PHARMACEUTICAL AND BIOTECHNOLOGY PATENT LIFE CYCLES AND PORTFOLIO STRATEGIES

The definitive biopharmaceutical patent prosecution strategies conference which addresses novel IP controversies in a post-Hatch-Waxman and BPCIA world

DoubleTree Suites by Hilton Hotel New York City – Times Square | February 26 – 27, 2014 | New York, NY

Industry Insights from:

AIPLA
BIO
PhRMA
Alexion Pharmaceuticals, Inc.
Boehringer Ingelheim
Bristol-Myers Squibb
Eli Lilly and Company
Genomic Health Inc.
Merck
Novartis Vaccines & Diagnostics, Inc.
Pfizer Inc.
Targacept, Inc.

Key Agency Spotlight

Hear from the:

→ FTC on The Actavis Fallout and Other New Antitrust Hot Buttons Impacting Patent Life Cycle Strategies in the Biopharmaceutical Industry
  - Christine L. White, Staff Attorney
  - Federal Trade Commission
  - Northeast Regional Office

→ PTO on:
  - AIA implementation and Its Impact on Pharmaceutical and Biotechnology Patents
  - Janet Gongola (Invited)
  - Associate Commissioner for Patent Examination Policy United States Patent & Trademark Office
  - Patent Term Adjustment and Patent Term Restoration
  - Mary C. Till (Invited)
  - Legal Advisor

Preeminent patent counsel and advisors to leading brand name and generic pharmaceutical companies, biotechnology companies, and biopharmaceutical companies, as well as representatives from key government agencies and industry associations will provide you with insights on the latest legal IP challenges impacting small and large molecule drugs and help you:

• APPLY second generation small molecule patent portfolio management strategies to large molecule patents
• UNDERSTAND how safe harbor and 272 (e)(1) controversies under Classen and Momenta are impacting pharmaceutical and biotechnology patent portfolio and life cycle management
• ASSESS the future of innovation within the confines new Supreme Court jurisprudence concerning 101 patentability and its implications for diagnostics and other life sciences-related patented inventions
• EXPLORE new exclusivity concerns over combination products and related Orange Book listing controversies
• DECIPHER the implications of the Watson/Activis on long term life cycle planning strategies
• WEIGH the pros and cons of BLA filings vs. biosimilars filings
• APPRECIATE how the dichotomy in the Federal Courts and PTO in obvious determinations is influencing patenting strategies for pharmaceutical and biotechnology inventions
• EXAMINE the relationship between inducement / divided infringement theories and methods of treatment claims in pharmaceutical and biotechnology patents
• DEVISE tactics to develop, protect, and enhance antibodies and related technologies
• COMPREHEND how new PTO proceedings such as PGR and IPR are influencing prosecution strategies for large and small molecules
• ANALYZE the PTO's new proposed Rules of Professional Conduct

February 25, 2014 – Interactive Pre-Conference Training and Strategy Sessions:

A. “First Inventor to File” Master Class: Successful Strategies for Pharmaceutical, Biopharmaceutical, and Biotechnology Patent Practitioners

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Distinguished Faculty

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(New York, NY)

(Formerly Past President of the American Intellectual Property Law Association (AIPLA))

WHO YOU WILL MEET:

Patent Attorneys (in-house and law firm), Business Executives and Policy Analysts for:

- Brand Name and Generic Pharmaceutical Companies
- Biopharmaceutical Companies
- Biotechnology Companies
American Conference Institute is Pleased to Present:

Pharmaceutical and Biotechnology Patent Life Cycles and Portfolio Strategies

For over a decade, American Conference Institute’s (ACI) Maximizing Pharmaceutical Patent Life Cycles and Biotech Patents conferences have brought you up-to-the-minute legal, regulatory, and policy information concerning small and large molecule drug products. In re-examining these events, and through listening to you, our valued delegates, we have determined that just as the pharmaceutical and biotechnology industries have evolved and are now on converging paths that these conferences should also undergo a similar metamorphosis. In deference to the legacy of these iconic events and your revered opinion, ACI proudly presents this new program on Pharmaceutical and Biotechnology Patent Life Cycles and Portfolio Strategies.

