Maximizing Pharmaceutical Patent Life Cycles

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


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 and BPCIA challenges and help you:

- **UNDERSTAND** how the introduction of biosimilars has profoundly altered pharmaceutical patent life cycle strategies
- **APPRECIATE** the relationship between life cycle management, brand optimization and new product development
- **SEE** how the Federal Circuit is paving the way for Patent Reform
- **DETERMINE** when and how secondary patents – for both small and large molecules should be pursued
- **COMPREHEND** how the clear delineation between written description and enablement is influencing claims drafting strategies for drugs and biologics *via Ariad v. Lilly*
- **ASSESS** how the Court’s determination in *Bilski* regarding methods claims may affect areas such as personalized medicine and other new pharmacological technologies
- **EXAMINE** the impact of *Caraco* on skinny labeling, carve-outs and Orange Book listing determinations
- **IDENTIFY** circumstances under which exclusivity is forfeited
- **NAVIGATE** the boundaries of the safe harbor

Hear from the:

- FTC’s Bureau of Competition’s Health Care Division on Competition Considerations for Pharmaceutical Patent Life Cycle Management
- FDA’s Office of Chief Counsel (Invited) on FDA Activities Relative to Pharmaceutical Patent Life Cycles for Small and Large Molecules
- USP’s General Counsel’s Office on Substitutions and Biosimilars
- USPTO’s Office of Patent Legal Administration on New Decisions Affecting PTA and PTE for Small and Large Molecules

Industry Insights from:

- Hoffmann-LaRoche
- Apotex
- Boehringer Ingelheim
- Endo Pharmaceuticals
- Lundbeck Research USA, Inc.
- Medicis
- Merck & Company
- Pfizer
- Sandoz

October 5, 2010: Pre-Conference Workshops

A. Hatch-Waxman and BPCIA 101 — A Primer on IP Basics and Regulatory Fundamentals
B. Pharmaceutical Patent Life Cycle Strategies for the EU and Emerging Markets

October 8, 2010: Post –Conference Workshop

C. The Master Class on Patent Term Adjustment and Patent Term Extensions for Pharmaceutical and Biological Patents

Register Now • 888-224-2480 • AmericanConference.com/Lifecycles
Speakers:

Edward John Allera
Shareholder
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(Washington, DC)

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Partner
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President
D. Sporn Consulting LLC (Darnestown, MD)
(Former Director, Office of Generic Drugs, CDER, U.S. Food and Drug Administration)

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Frommer Lawrence & Haug LLP
(New York)

Suja Subramaniam
Head of Legal
Roche Diagnostics India Pvt Ltd.
(Mumbai, India)

Mary C Till
Legal Advisor
Office of Patent Legal Administration
USPTO (Alexandria, VA)

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

Matthew B. Van Hook
Assistant General Counsel
USP - United States Pharmacopeia
(Rockville, MD)

Roy E. Waldron
Vice President & Assistant General Counsel
Head of Global Patents & IP Policy
Pfizer Inc (New York, NY)

Timothy X. Witkowski, M.S., J.D.
Executive Director & Executive Counsel,
Intellectual Property, Boehringer Ingelheim
(Ridgefield, CT)
A decade ago, at ACI’s first Maximizing Pharmaceutical Patent Life Cycles conference, we discussed the possible introduction of an abbreviated pathway for follow-on biological products and contemplated its impact on life cycle strategies. We continued to explore this topic at every iteration of this conference that followed.

FOBs are here: that which we once contemplated is now a reality.

The pharmaceutical industry must assess how this new application process for biosimilars under Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA) will interact with existing patent life cycle planning under Hatch-Waxman and other mechanisms.

We have entered a new era with the introduction of biosimilars, however, other and more familiar anxieties under Hatch-Waxman still abound.

Potential patent losses for small molecules are projected to exceed $40 billion by 2012 alone1 as patent protections on more brand name drugs, including some notable block busters, are set to expire. New decisions affecting forfeitures, Orange Book listings, methods claims and claims drafting are shaping the evolution of Hatch-Waxman. There is also concern over how proposed patent reform legislation may be yet another game changer. Moreover, the aggressive stance of various agencies including the PTO, FDA and FTC on various components of Hatch-Waxman adds to this uncertainty.

