

American Conference Institute's 8th Annual



Paragraph IV Disputes



Expert Insights on Hatch-Waxman Litigation Strategies for Brand Names and Generics

On the 30th Anniversary of the Hatch-Waxman Act, join preeminent patent litigators representing brand name and generic pharmaceutical companies as they provide critical insights on:

- IPR Utilization in Hatch-Waxman Litigation
- *Akamai's* Anticipated Impact on / Divided and Contributory Infringement
- The Goodlatte Bill's Proposed Codification of Obvious-Type Double Patenting
- *Lighting Ballast* and Interim Markman Strategies
- Revised Safe Harbor Exceptions
- GDUFA's Impact on Paragraph IV Strategies
- Exclusivities for Combination Products
- At-Risk Launches and Damages

April 30, 2014

Master Class on Paragraph IV Dispute Settlements in the Aftermath of *Actavis*



Distinguished Co-Chairs



Guy Donatiello
Sr. Vice President, Intellectual Property
Endo Pharmaceuticals



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

Judicial Insights from Chief Judges in Key Districts:



Hon. Ruben Castillo, Chief Judge
Northern District of Illinois



Hon. Gregory M. Sleet, Chief Judge
District of Delaware



Hon. Leonard Davis, Chief Judge
Eastern District of Texas



Hon. Garrett E. Brown, Chief Judge (ret.)
District of New Jersey

Plus a Special Magistrates Panel on Local Rules featuring:



Hon. Mary Pat Thyng
Chief Magistrate Judge
District of Delaware



Hon. Roy Payne
Eastern District of Texas



Hon. Tonia Bongiovanni
District of New Jersey

FTC Keynote on Actavis



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



IPR Insights from:

Hon. Brian P. Murphy (invited)
Administrative Patent Judge
Patent Trial and Appeal Board – USPTO

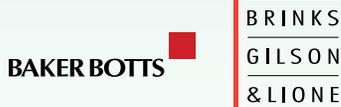
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Network With the “Who’s Who” of Hatch-Waxman Litigators and Stakeholders.

Prepare for the Next Wave of ANDA Litigation and Patent Challenges at the Courts and PTO.

Attend the Industry’s Premier Paragraph IV Disputes Conference.

Dear Colleague:

In the eight years since its inception, American Conference Institute’s (ACI’s) Paragraph IV Disputes conference has become the pharmaceutical industry’s leading forum on Hatch-Waxman litigation. Each spring, the “who’s who” of Hatch-Waxman litigators and industry decision makers, as well as members of the judiciary and key government representatives gather in New York City at this conference to assess the implications and imprimatur of court cases, legislation, and industry behaviors which affect the patent endgame and the pursuit of related profits. This “must-attend” event serves the legal and business needs of both branded and generic drug makers by providing invaluable “take aways” for legal strategies and cost-analysis for every facet of this complex litigation from pre-suit considerations to case filings through final adjudication.

In this 30th anniversary year of the Hatch-Waxman Act, the time for this conference has never been more apropos. In the course of the next eighteen months, the industry will scale the next escarpments of the proverbial patent cliff which will bring an additional 90 billion dollars in patent losses when block buster drugs such as Nexium, Lunesta, Abilify, Crestor and Restasis all go off patent. This will result in increased ANDA litigation between brands and generics, as well as increased challenges among generics vying to be the first to obtain the highly coveted prize of 180-day exclusivity. However, there will also be new challenges to face. Brands and generics must assess of the impact and utilization of PTO proceedings which have provided alternative and parallel forums to the Federal Courts. Then, there is the uncertainty of the fall out from the Supreme Court’s decision in *Actavis*, which may add to the already astronomical cost of these litigations as settlements may be both legally and economically infeasible.

In response to these challenges, ACI is pleased to present this year’s Paragraph IV Disputes conference. We welcome you to join our exceptional faculty and your peers as we explore

not only the latest legal nuances affecting the essentials of Hatch-Waxman litigation, but also new dilemmas affecting patent sustainability and vulnerability, the impact of IPR and PGR, the Goodlatte Bill’s proposed statutory definition of double-patenting type obviousness, and the probable outcome of *Lighting Ballast* on claim construction controversies. This year’s event will feature a discussion on local patent rules with both local counsel and leading Magistrates. Also, back by popular demand are the Judges’ Roundtable and FTC keynote speaker sessions. Finally, in response, to your requests, we are offering a day long working group on patent settlements which shall not only address predictions for how the courts may interpret *Actavis*, but also provide practical advice on how to structure and draft a settlement agreement with which the parties can live and that the courts and FTC will bless.

Clearly, there is not a moment to lose in this ruthless endgame of no-holds bar litigation. Do not be left behind. **Register today** by calling 1-888-224-2480, faxing your registration form to 1-877-927-1563 or visiting us on-line at www.AmericanConference.com/PIVDisputesNYC.

We look forward to seeing you in New York this April.

