

Life Sciences & Medical Technology | Newsletter - Fall 2017



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Greenberg Traurig's Life Sciences & Medical Technology Group will once again be hosting two events during the **2018 JP Morgan Healthcare Conference** in San Francisco.

Monday, January 8, 2018

Lunch Workshop: Insiders' Views of Deal Making

11:30 a.m. - 12:00 p.m. Registration and Networking

12:30 p.m. - 2:00 p.m. Panel Discussion and Lunch

[Embarcadero Conference Center](#)

4 Embarcadero Center | 3rd Floor Promenade Level
San Francisco, CA 94111

Confirmed Speakers:



Shaun Grady
VP Strategic Partnering and Business Development
AstraZeneca



Jeremy Sohn
VP, Head of Digital Business Development & Licensing;
Global Head of Digital Development
Novartis



Lizbeth Leveille
Associate VP; Head, Boston Innovation Hub
Business Development & Licensing
Merck Research Laboratories



Angela Wang
Senior VP
Neusoft Corporation



Qingxi (Charles) Wang
President, International Division
CSPC Pharmaceutical Group

RSVP



Monday, January 8, 2018
Wine Tasting and Networking Reception

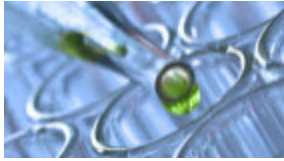
6:00 p.m. - 9:00 p.m.



201 3rd St.
San Francisco, CA 94103

RSVP

In this Issue



Industry Articles & Alerts

Greenberg Traurig Announces Confirmation of Eric Hargan as Deputy Secretary and Appointment as Acting Secretary of HHS

Greenberg Traurig, LLP is proud to announce the confirmation of former Health Care Shareholder Eric Hargan as Deputy Secretary of Health and Human Services (HHS). Eric was confirmed Oct. 4, 2017. On Oct. 10, President Trump appointed Eric as Acting Secretary of HHS.

Eric's government and legal experience spans nearly 25 years. Under the George W. Bush Administration, Eric held numerous positions at HHS, including Deputy General Counsel, Principal Associate Deputy Secretary, and Acting Deputy Secretary.

Eric earned his J.D. from Columbia Law School and his B.A., *cum laude*, from Harvard University.

“Eric has a long track record of public service and advising major companies on their most complex health care issues. We are proud of him as he takes this next step in his career.”
— Brian Duffy, Chief Executive Officer, Greenberg Traurig, LLP.

Cybersecurity in the Health Care Sector

By [Francis J. Serbaroli](#), *New York*

The health care industry is increasingly becoming a target for hacking and ransomware. Recently, the Health Care Industry Cybersecurity Task Force, established by Congress in 2015 and charged with analyzing and making recommendations regarding securing and protecting the health care sector against cybersecurity incidents, issued its “Report on Improving Cybersecurity in the Health Care Industry” (Report). The Report points out vulnerabilities to cyberattacks for organizations in the health care sector and makes recommendations on how to improve awareness and protections.

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Patenting Strategies for Medtech Startups

Interview with [David J. Dykeman](#), *Boston*

David Dykeman has advised numerous startup companies during his more than 20 years practicing patent law. The intellectual property attorney serves as co-chair of the global life sciences and medical technology group at international law firm Greenberg Traurig. Dykeman's overarching advice for startups is to embrace an old adage with a twist, “You get what you pay for, so spend on patents wisely.”

“Investing resources in patents offers medtech companies many rewards. You can cheaply file patent applications, but companies often learn a painful lesson later – when it's too late – that the protection is not as strong as the company hoped for.”

[Read More.](#)

Why You Should Care About Intellectual Property

Interview with [David J. Dykeman](#), *Boston*

What do early-stage companies really need to focus on? Patent attorney David Dykeman says,

first and foremost, that its intellectual property protection.

Dykeman –who co-chairs Greenberg Traurig’s global Life Sciences & Medical Technology Group – will speak at DeviceTalks Boston on October 2.