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 – and BPCIA – strategies and tactics against competitors in both camps.

This 11th 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:

• Focused panels on differences between Biosimilar Applications and ANDAs which will allow you to assess how elements of these applications processes will impact decisions in life cycle management
• Access to key figures from the USPTO (Invited), FTC, USP and FDA (Invited), who will provide you with direct insights into the logic of these agencies on some of the most pressing matters affecting pharmaceutical life cycle patent strategies, including:
  - PTA and PTE determinations
  - Pay-for-Delay settlements and product switching
  - Biological products and substitutions
  - Proposed forfeiture regulations
• Analyses of key cases that have affected patent life cycle planning and tips for using these rulings to your advantage

Also, by popular demand, we have brought back our specialized classes on:

• Hatch-Waxman and BPCIA 101 — A Primer on IP Basics and Regulatory Fundamentals
• The Master Class on Patent Term Adjustment and Patent Term Extensions for Pharmaceutical and Biological Patents
  and have updated them to address not only Hatch-Waxman matters, but some of the most pressing issues concerning biosimilars as well.

Additionally, in response to your request for more in-depth information on extending patent life in foreign jurisdictions and IP maneuvering in emerging BRIC markets, we are pleased to offer a workshop on:

• Pharmaceutical Patent Life Cycle Strategies for the EU and Emerging Markets

Nearly 2,500 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 over the last ten years. This updated event will bring you the latest legal strategies and tactics for successful maneuvering in the evolving pharmaceutical 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/LifeCycles.

1AP, April 2008.
8:00 **Registration and Continental Breakfast**

Product commercialization and the pre-approval process are critical aspects and considerations in the development and eventual patenting of small molecules and biologics. This hands-on workshop will give you critical insights into commercialization and the pre-approval process, and provide you with an in-depth review of Hatch-Waxman and the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as well as other IP and regulatory basics relative to small molecules and biologics. 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 new IP and regulatory challenges presented during the main conference.

8:30 **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 restraint – which prevent these companies from pursuing the development of the desired product
- Exploring 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 regulatory and 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 interchange considerations

9:30 **Morning Coffee Break**


**Arnold I. Friede**

Principal

Arnold I. Friede and Associates (New York, NY)

- Understanding the link between the FDA approval process and the patenting of drugs and biologics

Rx Drugs (new drugs)

- Identifying the application process for the approval of a new drug, *i.e.*, small molecule, new chemical entities, etc.

11:15 **Patent and IP Overview for Drugs and Biologics: Hatch-Waxman, Trade Dress, and More**

**Brian R. McCormick**

Attorney

Hogan Lovells (New York)

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
- 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 end game (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)
  - regulatory exclusivity

Biologics

- Understanding the approval process for a biologic
  - how does the approval process for a biologic differ from that of a drug?
- BLA (Biological Licensing Application)
  - how does a biologic differ from a drug?
  - what application needs to be filed and with whom is it filed?
  - which products require BLAs instead of NDAs?
  - what does a BLA look like?
- Why is it a “license,” rather than an “approved application”?
- What does the approval process for a 'biosimilar' under BPCIA entail and how is it different from the BLA approval process?
- 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)
- 30-month stay
- patent extensions
- the safe harbor
- FD&C 505b2 (an alternate pathway to an ANDA)

Biologics
- Overview of recent biosimilar legislation
- Title VII of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- 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

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

12:45  Workshop A Ends

WORKSHOP B
Pharmaceutical Patent Life Cycle Strategies for the EU and Emerging Markets
2:15 pm – 5:45 pm (Registration begins at 1:45 pm)

Gabriel Kleiman
Assistant General Counsel
Pfizer Inc. (New York, NY)

Edward H. Mazer
Senior Legal Director
Merck & Co., Inc. (Kenilworth, NJ)