This conference will give you a comprehensive and thorough picture of how small and large molecule products—as well as diagnostics—operate and influence the future of secondary patents. The program will offer practical solutions and in-depth instruction for those who are influencing the future of secondary patents and obvious-type double patenting.

- **Focused panels on some of the most pressing IP dilemmas facing manufacturers of both small and large molecules, including: safe harbor conundrums in light Classen and Momenta; new concerns in obviousness determinations as a result of the dichotomy between the District Courts and PTO decisions in these matters; inducement and divided infringement and related carve-out controversies relative to method of use patents; and the impact of new PTO proceedings, including PGR and IPR**

- **Tailored sessions bringing you the latest information biologic-centered IP controversies, including those presently impacting BLAs, biosimilars and antibodies**

- **In-depth discussions on Hatch-Waxman and Orange Book concerns relative to small molecules, including new exclusivity dilemmas for combination products, and the latest fall-out from Watson/Activis**

- **An in-house briefing on the future of medical diagnostics IP in the wake of Myriad and Prometheus and how these decisions may ultimately impact small and large molecules**

- **A comprehensive analysis of the USPTO’s Proposed New Rules of Professional Conduct**

We are also delighted to provide you with Master Class and Boot Camp workshops that will enhance your conference experience and provide you with in-depth knowledge and essential strategies in key competencies that are essential to life sciences patenting:

- **“First Inventor to File” Master Class: Successful Strategies for Pharmaceutical, Biopharmaceutical, and Biotechnology Patent Practitioners** will help you master filing strategies under the new “first to invent” system to help ensure patent issuance for your pharmaceutical, biopharmaceutical, and biotechnology invention both here and abroad; and

- **PTA- PTE Boot Camp: Basic Training in the Essentials of Patent Term Adjustment and Patent Term Restoration for Patent Lawyers Serving the Pharmaceutical, Biopharmaceutical, and Biotechnology Industries** will offer practical solutions and in-depth instruction for everything from eligibility requirements to calculation to the application and reconsideration processes and the interplay of PTA and PTE.

This event will bring you the latest legal IP strategies and tactics for successful maneuvering in the evolving pharmaceutical, biotechnology and diagnostics landscape.

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/BioPharmaLifeCycles.
On March 16, 2013, the United States under the auspices of the America Invents Act went from a “first to invent” to a “first to file” patent system. As a result, patent filing strategies for U.S. patents underwent and are continuing to undergo a metamorphosis. The phrase “file early and file often” has taken on new meaning and created new challenges from which the pharmaceutical, biopharmaceutical, and biotechnology industries are not immune. To some this transition from “first to file” to “first to invent”, simply put U.S. patent filing strategies on par with international filing strategies. However, new behaviors precipitated by this transition such as increased filings of provisional applications may leave new filings vulnerable to defeat in both the U.S and in foreign jurisdictions if not done properly.

ACI has designed this workshop to help you master filing strategies under the new “first to file” system to help ensure patent issuance for your pharmaceutical, biopharmaceutical, and biotechnology invention both here and abroad.