We asked him to give us some ideas on the important issues surrounding medtech M&A and patenting.

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Patent Strategy Is Critical for Robotics Innovations

By [David J. Dykeman](#), *Boston* and [Todd Basile](#), *Dallas*

The robotics industry is booming, with thousands of new industrial and service-based robotic innovations being introduced each year. These inventions are impacting the global economy and shaping how we live and work. According to the International Federation of Robotics (IFR), more than 1.4 million new industrial robots will be installed in factories around the world by 2019. Protecting robotic innovations is critical to success in the marketplace, so robotics companies should file strategic patents early and often.

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Congressional Research Service Issues Report on Patentable Subject Matter Under 35 USC § 101

By [James J. DeCarlo](#) and [George David Zalepa](#), *New Jersey*

On Sept. 8, 2017, the Congressional Research Service (CRS) published its first report addressing patentable subject matter following the Supreme Court’s decision in *Alice v. CLS Bank*, 134 S. Ct. 2347 (2014): “Patentable Subject Matter Reform,” by John R. Thomas, Sept. 8, 2017 (the Report). The Report primarily provides a factual accounting of post-Bilski jurisprudence but also highlights the side effects of the Court’s ruling in *Alice*, by now familiar to patent practitioners.

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Congressional Research Service Reports on AIA's Impact on Innovation and Proposed Reform

By [James J. DeCarlo](#) and [Nicholas Martin](#), *New Jersey*

Recently the Congressional Research Service published a report on the state of post-grant proceedings before the Patent Trial and Appeals Board (PTAB): “Inter Partes Review of Patents: Innovation Issues,” by John R. Thomas, July 26, 2017. The report analyzes of the current state of the 2011 Leahy-Smith America Invents Act (AIA) as a backdrop for proposed changes put forth in the Support Technology and Research for Our Nation’s Growth and Economic Resilience (STRONGER) Patents Act of 2017. Here, we discuss the report and key components of the bill regarding post-grant proceedings, particularly, inter partes reviews (IPRs).

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Spotlight on Nutraceuticals: Navigating the landscape of structure/function statements

By [Justin Prochnow](#), *Denver*

Structure/function statements are the “lifeblood” of dietary supplement advertising, marketing, and labeling. They can be used to promote supplement products and describe the role of a nutrient or a dietary ingredient in affecting the normal structure or function of the body in humans, such as, “Calcium helps build strong bones.” Additionally, structure/function statements may indicate how a product acts to maintain such structure or function, such as, “supports a healthy immune system” or, “Antioxidants promote cell integrity.”

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Contract Manufacturing Agreements

By [Justin Prochnow](#), *Denver*

Believe it or not, some companies still conduct business without a formal written agreement, operating by the proverbial “handshake agreement” and a hodgepodge of purchase orders, emails and other communications, often leading to uncertainty and unwanted strife down the road. A well-crafted agreement executed between parties for the manufacture, supply and distribution of products can alleviate uncertainties and clarify the respective obligations of the parties.

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FTC’s View on Claims Substantiation

By [Justin Prochnow](#), *Denver*

Advertising and labeling claims are a primary way companies try to grab consumer attention and distinguish one product from another. As the market becomes crowded, competition has increased and claims have become increasingly aggressive and, sometimes, overreaching. Companies must balance the desire to sell products against the fundamental principle that material claims must be substantiated with the appropriate level of support. If not, companies are at risk of action from regulatory agencies such as FTC and FDA, offices of state attorneys general, local district attorneys, competitors and, of course, plaintiffs’ lawyers.

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Changes to Beverage Serving Sizes

By [Justin Prochnow](#), *Denver*

On July 26, 2016, significant revisions to the federal regulations pertaining to the labeling of food, beverages and supplements in the form of two Final Rules (“Revision of the Nutrition Facts and Supplement Facts Labels” and “Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion”) became effective.