Suja Subramaniam
Head of Legal
Roche Diagnostics India Pvt Ltd. (Mumbai, India)

Workshop Objectives
- Developing a global patent life cycle management plan that responds to changes in Europe and emerging markets which impact intellectual property protection
- Factoring new compulsory licensing concerns relative to foreign markets into your global patent strategies
- revisiting TRIPS Article 31

EU
- Contemplating changes to European patent practice in relation to the findings of the EC’s DG Competition’s Pharmaceutical Sector Inquiry
- Understanding how fee changes in the European Patent Office have affected global patent life cycle strategies
- the economics of filing multiple claims in the EU in view of increased costs

Patent Extensions in the EU
- Supplementary Protection Certificates (SPCs) – extension of patent life in the EU
  - scope of the protection
  - how do you apply for it?
  - interaction between the Pharmaceutical Directive and the SPC Regulation
- Meeting the requirements to obtain an SPC
  - tips for maximizing the patent extension obtained under an SPC for human medicinal products
  - weighing the pros and cons of seeking a pediatric extension
  - obtaining a zero term or SPC or quasi patent term extension
  - determining what extension term is best for your product based on an assessment of the type of rights you will be granted
- Contemplating whether or not a new SPC can be obtained for new combinations, isomers, etc.
- Identifying what (if any) alternatives exist for obtaining an SPC when seeking to extend the patent term on your product
- Evaluating differing standards for obtaining an SPC on a country-by-country basis
- Considering issues unique to seeking an SPC when the original Marketing Authorisation (MA) was granted in a country that is not part of the European Economic Area (EEA), i.e. Switzerland
- Obtaining a springboard injunction for marketing and distribution after patent expiry in case of offering and inclusion in pricelists before patent expiry

Emerging Markets
- Exploring the treatment of pharmaceutical patents in emerging market countries
- Considering the practicalities of regulatory data protection in the emerging markets
- Understanding access to medicines and the challenge of compulsory licensing and enhanced patentability standards
- Overview of biologic products and the emergence of follow-on biologics/biocomparable/biosimilar pathways
- Examining genetic resources, indigenous heritage and the Convention on Biological Diversity
- Managing local working requirements

Country Focus:
Brazil
- Reverse-linkage – navigating a dual patent examination system
- Pipeline patents – enduring the storm

Mexico
- New pharmaceutical patent linkage strategies

Russia
- Wildcard: uncertainty of how pharmaceutical patents will be viewed in an emerging patent system

India
- Examining the Indian patent system
- Understanding why this system only recognizes primary patents
- What can we glean about this system and its treatment of U.S. patents from the Novartis Gleevec litigation in the Indian courts?

China
- Looking at China’s patent system and its treatment of U.S. pharmaceutical patents in particular
- When does it make sense to file your patent in China?
DAY ONE | WEDNESDAY, OCTOBER 6, 2010

7:00 Registration and Continental Breakfast

8:00 Chairs’ Opening Remarks

Chairman Emeritus:
John C. Vassil
(formerly Of Counsel to Morgan & Finnegan LLP)
(New York)

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

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

8:15 The Remaking of the Patent Endgame

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

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

• Exploring endgame changers: vehicles and trends
  - industry mergers and the changing face of the industry
  - limitations on the 30 month stay
• Understanding how the introduction of an abbreviated
  pathway for biosimilars has changed the patent endgame
  - what does this really mean for brand names and generics
    in terms of life cycle strategy?
• Appreciating the relationship between life cycle management,
  brand optimization and new product development
  - consideration of small molecule products
  - incorporating biologics
• Examining the evolution of Hatch-Waxman and the
  introduction of biosimilars under Biologics Price
  Competition and Innovation Act of 2009 (BPCIA)
  - increasing complex demands on FDA
• Contemplating the future of innovation within the confines
  established by the new endgame
  - ancillary patents – thinking beyond small and large
    molecules, e.g.,
    - patentability of different drug delivery modalities
      associated with drug patentability
    - anticipating new technologies that would combine
      diagnostics and drug administration
  - the future of gene patenting vis-à-vis, Myriad
• Assessing risks associated with new product development
  and potential litigation

