



**UPCOMING EVENT** 

**SPRING 2014** 

Please join us for a cocktail party at Co Co. Sala Rooftop during DRI's Drug and Medical Device Conference

Networking and Cocktails

Hosted by: Greenberg Traurig's <u>Pharmaceutical, Medical Device & Health Care</u>
<u>Litigation Practice</u> Chaired by <u>Lori G. Cohen</u>

Ulmer & Berne LLP and Baker Sterchi Cowden & Rice LLC

Wednesday, May 14, 2014 7:30 p.m. - 10:30 p.m.



### Co Co. Sala Rooftop at the Carroll Square Building

975 F Street NW | Washington, D.C. 20004

Tel: 202.347.4265

RSVP to GTRSVP@gtlaw.com

### IN THIS ISSUE

#### SUPREME COURT SETS STANDARDS FOR ATTORNEYS FEES UNDER THE PATENT ACT

By Scott J. Bornstein and Justin A. MacLean, GT New York Office

#### PATENT TROLLS INVADE MEDTECH

By David J. Dykeman and Michael Cohen, GT Boston Office

#### HOUSE PASSES PATENT LITIGATION REFORM BILL TO ADDRESS PATENT TROLLS

By David J. Dykeman and Michael Cohen, GT Boston Office

#### STAGNANT GOVERNMENT FUNDING DRIVES PATENT LICENSING

By David J. Dykeman and Michael Cohen, GT Boston Office

#### U.S. AND EU RESPOND TO UKRAINE CRISIS WITH SANCTIONS

By Erik de Bie, GT Amsterdam Office; Kara M. Bombach, Sanford M. Saunders and Nicoleta Timoffi, GT Washington, D.C. Office





By Luke Dixon and Stephen C. Tupper, GT London Office

## GENERAL OVERVIEW OF RECENT BILL UNDER REVIEW BY THE MEXICAN CONGRESS FOR NEW FEDERAL COMPETITION LAW

By Bertha Alicia Ordaz-Avilés, GT Mexico Office

## COURT OF APPEALS RULES THE FCC MAY NOT IMPOSE COMMON CARRIER REGULATORY REQUIREMENTS ON INTERNET BROADBAND PROVIDERS

By Mitchell F. Brecher, GT Washington, D.C. Office

#### STATE OF PLAY-IS 2014 THE YEAR OF THE INTERNET GAMING?

By Adam Braun, Martha A. Sabol, J. Daniel Walsh and Edward R. Winkofsky, GT Chicago Office; Erica Okerberg, GT Las Vegas Office; Jamey L. Tesler, GT Boston Office

## LEGAL MEASURES AGAINST COUNTERFEIT AND PIRACY IN THE EUROPEAN UNION AND THE NETHERLANDS

By Jan M. Brölmann and Radboud Ribbert, GT Amsterdam Office

## EUROPEAN COURT DECISION: COPYRIGHT OWNER CONSENT NOT REQUIRED TO HYPERLINK OR EMBED LINKS ON WEBSITES

By Radboud Ribbert and Nina Witt, GT Amsterdam Office

### JOIN THE PARTY. ANOTHER CALIFORNIA-BASED FORMER EMPLOYEE CHALLENGES OUT-OF-STATE COMPANY'S NON-COMPETE PROVISIONS AS UNFAIR BUSINESS PRACTICE

By Kurt A. Kappes, GT Sacramento Office and GT San Francisco Office

### REVISED HART-SCOTT-RODINO PREMERGER NOTIFICATION THRESHOLDS FOR 2014

By Andrew G. Berg, GT Washington, D.C. Office; Mary K. Marks, GT New York Office

## DELAWARE SUPREME COURT: CONTROLLER BUYOUT MERGERS CAN BE REVIEWED UNDER BUSINESS JUDGMENT RULE

By Clifford E. Neimeth, GT Phoenix Office

## LANDMARK DECISION FOR ATTORNEY-CLIENT PRIVILEGE: INTERNAL INVESTIGATIONS NO LONGER PROTECTED?

By Ryan C. Bradel and Jacob B. Pankowski, GT Washington, D.C. Office

# WILL YOUR COMPANY BE WEARING NEW SOX? SUPREME COURT EXPANDS SARBANES-OXLEY WHISTLEBLOWER PROTECTION TO EMPLOYEES OF PRIVATELY-HELD COMPANIES

By Robert M. Goldich, GT Philadelphia Office; Michael J. Slocum, GT New Jersey Office



CALIFORNIA PROPOSES ENHANCED PROPOSITION 65 WARNINGS AND POSSIBLE ONLINE DISCLOSURES - DIETARY SUPPLEMENTS AND FOODS SPECIALLY TARGETED

By Anthony J. Cortez, James Mattesich and Greg Sperla, GT Sacramento Office; Justin J. Prochnow, GT Denver Office

FDA ISSUES FINAL GUIDANCE DISTINGUISHING LIQUID DIETARY SUPPLEMENTS FROM BEVERAGES

By Justin J. Prochnow, GT Denver Office

GT IN THE INDUSTRY

### PATENT LITIGATION DEVELOPMENTS

### Supreme Court Sets Standards for Attorneys Fees Under The Patent Act

By Scott J. Bornstein and Justin A. MacLean, GT New York Office

On April 29, 2014, the Supreme Court issued its decisions in Octane Fitness, LLC v. ICON Health & Fitness, Inc. and Highmark Inc. v. Allcare Health Management Systems, Inc. regarding the governing standards for awarding attorney's fees under the Patent Act. The Supreme Court's decisions expand the circumstances under which fees may be awarded to prevailing parties. The authors discuss the decisions made in the cases and their potential influence on pending patent legislation. To read more about the attorneys fees under the Patent Act, [Click here].

