate to patents?  
  - patenting of bioequivalence characteristics - extended-release drug products
  - litigation involving FDA bioequivalence requirements


Kevin W. McCabe  
Director, Sterne, Kessler, Goldstein & Fox P.L.L.C  
(Washington, DC)

- Exploring the viability of extension applications to:  
  - basic and combination compounds; secondary patents
- 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

5:00 Workshop Ends

For the last decade, ACI has been at the forefront of bringing legal counsel and business executives for both brand name and generic pharmaceutical companies the finest programs to address the industry’s most pressing Hatch-Waxman challenges. ACI’s Hatch-Waxman series provides thoughtful analysis and practical solutions which will help you decipher the complexities of life cycle management, comprehend related policy considerations, and devise strategies and perfect trial advocacy skills for Paragraph IV litigation.

Maximizing Pharmaceutical Patent Life Cycles  
October 7-8, 2009  
(New York)

Paragraph IV on Trial  
November 11-12, 2009  
(New York)

Paragraph IV  
April 28-29, 2010  
(New York)
• Understanding how the legislation and the PTO Rules will collectively impact patent life cycle management and patent portfolio management in the pharmaceutical industry

Patent Reform Legislation
• Overview of the Patent Reform Act of 2009 and analysis of key provisions
• Importance of the Senate Judiciary Committee compromise in light of the failure of previous bills
• The current position of PhRMA and BIO
• Understanding how patent reform in the U.S. ties in with international IP developments
• Exploring the interplay between Patent Reform and proposed FOB legislation
• Strategies for the pharmaceutical industry for transitioning from a first to invent to a first to file system
- steps to ensure that your company is compliant with the new system

The PTO Rules
• A review of the restrictions on continuation practice, continued examination and claims filing as posed by the Rules
• Procedure v. substance - exploring the PTO’s Rule Making authority and the implications of Tafas v. Doll for:
  - continuations
  - the limits on claims filing as proposed by the Rules
  - ESDs (Examination Support Documents)
• Exploring whether the claims limits proposed by the Rules and ESDs open the door for inequitable conduct
• The final legislation: how will it address PTO Rule Making and the conundrums presented by Doll?

10:45 Morning Coffee Break

11:00 Follow–On Biologics: Understanding the Role of Patents in Health Care Reform and Related Consequences for Life Cycle Strategies

Stephen R. Auten
Vice President, Intellectual Property, Sandoz, Inc.
(Princeton, NJ)

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

Gregory J. Glover, MD, JD
Principal, Pharmaceutical Law Group PC
(Washington, DC)

David Korn
Assistant General Counsel, PhRMA
(Washington, DC)

Moderator:
Steven E. Irizarry
Senior Vice President, Capitol Hill Consulting Group
(Washington, DC)

- Exploring how patent legislation has been used as a vehicle to advance the health care reform agenda
- lessons learned from the Hatch-Waxman amendments of the MMA
- Assessing whether a Hatch-Waxman model is feasible for biological products
- Understanding the extent to which FOBs may alter patent life cycle management in the pharmaceutical industry
Focus on Decisions Impacting Patent Life Cycle Strategies

1:30 Wyeth v. Dudas: Revisiting Patent Term Adjustment Calculations

Patricia Carson
Partner, Kaye Scholer LLP (New York)

- Significance of the District Court for the District of Columbia’s ruling that the PTO had misinterpreted 35 U.S.C. §154 (b) (2) (A) and its implications for patent term adjustment
- Reviewing the patent term guarantee provisions of 35 U.S.C. §154 (b) (1)
  - A periods/ A delays 35 U.S.C. §154 (b) (1)(A)
  - B periods/ B delays 35 U.S.C. §154 (b) (1)(B)
- Dilemmas associated with the overlap of A and B provisions
- Preventing “double- dipping” in patent term adjustment
- PTO’s position on “double- dipping” v. District Court’s position in Wyeth
- The PTO’s appeal to CAFC
- Review of numerous lawsuits against PTO for miscalculation of patent term adjustment since Wyeth
- Planning life cycle strategies in view of Wyeth and the PTO appeal

2:00 Overcoming Obviousness: An Analysis of the Post-KSR Treatment of Primary and Secondary Patents and Finding New Ways to Extend Patent Life

Amy H. Fix
Of Counsel, Womble Carlyle Sandridge & Rice, PLLC (Research Triangle Park, NC)

- Understanding how method claims are currently used in pharmaceutical patent life cycle strategies
- Analysis of Bilski and its implications of method claims generally
- Comparison of Bilski’s foot note 26 concerning the patentability of certain medical diagnostic claims to the dissent’s findings in Labcorp v. Metabolite regarding processes
- What are the implications of Bilski on method claims for the pharmaceutical industry as based upon the inference that can be drawn from this comparison
- Understanding how Bilski may impact life cycle management strategies in the future

3:15 KSR in retrospect: analyzing the major post-KSR obviousness decisions in the District Courts and Federal Circuit