Points of discussion will include:

- Provisional application vs. patent application filing: evaluating the pros and cons of each
- Exploring PTO rejections rational for inadequate showings of enablement and written description relative to patent application filings under the new system
  - devising tactics to avoid such findings by the examiners
- Strategies for first priority filings
  - when is the best time to submit the first filing
- Mastering the fine art of filing provisional applications in the biopharma space
  - understanding how proper use of provisional filings can be used as a means to secure first priority filing date
  - determining the scope and extent of claims in the first provisional relative to subsequent provisionals and application conversion
  - weighing the risk of the inclusion of speculative claim in first provisional despite inclusion of more supportive claims in subsequent provisional filings
  - evaluating rejection possibilities associated with each provisional and subsequent conversion if claims are not fully drawn
- Other options and considerations
  - cost
  - filing fewer applications with certainty as opposed to more filings on purely speculative grounds
  - abandonment
  - risks and consequences of abandoning filings relative to filings made by other applicants
- Strategies for simultaneous filings in the U.S. and abroad relative to PCT and Patent Prosecution Highway
- Risk evaluation for foreign filings relative to U.S. applicants
  - question of novelty
  - question of inventive step
- Making freedom to operate determinations in the new “first inventor to file system”
  - 18 month publication window

Each day of patent life equals millions of dollars in profits. A loss of even one day can have substantial impact on a company’s profit margin.

Recent court decisions and the introduction of an abbreviated pathway for biosimilars have made knowing the “ins and outs” of PTE and PTA a critical competency for every patent practitioner servicing the pharmaceutical, biopharmaceutical and biotechnology industries.

ACI has designed this intensive half-day workshop to help you master the skills you need to face your greatest PTA and PTE challenges head on. A faculty of PTA and PTE experts...
will offer practical solutions and in-depth instruction for everything from eligibility requirements to calculation to the application and reconsideration processes and the interplay of these mechanisms.

**Points of discussion will include:**

- Overview of Patent Term Adjustment (PTA) and Patent Term Extension (PTE)
  - statutory authorities
  - * Patent Act
  - * Hatch-Waxman Act
- Understanding the unique role of PTA and PTA in the longevity of patent life cycles in the life sciences industries
- PTA vs. PTE
  - seeking redress for PTO delays
  - seeking redress for FDA delays
- Which point of patent life does each of these devices extend?
  - full scope of patent vs. full scope of patent life of patent product

**PTA**

- Review of 35 U.S.C. 154(b) and 37 C.F.R. 1.702 – 1.705
- Comprehending the criteria for PTA eligibility
- Reconciling discrepancies in certain PTA and PTO Rules
- Seeking PTA
  - starting point and the Notice of Allowance
  - addressing dispute with PTO’s initial PTA calculation
  - request for Reconsideration/ Application for Correction
  - when can PTA be corrected after the issuance of the patent
- PTO delays vs. applicant delays
- A-Delays: what are they and when are they granted?
  - understanding the PTO’s 14 – 4 – 4 clock
    * 14 months: first action response time
    * 4 months: response/appeal
    * 4 months: patent issuance
  - identifying the point in time when A delays accumulate?
- B-Delays: what are they and what is their criteria for issuance?
  - triggers: PTO 3 year patent issuance deadline
    * starting point for B-Delay accumulation
    * how are B-Delays measured?
- C-Delays: how are they different for A and B-Delays
  - triggering events:
    * interferences
  * secrecy orders
  * notices of appeal
  - when are they granted?
  - how are they calculated?
- Identifying events which stop the 3 year B-Delay clock and their relation to C-Delays
- Other clock stoppers
  - RCE- Request for Continued Examination
  - * Exelixis v. Rea
  - * Bristol-Meyers Squibb Co. v. Kappos
  - * Novartis AG v. Kappos
- Analyzing and solving A and B Delay overlap dilemmas
  - Wyeth v. Dudas
  - Japan Tobacco

**PTE**

- Overview of PTE
  - 35 USC 156
  - 37 C.F.R. 1.710 – 1.791
- Identifying important benchmarks in a drug’s development and patent timelines relative to seeking PTE
  - what is the patent term restored and to what does it apply?
    * defining “drug product” under PTE provisions of Hatch-Waxman Act
    * salts
    * esters
    * enantiomers
  - regulatory review period determinations
    * testing phase
    * review phase
- Understanding why PTE provisions in the Hatch-Waxman Act extend to products outside the scope of Hatch-Waxman, i.e., biologics and certain medical devices
  - the importance of PTE in a biosimilars scenario
  - exploring PTE applicability relative to:
    * antibiotics
    * animal drugs
    * food/color additives
    * combination products
- Reviewing eligibility requirements/prerequisites for patent term extension
- Calculating the patent term restored
  - FDA/PTO interplay
- Criteria and eligibility for interim extensions
- The PTE application
  - strategies for preparation and submission

