



## **PROGRAM AGENDA**

**THE DRISKILL HOTEL | AUSTIN, TX | APRIL 16-18, 2012**

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### **MONDAY, APRIL 16, 2012**

#### **Registration**

**11:30 am – 3:30 pm**

**The Driskill – Citadel Room Lobby, Second Floor  
604 Brazos Street  
Austin, TX 78701**

*Please pick up your conference badge and materials in The Driskill Hotel's Citadel Club on the second floor. If you are unable to pick up your materials during this time, registration will reopen on Tuesday, April 17<sup>th</sup> at 7:30 am.*

#### **IP Counsels Committee Business Meeting & Working Luncheon**

**12:00 pm – 3:15 pm**

**The Driskill – Citadel Room, Second Floor  
604 Brazos Street  
Austin, TX 78701**

*\*Open to IP Counsels Committee company members and their representatives only.  
Copies of the Committee Business Meeting Agenda will be provided onsite.*

#### **Pre-Conference Workshop:**

**3:30 pm – 4:30 pm**

#### **Putting The Pieces Together**

**The Driskill – Citadel Room, Second Floor  
Sponsored by: Foley & Lardner LLP**

Since its passage on September 16, 2011, practitioners have spent endless hours studying the AIA and the proposed rules for implementation in an attempt to understand its nuances and practical implications. Given the sweeping changes of the AIA on prior art, PGR, and IPR, the AIA's provisions related to the expanded prior commercial use defense ("PCU defense") may well have been overlooked. This workshop will explore the PCU defense (and the university exception thereto) under the AIA with a focus on its strategic role in disclosure, confidentiality, patenting and trade secret practices. The faculty will provide helpful insight into how documentation and record-keeping policies should be modified to preserve one's ability to invoke the defense as well as special considerations for acquiring or divesting technology that may be subject to the PCU defense.

**Workshop Faculty:**

*Thomas E. Kelley, Assistant General Counsel, Intellectual Property, Monsanto Company*  
*Dan Sharp, Interim Associate Director, Intellectual Property & Licensing, Office of Technology Commercialization, The University of Texas at Austin, and IP & Licensing Counsel, Office of the Vice President for Legal Affairs*  
*Lauren L. Stevens, Ph.D., Of Counsel, Foley & Lardner LLP*  
*Debbie Nye, Partner, Foley & Lardner, LLP*

**Welcome Reception**

**5:30 pm – 7:30 pm**

**Malverde**

*400-B West Second Street*  
*Austin, TX 78701*  
*\*Prior RSVP is required.*



Please join us at 5:10 pm in The Driskill hotel’s lobby, where we will gather before walking to Malverde. This unique reception venue is located above La Condesa on 2nd Street at Guadalupe, Malverde opens up to an outdoor patio overlooking the W Hotel, legendary Austin City Limits Live! and Austin City Hall. Malverde serves a host of hand crafted specialty cocktails featuring hand pressed juices and mixers along with an extensive selection of tequilas, whiskeys, and local beers to the soundtrack of Austin’s best DJs.

*Welcome Reception Sponsored by:*



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**TUESDAY, APRIL 17, 2012**

**Chairman’s Welcome & Breakfast Buffet**

**7:30 am – 8:30 am**

*The Driskill – Mezzanine, Second Floor*  
*Sponsored by: Fenwick & West LLP*

**Session 1:**

**8:45 am – 10:00 am**

**The Decline of Process Patents**

*The Driskill – Ballroom, Second Floor*  
*Sponsored by: Fenwick & West LLP*

This session will examine the enforceability of process claims and how it has led to the recent controversy around divided infringement. Unlike claims to machines, manufactures, and compositions, process claims can be divided up by different actors, or by jurisdiction, and conceivably even by time. Right now the focus is on different claim steps that are performed by different entities, where the law doesn’t provide a remedy for direct (and therefore indirect) infringement – a widening loophole in Section 271(a), (b), (c) and (f). We will discuss this issue and examine how it affected cases involving Abbott, Cardiac Pacemakers, McKesson and Centillion.

**Moderator:** *David Tellekson, Partner, Fenwick & West LLP*

**Panelists:**

*Bryan C. Zielinski, Vice President & Assistant General Counsel, Pfizer Inc.*

*Cameron Marshall, Partner, Carpmaels & Ransford*

*Elias J. Lambiris, U.S. Chief Patent Counsel, Novozymes North America Inc.*

**Session 2:**

**10:15 am – 11:45 am**

**Patentability – The Writing on the Wall: Personalized Methods  
of Treatment and the Evolving “Printed Matter” Doctrine**

**The Driskill – Ballroom, Second Floor**

**Sponsored by: Fenwick & West LLP**

In the U.S. Supreme Court appeal of *Prometheus v. Mayo*, a case dealing with the patent-eligibility of a biomarker-assisted treatment claim under Section 101, the United States have proposed an alternative theory of invalidity that may foreshadow the way the USPTO will treat claims that incorporate newly-discovered biological correlations. This panel will discuss the government’s theory - an extension of the “printed matter” doctrine recently developed in *King Pharmaceuticals v. Eon Labs* – and explore how it can be extended to, distinguished from, or reconciled with the holding in *Prometheus*. The panelists will trace the development of the printed matter doctrine from its origins in cases involving simple labeled articles and board games to its recent implications for complex biomedical processes, and provide recommendations for in-house prosecutors.