9:00 Patent Reform Revisited: Pondering Its Impact
On The Pharmaceutical Industry

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

Roy F. Waldron
Vice President & Assistant General Counsel
Head of Global Patents & IP Policy
Pfizer Inc (New York, NY)

• Understanding how the proposed legislation will impact
  pharmaceutical patent life cycle management and patent
  portfolio management
• Update on the status of the legislation
  - exploring differences in the House and Senate versions
    of the bill
  - PTO’s push for reforms
• Overview of the proposed patent reform legislation, i.e.,
  Patent Reform Act of 2010, and analysis of key provisions
  - first to file
  - opposition practice/patent re-examination
  - interference proceedings vs. derivation proceedings
  - best mode
  - false marking
  - willful infringement findings
  - inequitable conduct
  - expanded CAFC jurisdiction
  - damages limitations
• Trends from the bench: how is the Federal Circuit paving
  the way for Reform through recent decisions?
• Exploring the PTO’s stance
• The Patent and Trademark Office Funding Stabilization
  Act of 2010, HR 5322

9:45 Morning Coffee Break

10:00 Understanding the Particulars, Peculiarities and
Politics of Biosimilars and Their Impact on
Pharmaceutical Patent Life Cycle Management

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

Sandra Dennis
General Counsel, Healthcare
Biotechnology Industry Organization
(Washington, DC)

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

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

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

Matthew B. Van Hook
Assistant General Counsel
USP - United States Pharmacopeia (Rockville, MD)

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

• Overview of Title VII of the Patient Protection and
  Affordable Care Act (PPACA, P.L. 111-148), i.e., Biologics
  Price Competition and Innovation Act of 2009 (BPCIA)
• Biosimilar pathway vs. 505(b)(2) and BLAs
• Defining “biological” and “biosimilars” under BPCIA
  - addition of the word “protein” to the PHSA definition
    of biologics
- identifying the “reference” product and proving biosimilarity
- analytical data requirements
- when will clinical data submission be necessary?

• Exploring interchangeability requirements
• Understanding the significance of the methods of making claims in this legislation
  - query: if a protein is made by a completely different process than the reference product, is the patent infringed?
• Examining the effect of this abbreviated approval pathway on innovation
  - how will this impact brand name and generic companies
• A look at FDA Rule making and guidance relative to biosimilars
• How will biosimilars fit in with life cycle strategies?
  - targeting R&D efforts
  - re-examining prosecution efforts
  - anticipating vulnerable patents and litigation

11:30 **Of Biosimilar Applications (BPCIA) and ANDAs (Hatch-Waxman)**

**Branded Side**

*Joseph R. Robinson*

Partner

McDermott Will & Emery LLP (New York, NY)

**Generic Side**

*Steven J. Lee*

Partner

Kenyon & Kenyon LLP (New York, NY)

• Approved product listings
  - will there be an eventual official listing requirement for biosimilars, e.g., will there be a Purple Book?
  - listing of Approved Drug Products with Therapeutic Equivalence Evaluation, i.e., the Orange Book
• Starting point – application submission
  - an act of infringement under:
    - BPCIA?
    - Hatch-Waxman?
• Which patents are asserted as infringed under each statutory schematic?
• Certification requirements
• Exploring notice and legal and factual assertions set forth under each law
  - documents and responses
  - list exchanges
• Law suit commencement
  - negotiations – second list exchange and more
  - royalties?
  - first and second wave litigation
  - 45 day commencement vs. forfeiture
  - use of DJ under both statutes
• Availability of injunctive mechanisms
  - preliminary injunction?
  - 30 month-stay
• Exclusivity
  - 12 year
  - 5 year

1:45 **New Patent Term Adjustment and Patent Term Extension Decisions and Their Significance for Small and Large Molecules**

*Patricia Carson*

Partner

Kaye Scholer LLP (New York)

*Mary C Till*

Legal Advisor, Office of Patent Legal Administration

USPTO (Alexandria, VA)

