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Industry Articles and Alerts

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Increasing Focus on Claims Against Health Care Industry Representatives
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FDA Issues Guidance for Blood Banks to Reduce Risk for Collection of Zika Infected Blood
By Nancy Taylor , Washington, D.C.

Prevention Instead of Correction: FDA Implements New System for Food Safety Regulation
By Antonio Gallegos , Denver

READ MORE .

Greenberg Traurig in the Industry

Awards and Recognitions

Greenberg Traurig's Food and Beverage Group Named a *Law360* Practice Group of the Year for 2015

The firm's attorneys in this practice are positioned in key jurisdictions and were called on to represent some of the most significant players in the food, beverage, and dietary supplement industries. **READ MORE.**

Upcoming Events & Speaking Engagements

Greenberg Traurig to Host Wharton Israel Conference
Monday, June 6, 2016

On June 6, Greenberg Traurig will be hosting the Wharton Israel Conference in the Boston office. Roman Fayerberg (Boston) will be giving the welcome remarks and Chinh Pham (Boston) will be a panelist on the "From Idea to Implementation: Creating a Company in a Dynamic Market Environment" panel. Dave Dykeman (Boston) will moderate the "Healthcare IT and Big Data Analytics: Patent Centricity in a Data Driven World" panel.

DeviceTalks Minnesota by MassDevice
Monday, June 6, 2016

Greenberg Traurig's attorneys David Dykeman (Boston), Lori Cohen (Atlanta), and Daniel Smulian (New York) will be attending MassDevice's 2016 DeviceTalks in Minnesota. Greenberg Traurig is a sponsor of this event and Cohen and Smulian will be speaking on "M&A, IP and Product Liability Trends impacting medtech." Dykeman will be the moderator of this panel. **For more information, click here.**

MassMEDIC Summer Networking Event
Thursday, June 23, 2016

About Greenberg Traurig's Life Sciences & Medical Technology Group

Our **Life Sciences & Medical Technology Group** supports clients ranging from startups to large multi-national public companies and not-for-profit care providers, as well as investors, venture capital and private equity funds, investment banks, and public agencies. Our wide-ranging work encompasses numerous industry sectors, including biomedical engineering, biotechnology, chemistry, cosmetics, dietary supplements, disease management, drug delivery, EMR, billing and coding, immunology, medical devices, microbiology, nanotechnology, pharmaceuticals, stem cells, and vaccines. For more information on

Greenberg Traurig's attorneys David Dykeman (Boston) and Roman Fayerberg (Boston) will be hosting an evening of cocktails and conversation at the MassMEDIC Summer Networking Event. **For more information, click here.**

View Recent and Past Events.

our Life Sciences and Medical Technology Group, please visit http://www.gtlaw.com/Experience/Industries/Life-Sciences-Medical-Technology.

Greenberg Traurig, LLP is an international, multi-practice law firm with approximately 1900 attorneys serving clients from 38 offices in the United States, Latin America, Europe, Asia, and the Middle East. The firm is among the 2015 BTI Brand Elite and among the most "Tech Savvy." It was on the 2013-2015 BTI Client Service 30 listings of firms "most recognized by clients for providing excellent client service," and one of the 2014 BTI Client Relationship Scorecard "Power Elite," based on the nature and strength of its client relationships. More information at: www.gtlaw.com.

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In this Issue - Spring 2016:

Increasing Focus on Claims Against Health Care Industry Representatives

By Ginger Pigott and Natassia Kwan, Los Angeles

As plaintiffs pursuing medical device and pharmaceutical product liability actions run into various dispositive legal defenses to traditional tort claims, such as express and implied preemption, defense attorneys are seeing an increasing trend toward creative pleading in an effort to raise potential issues regarding the conduct of health care industry representatives who are either present in surgery or otherwise providing technical support to medical providers. Read more.

Sports Nutrition: FDA Regulation of Adulterated Products

By Justin Prochnow, Denver

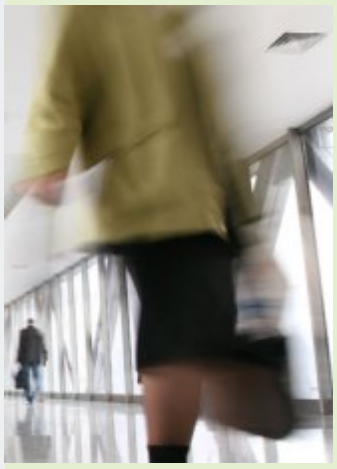
Drop in on a fitness show or expo hall and you will see booth after booth of the latest and greatest sports nutrition products touting everything from weight-loss benefits and toned physiques to ripped

abs and bulging biceps. Such nutrition products are ubiquitous and the market is booming. To meet this demand, sports nutrition companies are always looking for new ingredients to deliver new and better benefits to their rabid customer base and give them an extra edge. However, the presence of undeclared drug ingredients, or ingredients with unproven records of safety that could cause health risks for consumers, in a small number of products has caused federal regulators and others to look more closely at the whole category of products. Companies must be aware of these concerns to ensure they stay on the right side of the law. Read more.

