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This year marks 30 years since the inception of C5 Group.
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See inside for details…

June 13-15, 2016 | New York Marriott Downtown | New York, NY

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American Conference Institute's 7th Annual Summit on

Biosimilars

Legal, Regulatory, Commercial, and Patent Strategies for the Emerging U.S. Biosimilars Landscape

Network with an esteemed faculty and Advisory Board comprised of industry insiders including:

Amgen Inc.
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Coherus BioSciences, Inc.
Eisai Co., Ltd.
Generic Pharmaceutical Association ("GPhA")
Merck & Co., Inc.
Momenta Pharmaceuticals
National Council for Prescription Drug Programs
Novartis
Novo Nordisk
Pfizer Inc.
Sandoz Inc.
Widener University

With the second FDA approval of a biosimilar, there is no time to waste to develop your biosimilars strategy. This must-attend program has been revamped and updated to provide detailed analysis of:

- *Amgen Inc. v. Sandoz Inc.* and related biosimilars litigation
- Exploring the strategic implications of the transition from NDA approval to BLA licensure
- Reformulating biosimilar patent strategies under new Section 101 and 112 case law
- Appreciating promotion and products liability concerns when marketing a biosimilar product
- Exploring IPR strategies, including the impact of *Cuozzo Speed Technologies, LLC v. Lee* on biosimilars cases

Plus, a half-day session on Legal Ethics and Professional Responsibility: Avoiding Conflicts of Interest, Maintaining Confidentiality, and Other Special Concerns for the Biosimilars Space to help you sustain your duty of care to your clients.

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"As of January 21, 2016, 59 proposed biosimilar products to 18 different reference products were enrolled in the Biosimilar Product Development (BPD) Program . . . . Over the past year, we have seen the number of meeting requests and marketing applications grow. We are excited about this growing demand, and we will continue to facilitate development, submission, and timely review of biosimilar product applications."

Testimony of **Janet Woodcock**, **M.D.**, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives (Feb. 4, 2016).

Dear Colleague,

On March 6, 2015, the FDA approved Sandoz's Zarxio, the first biosimilar product in the U.S. Just one year later, on April 5, 2016, FDA approved the second biosimilar product, Celltrion's Inflectra. It is clear that innovator and biosimilar companies must develop a comprehensive strategy for the upcoming battles to protect or increase market share in this space.

Based on industry demand, ACI is proud to bring you the leading event on biosimilars, comprised of industry insiders who are actively shaping the evolving U.S. biosimilars landscape. At this annual conference, the esteemed faculty will provide you with real-life strategies designed to meet the year's biggest legal, regulatory, and IP challenges. Designed with input from the industry and the distinguished members of ACI's Biosimilars Advisory Board, this year's event features several ***new*** sessions aimed at giving you unique, up-to-the-minute information for biosimilars:

- Detailed case study on the impact of *Amgen Inc. v. Sandoz Inc.* and related biosimilars litigation
- Analysis on the various partnerships, collaborations, and joint ventures between biotechnology and pharmaceutical companies to develop a biosimilar product
- Dissecting IPR trends and statistics in the pharmaceutical industry, including an exhaustive study of the Supreme Court's holding in *Cuozzo Speed Technologies, LLC v. Lee*
- Examination of FDA's proposed naming guidance and the potential impact on current and future biosimilars
- Biosimilars patent strategies under new section 101 and 112 case law
- Considerations for promotion of biosimilar products, including an exploration of potential off-label and products liability issues
- Preparing to transition NDAs to BLAs in 2020 under the BPCIA

In addition, don't forget to join us for a comprehensive post-conference workshop delving into legal ethical and professional responsibility concerns for attorneys in the biosimilars space.

Whether you are on the innovator or biosimilar side, you will walk away with a comprehensive plan for biosimilars market entry in the U.S.

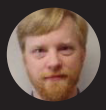
Join the leaders of the biosimilars industry and learn to navigate your way through the various legal, regulatory, commercial, and IP hurdles impacting your business. Save your spot by calling 888-224-2480 or by visiting AmericanConference.com/Biosimilars.

I look forward to seeing you in New York in June.

Very truly yours,

Bolam Kim
Legal Analyst & Conference Director

Biosimilars Advisory Board



Mark I. Bowditch
Vice President,
Intellectual Property
and Litigation
Coherus BioSciences, Inc.

Reza Green
Vice President,
Intellectual Property
Novo Nordisk

Bruce A. Leicher
Senior Vice President
and GeneralCounsel
Momenta Pharmaceuticals

Christian Smolizza
Assistant General Counsel
Pfizer Inc.