Very truly yours,



Lisa J. Piccolo, Esq.
Senior Industry Manager, Life Sciences and Health Care
American Conference Institute

Media Partners:



“The Pink Sheet”

Monday, April 28, 2014

Main Conference – Day 1

7:00 Registration and Continental Breakfast

Continental Breakfast Sponsored by: **Taft/**

8:15 Co-Chairs' Opening Remarks
On the 30th Anniversary of the Drug Price Competition and Patent Term Restoration Act: Understanding Hatch-Waxman's Transformative Impact on the Pharmaceutical Industry

Co-Chairs



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



Timothy X. Witkowski, M.S., J.D.
Executive Director & Executive Counsel
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With Commentary from:



Bob Billings
Special Advisory to the President and CEO
Generic Pharmaceutical Association
(Washington, DC)

Brand Name Industry Representative, TBA

September 2014 will mark the 30 year passage of the Drug Price Competition and Patent Term Restoration Act, *i.e.*, the Hatch-Waxman Act. This law established a balance of power between the brand name and generic pharmaceutical sectors by setting IP timelines and procedures which changed the dynamics of both patent litigation and profits. Section 505(j) (2) (A) (vii) (IV), *i.e.*, the Paragraph IV provision is the cornerstone of the Act's litigation schematic – as well as the cornerstone of this conference.

Please join our co-chairs and representatives for both the brand name and generic sectors as they will explore this transformative law and other related matters. Points of discussion will include:

- The evolution and changing dynamics of both industry sectors in view of Hatch-Waxman
- The interplay of new and proposed legislation and the Hatch-Waxman schematic
 - The America Invents Act
 - H.R. 3309, The Goodlatte "Innovation Act", *i.e.*, Patent Reform II
 - anti-troll provisions and possible impact on Hatch-Waxman suits
 - H.R. 3091, The MODDERN Cures Act of 2013

9:00 **Assessing Pharmaceutical Patent Sustainability and Vulnerability: Strategies and Considerations for Brand Names and Generics in Anticipating, Identifying and Determining Which Patents Will Be Ripe for Challenges of Invalidity and Non-Infringement**



Stephen R. Auten
Partner, Chair of Pharmaceutical & Life Sciences
Litigation
Taft Stettinius & Hollister LLP (Chicago, IL)
(Former Vice President, IP, Sandoz, Inc.)



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(New York, NY)



Charles Ryan
Senior Vice President, Chief Intellectual Property
Counsel
Forest Laboratories (New York, NY)

- Revisiting the ANDA applicant's assertion under Paragraph IV, *i.e.*, "such patent is invalid or will not be infringed by... the new drug for which the application is submitted" from the perspective of both brand name and generic manufacturers
 - reviewing the presumption of validity
 - *Sciele Pharma Inc. v. Lupin Ltd.* (Fed. Cir. 2012)
 - *reaffirmation of Microsoft v. i4i* (131 S. Ct. 2238 (2011))

- overcoming the presumption by "clear and convincing" evidence to the contrary
- questions of law vs. questions of fact
- understanding circumstances in which the burden may shift from patent holder to alleged infringer
- Applying the presumption of validity to 101 subject matter questions
 - *CLS Bank Int'l v. Alice*, 717 F.3d 1269 (Fed. Cir. 2013), *cert. granted* Dec. 6, 2013
 - impact on 101 validity challenges to APIs
 - potential uptick in 101 utility challenges
- Analyzing the question of who bears the burden of proof in a licensee's challenge to pharmaceutical patent validity
 - *Medtronic, Inc. v. Boston Scientific Corporation*, (Supreme Court docket number 12-1128)
 - *MedImmune, Inc. v. Genentech, Inc.* 549 U.S. 118 (2007)
 - New questions of infringement
 - *Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 13-1335 (Fed. Cir. Sept. 26, 2013)
 - understanding when a promise not to infringe is an act of infringement
 - scope of infringement vis-à-vis 271 (e) (2) (a)

PATENTS RIPE FOR PARAGRAPH IV CHALLENGE

Brand Side Considerations:

- Evaluating the strength of the patents in your current portfolio
 - blockbusters vs. smaller products
 - determining vulnerabilities
 - IP and economics
 - small molecules vs. small proteins
 - small proteins post-BPCIA
- Non-Orange Book patents

Generic Considerations:

- Choosing which Orange Book patents to challenge
- Understanding the role of non-Orange Book patents in your PIV ANDA strategies
 - innovator / non-innovator
 - API

- Question of valuation – which patents on brand name products are worth challenging?
 - changing dynamics

Re-evaluating Orange Book Listed Patents and Orange Book Patent Challenges in View of New Legal and Regulatory Developments:

- Compound patents vs. methods vs. polymorphs
 - utilization of use codes in the aftermath of *Caraco*
 - small proteins post-BPCIA
- PTA and PTE considerations
 - possible impact of *Exelixis v. Kappos* (E.D.Va 2013)
- Analyzing new controversies in brand name exclusivities that may affect your due diligence analysis

PREPARING FOR LITIGATION

Brand Side Considerations:

- Developing discovery check-lists
 - implementation of document retention policy
 - when is a litigation hold put on all documents which may be discoverable
- e-Discovery
 - possible e-discovery restraints in various jurisdictions
 - “call back” rule for inadvertent disclosure

Generic Considerations:

- Procuring legal opinions on invalidity and non-infringement
 - assessing when opinions are needed
 - opinion of in-house v. outside counsel
 - questions of privilege
 - Rule 26 (b) (4)
- Filing the ANDA
 - fulfilling requirements for FDA approval:
 - pharmaceutically equivalent
 - bioequivalent
 - identifying triggers which may necessitate new bioequivalence studies

STRATEGIES FOR BOTH SIDES TO AVOID LITIGATION

- Licensing and authorized generics agreements
 - new considerations in light of amendments to Hart Scott Rodino and *Effexor* amicus brief
- Claiming the label
- Use of citizens’ petitions
- OTC switching