**Moderator:** *Michael Sacksteder, Partner, Fenwick & West LLP*

**Panelists:**

*Richard P. Bress, Partner, Latham & Watkins LLP*

*Hugh Goodfellow, Partner, Carpmaels & Ransford*

*Raymond Chen, Deputy General Counsel for Intellectual Property and Solicitor, U.S. Patent & Trademark Office*

**Luncheon & Guest Speaker**

**12:00 pm – 1:15 pm**

**The Driskill – Ballroom, Second Floor**

**Sponsored by: Foley Hoag LLP**

**Guest Speaker:** *Natalie J. Wright, Managing Director, Office of Technology Commercialization, The University of Texas M.D. Anderson Cancer Center*

**Session 3:**

**1:30 pm – 2:45 pm**

**The Regulatory Tide Is Coming In: FDA and Industry  
Get Ready for Biosimilars**

**The Driskill – Ballroom, Second Floor**

**Sponsored by: Foley Hoag LLP**

This panel will provide an update on the guidance, what's happening in the industry, including updates on likely biosimilar applications, what's next at FDA, FDA's involvement in determining applicable dates for the 12-year data exclusivity period, how FDA will handle data packages, and reviewer access to BLAs.

**Moderator:** *Paul T. Kim, Partner, Foley Hoag LLP*

**Panelists:**

*Jay Sitlani, Regulatory Counsel, Office of Regulatory Policy, Center for Drug Evaluation and Research, FDA*

*Laura McKinley, Ph.D., Worldwide Regulatory Strategy, Pfizer Inc.*

**Session 4:**

**3:00 pm – 4:00 pm**

***The Coming Storm of Biosimilars Litigation***

***The Driskill – Ballroom, Second Floor***

***Sponsored by: Foley Hoag LLP***

With the creation of the biosimilars litigation scheme and the recent enactment of the AIA, there will be many different avenues by which patents can be asserted and challenged. If patent litigation were a chess game, this new world of chess is on a 3-dimensional board. This panel will discuss patent enforcement and challenges in federal court before, during and after a biosimilar application is considered by the FDA, including acts of artificial infringement under the BPCIA and the scope of the 271 (e)(1) safe harbor, as well as ITC actions and Patent Office proceedings.

**Moderator:** *Donald Ware, Partner, Foley Hoag LLP*

**Panelist:**

*Perry Siatis, Section Head, Intellectual Property Legal Strategy, Abbott Laboratories*

*Steven J. Lee, Partner, Kenyon & Kenyon LLP*

***The Go Game***

**5:00 pm – 7:00 pm**

***The Driskill – Citadel Room, Second Floor***

***\*Prior RSVP is required.***



Please join us promptly at 5:00 pm *in casual attire*

*and comfortable shoes* in the Maximilian Room on the second floor for orientation before the game begins. Here, attendees will be divided into teams and provided with The Go Game kits containing all necessary supplies for an entertaining adventure around Austin.

***Dinner Reception***

**7:00 pm – 9:00 pm**

***Iron Cactus***

***606 Trinity Street***

***Austin, TX 78701***

***\*Prior RSVP is required.***



Just two blocks from The Driskill Hotel, Iron Cactus is located in the heart of historic 6<sup>th</sup> Street. The turn of the century building was remodeled in 1995 to include the famous Rooftop Patio. This three-level restaurant has become the standard to which locals and visitors alike, compare the rest. Join your colleagues and enjoy an informal dinner reception at Iron Cactus.

*Dinner Reception Sponsored by:*



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**WEDNESDAY, APRIL 18, 2012**

***Networking Breakfast***

***8:00 am – 9:00 am***

***The Driskill – Ballroom, Second Floor***

***Sponsored by: Alston & Bird LLP***

***Session 5:***

***9:15 am – 10:45 am***

***AIA Implementation and Strategy***

***The Driskill – Ballroom, Second Floor***

***Sponsored by: Alston & Bird LLP***

This session will survey the recent waves of PTO draft regulations implementing the America Invents Act and highlight important considerations for in-house practitioners in preparation for upcoming effective dates. Among other topics, an expert panel of in-house, USPTO, and law firm practitioners will discuss PTO draft regulations governing supplemental examination and the new opposition-type proceedings, the operation of the new “reasonable likelihood” threshold for inter partes reexam and inter partes review, demystifying the grace period for inventor disclosures, assignee filing under the AIA, a Primer on the new prior commercial user defense, and filing and disclosure strategies under the AIA.

***Moderator: David M. Saravitz, Ph.D., Partner, Alston & Bird LLP***

***Panelists:***

***Murray Spruill, Ph.D., Partner, Alston & Bird LLP***

***Remy Yucel, Director, Central Reexamination Unit, U.S. Patent & Trademark Office***

***Ira Finkelstein, Senior Patent Counsel, Baxter Healthcare***

***Session 6:***

***11:00 am – 12:15 pm***

***Seeking Guidance: Updates on Federal Circuit Activity***

***The Driskill – Ballroom, Second Floor***

***Sponsored by: Alston & Bird LLP***

Our panel will provide an update on recent patent cases from the Federal Circuit, including how the district courts have dealt with the same issues in the wake of the Federal Circuit’s guidance. Particularly, the panel will focus on cases dealing with injunctions and patentability, and provide

perspectives from in-house counsel, outside counsel, and academia. The panel will engage the audience in a hypothetical fact pattern applying the principles from one of the lines of cases presented.

***Moderator:*** John W. Cox, Ph.D., Counsel, Alston & Bird LLP

***Panelists:***

*Jitty Malik, Ph.D., Senior Associate, Alston & Bird LLP*

*Judy Jarecki-Black, Ph.D., Global Head of Intellectual Property, Meril Limited*

*Deepro Mukerjee, Partner, Alston & Bird LLP*

*Stephen Reese, Partner, Olswang LLP*