Immac ("Casey") J. Thampoe, Ph.D., J.D.
Managing Counsel, Biologics
Merck & Co., Inc.

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Our new brand look and language will be fully revealed soon. Stay tuned for more exciting changes.

DAY ONE
MONDAY, JUNE 13, 2016

8:00
Registration and Continental Breakfast - Sponsored by:

Proskauer

9:00
Co-Chairs' Opening Remarks

Betty Ryberg
Vice President, IP Litigation
Novartis Services, Inc. (New York, NY)

Donald R. Ware
Partner and Chair, Intellectual Property Department
Foley Hoag LLP (Boston, MA)

9:15
Strengthening Your Regulatory Biosimilars Strategy for Interchangeability, Naming, and More in an Uncertain Landscape

Thomas Felix, MD
Medical Director, R&D Policy
Global Regulatory Affairs and Safety
Amgen Inc. (Washington, DC)

John Klimek, R.Ph.
Senior VP, Standards and
Information Technology
National Council for Prescription
Drug Programs ("NCPDP") (Scottsdale, AZ)

Bruce A. Leicher
Senior Vice President and General Counsel
Momenta Pharmaceuticals (Cambridge, MA)

Moderator:

Lisa Barclay
Counsel
Boies, Schiller & Flexner, LLP (Washington, DC)

- Status of current FDA regulations affecting biosimilars
- Examining the FDA's potential requirements for interchangeability
  - Analyzing citizen petitions from the industry on interchangeability and similarity requirements
- Resolving whether a biosimilar must be interchangeable for all of the indications that a reference product is approved for by the FDA
- Dissecting FDA's draft guidance on the Nonproprietary Naming of Biological Products
  - Exploring industry comments to the draft guidance
  - Reviewing the FTC's comments on the FDA's naming guidance
  - Forecasting the impact on the global market
  - Identifying the impact of FDA's draft guidance on the name of the first U.S. biosimilar—filgrastim-sndz
  - Evaluating the benefits and drawbacks of using a distinct nonproprietary name to distinguish biosimilars from reference products
  - Comprehending the WHO's approach to naming of biosimilars and how it differs from the FDA's draft guidance
  - Understanding the risks and benefits of having the biosimilar separately identifiable by its name from the reference product
- Developing best practices for moving ahead despite uncertainty stemming from draft FDA guidances
- Distinguishing the various stages of the Biosimilar Product Development Program meetings and what happens in each stage
- Preparing for an Advisory Committee meeting for biosimilar review

10:30
Morning Refreshment Break - Sponsored by:

KRAMER LEVIN
KRAMER LEVIN NAFTALIS & FRANKEL LLP

10:45
Case Study: *Amgen Inc. v. Sandoz Inc.* and the Impact on the Patent Dance and the Notice of Commercial Marketing

Mark I. Bowditch
Vice President, Intellectual Property and Litigation
Coherus BioSciences, Inc. (Redwood Shores, CA)

Robert S. Schwartz, Ph.D.
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Sheila N. Swaroop
Partner
Knobbe, Martens, Olson & Bear, LLP (Irvine, CA)

Donald R. Ware
Partner and Chair, Intellectual Property Department
Foley Hoag LLP (Boston, MA)

In July 2015, the Federal Circuit held in *Amgen Inc. v. Sandoz Inc.* that the BPCIA did not require the biosimilar applicant and the reference product sponsor to engage in the patent dance. The court also found that the notice of commercial marketing was required where the biosimilar applicant did not engage in the patent dance and that such notice could only be given after FDA approval of the biosimilar product. Despite the Federal Circuit's ruling, much uncertainty still exists in the industry regarding the patent exchange process and the 180-day notice of commercial marketing. After the Federal Circuit's denial of petitions for an *en banc* rehearing in October, a petition for certiorari was filed with the Supreme Court. Meanwhile, the industry is left assessing the repercussions of the Federal Circuit's decision.