10:00 Morning Coffee Break

Morning Coffee Break Sponsored by: 

10:15 Use of IPR and Other PTO Proceedings in A Paragraph IV Challenge: Strategies For Brand Names and Generics in Navigating PTO Proceedings in ANDA Litigation



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Moderator:



Kelly J. Eberspecher
Shareholder
Brinks Gilson & Lione (Chicago, IL)

New and amended PTO proceedings initiated under the AIA are now in full effect and have garnered a great deal of attention in the Hatch-Waxman space in light of the recent decisions and petitions. This session will provide insights on how these procedures may alter Paragraph IV litigation strategies by providing a means for alternate redress or incorporation of parallel proceedings into District Court actions. Points of discussion will include:

Actual and Anticipated Uses of Inter Partes Review in a Paragraph IV Scenario

- Understanding when it is strategically prudent to file an IPR
- Survey of recent IPR filings and dispositions
 - *Garmin v. Cuozzo Speed Tech*, IPR2012-00001 (PTAB 2013): first IPR decision
 - what can pharmaceutical companies learn from this decision?
 - exploring how recent writ of mandamus filings are being used as a means to bypass the statutory bar to appeals of PTO’s IPR denials
 - *In re MCM Portfolios LLC* (Fed. Cir. 2013)
- Examining the *Apotex* and *Ranbaxy* petitions, subsequent settlements and their significance
 - how might these filings change the dynamics of Paragraph IV litigation?
- Understanding why the PTAB may exercise its discretion to hear the *Teva* (Moxifloxin) petition despite settlement of that matter
- Will District Court Paragraph IV cases be stayed in light of IPR filings?
- How are brands rethinking Paragraph IV litigation strategies in light of this new proceeding and its use by generics?
- Analyzing concerns that IPR and other proceedings may be used to get a “second bite at the apple”
 - *Fresenius USA v. Baxter Int’l*. (Fed. Cir. 2013)
- Exploring uses of IPR for second, third and other subsequent ANDA filers
 - forfeiture triggers
 - exploring tactics by other generics to avoid this scenario
- Query: if an Orange Book-listed patent is found invalid in an IPR proceeding – does it need to be delisted?

Other PTO Proceedings to Watch

- Specific concerns for joinder relative to District Court and PTO Procedures under the AIA
- Possible scenarios in which the following procedures would run parallel to district court proceedings
 - third party re-issuance submissions
 - supplemental examination
 - post-grant review
- Examining circumstances in which redress is only sought before the PTO

11:15 The Gauntlet Rethrown: The Paragraph IV Certification and Notice Letter

For the Brand Name Side



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Peter Waibel
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(Woodcliff Lake, NJ)

Moderators:



Gary E. Hood
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GENERIC SIDE

Procedural requirements

- Perfecting the Paragraph IV Certification
 - contents
 - delivery/service
 - avoiding “premature notice”
 - “late notice”
- Perfecting the Paragraph IV Notice Letter
- Making necessary amendments to the ANDA

Substantive requirements

- Identifying the proposed product covered by the ANDA
 - finding the patent of the corresponding branded product which is the subject of the Paragraph IV letter
- Legal and factual basis of the Certification
- Examining the detailed statement and questions of confidentiality
- Exploring the use of opinion letters in relation to the Notice Letter
 - are they still needed in view of Patent Reform?
 - details and other requirements
 - sanctions

BRANDED SIDE

The response

- Making productive use of the 45 day period
- Information gathering techniques strategies
 - confidentiality agreements and document requests
 - obtaining the ANDA
 - terms
 - scope of information that can reasonably expected
 - negotiations
- Extending the 45 day period
 - 21 CFR 314.95 (f)
- When should a patent owner file suit?
 - other options to explore
- Strategies to consider with multiple ANDA filers

Questions for both sides to consider

- Options to explore if suit is not commenced in 45 days
 - pros, cons and consequences of:
 - forfeiture of 30 month stay
 - suing for damages
 - declaratory judgment actions
 - no contest letter

12:15 Networking Luncheon

Networking Luncheon Sponsored by: **EDWARDS WILDMAN**

1:30 Of Prior Art and Double Patenting: Exploring the Dichotomy Between the Federal Circuit and PTO on Obvious Findings and the Potential Impact of the Goodlatte Bill on Double-Patenting Type Obviousness



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Moderator:



Mark T. Jansen
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(San Francisco, CA)

Prior Art

- Examining the contrast between the Federal Courts and PTO on prior art obviousness findings
- Analyzing Federal Circuit’s reversals of PTO obvious determinations

- *Rambus Inc. v. Rea* (Fed. Cir. 2013)
- *Leo Pharmaceutical Products v. Rea* (August 12, 2013) (*inter partes* reexamination)
 - exploring these decisions and the Federal Circuit's emphasis to all judiciary in the federal courts and PTAB on the importance of objective evidence in an obviousness determination
- Assessing the impact of the AIA's prior art provisions in Paragraph IV related obvious challenges
 - examining secondary considerations before the PTO under current procedures
 - under new IPR and PGR Procedures
- Exploring how PTO procedures may be used to bypass findings of non-obviousness in the federal courts
 - how the different burdens of proof in obviousness challenges before the federal courts and PTO may impact litigation strategies
 - questions of collateral estoppel
 - questions of federal court authority vs. administrative authority
 - possible Supreme Court review
 - impact on tactics of first and second filers in Paragraph IV disputes
- *Teva v. Sandoz* (Fed. Cir. 2013)
 - methods of measure and obviousness
- *Allergan, Inc. v. Sandoz Inc.*, (Fed. Cir 2013)
 - combining obviousness and inherency
- *Bristol-Myers Squibb v. Teva Pharms.*, No. 10-805-CJB (D. Del.)
 - structural obviousness
 - findings of invalidity after trial
- *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.* (Fed. Cir. 2013)
 - combination products
- Deciphering new jurisprudence relative to obviousness determinations in primary compound and composition claims vis-à-vis a Paragraph IV challenge
 - impact on methods and compositions
 - impact on secondary patents