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Healthy INSIDER Podcast 49: Claims Substantiation Complexities

By [Justin Prochnow](#), *Denver*

In the United States, claims for supplement products are governed by two federal agencies—FDA and FTC—but they want different things. FDA polices claims to ensure they are fit for the product that carries the claim. FTC isn’t concerned with product type, but enforces that claims are truthful (not misleading). To add to the confusion, a study may satisfy FTC’s demands, but may not be able to support a claim in FDA’s eyes.

To help sort out claims substantiation, attorney Justin Prochnow, shareholder, Greenberg Traurig LLP, discusses these complexities with Sandy Almendarez, editor in chief, INSIDER, at Natural Products Expo West 2017. In this episode, they discuss:

- FTC, FDA and NAD: who they are and what they “govern” regarding claims
- The substantiation standard of “competent and reliable scientific evidence,” and how health and nutrition brands can meet this standard
- The type of studies that will most likely substantiate claims (like real estate, location matters!)

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Greenberg Traurig in the Industry

Greenberg Traurig Advises Intec Pharma on \$57.5M Offering

Robert Grossman and Joshua Samek are quoted in a *Daily Business Review* article titled "Greenberg Traurig Advises Intec Pharma on \$57.5M Offering." Elliott Rimón, Seth Entin, Ilya Ross, Natalie Salem, Barry Schindler, and Ephraim Schmeidler were also mentioned in the article.

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17 Greenberg Traurig Attorneys Named "Life Science Stars" in LMG Life Sciences 2017 Guide

The *LMG Life Sciences* 2017 Guide's "Life Science Stars" includes 17 attorneys from Greenberg Traurig, LLP. David J. Dykeman (Boston) was also shortlisted for "Patent Strategy & Management Attorney of the Year – Massachusetts."

In addition to individual attorney rankings, Greenberg Traurig was listed as a "Recommended Firm" in the following practice areas: M&A, Hatch-Waxman (Generic), Patent Prosecution, and Patent Strategy & Management.

The *LMG Life Sciences* Guide serves as a resource for in-house counsel identifying leading lawyers and firms in multiple practice areas.

The Greenberg Traurig attorneys named "Life Science Stars" are: Jonathan D. Ball, Ph.D. (New York), Scott J. Bornstein, (New York), Robert P. Charrow (Washington, D.C.), Lori G. Cohen (Atlanta), Karen C. Corallo (Washington, D.C.), David J. Dykeman (Boston), Wayne H. Elowe (Atlanta), Robert L. Grossman (Miami), Melissa Hunter-Ensor, Ph.D. (Boston), Allan Kassenoff (New York), David C. Peck (Fort Lauderdale), Richard C. Pettus (New York), Ginger Pigott (Los Angeles), Justin J. Prochnow (Denver), Barry J. Schindler (New Jersey), Nancy E. Taylor (Washington, D.C.), and Fang Xie, Ph.D. (Boston).

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3 Patents Prepared and Prosecuted by Greenberg Traurig Receive 2017 BPLA *Invented Here!* Honor

Four of Greenberg Traurig's clients - GRIT, LuxCath LLC, The George Washington University, and IlluminOss Medical, Inc. – were recognized with the 2017 Boston Patent Law Association (BPLA) *Invented Here!* award for their patented innovations at an awards reception on Oct. 23, 2017. These clients were honored for three patents prepared and prosecuted by Greenberg Traurig. They are among only 12 patents honored that were selected from over 50 nominations.

The Greenberg Traurig clients were selected for the following patents:

- "Wheelchair with Lever Drivetrain" (US Patent No. 8,844,959), assigned to Global Research Innovation and Technology (GRIT); represented by Chinh H. Pham
- "Systems and Methods for Visualizing Ablated Tissue" (US Patent No. 9,084,611), assigned to LuxCath LLC and The George Washington University; represented by David J. Dykeman and Roman Fayerberg
- "Apparatus for Delivery of Reinforcing Materials to Bone" (US Patent No. 9,265,549), assigned to IlluminOss Medical, Inc.; represented by Dykeman and Fayerberg

In addition, IlluminOss Medical and LuxCath were named two of the three *Invented Here!* 2017 Top Honorees. Both IlluminOss founder Robert Rabiner and LuxCath founder Omar Amirana, MD, were interviewed during the reception.