* Luncheon will be served at 12:15 PM for delegates who are attending both workshops.*
The America Invents Act is now fully implemented. This Act, the most sweeping legislation of its kind reinvented the U.S. Patent System and brought this country on par with the rest of the world in moving from a “first to invent” to “first inventor to file” system. However, there have been many challenges in this implementation and growing pains continue. The pharmaceutical and biotechnology industries have not been immune from this. In this session, our PTO speaker will address the challenges, complexities, and conundrums—as well opportunities that this new system poses for the biopharmaceutical industries and its patent life cycle and portfolio management strategies.

10:30 MORNING COFFEE BREAK

10:45 SECOND LIFE MOLECULE PATENT PLANNING STRATEGIES AND TACTICS: WHAT LARGE MOLECULES CAN LEARN FROM SMALL MOLECULES IN PATENT LIFE CYCLE MANAGEMENT

Thomas Hoxie
Founder
Hoxie & Associates LLC
(Millburn, NJ)

Shashank Upadhye
Partner
Seyfarth Shaw LLP
(Chicago, IL)
(Formerly Vice President — Global Intellectual Property, Apotex, Inc.)

Timothy X. Witkowski, M.S., J.D.
Executive Director & Executive Counsel
Intellectual Property
Boehringer Ingelheim
(Ridgefield, CT)

• To what extent can lessons learned from small molecule patent life cycle extension strategies be applied to large molecules?
  - exploring life cycle strategies in the small molecule world for second life/generation molecules
  - examining how this strategy differs from patent life cycle strategies under the Hatch-Waxman schematic
  - understanding how these second generation small molecule drugs differ from “me too” drugs

• Application of second generation small molecule strategies in portfolio management that are applicable to large molecule portfolio planning
  - how to generate a second life molecule which is better and more efficient than the original product
  - development of biobetters in the large molecule space in contrast to biosimilars
  - development of second generation small molecules as opposed generic drugs
  - understanding the role of Hatch Waxman in the life cycle planning of small molecules and what the large molecule world can glean about biosimilars through the Hatch-Waxman rubric
  - competitive drivers
    * small molecule world: brand vs. generic
    * large molecule world: brand vs. brand
PROMETHEUS AND MYRIAD: QUESTIONS OF
NATURAL LAW AND 101 PATENTABILITY AND THEIR
IMPLICATIONS FOR LIFE SCIENCES INNOVATION
AND THE FUTURE OF PERSONALIZED MEDICINE

Carol L. Francis  
Partner  
Bozicevic, Field & Francis LLP  
(San Francisco, CA)

Ken Goldman  
Global Head, Diagnostics Patents  
Novartis Vaccines & Diagnostics, Inc.  
(Emeryville, CA)

David Hoffman  
Patent Counsel  
Genomic Health Inc  
(Redwood City, CA)

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

Moderator:

Jennifer L. Fox  
Counsel  
Brinks, Gilson and Lione  
(Durham, NC)