#### Patent Trolls Invade MedTech

By David J. Dykeman and Michael Cohen, GT Boston Office

Last year will be remembered as the year that patent trolls invaded the medical technology industry. "Patent trolls," also known as patent assertion entities or nonpracticing entities (NPEs), are businesses that acquire patents for the purpose of collecting royalties from companies whose products or practices allegedly infringe patents owned by the NPE. Detractors view NPEs as bullies that impose a tax on innovation and abuse the patent system by attempting to extort "licensing fees" from product manufacturers. NPEs themselves are often immune from patent infringement claims because they do not produce or intend to produce any products. NPEs claim to help individual inventors by providing the necessary resources to protect and enforce the inventors' rights to their inventions.

**Patent Trolls Focus on Medical Devices.** Until recently the wave of patent troll lawsuits has largely been focused on the software industry and has stayed away from the medical device industry. A September 2013 survey by Santa Clara Law School professor Colleen Chien found that only 13% of pharmaceutical and medical device venture capitalists reported a company in their portfolio had received a demand from an NPE. This compares extremely favorably against the information technology sector, where 90% of venture capitalists reported receiving demands from NPEs. Unfortunately, there are signs that NPE activity in the medtech industry is increasing.

**Patent Trolls Aren't Going Away.** Last year saw the rise of patent trolls in medtech, and patent trolls are likely to become an even bigger problem in 2014 and beyond. Expect more patent troll lawsuits to be filed accusing medtech companies of patent infringement. Prudent medtech companies that receive demand letters or know of competitors that have received demand letters should weigh their options with legal counsel experienced in both medtech and NPE litigation. While Congress may come to the rescue, with millions of dollars at stake, NPEs are expected to cede the battle quickly. To read more about the patent trolls, [Click Here].

#### House Passes Patent Litigation Reform Bill to Address Patent Trolls

By David J. Dykeman and Michael Cohen, GT Boston Office

Last year, patent trolls invaded the medical technology industry after years of focusing on the information technology industry. The U.S. House of Representatives took a major step to address the problem of patent troll litigation by passing the Innovation Act of 2013 on December 5, 2013 with strong support (325–91). While medical device makers expect the Senate to take the bill up in 2014, the Innovation Act has the potential to deter some of the more flagrant patent trolls, but not eliminate patent troll litigation entirely. See the following article. To read more about the House Patent Litigation Reform Bill, [Click Here].

#### Stagnant Government Funding Drives Patent Licensing

By David J. Dykeman and Michael Cohen, GT Boston Office

One of the biggest challenges facing the medical technology industry today is a lack of funding for research. As part of January's federal budget deal, Congress announced that NIH funding for FY2014 will increase only 3 percent compared with FY2013 levels to just less than \$30 billion. Stagnant to declining federal government funding continues the trend of the past decade, where in all but two years of the last 10, the NIH has seen declines in its real dollar appropriation. Outside of the life sciences, the story regarding declining funding is scarily similar. National Science Foundation data shows that from FY2005 to FY2013 annual appropriations for basic and applied research in all academic disciplines fell at least 17.6 percent in real dollars.

The medical device and life-sciences industries remain dependent on universities as a source of innovation that feeds current and future products. Universities and research institutes already have started to adapt to this "new" normal by looking under the couch cushions for additional revenue sources to fill the gaping hole the federal government has created on the top line of the group's income statements. New "ready-to-sign" (RTS) university licensing programs provide an example of how serious universities are about licensing their patent portfolios.

The increased licensing efforts of universities are starting to show up on the top line of their income statements. With funding pressures in mind, members of industry who are on the fence about reaching out to academia would be wise to do so now as universities and research institutes are more interested in striking licensing deals than ever before. To read more about the above challenges, [Click here].

# INTERNATIONAL HEADLINE ISSUES AND ACTIONS – EU AND U.S. GOVERNMENTAL AUTHORITIES

#### U.S. and EU Respond to Ukraine Crisis with Sanctions

By Erik de Bie, GT Amsterdam Office; Kara M. Bombach, Sanford M. Saunders and Nicoleta Timofti, GT Washington, D.C. Office

In March 2014, the U.S. and EU authorities issued a series of sanctions against those deemed to be compromising Ukraine's peace, sovereignty, democratic processes, and state assets. The U.S. also placed a hold on issuance of new export licenses for items destined for Russia. The U.S. and EU joined Australia, Canada and Japan, all of whom have also recently issued measures against the Russian Federation after its annexation of the Crimea region of Ukraine.