According to its website, the *Invented Here!* award celebrates local and regional New England innovation communities by honoring selected innovators, their inventions, and the stories behind them. The BPLA's *Invented Here!* program aims to present breakthrough technologies from New England that will shape the way people interact with each other and with the world around them, fulfill important individual and/or social needs in novel ways, and ensure a more sustainable future for our environment.

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Greenberg Traurig Patent Attorney, Dr. Fang Xie, Recognized in IAM Strategy 300 - The World's Leading IP Strategists 2017

Dr. Fang Xie (Boston) was recognized as one of the world's top intellectual property (IP) value creators in the 2017 edition of the *Intellectual Asset Management's (IAM) Strategy 300 – The World's Leading IP Strategists 2017*. According to the [publication](#), the guide identifies the individuals who are leading the way in the development and implementation of strategies that maximize the value of IP portfolios. This is Dr. Xie's second consecutive year being named to this prestigious list.

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Greenberg Traurig has 3 Winners and 11 Finalists at the Euromoney 'Americas Women in Business Law' Awards

Shareholders from three offices at [Greenberg Traurig, LLP](#) were winners at the *Euromoney* Legal Media Group's annual "Americas Women in Business Law Awards" ceremony held June 8 at Essex House in New York. The Greenberg Traurig winners were as follows: [Susan L. Heller](#) (Orange County), [Linda B. Hirschson](#) (New York), and [Mary-Olga Lovett](#) (Houston and New York).

According to the *Euromoney* website, firm, country, and regional winners are chosen based on their ability to support the development of women in the legal profession and provide a work/life program that empowers women to pursue legal careers. Greenberg Traurig women attorneys were shortlisted in the following categories:

- Best in Life Sciences – [Lori G. Cohen](#) (Atlanta)
- Best in Insolvency & Restructuring – [Nancy A. Mitchell](#) (New York)
- Best in Mergers & Acquisitions– [Patricia Menéndez-Cambó](#) (Miami)
- Best in Private Equity – [Stacey T. Kern](#) (Chicago)
- Best in Structured Finance – [Sylvie A. Durham](#) (New York)
- Best in Tax – [Mary F. Voce](#) (New York)
- Best in Tax Dispute Resolution – [G. Michelle Ferreira](#) (San Francisco) and [Barbara T. Kaplan](#) (New York)
- Best in Technology – [Francoise Gilbert](#) (Silicon Valley)
- Best in Wealth Management - [Diana S.C. Zeydel](#) (Miami)
- Rising Star – Litigation – [Elizabeth J. Sullivan](#) (New York)

In addition, for 2017 the firm was shortlisted in the following categories: Best International Firm for Women in Business Law, Best International Firm for Diversity, Best International Firm for Pro Bono Work, Best International Firm Latin America Practice, Best International Mentoring Program, and Best Law Firm.

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Upcoming and Past Events and Speaking Engagements

Greenberg Traurig's Lori G. Cohen and Victoria Davis Lockard to Speak at ACI's Drug and Medical Device Litigation Conference

[Lori G. Cohen](#) (Atlanta) and [Victoria Davis Lockard](#) (Atlanta) will speak at the American Conference Institute's (ACI) Drug & Medical Device Litigation conference in New York, NY, Dec. 4-6, 2017. Lori will moderate the "GC and CLO Roundtable: What Keeps Them Up at Night When Faced with a Products Liability Action" on Dec. 5 at 8:45 am. Victoria will speak at 4 pm

on Dec. 5 on the session titled “Anticipating the Next Wave of Cyber Attacks in the Medical Device Industry: Examining the Issues Surrounding the Potential Hacking of Software in Connected Medical Devices” Greenberg Traurig is also a sponsor of the event.