• Understanding the impact of key PTA and PTE decisions in the last year on life cycle management strategies

**PTA**

• Comprehending what *Wyeth* did in terms of solving the A and B overlap dilemma
• How does the PTO now address the A and B overlap period?
  - understanding when A-delays and B-delays are added together and when they truly overlap
• Post-*Wyeth* PTO procedures
  - PTO’s PTA computer program overhaul
  - expedited procedures –reconsideration requests
  - eligibility – *Wyeth* only petitions
• When filing a District Court complaint before the DC Circuit is your best option for PTA redress
• Other PTA considerations
  - *Japan Tobacco* and the B-delay question it raised in light of *Wyeth*
  - vis-à-vis PCT applications

**PTE**

• Examining substantive and procedural PTE controversies impacting not only drugs but biological products as well
• *Wyeth Holdings v. US*
  - challenging FDA’s determination of when the approval phase began for a phased submission of an NADA
• *PhotoCure v. Kappos*
  - challenging eligibility of ester in light of previously approved salt
• *Ortho McNeil v. Lupin*
  - challenging validity of PTE to enantiomer in light of previously approved racemate
• *The Medicines Company v. PTO*
  - denying PTE application filed on day 62

2:30 **Obviousness Continued: How *KSR* and Its Progeny are Impacting the Patent Life of Drug and Biological Products**

*Peter J. Armenio*

Partner

Quinn Emanuel Urquhart & Sullivan, LLP (New York, NY)

*Margararet “Peg” M. Buck*

Head of Section, US Legal Affairs & Patents

Lundbeck Research USA, Inc. (Paramus, NJ)

*Amy H. Fix*

Of Counsel

Womble Carlyle Sandridge & Rice, PLLC (Research Triangle Park, NC)

*Adda C. Gogoris*

Partner

Merchant & Gould P.C. (New York, NY)
Afternoon Refreshment Break

4:00 Ariad v. Lilly: The Reaffirmation of Written Description and Enablement and Their Collective Role in Patent Life Cycle Management

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

Shashank Upadhye
Vice President - Global Intellectual Property
Apotex, Inc. (Toronto, ON)

• Overview of Ariad v. Lilly and its significance for patent portfolio management
• What impact will the clear delineation between written description and enablement have on claims drafting strategies in the life sciences?
  - understanding the impact of Ariad on the re-evaluation of new claims raised from old applications
  - implications for questions of prior art
  - ALZA Corp. v. Andrx Pharms., No. 2009-1350 (Fed. Cir. 2010)
• How will this impact life cycle strategies for small and large molecules?

4:45 Bilski, Prometheus and Myriad: Understanding the Madness over Methods Claims in the Pharmaceutical Industry

Edward T. Lentz
Patent Attorney
(Minneapolis, MN)

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

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

• Analysis of Bilski and its implications of methods claims generally
• Understanding how method claims are currently used in pharmaceutical patent life cycle strategies
  - 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
  - impact of Bilski on the Prometheus decision
  - potential consequence for Myriad and gene sequencing patentability
• How the Court’s determination in Bilski may impact areas such as personalized medicine and other new pharmacological technologies
• Understanding how Bilski may impact life cycle management strategies in the future

5:45 Conference Adjourns to Day Two
The FTC continues to vigorously use its enforcement and policy tools to prevent anticompetitive business practices in the pharmaceutical industry. In the last 18 months, the Commission has issued pronouncements on the antitrust implications of different components of health care reform that impact the pharmaceutical industry. Markus Meier, Assistant Director of the FTC’s Bureau of Competition’s Health Care Division will discuss the FTC’s position in these matters, including:

- The current status of the FTC’s efforts to end “pay-for-delay” settlements
- enforcement of MMA reporting requirements
- alignment of FTC and DOJ on “pay-for-delay”
- status of pending legislation
- Analysis of the competitive implications of other pharmaceutical life-cycle management strategies that may be used to improperly hinder generic competition