Obvious-Type Double Patenting

- Understanding how the Goodlatte Bill, *i.e.*, Innovation Act may both codify and drastically alter the judicial doctrine of obvious-type double patenting

- Dissecting the controversy over Section 9(d)§106 of the proposed Innovation Act, *i.e.*, prior art in cases of double patenting
 - potential codification of obvious-type double patenting into §103
- Exploring the potential expansion of IPR to include double patenting-type obviousness as a cause of action
 - consequences of this expansion

2:30

Afternoon Refreshment Break

2:45

Let the Games Begin: Advanced Strategies for Drafting and Perfecting Pleadings and Effectively Using Dispositive Motions in Paragraph IV Disputes

For the Brand Name Side



Scott Brown

Assistant General Counsel – Patent Litigation
Bristol-Myers Squibb (Princeton, NJ)



Michael F. Buchanan

Partner
Patterson Belknap Webb & Tyler LLP
(New York, NY)

For the Generic Side



John L. Dauer, Jr.

Chief Patent Counsel
Sun Pharma /
Caraco Pharmaceutical Laboratories, Ltd.
(Cranbury, NJ)



Don J. Mizerk

Partner
Husch Blackwell LLP (Chicago, IL)

Moderators:



Benjamin A. Katzenellenbogen

Partner
Knobbe Martens Olson & Bear LLP (Irvine, CA)



Paul A. Ragusa

Partner
Baker Botts L.L.P. (New York, NY)

Initial considerations

- Where should suit be filed?
 - attempting to influence where and when the suit will occur
 - evaluating transfer motions and writs of mandamus relative to venue/jurisdiction
 - examining joinder provisions and Hatch-Waxman exceptions under AIA relative to venue
- Assessing subject matter jurisdiction
 - *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-3289 (D.N.J. 2013)
- Questions of standing
 - considerations for multinationals and subsidiaries
 - weighing probability for motions to dismiss
- Handicapping of judges and jurisdiction
 - local patent rules
- Question of jury trial: exploring circumstances that may put you in front of a jury
- Examining parallel proceedings before the PTO in view of Patent Reform

Crafting the initial pleadings

- The complaint
 - challenging the Paragraph IV certification: alleging the patent is valid and infringed
 - what claims are made in the ANDA?
 - avoiding Rule 11 sanctions
 - assessing whether attorney's fees can be properly sought?
 - considerations with multiple ANDA filers
 - when does it make sense to only sue the first filer or a few as opposed to all ANDA filers?
 - what are the consequences of not suing all ANDA filers?
- The answer and counterclaims
 - de-listing improperly listed patents
 - antitrust and unfair competition claims
 - assertions of inequitable conduct
 - the generic point of view:
 - attorneys fees
 - Rule 11

Factoring – in the 30 month stay

- Commencement of the statutory 30 month stay
 - understanding the scope and limits of the 30 month stay under the MMA
- The 30-month stay in the course of litigation
 - options and strategies for the patent holder if the stay expires during the course of litigation
 - early termination of the stay

Generic Generic Law Suits

- Exploring circumstances in which the generic behaves as an innovator
- Pleading protection of market exclusivity

Declaratory Judgment Motions

- When is it appropriate to move for a DJ
- Understanding the MMA declaratory judgment provisions and the CAFC's interpretation of these provisions
 - two prong test
- Circumstances when a DJ will be granted
- Should DJ be sought on all patents – listed and not listed?

Summary Judgment Motions

- Identifying circumstances in a Paragraph IV litigation when filing a motion for summary judgment makes sense
 - when is it advantageous for the generic side to do so?
 - on grounds of invalidity or infringement?
 - does it ever make sense for the brand?

3:45

Working With Local Counsel and within Local Rules: Magistrate and Local Counsel Roundtable



Honorable Mary Pat Thyng

Chief Magistrate Judge
United States District Court, District of Delaware
(Wilmington, DE)



Honorable Tonianne Bongiovanni, U.S.M.J.

United States District Court
District of New Jersey (Trenton, NJ)



Honorable Roy Payne, U.S.M.J.