Greenberg Traurig’s Roman Fayerberg and Ginger Pigott to Present at DeviceTalks West

[Roman Fayerberg](#) (Boston) and [Ginger Pigott](#) (Los Angeles) will participate in DeviceTalks West, Dec. 11-12, 2017, in Costa Mesa, CA. Roman and Ginger will be speakers on the panel “Hot Topics: Financing, IP, and Products Liability Trends Impacting Medtech” and will cover:

- Financing best practices from early stage to exit
 - IP protection is key to a successful exit
 - Avoiding and mitigating litigation risk
-

Greenberg Traurig’s Karen C. Corallo Speaks at MD&M Minneapolis

[Karen Corallo](#) (Washington, D.C.) spoke at the Medical Design & Manufacturing (MD&M) Minneapolis conference, Nov. 8-9, 2017. Karen’s session “Intended Use vs. Indications for Use: How to Get Your Regulatory Submission Right the First Time” took place on Wednesday, Nov. 8 from 2 – 2:30 pm. Topics covered included:

- What is the difference in terminology?
 - Why does product classification matter?
 - Understanding the impact on design controls and quality measures
-

Greenberg Traurig’s Justin Prochnow Presents at Rocky Mountain Dietary Supplement Forum

On October 10, [Justin Prochnow](#) (Denver) presented at the Rocky Mountain Dietary Supplement Forum in Boulder, CO. Justin was a panelist on the “Hot Regulatory and Legal Topics in the Supplement Industry” session.

Greenberg Traurig’s David Dykeman Presented at BBA’s Life Sciences Conference

[David J. Dykeman](#) (Boston) spoke at the Boston Bar Association’s (BBA) Life Sciences Conference, Oct. 3 at the Boston Marriott, Cambridge. The conference explored the interplay between the life sciences sector and the law through panels covering corporate, regulatory, and intellectual property (IP) law.

Dykeman participated on the panel, “Personalized Medicine,” which provided perspectives from venture capitalists, company executives, and attorneys on new developments in precision medicine and what’s ahead. He was joined by Robert Ang, MD MBA, Chief Business Officer, Neon Therapeutics; Neil Exter, Partner, Third Rock Ventures; Marc Rubenstein, Partner, Ropes & Gray; and Diane Wuest, PhD, Director, Precision Medicine Initiatives, GNS Healthcare. Dina Ciarimboli, General Counsel, Third Rock Ventures, served as the moderator.

[Chinh H. Pham](#) (Boston) served on the conference advisory committee.

Greenberg Traurig Attorneys Speak at DeviceTalks Boston

[David J. Dykeman](#) (Boston), [Trevor J. Chaplick](#) (Washington, D.C.), [Karen C. Corallo](#) (Washington, D.C.), and [Christiana C. Jacxsens](#) (Atlanta), spoke at DeviceTalks Boston on Oct. 2 at the Westin Boston Waterfront. Greenberg Traurig is a founding sponsor of the DeviceTalks series, and attorneys from the firm’s global [Life Sciences & Medical Technology](#) Group have been featured speakers at every DeviceTalks conference since 2011.

Dykeman moderated the panel, “Hot Topics: Financing, IP, Regulatory and Products Liability Trends Impacting MedTech.” He was joined by Chaplick, Corallo, Jacxsens, Brian Rosnov, senior director, Philips HealthWorks; and Peter Stebbins, transactions lead, Medical Devices, Johnson

& Johnson.