- Understanding the Supreme Court's analysis of section 101 patentability relative to its holdings in *Prometheus* and *Myriad*
  - reasoning behind “law of nature” determinations in both cases
  - 102 and 103 implications
- Exploring the implications of this new jurisprudence to the future of diagnostic patents
  - companion diagnostics
    * impact on patent value of companion small molecule drugs
- Applying *Myriad's* holding that DNA is not patentable to questions of 101 patentability for:
  - cDNA
  - RNA and gene expression
  - gene therapies
  - gene isolation
- Rethinking claims drafting strategies for diagnostic method claims in light of these Supreme Court decisions
  - learning to draft diagnostic method claims so that "the claimed processes will have transformed … unpatentable natural laws into patent-eligible applications of those laws"
  - broad claims vs. narrow claims
  - machine transformation test
    * incorporation of active step in to process
    * avoidance of mental step
  - addressing conundrums on divided infringement and inducement relative to such claims
    * question of therapeutic inventive step
    * *Akamai*
  - applying the USPTO's preliminary guidance on nucleic acid-related technology in aftermath of *Myriad* to prosecution strategies for these technologies
- Exploring the use of trade secrets as an alternative to IP protection for diagnostics
- Predictions for the CAFC's application of *Prometheus* and *Myriad*
- Implications of the Court's rulings on the future of personalized medicine and related provisions under PPACA

1:00  NETWORKING LUNCHEON

2:15  CIRCUMVENTING THE TEMPEST WHICH HAS ENTERED THE SAFE HARBOUR: IP AND R&D STRATEGIES FOR PHARMACEUTICAL AND BIOTECHNOLOGY PATENTS IN THE WAKE OF NEW 271(e)(1) CONTROVERSIES

Paul G. Alloway, Ph.D.  
Senior Director and Patent Counsel  
Alexion Pharmaceuticals, Inc.  
(Cheshire, CT)

Amy H. Fix  
Senior Director of Legal Affairs  
Intellectual Property and Patent Counsel  
Targacept, Inc.  
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Lead R&D and Patent Counsel  
(Madison, NJ)

David E. Korn  
Vice President, IP and Law  
Pharmaceutical Research and Manufacturers of America (PhRMA)  
(Washington, DC)

Moderator:

Jeffrey I. D. Lewis  
Partner  
Patterson Belknap Webb & Tyler LLP  
(New York, NY)  
(*Immediate Past President of the American Intellectual Property Law Association (AIPLA*))

- Understanding the implications of *Classen v. Biogen* (Fed. Cir. 2011) and *Momenta v. Amphastar* (Fed. Cir. 2012) for pharmaceutical and biotechnology patent portfolio and life cycle management relative to the boundaries of 271(e)(1)
  - impact on Roche Bolar
  - significance of the Supreme Court's denial of cert in *Momenta*
- Deciphering how the Federal Circuit's conflicting opinions in these cases will impact R&D as well as patent filings relative small and large molecules
  - brand name and generic small molecule perspectives vis-a-vis Hatch-Waxman
  - biotechnology concerns
  - implications for diagnostic and companion diagnostic patents
- Determining Safe Harbor exceptions under *Roche Bolar, Classen, and Momenta*
  - when and to what activities does the safe harbor exception apply?
    * pre-market vs. post-market activity
    * infringing vs. non-infringing activity
    * “development and submission information under a Federal law” vs. “information that may be routinely reported to the FDA, long after marketing approval has been obtained”
- Exploring Judge Radar's contention in the *Momenta* dissent that the majority's “interpretation of 271(e)(1) would essentially render manufacturing method patents worthless

3:30  AFTERNOON REFRESHMENT BREAK
Biosimilars Update

- Anticipating when and if additional guidance documents on biosimilars will be released by FDA
  - what can we glean from current guidance with respect to the practicality and cost of a biosimilars pathway
- Status of interchangeability and pharmacist authority for automatic substitution at state and federal levels
- Understanding how question of interchangeability may be a non-starter as innovator biological products change from time to time
- Lessons to be learned from Europe with respect to biosimilars

Biosimilar vs. BLA

- Evaluating the risk of filing an application for a biosimilar in view of regulatory uncertainty
- Risk benefit analysis of BLA filing vs. biosimilars filing
  - cost
  - studies
  - exclusivities
  - market appeal of new product vs. something similar
  - market access and formulary placements


As per the MMA, the FTC is required to continue to review Hatch-Waxman settlements and also may continue to challenge reverse payment settlement agreements – including those filed prior to the Actavis decision. Most, recently, the FTC challenged the legality under Actavis of a Hatch-Waxman settlement providing for an authorized generic. It is now anyone’s guess as to how far the FTC will go. Indeed, there is speculation that the FTC may look to other avenues in these matters such as REMS in wake of Actavis’ undefined victory.