This case study of the *Amgen Inc. v. Sandoz Inc.* decision will explore the ramifications on the patent process in the biosimilars industry. Points of discussion shall include:

- Reviewing the Federal Circuit's final holding in *Amgen Inc. v. Sandoz Inc.*
- Delving into other biosimilars cases interpreting the BPCIA
  - *Amgen Inc. v. Apotex Inc.* and *Janssen Biotech Inc. v. Celltrion Healthcare Co. Ltd.*: is the 180-day notice of commercial marketing mandatory where the parties engaged in the patent dance?
    - » If mandatory, when is the earliest that a biosimilar applicant can give notice to the reference product sponsor?
  - *Amgen Inc. v. Hospira Inc.*: if participating in the patent dance, how much information must you provide in order to be compliant with the BPCIA provisions
  - *Janssen Biotech Inc. v. Celltrion Healthcare Co. Ltd.* and *Immunex v. Sandoz*: is it mandatory to complete all steps of the patent dance, once started?
- What are the risks and benefits for both parties of engaging in the patent dance?
- Exploring various strategies to minimize litigation risk if you are filing a biosimilars application

12:15
Networking Luncheon - Sponsored by:

LOEB & LOEB LLP

1:30
Charting State Regulation: Sailing Through the Murky Waters of State Laws Affecting Biosimilars

Brynna Clark
Senior Director, State Affairs
Generic Pharmaceutical Association ("GPhA")
(Washington, DC)

- Revisiting the relationship between FDA's upcoming guidance on interchangeability and state substitution laws and understanding the types of biosimilars that would and would not be eligible for substitution

- Identifying the different states with legislation regulating biosimilars especially pertaining to substitution and interchangeability
- Monitoring other states that are expected to pass laws impacting the biosimilars landscape
- Addressing how states have determined whether physicians should be notified in case of a substitution by the pharmacy
  - Understanding whether pharmacists can automatically substitute a prescription for a biosimilar
  - How should the pharmacist notify the physician of the substitution?
  - Exploring pharmacist record keeping requirements under various state substitution laws

2:30

Demystifying IPRs for Effective Use in the Biosimilars Landscape

Barbara A. Fiacco
Partner
Foley Hoag LLP (Boston, MA)

Gregory A. Morris, Ph.D.
Partner and Leader, Life Sciences Litigation Practice Group
Honigman Miller Schwartz and Cohn LLP (Chicago, IL)

Stacie Ropka, Ph.D.
Counsel
Axinn, Veltrop & Harkrider LLP (Hartford, CT)

Mark E. Waddell
Partner and Chair, Patent Litigation and Counseling
Loeb & Loeb LLP (New York, NY)

Moderator:

J. Patrick Elsevier, Ph.D.
Partner
Jones Day (San Diego, CA)

- *Cuozzo Speed Technologies, LLC v. Lee*: examining the proper standard to construe patent claims
  - Reviewing the differences between the broadest reasonable interpretation standard and the *Phillips* standard and how each standard impacts biosimilar strategies
- Analyzing IPR trends and statistics in the pharmaceutical industry
  - Are IPRs the "death squad" for life sciences patents?
  - When are IPRs an effective tool for the life sciences industry?
- Preparing strategies for an IPR versus litigating in federal court
  - What are the pros and cons of using an IPR in the biosimilar context?
  - Understanding how IPR proceedings affect patent practice before the USPTO while also serving as a parallel or alternate administrative venue to district court litigation
  - Choosing your forum wisely: comprehending how estoppels, timing, and costs can cause IPRs to work for or against the biosimilars industry
- Exploring IPR cases in the life sciences context where PTAB has declined to review to develop strategies for successful arguments
- Best practices for appearing before the PTAB

4:00

Afternoon Refreshment Break - Sponsored by:

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4:15

Spotlight on the Judiciary: Lessons Learned for Biosimilars Litigation

Honorable Jacqueline Wright Bonilla
Lead Administrative Patent Judge
Patent Trial and Appeal Board, USPTO (Alexandria, VA)

Honorable Faith S. Hochberg (ret.)
U.S. District Court, District of New Jersey

Moderator:

Irena Royzman, Ph.D.
Partner & Co-Chair of Biotechnology Practice
Patterson Belknap Webb & Tyler LLP (New York, NY)

In this session, distinguished judges experienced in pharmaceutical patent litigation will provide their insights concerning claim construction, seeking injunctions, parallel USPTO proceedings, motion practice, settlements, and damages which are sure to come into play in biosimilars litigation.

5:15

Conference Adjourns to Day Two

Cocktail Reception - Sponsored by:

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DAY TWO
TUESDAY, JUNE 14, 2016

8:30

Continental Breakfast - Sponsored by:

Proskauer

8:45

Co-Chairs' Opening Remarks and Recap of Day 1

9:00

New Considerations for Practical Commercial Strategies and Debating the Economic Viability of Biosimilars

Joseph P. Fuhr, Jr., Ph.D.
Professor, Economics
Widener University (Chester, PA)

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

Patrick C. Woolley
Partner and Practice Group Chair
Polsinelli PC (Kansas City, MO)