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

Douglas L. Sporn (on labeling issues)
President
D. Sporn Consulting LLC (Darnestown, MD)
(former Director, Office of Generic Drugs, CDER, U.S. Food and Drug Administration)

- Re-examining the role of Orange Book listings in patent life cycle management and patent portfolio management
- considerations for non-Orange Book patents
- Exploring the continuing dilemma of which patents should be listed, delisted and held in reserve
- revisiting the question of DJ vulnerability post-Teva
- examining the FDA’s position on not listing
- Special listing considerations for small proteins filed through NDA – as opposed to BLA
- Overcoming challenges associated with listing patented information in the product label and indications discovered in clinical testing
- incorporating long term patent listing strategies into label negotiations with FDA
- Assessing the effect of de-listing/disclaiming a patent on 180-day exclusivity
- Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd. (Fed. Cir. 2010)
- skinny labeling and carve-outs
- Assessing the scope of potential Orange Book listing controversies relative to:
  - device patents: product-by-process claims
  - metabolites; polymorphs; intermediates
  - patents on unapproved uses

Networking Luncheon
• Exploring the interplay between the 30-month stay and 180-day exclusivity
• When can the 180-day exclusivity period be transferred to another ANDA applicant?
• Defining “shared exclusivity”
• Evaluating when the 180-day exclusivity period can be relinquished, and exploring the consequences

**Forfeiture**
• Forfeiture provisions: identifying circumstances under which exclusivity is forfeited
  - failure to market
  - application issues
  - certification issues
  - approval issues
• *Teva Pharmaceuticals USA, Inc. v. Sebelius* (losartan)

**Non-Patent/FDA Exclusivities**
• Overview and analysis of non-patent exclusivities:
  - data exclusivity
  - orphan drug exclusivity

**2:45 Afternoon Refreshment Break**

**3:00 FDA Keynote: Update on FDA Activities Relative to Pharmaceutical Patent Life Cycles for Small and Large Molecules**

*Elizabeth Dickinson (Invited)*
Associate Chief Counsel, 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, its decision-making powers concerning the consequences of de-listing patents, as well as its recent determinations regarding exclusivity forfeitures illustrate the agency’s critical role in the pharmaceutical patent endgame. The discretionary Rule Making authority granted to the agency in matters of follow-on biologics under BPCIA further enhances this role. This session will cover the present state of the FDA’s authority in Orange Book listings, the possible release of proposed regulations on forfeiture and other Hatch-Waxman and FOB-related matters.

**4:00 Learning to Navigate the New Limits and Boundaries of The Safe Harbor**

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

• Understanding the vital role that the Hatch-Waxman safe harbor plays in patent portfolio management and life cycle management
• Examining the impact of Proveris Scientific Corp. *v. Innovasystems Inc.* (CAFC 2008) on safe harbor protections afforded to research tool patents
• Identifying the safe harbor’s scope of protection for otherwise infringing activities in District Court and ITC litigation post-Proveris
  - Amgen Inc. *v. International Trade Commission*
• Re-exploring the safe harbor within the scope of:
  - basic R&D; new product screening
  - optimization
  - pre-clinical testing; post-FDA submission testing
  - post-approval testing
• What are the potential consequences of an incorrect safe harbor determination within the *Proveris* rubric?

**5:00 Conference Adjourns**
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 and biological products, where the regulatory review required for market approval can take many months or even years. Patent Term Adjustment and Patent Term Extensions are vehicles which have been employed to make up for this lost time before the PTO and FDA, respectively. Recent decisions in this area of PTA and PTE law as well as the passage of biosimilars legislation this past March have highlighted the importance of these devices. Additionally, certain regulatory exclusivities and careful use of secondary patents also play an important role in patent longevity in the life sciences.

This hands-on session will provide you with practical advice, as well as tips and techniques for PTA and PTE. The session leaders will take you through the intricacies of the four major ways of getting more time on your patent, and provide you with the tools that you need to accomplish this goal in this time of changing rules and regulations. Points of discussion include:

   • Important benchmarks in the drug’s/biologic’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

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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