Specific topics included:

- Financing best practices from early stage to exit
- IP protection is key to a successful exit
- FDA regulatory trends
- Avoiding and mitigating litigation risk

Greenberg Traurig's Justin Prochnow and James Prochnow Speak at SupplySide West

[Justin Prochnow](#) (Denver) and [James Prochnow](#) (Denver) spoke at SupplySide West on Sept. 28-29 at Mandalay Bar in Las Vegas, NV. James spoke at "The State of CBD in Dietary Supplements" session on Thursday, Sept. 28. Justin spoke at "Details Matter: Achieving a Successful Contract Manufacturing Partnership" session on Friday, Sept. 29.

Greenberg Traurig's Justin Prochnow Presents at Natural Products Expo East

[Justin J. Prochnow](#) (Denver) presented at this year's Natural Products Expo East convention, held Wednesday, Sept. 13 to Saturday, Sept. 16, at the Baltimore Convention Center. Prochnow's seminar "Supplement or Food? Labeling Opportunities & Limitations for Your Product" discussed the differences in how conventional foods and beverages are regulated compared with dietary supplements, including the regulation of ingredients, manufacturing requirements and claims. Greenberg Traurig was also an exhibitor.

Lori Cohen Co-Chairs, Hosts "Fireside Chat" at ACI's Women in Life Sciences Law Conference

For a fourth consecutive year, [Lori G. Cohen](#) (Atlanta) was co-chair and a speaker at ACI's 4th Annual Conference on Women Leaders in Life Sciences Law, July 19 - 21 at the Hyatt Regency Boston. Cohen and her co-chairs provided the introductory remarks and led a welcoming exercise on Thursday, July 20. Immediately following, Cohen hosted a Fireside Chat with Martine Rothblatt, PhD, the Chairman and CEO of United Therapeutics. Greenberg Traurig was also a sponsor of the conference for the fourth consecutive year. The firm hosted a reception on Thursday, July 20.

Greenberg Traurig's David J. Dykeman to Moderate MassBio Symposium

On May 12, [David J. Dykeman](#) (Boston) moderated the Massachusetts Biotechnology Council (MassBio) symposium, "The Convergence of Medical Device & Drugs: The Future of Combination Products." The panel discussion covered innovation and development in combination products, including scientific advances, medical challenges being addressed by combination products, strategies for funding new combination product ventures, development issues specific to combination products, and the regulatory environment. Panelists included: Steve Bowman, Device Project Lead, Shire; Laura Indolfi, CEO, PanTher Therapeutics, TED Fellow, Entrepreneur in Residence, MGH Cancer Center; Peter Markham, President & CEO, CBSET; and Ailis Tweed-Kent, CEO, Co-founder, Cocoon Biotech Inc.

Greenberg Traurig Patent Attorney, Dr. Fang Xie, to Speak at BBA Conference on U.S.-China Competition and Collaboration

On April 18, [Dr. Fang Xie](#) (Boston) spoke at the Boston Bar Association (BBA) conference, "Intellectual Property (IP) Protection In China: Successes and Challenges." Dr. Xie moderated the panel, "U.S.-China: Competition and Collaboration – Strategies for the Years Ahead," which covered topics such as cross-border collaborative R&D and licensing, how to bridge and leverage the difference in patent laws between U.S. and China, antitrust consideration when doing deals in both countries, as well as what the data says about U.S.-China collaboration and future prospects.

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Greenberg Traurig's **Life Sciences & Medical Technology Group** advises clients ranging from startups to large multinational public companies to leading research institutions. The group's attorneys work closely with clients, providing innovative legal counsel to help them achieve their objectives – from discovery through commercialization and product marketing. For more information on our Life Sciences and Medical Technology Group, please click [here](#).

Greenberg Traurig, LLP (GTLaw) has more than 2,000 attorneys in 38 offices in the United States, Latin America, Europe, Asia and the Middle East and is celebrating its 50th anniversary. One firm worldwide, GTLaw has been recognized for its philanthropic giving, was named the largest firm in the U.S. by *Law360* in 2017, and among the Top 20 on the 2016 *Am Law* Global 100. Web: www.gtlaw.com Twitter: @GT_Law.

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