- Exploring the different financial incentives to develop biosimilars in Europe and taking away key lessons for the U.S. market
- Comparing different partnerships, collaborations, and joint ventures with other biotech or pharmaceutical companies to develop a biosimilar
- Analyzing the current U.S. innovator biologics products pipeline and revenue
  - Discussing which biologics are particularly vulnerable to biosimilars competition going forward
- Scrutinizing the numbers: how much does a biosimilar need to make in order to be profitable?
  - Determining the potential value of biosimilars revenue based on relevant IP, regulatory, and commercial factors
  - Reviewing estimated development costs and amount of production capital needed
- Pricing considerations: biosimilar prices versus reference product prices
- Comprehending CMS guidance documents relating to payment, pricing, and reimbursement policies for biosimilars
- Investigating the economic implications of CMS allowing one J code for biosimilars and reference products

10:00
Morning Refreshment Break - Sponsored by:

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10:30
Mapping Out the BPCIA Process: A Cheat Sheet on Navigating the Biosimilars Pathway

Carol Pitzel Cruz
Partner
Knobbe, Martens, Olson & Bear, LLP (Seattle, WA)

Chad Landmon
Partner
Axinn, Veltrop & Harkrider LLP (Hartford, CT & Washington, DC)

Brian V. Slater
Partner and Chair, Life Sciences
Kramer Levin Naftalis & Frankel LLP (New York, NY)

Anita Varma
Partner
Ropes & Gray LLP (Boston, MA)

Jason A. Wietjes
Shareholder
Polsinelli PC (Dallas, TX)

- Making the decision to navigate the pathway by comparing and contrasting the biosimilars pathway under the statute to 505(b)(2) and BLA pathways including timing, costs, IP litigation considerations, and exclusivities
- Evaluating the patents in your portfolio which may be the subject of litigation
  - Performing the required due diligence ahead of time
- Understanding the Purple Book provisions on biosimilar and interchangeable products
  - Using the Purple Book to create "slates" of suggested patents or deciding which patents to challenge
- Exploring whether to provide a (k) application and if so, determining what other information to provide
  - Preparing the initial patent list and non-infringement and validity contentions in advance
  - Comprehending the potential consequences of the Reference Product Sponsor not responding with a detailed claim-by-claim response
- Updating the BPCIA timeline
  - Comprehending what has worked for biosimilars applicants and the RPS in the first wave of litigation and analyzing what to expect in the second wave
  - Identifying strategic considerations for deciding whether to limit the number of patents the RPS can assert in the early phases of litigation
  - Vetting your patents to decide which ones to assert in the first wave of litigation versus the second wave of litigation
- Examining whether it is possible to litigate patents prior to filing a biosimilars application
- Review of most recent at-risk launches in the Hatch-Waxman context to glean lessons for the biosimilars landscape
  - Are at-risk launches possible for biosimilars?
  - Conducting a benefits analysis of launching at risk during the trial or appeal period
  - Asserting damages in an at-risk scenario for biosimilars
  - Mitigating factors impacting damage award

12:00
Networking Luncheon - Sponsored by:

Knobbe Martens
INTELLECTUAL PROPERTY LAW

1:15
Exploring the Strategic Implications of the Transition from NDA Approval to BLA Licensure

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

Under the provisions of the BPCIA, a number of products that are currently approved under NDAs and ANDAs will be deemed to have approved BLAs in March 2020. The introduction of new versions of these products will now require licensure under a full BLA or as a biosimilar. FDA has recently issued a guidance regarding this transition, including the agency's interpretation of the application of exclusivity provisions to products deemed to have an approved BLA. This session will explore the implications of the transition for exclusivities, generic drugs, and biosimilars. The discussion will highlight the need for careful strategic analysis to understand exclusivity issues and the opportunities for competitive product entry.

2:00
Section 101 and Written Description issues in Biologic Products - Prosecutor and Litigator Perspectives

Leslie Fischer, Ph.D., J.D.
Senior Patent Counsel
Novartis Pharmaceuticals Corporation (East Hanover, NJ)

John J. Molenda, Ph.D., J.D.
Partner and Co-Chair, Healthcare & Life Sciences Industry Group
Steptoe & Johnson LLP (New York, NY)

Kathleen Ranney, J.D.
Senior Patent Counsel
Eisai, Inc. (Andover, MA)

Moderator (and Speaker):

Betty Ryberg, J.D.
Vice President, IP Litigation
Novartis Services, Inc. (New York, NY)