United States District Court
Eastern District of Texas (Marshall, TX)



Eric I. Abraham

Partner
Hill Wallack LLP (Princeton, NJ)



Bo Davis

Founder
The Davis Firm (Longview, TX)



Brian Farnan

Partner
Farnan LLP (Wilmington, DE)

Moderators:



W. Blake Coblentz

Member
Cozen O'Connor (Washington, DC)



Ralph J. Gabric

Shareholder & Chair, Litigation Group
Brinks Gilson & Lione (Chicago, IL)

Many key jurisdictions in which Paragraph IV disputes are heard have their own local patent rules. Some jurisdictions even go as far as having a subset of local patent rules for Hatch-Waxman matters. This is why the assistance of local counsel is often crucial in navigating the “ins and outs” of these rules and jurisdictions. This panel of magistrates and local and national counsel will explore the requirements and nuances of these rules as well as the importance of working with local counsel. Points of discussion will include:

- Choosing and working with local counsel
- Surveying local patent rules in key jurisdictions
 - New Jersey
 - E.D. Texas
 - Delaware
 - Northern District of Illinois
- Schedule setting rules
- Applicable discovery rules
- Local patent rules and dispositive motions
- Local patent rules and Markman hearings
- Trial procedures under local rules

4:45

A View from the Bench



Honorable Ruben Castillo

Chief Judge
United States District Court
Northern District of Illinois (Chicago, IL)



Honorable Leonard Davis

Chief Judge
United States District Court
Eastern District of Texas (Tyler, TX)



Honorable Gregory M. Sleet

Chief Judge
United States District Court, District of Delaware
(Wilmington, DE)



Honorable Garrett E. Brown, U.S.D.J. (ret.)

Former Chief Judge, United States District Court
District of New Jersey (Trenton, NJ)
Neutral, JAMS, The Resolution Experts
(New York, NY)

Moderators:



Meredith Martin Addy

Partner
Steptoe & Johnson LLP (Chicago, IL)



Michael A. Sitzman

Partner
Gibson, Dunn & Crutcher LLP (San Francisco, CA)

Renowned jurists with some of the most active Paragraph IV litigation dockets in the country will share their thoughts and insights on the most important issues facing both patent holders and patent challengers. Come prepared with your most pressing questions.

6:00

Conference Adjourns to Day Two

Cocktail Reception immediately following Judges' Panel

Cocktail Reception
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Tuesday, April 29, 2014 Main Conference – Day 2

7:30 Co-Chairs' Opening Remarks and Recap of Day 1

Continental Breakfast Sponsored by: **Taft/**

8:15 Claim Construction and Markman Hearings: Standards, Jurisprudential Splits and Strategies for Paragraph IV Litigation



Keith J. Grady
Practice Group Chair
Polsinelli PC (St. Louis, MO)



Pablo D. Hendler
Partner
Ropes & Gray LLP (New York, NY)



Beth D. Jacob
Partner
Kelley, Drye & Warren (New York, NY)



Jeffrey N. Myers, Ph.D.
Vice President & Assistant General Counsel
Pfizer Inc (New York, NY)

Moderator:



Martin B. Pavane
Member
Cozen O'Connor (New York, NY)

Claim construction has been described as the most important event in the course of patent litigation – let alone Paragraph IV litigation. The Supreme Court in Markman described claim construction as a “mongrel practice.” This is evident through the considerable split in Federal Circuit claim construction jurisprudence which has caused considerable uncertainty in the planning of Markman strategies. As the Supreme Court did not grant certiorari in *Retractable Technologies, Inc. v. Becton, Dickinson and Company* (Fed. Cir. 2011), any hopes for consistent guidance in these matters were dashed. All eyes are now on the Federal Circuit’s *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, 500 Fed.

App’x 951, 951-52 (Fed. Cir. 2013) case in hopes that it will finally establish the standard of review for such matters.

This panel will provide practical strategies for formulating Markman hearing strategies in view of the still existing intra-circuit split and possible new standard of review. Points of discussion will include:

- Understanding how *Lighting Ballast Control LLC v. Philips Electronics North America Corp.*, 500 Fed. App’x 951, 951-52 (Fed. Cir. 2013) may mend the intra circuit split in claim construction jurisprudence
 - what the adoption of a deferential standard of review may mean for Markman strategies going forward
- How the split in the Federal Circuit on claim construction has impacted Paragraph IV challenges and related Markman hearings
 - more narrow reading of claims vs. broader reading
 - findings of fact vs. questions of law
 - *Cybor and Phillips*
 - Retractable Technologies
- Revisiting 112 written description and enablement distinction requirements relative to clarity of claims
 - reviewing specification requirements
 - understandability
 - inventorship
- Strategies for working around these inconsistencies at Paragraph IV Markman hearings

9:15 FTC Keynote: Reverse Payment Settlements and Other Antitrust Concerns Impacting Paragraph IV Litigation in the Wake of Actavis



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

On June 17, 2013, the U.S. Supreme Court issued its decision in the *Actavis* case and finally addressed the matter of reverse payment settlements in Hatch-Waxman cases. The Court’s 5-3 decision clearly establishes the antitrust “rule of reason” as the standard for evaluating reverse payment settlement cases. The significance of the Supreme Court’s decision, however, will only become clear as the lower courts grapple with its application to challenged reverse payment settlements.

As per the MMA, the FTC is required to continue to review Hatch-Waxman settlements, and it has publicly announced that it will continue challenging reverse payment settlement agreements, possibly including settlement agreements filed prior to the *Actavis* decision. Private plaintiffs certainly have stepped up their challenges, and there are currently fifteen reverse payment cases in litigation. Additionally, the FTC recently has questioned the legality under *Actavis* of a Hatch-Waxman settlement based on the brand’s agreement not to launch an authorized generic. It is now anyone’s guess as to how far the FTC and private plaintiffs will go.

In this session, Markus Meier will address these matters, in addition to other anticompetitive concerns in the Hatch-Waxman space.