Design Patents Provide Additional Protection for Products

By David Dykeman and Roman Fayerberg, Boston

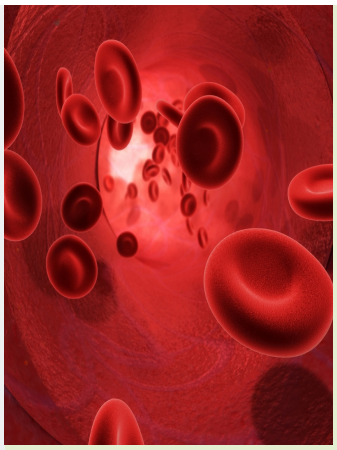
In today's challenging economic climate, a strategic patent portfolio is crucial to a medical technology company's growth and survival, because it can provide numerous business advantages. Although patents are extremely important for medtech companies of all sizes, patents make up a significantly greater portion of enterprise value for early-stage medtech companies. Patent portfolios are often the only way for investors to place a value on an early-stage company's technology, as sales often cannot begin until after FDA approval. Read more.



How the Zika Virus Affects Employment-Related Travel

By Laurent Badoux, Phoenix

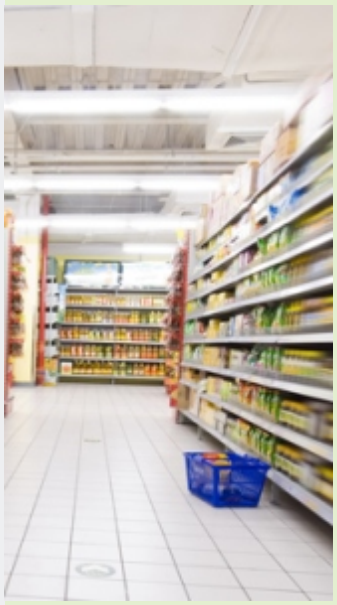
The Zika virus is the latest source of sleepless nights for public health officials, but it is also starting to take its emotional toll on U.S. employers. Reports of children born with microcephaly and an uptick in reported cases of Guillain-Barré syndrome, which can cause numbness, nerve damage, paralysis, and sometimes death in affected patients, are raising fears for many companies with cross-border operations that employees traveling to areas where an outbreak is occurring may come back affected by the rapidly spreading Zika virus. Read more.



FDA Issues Guidance for Blood Banks to Reduce Risk for Collection of Zika Infected Blood

By Nancy Taylor, Washington, D.C.

On Feb. 16, 2016, the Food and Drug Administration (FDA) issued guidance for blood banks with recommendations for donor screening, donor deferral, and product management to reduce the risk of transmission of the Zika virus through transfusion. The FDA issued this guidance because the risk of transmission of Zika by blood transfusion is considered likely. Read more.



Prevention Instead of Correction: FDA Implements New System for Food Safety Regulation

By Antonio Gallegos, Denver

The FDA Food Safety Modernization Act (FSMA) became law in Jan. 2011 with the primary intent of redirecting the country's food safety regulatory regime to a system that identifies and prevents hazards in the food supply chain instead of a reactionary system based largely on enforcement and punishment. […] The heart of FSMA lies in food safety regulations first proposed by the FDA in 2013, and then published in final form in fall 2015, after extensive public comment. The most widely applicable set of regulations, and also the most comprehensive, require the food industry to implement hazard analysis and risk-based preventive controls (HARPC) measures at food facilities. The HARPC regulations for human foods are extensive, but they generally address three core requirements: 1) a food safety plan; 2) a supplier verification program; and 3) a recall plan. Read more.