- Sanofi v. Apotex (Plavix) (Fed. Cir. 2008)
- Aventis v. Lupin (Ramipril) (Fed. Cir. 2007)
- Forest Labs v. Ivax (Celexa ) (Fed. Cir. 2007)
- Ortho McNeil v. Mylan Labs (Topamax) (Fed. Cir. 2008)
- Takeda v. Alpharma (Actos) (Fed. Cir. 2008)
- Incorporating the post-KSR obviousness precedent into pharmaceutical life cycle and patent portfolio management strategies
- How have these decisions impacted the patentability of secondary patents:
  - Enantiomers; isomers
  - New formulations; new indications
  - Crystallization; salts
- Determining when and how secondary patents should be pursued/challenged in light of this jurisprudence
- What judicial trends can be discerned from these decisions?
- In re Kubin: what can the pharmaceutical industry learn from this case and its implications for biotechnology inventions?

3:30 In Re Bilski: Exploring Its Implications for Pharmaceutical Method Claims

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

- Understanding how method claims are currently used in pharmaceutical patent life cycle strategies
- Analysis of Bilski and its implications of method claims generally
- Comparison of Bilski’s foot note 26 concerning the patentability of certain medical diagnostic claims to the dissent’s findings in Labcorp v. Metabolite regarding processes
- What are the implications of Bilski on method claims for the pharmaceutical industry as based upon the inference that can be drawn from this comparison
- Understanding how Bilski may impact life cycle management strategies in the future

4:15 Eye on the Federal Circuit and District Courts: Life Cycle Lessons Derived from Paragraph IV Litigation

Edward T. Lentz
Patent Attorney (New Lisbon, NY)

- Understanding how method claims are currently used in pharmaceutical patent life cycle strategies
- Analysis of Bilski and its implications of method claims generally
- Comparison of Bilski’s foot note 26 concerning the patentability of certain medical diagnostic claims to the dissent’s findings in Labcorp v. Metabolite regarding processes
- What are the implications of Bilski on method claims for the pharmaceutical industry as based upon the inference that can be drawn from this comparison
- Understanding how Bilski may impact life cycle management strategies in the future

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Promoting Competition in the Pharmaceutical Industry

Markus H. Meier
Assistant Director of the Health Care Division
Bureau of Competition, Federal Trade Commission
(Washington, DC)

The FTC continues to vigorously use its enforcement and policy tools to prevent anticompetitive business practices in the pharmaceutical industry. Markus Meier will discuss and explore the FTC’s agenda in this area, including:

- Rule 11 sanctions
- Double patenting
- Inequitable conduct
- Preliminary/permanent injunctions
- Covenants not to sue
- Declaration actions
- GlaxoSmithKline v. Mutual Pharm., No. 08-549 (E.D. Pa. 2008)
- Impax Labs. v. Medicis Pharm., No. C-08-0253 MMC (N.D. Cal. 2008)
- Janssen v. Teva (Fed. Cir. 2008)
- Caraco Pharm. Labs. v. Forest Labs., No. 2007-1404 (Fed. Cir. 2008)
- Eisai Co. v. Teva Pharms., USA, No. 05-5727 (D.N.J. 2008)
- Altana Pharma and Wyeth v. Teva, No. 2008-1039 (Fed. Cir. 2009)
- Eisai Co. v. Teva Pharmas. USA, No. 05-5727 (D.N.J. 2008)
- Inequitable conduct
- Aventis Pharma v. Amphastar and Teva, No. 2007-1280 (Fed. Cir. 2008)
- Pfizer v. Teva (Fed. Cir. 2008)
- Rule 11 sanctions
- Celgene and Novartis v. KV Pharm., No. 07-4819 (D.N.J. 2008)

The FTC’s current stance on “pay-for-delay” settlements
- Enforcement of MMA reporting requirements
- Possible legislation regarding settlements
- Analysis of the competitive implications of other pharmaceutical lifecycle management strategies
- Findings from the FTC’s authorized generics study

The European Commission Pharmaceutical Sector Inquiry - Main Findings and Policy Recommendations

Monica Alfaro Murcia
European Commission, DG Competition Pharmaceuticals Task Force (Brussels, Belgium)

In January 2008, the European Commission conducted a series of pre-dawn raids on several global pharmaceutical companies as part of a competition inquiry to determine whether industry practices curtailed innovation and generic product entry. Last November, the Commission released a preliminary report on its findings from this inquiry and determined that “there is evidence that originator companies have engaged in practices with the objective of delaying or blocking market entry of competing medicines.” The Commission is slated to release its final report in the Spring/Summer of 2009. Monica Alfaro Murcia will discuss the latest developments relative to the sector inquiry and subsequent recommendations.