10:00 Morning Coffee Break

Morning Coffee Break Sponsored by: **Steptoe**
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10:15 Perils of the Safe Harbor: Understanding How the Resetting of the Boundaries of 271 (e)(1) In the Aftermath of Classen and Momenta is Impacting Paragraph IV Litigation Strategies



Kathleen B. Carr
Partner and Co-Chair of its Intellectual Property
Litigation Group
Edwards Wildman Palmer LLP (Boston, MA)



Donna M. Meuth
Associate General Counsel
Intellectual Property
Eisai Inc. (Andover, MA)



Sailesh K. Patel
Partner
Schiff Hardin LLP (Chicago, IL)



Maureen L. Rurka
Partner
Winston Strawn LLP (Chicago, IL)

Moderator:



Tracey B. Davies
Partner
Gibson, Dunn & Crutcher LLP (Dallas, TX)

- Understanding why the Supreme Court's denial of cert. in *Classen v. Biogen* (Fed. Cir. 2011) is not an affirmation of *Classen* or *Momenta v. Amphastar's* (Fed. Cir. 2012) safe harbor holdings
 - dismissal without prejudice as premature
 - review of the Solicitor General's findings and significance for further Supreme Court review
- Deciphering how the Supreme Court's present denial of cert. and the present state of the law concerning safe harbor exceptions will impact ANDA filings
 - 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 of a Federal law" vs. "information that may be routinely reported to the FDA, long after marketing approval has been obtained"
 - position of brands vs. that of generics relative to Paragraph IV challenges
 - how may this jurisprudence impact the relationship between brands and generics as established by the Hatch-Waxman Act?
- Devising strategies for Hatch-Waxman litigation relative to the boundaries of 271(e)(1) in view of the law's present state
 - brand name and generic perspectives

11:15 **In the Limelight: Strategies and Theories of Inducement, Contributory and Divided Infringement in Paragraph IV Litigation Concerning Method of Treatment Patents**



Nicolas Barzoukas
Partner
Baker Botts L.L.P. (Houston, TX)



Steven Lieberman
Partner
Rothwell, Figg, Ernst & Manbeck, P.C.
(Washington, DC)



David A. Manspeizer
Partner
Wilmer Cutler Pickering Hale and Dorr LLP
(New York, NY)



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



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

- Understanding the significance of the Supreme Court granting cert. in *Limelight v. Akamai*, S. Ct. No. 12-786
 - examining the Solicitor General's recommendation that the Court "hold that a party cannot be liable for inducement under 35 U.S.C. 271(b) if no party has directly infringed the patent
 - revisiting the Federal Circuit's en banc ruling on inducement of infringement and divided infringement in *Akamai Technologies, Inc. v. Limelight Networks, Inc.* (Fed. Cir. 2012)
 - *Global Tech v. SEB*, 563 U.S. _____ (May 31, 2011),
 - *mens rea* requirements
 - willful blindness vs. deliberate indifference
 - indirect vs. direct infringement
 - *Commil USA, LLC v. Cisco Sys., Inc.*, No. 2012-1042 (Fed. Cir. 2013)
 - question of reasonable belief of invalidity at the time of the inducing act and consequences
 - Exploring the relationship between inducement actions and divided and contributory infringement and how they apply to methods of treatment claims in pharmaceutical patents
 - applicability to methods of treatment claims listed in the Orange Book
 - Examining how new proposed FDA Rulemaking on Generic Labeling may impact carve outs and skinny labeling relative to method of treatment claims

12:15 **Networking Luncheon**



1:30 **Assessing GDUFA Implementation and Additional Regulatory Developments at FDA Which Impact Paragraph IV Litigation**



Bradley W. Crawford
Shareholder
Polsinelli PC (Chicago, IL)



Kurt Karst
Director
Hyman, Phelps and McNamara (Washington, DC)



Peter O. Safir
Partner
Covington & Burling LLP (Washington, DC)



Carmen M. Shepard
Sr. Vice President
Global Policy and Regulatory Counsel
Mylan (Washington, DC)

- Evaluating the success of FDA's implementation of the Generic Drug User Fee Amendments of 2012 ("GDUFA")
 - GDUFA steering committee – purpose and intent
 - re-visiting FDA's ANDA backlog in light GDUFA implementation
 - possible end of multiple review cycles
 - addressing concerns over how a continuing backlog may impact not only generic approvals, but the 30 month stay allowed under Hatch-Waxman
 - exploring possible repercussions for first filer status
- Exploring proposed legislation to remedy GDUFA hardship for small generic manufacturers
 - H.R. 3631, the Small Manufacturer Protection Act of 2013
- Anticipating GDUFA repercussions based on Agency goals that may impact ANDA filers beyond user fee costs
 - forfeitures
 - inspections and cGMP violations
- Understanding how FDA regulatory redress under FDASIA may impact the future of Paragraph IV litigation
- Citizens petitions revisited
 - examining the uptick in citizen's petitions filings in Hatch-Waxman matters
 - when should they be filed
 - avoiding accusations the citizen petition is being filed as a delaying tactic
 - FDA response time/505(q)
 - Citizens Petitions relative to REMS and generic drugs
- Lawsuits against FDA
- When should you consider suing the FDA relative to a Hatch-Waxman determination?

2:30

Looking Beyond 180 Days: New Exclusivity Challenges for Brand Names and Generics and Related Implications for Paragraph IV Challenges



David P. Frazier Ph.D.