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Awards and Recognitions

In this Issue - Spring 2016:

Greenberg Traurig's Food and Beverage Group Named a *Law360* Practice Group of the Year for 2015

Law360 selected Greenberg Traurig's Food & Beverage Practice among its 2015 Practice Groups of the Year. The firm's attorneys in this practice are positioned in key jurisdictions and were called on to represent some of the most significant players in the food, beverage, and dietary supplement industries. Throughout the year, as clients identified new opportunities and faced robust challenges, the firm's food and beverage attorneys were retained to advise and defend some of the most influential companies in the marketplace. The group has a great deal of experience guiding established brands and emerging leaders through false advertising claims litigation, product labeling, FDA scrutiny, and many other facets required to be successful in this dynamic industry. "This recognition is a reflection of the innovative work our practice has done in the last year," stated Justin Prochnow, a shareholder in Greenberg Traurig's Food & Beverage Group. "We continue to be involved in cutting-edge issues in this evolving space and are proud to have provided positive solutions for our clients." READ MORE

Greenberg Traurig's Christiana Jacxsen Named a *Law360* "Rising Star"

Christiana Callahan Jacxsens (Atlanta) was named to the *Law360* "Rising Stars" list for her products liability work. The list features 179 attorneys under 40, selected from more than 1,100 submissions, representing 87 law firms across 32 practice areas. The winners were selected based on their career accomplishments in their respective practice areas, according to the legal newswire.

Jacxsens concentrates her practice on complex medical and products liability litigation, with a focus on pharmaceutical and medical device litigation. She has served as second-chair trial counsel in complex medical negligence cases and has assisted in the trials of medical device products liability and clinical trial cases. Jacxsens has experience managing litigation, including mass tort litigation, involving a variety of products and medical issues, such as pharmaceuticals, orthopedic and spinal medical devices, ICDs, sutures, surgical mesh devices, and investigational products. In addition, she advises hospitals, physician groups, and pharmaceutical and medical device companies on regulatory and compliance matters, including informed consent issues, adverse event reporting, and HIPAA compliance. Jacxsens has a unique passion for preventive law counseling and assisting her clients in managing litigation risk, including issues with product development or acquisitions, product surveillance and FDA reporting, clinical trial and distribution agreements, field actions and quality assurance documents, and compliance with FDA regulations and other applicable federal and state laws. Her counseling work includes training employees, including sales representatives, regulatory, technical product, and product surveillance employees, and on a variety of risk issues.

Recent Success

Greenberg Traurig's Lori Cohen and Team Obtain Complete Defense Verdict for C.R. Bard

A team led by Lori Cohen (Atlanta) obtained a complete defense verdict on behalf of C.R. Bard, Inc. in *Sherrer v. Boston Scientific, et al.,* Case Number 1216-CV27879, in the 16th Judicial Circuit of Missouri. In addition to Cohen, key trial team members included Shareholder Cliff Merrell (Atlanta) and associates Marcella Ducca (Atlanta), Sean Jessee (Atlanta), Sara Deskins Tucker (Atlanta), and Eric Schnapp (Atlanta).

The *Sherrer* trial began on Nov. 30, 2015, and the jury began deliberations on Feb. 1, 2016. On the afternoon of Feb. 2, 2016, the jury announced a complete defense verdict for C.R. Bard and co-defendant Boston Scientific. This was the first pelvic mesh trial to involve two different manufacturers and the first in a Missouri state court. The plaintiff requested $28 million in compensatory damages, claiming the companies' pelvic mesh implants rendered her incontinent and suffering from pain and other ailments. The plaintiff also sought punitive damages against both defendants.

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In this Issue - Spring 2016:

Recent and Past Events and Speaking Engagements

Greenberg Traurig Hosts the 2016 Chinese Biotech Executives and Investors Delegation in Boston

On May 10, Greenberg Traurig hosted the 2016 Chinese Biotech Executives and Investors Delegation visiting Boston for a dinner reception and panel discussion in the firm's Boston office. Comprised of top executives from some of China's leading life sciences companies as well as institutional investors, the Chinese delegation seeks potential partnership and investment opportunities in the Boston/ Cambridge area, one of the foremost biotech centers in the world. From 5:30 – 7:00 p.m., Greenberg Traurig attorneys Dr. Fang Xie (Boston) and Wayne H. Elowe (Atlanta) led a panel on "The Present and Future of Precision Medicine and Some Legal Considerations for Doing Business in the New Era." Topics included legal issues on U.S.-China cross-border transactions, IP protection and recent changes in law in U.S. and China, as well as industrial perspectives on current trends in precision medicine. Terence P. McCourt (Boston) also presented on U.S. employment law considerations for China based companies.

Greenberg Traurig's David Dykeman at BIOMEDevice Conference in Boston

David Dykeman (Boston) moderated a panel discussion on the topic of "Winning over the hospital value analysis committees." The panel addressed several issues, including: the changing marketplace and how to position medical devices in a tight economic

environment; what hospitals in the U.S. and Europe are looking for; medical devices and assessing their value from a physician standpoint; value-added services in medical devices; and understanding the necessity of usability and how it can determine widespread adoption.
The panel discussion was part of the BIOMEDevice Conference on April 13-14, 2016, at the Boston Convention & Exhibition Center.