Rethinking Life Cycle Strategies for Established and Emerging International Markets: Focus on Europe and Asia

Bert Oosting
Partner
Lovells (Amsterdam, NE)

- Developing a global patent life cycle management plan that responds to changes in Europe and emerging markets in Asia which impact intellectual property protection
- Factoring new compulsory licensing concerns relative to foreign markets into your global patent strategies - revisiting TRIPS Article 31
- Contemplating changes to European patent practice in relation to the findings of the EC pharma sector inquiry
- Understanding how fee changes in the European Patent Office will impact global patent life cycle strategies
- Assessing the economics of filing multiple claims in the EU in view of increased costs
- Examining the Indian patent system and its treatment of pharmaceutical patents
- Lessons learned from the Novartis Gleevec litigation relative to life cycle management strategies in India
- Understanding the significance of China’s current treatment of U.S. and European pharmaceutical patents and its impact on life cycle management
2:30 FDA Keynote

FDA Update on FDA Activities Relative to Pharmaceutical Patent Life Cycles

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

The FDA’s jurisdiction over the Orange Book and patents which can be listed within it (as demonstrated by the QI Act’s treatment of “old antibiotics”), its decision-making powers concerning the consequences of delisting patents, as well as its recent determinations regarding exclusivity forfeitures illustrate the agency’s critical role in the patent endgame. Additionally, under FDAAA, the agency has also exercised new powers relative to pediatric exclusivity and associated REMS requirements. This session will cover the present state of the FDA’s authority in Orange Book listings and other Hatch-Waxman related matters.

3:30 Exclusivity: Modes, Methods and New Interpretations

Thomas D. Hoffman
Patent Counsel – Consultant
Sandoz Inc. (Princeton, NJ)

Michael S. Labson
Partner
Covington & Burling LLP (Washington, DC)

180-Day Exclusivity

• Understanding 180-day generic market exclusivity
  - what are the qualifying criteria for exclusivity?
• Deciphering the FDA’s new interpretation of pre- and post-MMA 180 day exclusivity
  - what are the implications of this interpretation for products having ANDAs filed prior to the enactment of the MMA?
• How can an ANDA applicant really determine who is “first-to-file” and win 180-day exclusivity?

• Identifying triggers for the running of the 180-day exclusivity period
• Circumstances that may trigger the loss of 180-day exclusivity
• Exploring the interplay between the 30-month stay and 180-day exclusivity
  - applicability of the 30 month stay to so-called old antibiotics under QI Act
• Forfeiture provisions: identifying circumstances under which exclusivity is forfeited
• When can the 180-day exclusivity period be transferred to another ANDA applicant?
• Evaluating when the 180-day exclusivity period can be relinquished, and exploring the consequences
• Defining “shared exclusivity”

Non-Patent/FDA Exclusivities

• Overview and analysis of non-patent exclusivities:
  - data exclusivity
  - orphan drug exclusivity
  - pediatric exclusivity vis-à-vis FDAAA
  - query: what happens if a patent is found invalid before pediatric exclusivity can attach?
B. Brand Name Master Class

New Strategies for Obtaining Pharmaceutical Patent Extensions in a Post-KSR World

9:00 – 12:30 (Registration begins at 8:30)
(Continental Breakfast will be served)

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

The effective term of a patent covering a marketed product can be less than the full 20 years if the product is not brought to market by the patent's issue date. This situation is of special interest for pharmaceutical products, where the regulatory review required for market approval can take many months or even years. The post-KSR standard of obviousness coupled with pending patent legislation and the PTO Rules have made choosing a mode of patent extension tailored to fit your pharmaceutical product a particularly urgent matter.

This hands-on session will provide you with practical advice, as well as tips and techniques for how to extend your patent. The session leaders will take you through the intricacies of the four major ways of obtaining extensions: (1) under 35 U.S.C. § 156 and 37 CFR 1.710 – 1.791, (2) under 35 U.S.C. § 271(e) and 37 CFR 1.792, (3) under 35 U.S.C. § 259 and 37 CFR 1.791, and (4) under 35 U.S.C. § 311 and 37 CFR 1.791.

   - 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”
   - Definitions for “drug product” and “regulatory review period”

2. The preparation and submission of a patent term restoration application

3. Patent term extensions outside the U.S.

4. Patent term adjustment due to delays in prosecution before the USPTO and strategies for:
   - Diligence in prosecution by the patent applicant
   - Calculating the adjustment period via Wyeth

5. Extensions obtained through FDA Pediatric Exclusivity and Orphan Drug Exclusivity:
   - Criteria for eligibility
   - Opportunities and pitfalls
   - Latest regulatory and legal developments
   - FDAAA

6. 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
   - effect of post-KSR obviousness rulings on their validity

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October 6, 2009: Pre-Conference Workshop

A. Hatch-Waxman Boot Camp — A Primer on IP Basics and Regulatory Fundamentals

B. Brand Name Class — New Strategies for Obtaining Pharmaceutical Patent Extensions in a Post-KSR World

C. Generic Master Class — Updated Drafting Guidelines for Paragraph IV Certifications and Notice Letters

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