Partner
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP (Washington, DC)



Lisa Barons Pensabene

Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)



Richard T. Ruzich

Partner
Taft Stettinius & Hollister LLP (Chicago, IL)



Meg Snowden

VP, Intellectual Property
Impax Laboratories (Hayward, CA)

Brand Name Exclusivity Challenges

- Analyzing new NCE exclusivity concerns
 - Eisai (Belviq) and UCB (Vimpat) citizens petitions
 - can the NCE exclusivity start date begin for a controlled substance prior to DEA scheduling?
- Exploring new 3-year new clinical investigation exclusivity matters
 - Covis (Lanoxin)
 - Astra Zeneca (Seroquel)
- Status of lawsuits against FDA in regulatory exclusivity denials
 - Center for Drug Evaluation and Research's ("CDER's) Exclusivity Board
 - review of NCE exclusivity, 3-year new clinical trial exclusivity, and exclusivity for biological products

Exclusivity for Combination Products

- Status and review of Combination Drug Development Incentive Act of 2013 (H.R. 2985)
- Exploring exclusivities for combination products comprised of two new Orange Book listed drugs
 - review of necessary criteria for each of the component drugs to receive 5 year NCE exclusivity

- Gilead (Stribild) Ferring (Prepopik) and Bayer (Natazia) Citizens Petitions
- 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?

180-Day Exclusivity Challenges for Generic Small Molecules

- 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
- Forfeiture provisions: circumstances under which exclusivity is forfeited under FDC Act § 505(j)(5)(D)(i)
 - Caraco: question of 180-day exclusivity forfeiture for an ANDA product that receives tentative approval on the 30-month ANDA submission anniversary date
- Assessing the use of IPR as a forfeiture triggering event
- 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

3:15

Afternoon Refreshment Break

3:30

A Pros and Cons Analysis of Launching At Risk and Survey of New Developments in Seeking Injunctive Relief and Damages



Thomas H. Beck

Partner
Sidley Austin LLP (New York, NY)



Gregory K. Bell

Group Vice President
Global Practice Leader – Life Sciences
Charles River Associates (Boston, MA)



Greg Chopskie

Senior Counsel
Gilead Sciences (Foster City, CA)



Glenn S. Newman, CPA/ABV/CFE, MBA

Partner, Forensic Litigation & Valuation Services
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James K. Stronski

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George Yu

Counsel
Schiff Hardin LLP (San Francisco, CA)

Moderator:



Paul W. Browning Ph.D.

Partner
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP (Washington, DC)

On June 12, 2013, the parties in the Protonix litigation reached an agreement in the amount of \$2.15 Billion for lost profit damages. This number is astronomical. However, as the damages portion did not go to trial, it is anyone's guess as to how great an amount may have ultimately been awarded in court. Brand names and generics are still in the dark as to what may transpire if a trial for an at risk launch of the generic version of a branded product were ever to reach final adjudication at the damages phase.

This panel will explore lessons learned from Protonix in terms of new considerations for damages estimation and award in an at-risk launch and the continuing debate over divergent standards for injunctive relief. Points of discussion will include:

The At-Risk Launch

- Launching at risk during litigation or the appeal period
 - taking a closer look at Protonix
 - benefits and risks analysis
 - assessing whether the magnitude of the Protonix litigation will deter future launches at risk
 - evaluating the overall decline in at risk launches over the last few years
 - linkage to FTC “pay –for-delay” activity
 - impact of *Actavis* on such filings

Injunctions

- Examining how District Court determinations regarding preliminary injunctions are being made in view of the inconsistencies between the Federal Circuit and the Supreme Court relative to the granting of a preliminary injunction
 - *Winter v. Natural Resources Defense Counsel, Inc.*, 555 U.S. 7 (2008)
 - *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006)
 - intra-Circuit split at the Federal Circuit
 - taking the Federal Circuit to task for not following the Supreme Court’s standard for preliminary injunctions
 - *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, Case No. 10-1382 (Fed. Cir., Sept. 29, 2011)
- Review of recent Hatch-Waxman matters concerning preliminary injunctions
 - *AstraZeneca LP v. Breath Ltd.* (Fed. Cir. 2013)
- Practical strategies for brand names and generics in dealing with this discord before the District Courts and Federal Circuit
- Seeking a preliminary injunction in the event that the stay ends in the course of the litigation
 - posting of bond by the branded side
- Strategies for opposing injunctive relief

- Exploring the possibility of a stipulated injunction
 - why a stipulated injunction may be of benefit to both sides

Damages Analysis

- What has the Protonix settlement taught us about damages assessment?
- The quantification of damages
 - brand – name vs. generic point of view
 - small v. large generic company concerns
- Lost profits:
 - assessment of profit as a true measure of damages
 - is the drug profitable?
 - a question of sales
 - when is it the only thing that you can seek?
 - circumstances under which lost profits can be denied
 - *Sanofi v. Glenmark* (D.N.J. 2012)
 - question of authorized generic
- Reasonable royalties:
 - basis for royalty
 - looking at market share
 - the point where infringement began
- Mitigating factors impacting damage award

4:45 Ethical Considerations for Paragraph IV Matters Before the PTO and District Courts: Inequitable Conduct and More



Bradford J. Badke
Partner
Ropes & Gray LLP (New York, NY)



David G. Conlin
Partner
Edwards Wildman Palmer LLP (Boston, MA)



Anthony E. Dowell
Attorney
Taft Stettinius & Hollister LLP (Chicago, IL)