In this session, Christine White will address the impact of Actavis on biopharmaceutical patent portfolio planning and life cycle strategies.
• Bristol-Myers Squibb v. Teva Pharms., No. 10-805-CJB (D. Del.)
  - structural obviousness
  - findings of invalidity after trial
• Otsuka v. Sandoz (Abilify) (Fed. Cir. 2012)
  - obviousness analysis for lead compounds
  * obviousness vs. obviousness-type double patenting
  * reaffirmation of the clear and convincing standard
  - “a poster child for impermissible hindsight reasoning”
• Deciphering the impact of Otsuka and KSR's progeny on:
  - primary compound and composition claims
  - methods and compositions
  * Pozen Inc. v. Par Pharmaceutical, Inc (Fed. Cir. 2012)
  - impact on secondary patents
• Re-visiting questions of inherency and its relation to obviousness
  - determining when a new use for an old composition is not obvious and therefore patentable
  - In re Montgomery (Fed. Cir. 2012)
  - exploring the significance of Judge Newman's dissent in Hoffmann-La Roche Inc. v. Apotex Inc. (Fed. Cir. 2012) concerning 'unpredictable results' and its relation to inherency

9:45  MORNING COFFEE BREAK

10:00  STRATEGIES FOR ANTIBODY PATENTING IN THE WAKE OF MYRIAD

Michael A. Davitz M.D. J.D.
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Fahmi Sellers Embert & Davitz
(New York, NY)

Ted J. Ebersole, Ph.D.
Assistant General Patent Counsel
Eli Lilly and Company
(Indianapolis, IN)

Robin M. Silva
Partner
Morgan, Lewis & Bockius LLP
(San Francisco, CA)

• Devising strategies to develop, protect, and enhance antibody therapies
• Developing a portfolio of antibodies made against known and unknown targets
• Examining questions of structure, function and obviousness
  - concern of obviousness rejection
  - question of inventive step
  - implications of Myriad
• Importance of structural non-obviousness for antibodies
  - is there prior art?
  - what of unexpected properties?
• Structural claiming and drafting strategies relative to antibodies
• Complying with written description and enablement requirements
  - how does written description apply to functional claims
  * Noelle v. Lederman,
  * Ariad v. Lilly,
  * Centocor v. Abbott,
  * Abbott v. Centocor (IL12), Abbott v. Centocor (TNFa)
• Survey of post-KSR case law and EP cases: showing nonobviousness for antibodies

• Developing and assessing worth of subsequent innovative patents
  * which subsequent patents should be protected in light of this jurisprudence?
  * process
  * formulation
  * diagnostic
  * delivery device
  * indication patents
• Exploring questions of biosimilar competition to antibody patents
• Doctrine of Equivalent dilemma – are claims being made structurally the same as innovator’s patent claims?
• Question of the role of Cabilly patents and infringing activities relative to monoclonal antibody development
  - status update on the Cabilly patents and various litigation involving the portfolio
  - other submarine-like patents to watch for
  - freedom to operate analysis relative to antibody development
• AIA considerations

11:15  EVOLVING THEORIES OF INDOUCEMENT AND DIVIDED INFRINGEMENT CONCERNING METHOD TREATMENT CLAIMS AND THEIR IMPLICATIONS FOR PHARMACEUTICAL AND BIOTECHNOLOGY PATENTS

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

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

Terry G. Mahn
Managing Principal
Fish & Richardson P.C.
(Washington, DC)