Greenberg Traurig's Fang Xie Spoke at Webinar on "Patent Protection for Pharma and Biotechnology in 2016"

On April 18, 2016, Fang Xie, Ph.D (Boston) was co-presenter on a webinar addressing patent protection for the pharmaceutical and biotechnology industries. Key topics included; an overview of notable Supreme Court Decisions, *Mayo Collaborative Servs. v. Prometheus Labs., Inc., Molecular Pathology v. Myriad Genetics* and *Limelight Networks, Inc v. Akamai Technologies, Inc.;* patent protection challenges in light of these decisions; best strategies on protecting patent for pharmaceutical and biotech innovation; and legislative trends on pharmaceutical and biotech patents.

Greenberg Traurig's David Gitlin and Mark Mattioli Present at PACT Digital Health Half-Day Summit

David Gitlin (Philadelphia) and Mark Mattioli (Philadelphia) spoke on panels at the Philadelphia Alliance for Capital & Technologies (PACT) Digital Health Half-Day Summit on March 17, 2016. The summit provided instrumental insight to small companies and entrepreneurs, where they engaged on key topics within the digital health sector and learned from industry experts. In addition, entrepreneurs had the opportunity to pitch and receive venture capitalist feedback, and receive reverse pitches from large companies in the digital health sector.

Gitlin presented on the panel titled "Working with Large Companies" which discussed how entrepreneurs and smaller businesses can work with larger entities. The panel also featured members of the Healthcare Innovation Collaborative and Digital Health startups which have successfully engaged with large organizations. Mattioli presented on the panel titled "Navigating Risk" which concentrated on what startups must address when pitching to a larger company, including the basics of cybersecurity, liability, data, compliance, and regulatory concerns.

Greenberg Traurig Food & Beverage Group Speaks at Natural Products Expo West

Robert Herrington (Los Angeles/San Francisco), Justin Prochnow (Denver), Rick Shackelford (Los Angeles), Anthony Cortez (Sacramento) and Antonio Gallegos (Denver) presented a seminar on "Labeling Litigation: Strategies for Marketing Products While Avoiding the Courtroom" at this year's Natural Products Expo West convention. The seminar discussed strategies for defending food labeling class action lawsuits, as well as business practices for limiting the risk of such claims. Expo West was held March 9-13, 2016, and is the world's largest trade show for natural, organic, and healthy foods, dietary supplements and other consumer products.

Greenberg Traurig at DeviceTalks Raleigh

Christiana Jacxsens (Atlanta) participated in a panel at the DeviceTalks conference on Feb.

29, 2016, at the Sheraton Raleigh Hotel. Hosted by online journal MassDevice.com, DeviceTalks is a conversation among leaders, and an evening for an exchange of ideas, insight and contacts among the pioneers of the medical technology industry.

Greenberg Traurig Hosts Australia MedTech Delegation in Boston as Part of Australia United States Business Week

On Feb. 22, 2016, David Dykeman (Boston) hosted an Australia Medical Technology Delegation in the firm's Boston office. Led by Australian Minister for Trade and Investment Andrew Robb, the MedTech Delegation was part of the inaugural Australia United States Business Week (AUSBW) 2016, a major initiative to increase Australia's business links with the United States.

Dykeman moderated a panel discussion addressing how Massachusetts and Australia are bringing together public, private, academia, and the health sectors to commercialize research and encourage a more connected medical research ecosystem. He was joined by panelists:

- Lita Nelsen, Director of the Technology Licensing Office (TLO) at the Massachusetts Institute of Technology (MIT);
- Sanjay Gokhale, Digital Health Cluster Director at the Massachusetts eHealth Institute; and
- Mark Kendall, professor at the Australian Institute for Bioengineering and Nanotechnology at the University of Queensland.Panelists shared insights and best practices for the partnering process, from building an attractive IP portfolio to identifying the right entry point of contact at prospective partner organizations. The delegation concluded with a wine tasting and networking reception.

MedTech Partnering Day with Sanofi

On Thursday, Feb. 11, 2016, Greenberg Traurig LLP's Global Life Sciences & Medical Technology Group hosted its third MedTech Partnering Day from 8:30 a.m. – 2 p.m. at the Genzyme Center in Cambridge, Massachusetts. Hosted by Sanofi, the event explored the convergence of biotech and medical devices and highlighted Sanofi's medical devices for drug delivery. MedTech Partnering Day connects some of New England's most innovative emerging medtech companies with strategic partners to maximize opportunities for collaboration, new business development, and market expansion. The program, supported by MassMEDIC, MassBio, and LB Ventures, included a panel discussion focused on innovation; company presentation from representatives of Sanofi; keynote addresses by Thomas Sommer, President of MassMEDIC, and Robert Coughlin, President & CEO of MassBio; one-on-one meetings between the strategic partners and early stage companies; and networking opportunities throughout the day.