- 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

- understanding how the adoption of these rules will impact Paragraph IV litigation
- Examining the Federal Circuit’s tightening of the inequitable conduct standard in *Therasense*
 - intent to deceive
 - single most reasonable inference
 - materiality
 - ‘but for’ test
- Analyzing the downward trend in inequitable conduct allegations since *Therasense*
- Exploring the PTO’s adoption of the *Therasense* standard in its proceedings with respect to inequitable conduct findings
 - inequitable conduct and Patent Reform
 - supplemental proceedings under the AIA: an opportunity to cure inequitable conduct?
- *Apotex, Inc., et al., v. UCB, Inc., et al.*, (S.D. Florida 2013)
 - obtaining a competitor’s product by deception
- *Sony Computer v. 1st Media LLC* (on petition for writ of certiorari 2013)
 - possible return to pre-*Therasense* standard
- Rule 11 obligations to bring an ethics suit in a Hatch-Waxman case
 - exploring the debate of whether state or federal law applies to IP malpractice actions

5:45 Conference Ends

(Registration with Continental Breakfast opens at 8:15 AM. Luncheon will be served from 12:00 PM – 1:00 PM.)

The Master Class on Settling Paragraph IV Disputes: Drafting and Negotiating Strategies for Brand-Names and Generics – A Hands-On, Practical Approach in the Aftermath of Actavis



Gregory K. Bell
Group Vice President
Global Practice Leader – Life Sciences
Charles River Associates (Boston, MA)



Meenakshi Datta
Partner
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Donald R. McPhail
Member
Cozen O'Connor (Washington, DC)



Glenn S. Newman, CPA/ABV/CFE, MBA
Partner, Forensic Litigation & Valuation Services
ParenteBeard LLC (Philadelphia, PA)



Christopher J. Kelley
Partner
Mayer Brown LLP (Palo Alto, CA)



Steven A. Maddox
Partner
Knobbe, Martens, Olson & Bear, LLP (Washington, DC)

Moderators:

Workshop Objectives:

- Understand the application of antitrust law's "Rule of Reason" to pharmaceutical patent settlements
- Draft and structure an agreement that will pass FTC review
- Identify and avoid red flags that could trigger FTC scrutiny
- Incorporate elements that emphasize the procompetitive nature of the agreement
- Assess the role of commitments as to authorized generics and the FTC's view on this topic
- Understand the significance of other business opportunities in making these agreements viable
- Provide a working knowledge of concepts such as valuation, pricing, royalties and lost profits as they apply to these agreements
- Develop timelines for business and legal milestones relative to the terms of the settlement
- Devise strategies to employ pending completion of the FTC's review

The MMA requires pharmaceutical companies to notify the FTC and the DOJ of settlements of pharmaceutical patent disputes. This mandate has caused both brand names and generics alike great apprehension as it replaces patent-based uncertainty with antitrust risk. Although the FTC has challenged only two settlements out of the hundreds filed in recent years, its public statements condemning "reverse payments" have created uncertainty and frustration among both the branded and generic pharmaceutical industries.

All eyes were on the Supreme Court last spring when it ruled in *FTC v. Actavis (formerly Watson)* in hopes that there would be some guidance as to what was fair or foul in these settlements.

However, the Court's decision has still not brought certainty to the antitrust analysis of these settlements. While, the Court established that the Rule of Reason is the controlling antitrust principle in these cases, it did not explain fully how to apply it. Moreover, the Commission's invocation of *Actavis* in pursuing agreements relating to items such as authorized generics only continues to cause the industry anxiety.

This hands-on, interactive workshop will examine how, in this post-*Actavis* environment, parties to a Paragraph IV dispute can resolve their differences, reach an agreement that they both can live with, and minimize the chances of costly and distracting government scrutiny. The workshop leaders will walk you through the antitrust implications of *Actavis* and provide practical pointers and strategies for the drafting and structuring of successful and sound settlement agreements within the parameters of the workshop's objectives. Points of discussion will include:

- Overview of the antitrust law and competitive principles governing pharmaceutical patent settlements
- Analyzing the Supreme Court's ruling in *Actavis*
- Review of the "Rule of Reason" and its application to pharmaceutical patent settlements
- Anticipating the FTC's next area of focus in wake of the *Actavis* ruling
- Creative settlement strategies within the scope of what is permissible
- Assessing roles of in-house and outside counsel, and the in-house business team, in developing and executing settlement strategies
- Analysis of antitrust implications of possible agreement terms and conditions

- Risk allocation between the parties
 - supply agreements and strategies for successful structuring and permissible terms
 - avoidance of the appearance of hidden payments
 - careful use of documentation to promote transparency, clarify intent and avoid any allegation of non-disclosure
- Developing legal and business timelines to determine optimal settlement terms for both sides
 - key points for business and legal timelines
 - assessing the product's place in the marketplace in comparison to other therapeutic classes of drug
 - valuation of product over course of patent life cycle
 - criteria for determining value
 - stock value over course of lifecycle
 - return on investment over course of life cycle
- Potential royalty streams from licensing
- Assessing likelihoods and values of litigation outcomes
- The 30 month stay
- Review of pricing terms relative to settlement agreements
 - transfer pricing
 - best price
 - Medicare Part D pricing
 - WAC
 - price adjustments
- *Effexor* amicus brief and authorized generics
 - examining the applicability of the Scott Hart Rodino premerger notification rules amendments concerning exclusive patent licenses for pharmaceutical products to the settlement of cases brought under Paragraph IV

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WHO YOU WILL MEET

Patent attorneys and litigators (in-house & law firm) who represent:

- Brand name pharmaceutical companies
- Generic pharmaceutical companies
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