• Exploring the relationship between inducement actions and divided infringement and how they apply to methods of treatment claims in pharmaceutical and biotechnology patents
  - significance to small molecule Orange Book listed method patents
  - understanding how method of treatment claims and inducement and divided infringement theories may affect diagnostic method claims in the aftermath of Prometheus and Myriad
  * assessing the possible impact of the PTO’s Myriad memo on the examination of such diagnostic methods claims
  * “[o]ther claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility”
• Overview of inducement of infringement and divided infringement under current law
  - how the Supreme Court’s ruling in Global Tech v. SEB has altered the standard for inducement findings
  * mens rea requirements
  - willful blindness vs. deliberate indifference
  * indirect vs. direct infringement
• Examining the Federal Circuit’s en banc ruling on inducement of infringement and divided infringement in Akamai Technologies, Inc. v. Limelit Networks, Inc. (Fed. Cir. 2012) and McKesson Technologies Inc. v. Epic Systems Corp. (Fed. Cir. 2012) in light of this jurisprudence
• Examining the bases for Limelit’s and Akamai’s cert. petitions to the Supreme Court
• Update on the status of the Supreme Court’s invitation to the Solicitor General to file a brief in Akamai
• Predictions for the granting of cert in this matter and how the Supreme Court may ultimately rule
• Possible implications for the life sciences industries
• Understanding the relationship between carve-outs/skinny labeling and inducement and divided infringement
  - repercussions of Caraco and relevance to method of treatment claims

12:15 Networking Luncheon

1:30 Impact of PGR, IPR and Other PTO Proceedings on Life Cycle Planning Strategies for Large and Small Molecules

Justin J. Oliver
Partner
Fitzpatrick, Cella, Harper & Scinto
(Washington, DC)

Michael J. Twomey
Partner
WilmerHale
(Boston, MA)

New and amended PTO proceedings initiated under the AIA are now in full effect and have garnered a great deal of recent attention in the Hatch-Waxman space in light of the recent Mylan and Ranbaxy IPR petitions – but also have implications for small molecules outside the scope of Hatch-Waxman and for large molecules. This session will provide insights on how these procedures may alter life cycle and patent portfolio planning. Points of discussion will include:

Post Grant Review (PGR)

• Keeping abreast of PGR start dates for life cycle and patent planning purposes
  - is the challenge brought within nine months of patent issuance?
  - exploring the possible bases for the invalidity challenge
    * prior art
    * 112 deficiency under written description
    * lack of enablement
    * obviousness
    * inherent anticipation
    - fate of best mode
  - Estoppel considerations looking ahead to potential Paragraph IV or BLA litigation
    - possible application of PGR in biosimilars scenario?
  - Analyzing the petitioner’s burden of proof
    - proving that it is “more likely than not that one of the claims challenged in the petition is unpatentable”

Inter Partes Review

• Overview of inter partes review
  - timing
  - burden of proof
  - substantial new question of patentability

• Examining the new inter partes review procedures from the prospective of life cycle and patent portfolio planning
  - petitioner’s burden of proof
  - how does it compare to prior standard under inter partes reexamination?
    * reasonable likelihood that the petitioner will prevail on claim vs. substantial new question of patentability
  - understanding the immediate repercussions of this shift relative to pending inter partes reexamination filings
    * which standard will be utilized for inter partes reexamination petitions filed prior to the September 16th date?
  - Exploring the scope of review for pending prior and new procedures under 102 and 103
    - patents (prior art) and publications
    - comprehending the relationship between scope of review and estoppel
  - Transition and phase out
    - examining the transition for post grant review and inter partes review
    - reevaluating strategies for pharmaceutical and biotechnology patent litigation relative to phase out of for inter partes review and transition inter partes review
  - Lessons learned: Ranbaxy and Apotex petitions relative to Hatch-Waxman litigation
    - challenging exclusivities
    - questions of economics, efficiencies and risk
    - implications for use in biosimilars scenario?