- Section 101 Issues in Biologics Patent Applications
- The scope of patent protection that can be obtained in the biosimilars context in light of the USPTO's July 2015 guidance on patent subject matter eligibility
  - USPTO's Current Guidance
  - Examples
  - Overcoming rejections
- Section 101 Issues in Litigation
  - Compounds, Compositions
  - Methods of Administration, Diagnostic Methods
- *Abbvie v. Janssen* and Implications for Written Description in Biologics Patent Applications
  - Comprehending and applying the current standard for written description in view of the *AbbVie* case
  - Demonstrating structural diversity
- Strategic considerations in litigating written description issues in biologics litigation
  - Formulating written description arguments, with a focus on monoclonal antibodies
    - » How many examples are enough to demonstrate representative species
    - » Challenges in showing common structural features
  - Key evidentiary issues arising in the written description context

3:15
Afternoon Refreshment Break - Sponsored by:

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3:30

Developing Real World Strategies for Marketing and Promoting a Biosimilar: Distinguishing the Biosimilar From the Reference Product

Robert V. Cerwinski
Partner
Goodwin Procter LLP (New York, NY)

Jenevieve J. Maerker
Attorney
Foley Hoag LLP (Boston, MA)

Jennifer Zarutskie Sieczkiewicz, Ph.D., J.D.
Research and Business Development Counsel
Biogen Inc. (Cambridge, MA)

- Distinguishing one biosimilar from another biosimilar treating the same condition through innovative marketing and promotion principles
  - What is the impact of *Amarin Pharma, Inc. v. FDA* on off-label marketing of biosimilars?
- Preparing for products liability claims based on the marketing and promotion of biosimilars
- Best practices for preserving trademark rights for biosimilar products

4:30

Comparing and Contrasting the US and Global Biosimilars Experience

Dominic Adair
Partner
Bristows LLP (London, UK)

Christopher P. Borello
Partner
Fitzpatrick, Cella, Harper & Scinto (New York, NY)

Siegmund Y. Gutman
Partner
Proskauer Rose LLP (Los Angeles, CA)

Julia Pike
Vice President of IP, North America
Sandoz Inc. (Munich, Germany)

As established and emerging markets look increasingly towards the biosimilar landscape as a way of cutting costs, the U.S. process can be drastically different from the way that major international markets regulate biosimilars. Given the lack of international harmonization, there has never been a more important time to master the finer points of global biosimilars compliance.

- Regional updates:
  - Asia – Japan and South Korea
  - Australia
  - Europe
  - Latin America
- How is interchangeability treated outside of the United States?
- How do different nations try to replicate the brand drug-generic drug relationship with biosimilars?
- Preparing your global biosimilars portfolio to coordinate regulatory and litigation strategies and positions in a global setting
- Examining key international biosimilars litigation to take away strong arguments and defenses
- Surveying biosimilars approvals to date in the global market
- Exploring lessons learned in the international framework:
  - Regulatory policies
  - Commercial and economic strategies

5:30
Conference Adjourns

POST-CONFERENCE WORKSHOP: WEDNESDAY, JUNE 15, 2016

9:00 am – 12:00 pm *(registration starts at 8:30 am)*

Legal Ethics and Professional Responsibility: Avoiding Conflicts of Interest, Maintaining Confidentiality, and Other Special Concerns for the Biosimilars Space

Michael E. McCabe, Jr.
Member
Funk & Bolton P.A. (Baltimore, MD)

Kevin E. Noonan, Ph.D.
Partner
McDonnell Boehnen Hulbert & Berghoff LLP (Chicago, IL)

- Avoiding conflicts of interest as the lines between branded companies and generic companies blur in the biosimilars space
  - Overview of the Rule 11 mandates
  - What is the duty of care required?
  - Law firms representing both reference products and biosimilars: will the arguments you made in one case come back to haunt you in another?
  - Applying traditional conflicts analysis and principles when agreeing to work for a client: are ABA comments to the model rules instructional?
- Navigating the tricky confidentiality issues inherent in the dossier exchange process under the BPCIA
  - How do you use the information that you get access to during the patent dance?
  - Maintaining required confidentiality while advocating for your company or client
  - What are the limitations of disclosure of biosimilar applications?
  - Obtaining the help of an outside expert or technical specialist
- USPTO spotlight: What are OED's expectations of attorneys in this space?
  - Understanding when to raise the inequitable conduct defense under the continually evolving *Therasense* standard
  - Rule 36 affirmations of inequitable conduct cases
  - Update on recent relevant inequitable conduct cases
  - Complying with the USPTO duty of disclosure: what to submit and how much?
  - Analysis of the PTO's 2013 Rules of Professional Conduct
  - Overview of key provisions including conflicts, sanctions and experts
  - How do these work with the ABA model rules and state bar rules?

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