This event gathered 150 innovators and leaders from across the medical device and technology industries and featured Greenberg Traurig attorneys, David Dykeman (Boston) and Frank Martire (New York). Greenberg Traurig's prior MedTech Partnering Days featured representatives from Boston Scientific, Johnson & Johnson, Medtronic, and ZOLL Medical Corporation as well as a range of early-stage companies from seven different states and Canada, who met with company executives.

Greenberg Traurig's Life Sciences & Medical Technology Group Holds Deal-Making Workshop and Networking Reception in Conjunction with JP Morgan Healthcare

Conference

Wayne Elowe (Atlanta), Robert Grossman (Miami), and Barbara Jones (Boston) presented "Deal-Making Around the World: Catching Up on the Latest Trends and Best Practices," a panel discussion focused on the state of global deal-making in the life sciences and medical technology industries. The workshop was held Jan. 11, 2016 in San Francisco and coincided with the J.P. Morgan 34th Annual Healthcare Conference. The workshop covered deal-making trends, deal preparation and valuation, best practices for executing deals, and the deal environment in China, Europe, Israel, and Latin America. The panel was moderated by David Dykeman (Boston) and David Peck (Fort Lauderdale). The workshop was followed by a wine tasting networking reception at First Crush Restaurant & Wine Bar which was attended by more than 300 healthcare industry executives and investors.

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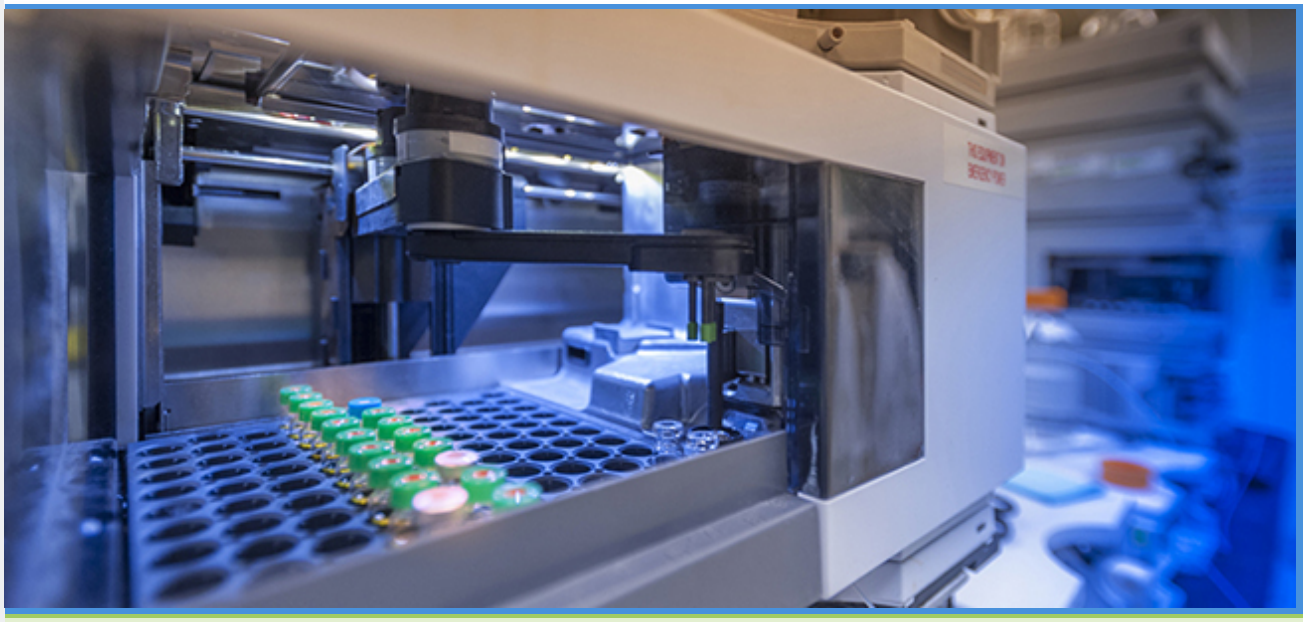

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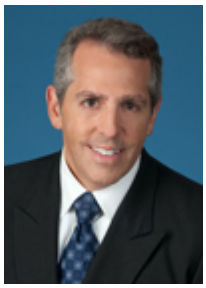

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