Other PTO Proceedings to Watch

• third party re-issuance submissions
• supplemental examination

2:45 Afternoon Refreshment Break

3:00 Exclusivities: New Developments, Controversies and Concerns for Small Molecules, Large Molecules and Combination Products

Barry Jacobsen
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(Washington, DC)

Theresa Kavanaugh Ph.D.
Partner
Goodwin Procter LLP
(Boston, MA)

Brand Name Small Molecule Exclusivity Challenges

• Understanding why challenges to brand name regulatory exclusivities such as NCE and orphan drug are now under scrutiny by FDA
  - Veramyst
  - Torisel
  - Makena
• Status of lawsuits against FDA in regulatory exclusivity denials
  - Center for Drug Evaluation and Research’s (“CDERs”) Exclusivity Board
    * review of NCE exclusivity, 3-year new clinical trial exclusivity, and exclusivity for biological products
180-Day Exclusivity Challenges for Generic Small Molecules

- Forfeiture provisions: circumstances under which exclusivity is forfeited under FDC Act § 505(j)(5)(D)(i)
- Deciphering the FDA’s stance on pre and post-MMA 180-day exclusivity
- Interpreting the “earlier of,” “later of” language in making a forfeiture determination
- Evaluating the strength of “the failure to market” provision post-Lipitor
- Taking a closer look at the failure to obtain timely tentative approval” forfeiture provision
  - Mylan v. FDA
- Evaluating the impact of “delisting” on forfeiture
- Forfeiture relative to patent expiration
- Evaluating when the 180-day exclusivity period can be relinquished or transferred, and exploring the consequences
- When can a brand “park” a generic’s exclusivity?
- Defining “shared exclusivity”
- How have authorized generics changed the playing field relative to 180-day exclusivity?
- Exploring regulatory bars to exclusivity
  - GMP violations
  - SEC actions
- Revisiting the relationship between exclusivity, forfeiture and the 30 month stay
  - circumstances under which a second stay may be granted
  - impact on grant of exclusivity

Exclusivity Considerations for Large Molecules

- 12 year market exclusivity vs. 4 years data exclusivity
- Additional 6 month allowance for pediatric testing
- Additional orphan drug exclusivities

Exclusivity for Combination Products

- Exploring exclusivities for combination products comprised of two new Orange Book listed drugs
- What are the available exclusivities for a combination product comprised of two old Orange Book listed drugs?
- What exclusivity protections are afforded to a combination product comprised of a new and old Orange Book listed drug?
- What of available exclusivities for combination products comprised of:
  - an Orange Book listed drug and device?
  - an Orange Book listed drug and biological product?

ETHICS AND BIOPHARMACEUTICAL IP: AN UPDATE ON THE PTO’S RECENT ACTIVITY CONCERNING ETHICS AND CONDUCT AND RELATED MATTERS

Barton W. Giddings, Ph.D., J.D.
Partner, Stoel Rives LLP
(Salt Lake City, UT)

- Analysis of the PTO’s new Rules of Professional Conduct
  - relationship to ABA model rules and significance
    * harmonization with most ethics rules adopted by most state bars
- Examining the Federal Circuit’s tightening of the inequitable conduct standard in *Therasense*
  - intent to deceive
    * single most reasonable inference
    * materiality
    * ‘but’ for test- possible Supreme Court review?
- Exploring the PTO’s adoption of the *Therasense* standard in its proceedings with respect to inequitable conduct findings
  - review of the *Therasense* decision
    * intent to deceive
    - single most reasonable inference
    - materiality
    - ‘but’ for test-
    - inequitable conduct and Patent Reform
    * supplemental proceedings under the AIA: an opportunity to cure inequitable conduct?
- Exploring the debate of whether state or federal law applies to IP malpractice actions
  - Rule 11 obligations to bring an ethics suit in a Hatch-Waxman case

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