**U.S. Sanctions.** The U.S. Government has blocked (or frozen) assets of specifically named individuals and entities, and banned issuance of visas for those individuals' entry into the United States. These measures effectively prohibit U.S. individuals or companies from engaging in any transactions with sanctioned persons, or any entity owned or controlled by one of the sanctioned persons. Sanctioned individuals include various members of the Russian government, as well as Crimea-based separatists, and the former Ukrainian President. Under the sanctions, U.S. financial institutions are also prohibited from processing transactions involving Rossiya, the 17th largest bank in Russia (with assets of approximately US\$ 10 billion), known to be used as the personal bank for senior officials of the Russian Federation.

**EU Sanctions.** On March 5, 2014 the EU issued restrictive measures against certain persons, entities and bodies, including former officials of Ukraine. These sanctions include, among other things, freezing funds and restricting funds or economic resources for the benefit of the listed persons. On March 17th and 21st, the EU agreed on expanded sanctions. The March 17th and 21st sanctions focus on natural persons, specifically, officials of the Autonomous Republic of Crimea and the Russian Federation, and natural or legal persons, entities or bodies associated with them.

In addition, the EU also proposed and adopted measures intended to assist Ukraine in stabilizing its economy and improving its financial situation. The European Commission proposed a 'Support Package for Ukraine', including loans to Ukraine from the EU budget, setting up a donor coordination platform, modernization of the Ukraine gas transit system and work on reverse flows, notably via Slovakia and the provisional application of the Deep and Comprehensive Free Trade Area ("DCFTA"). The plan proposed that the EU and Ukraine will sign the DCFTA later this year, after which the full free trade agreement will be in force.

**Compliance with the Sanctions Measures.** Given the fluid nature of the Russia/Ukraine situation and economic sanctions, U.S. and EU persons should exercise due diligence and caution in dealings (direct and indirect) with or benefitting entities in Russia and Ukraine. Importantly, they should, at a minimum, screen all entities in proposed transactions against the U.S. and EU lists of sanctioned entities and individuals.

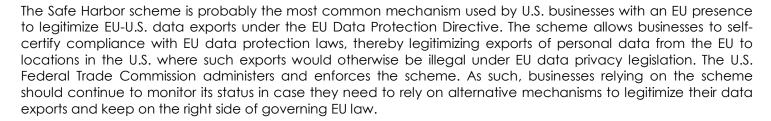
To read more about the U.S. and EU sanctions, [Click Here].

#### European Parliament Votes on Mass Surveillance with Implications for EU-U.S. Safe Harbor

By Luke Dixon and Stephen C. Tupper, GT London Office

The European Parliament has voted emphatically in support of a report produced by its Civil Liberties, Justice and Home Affairs Committee (LIBE) on the mass surveillance undertaken by the U.S. National Security Agency (NSA) and EU Member States. In doing so, the Parliament called for the immediate suspension of the EU-U.S. Safe Harbor scheme, pending a review of how the scheme is conducted. The European Parliament's vote is the latest example of the uncertainty that surrounds the future of the Safe Harbor scheme, however, under EU law, the decision whether to suspend the Safe Harbor rests with the European Commission, and not the Parliament.





To read more about the European Parliament voting on mass surveillance, [Click Here].

# DEVELOPMENTS IN REGULATION AND EXPANSION OF TELECOMMUNICATIONS, BROADCASTING AND THE INTERNET

## General Overview of Recent Bill Under Review by the Mexican Congress for New Federal Competition Law

By Bertha Alicia Ordaz-Avilés, GT Mexico Office

On February 20, 2014 the Parliamentary Gazette disclosed a bill sent by the Executive Branch to the Mexican Congress for a new Federal Economic Competition Law in Mexico, and to amend article 254 bis of the Federal Criminal Code (the "Competition Bill"). The Competition Bill derives from the constitutional reform of telecommunications, broadcasting, and economic competition in Mexico, as published in the Official Gazette on June 11, 2013 (the Constitutional Reform), which extinguished the former Federal Competition Commission and created the Federal Economic Competition Commission (COFECE) as an autonomous agency and the authority governing competition for all industries in Mexico other than telecommunications and broadcasting. The Constitutional Reform also extinguished the former Federal Telecommunications Commission and created the Federal Telecommunications Institute (IFT) as an autonomous agency in Mexico, serving in its capacity as regulator and competition authority for the telecommunications and broadcasting industries in Mexico. To read more about the Competition Bill, [Click Here].

## Court of Appeals Rules the FCC May Not Impose Common Carrier Regulatory Requirements on Internet Broadband Providers

By Mitchell F. Brecher, GT Washington, D.C. Office

On January 14, 2014, a three-judge panel of the United States Court of Appeals for the District of Columbia Circuit issued its decision in Verizon v. Federal Communications Commission, in which it vacated several key FCC rules governing the regulation of Internet traffic. Those rules were promulgated by the FCC in 2010 in a proceeding commonly referred to as the "Net Neutrality" or "Open Internet" proceeding. Having been rebuked in 2010 by the appeals court in its prior efforts to regulate Internet traffic (which culminated in a decision often referred to as the "Open Internet Order,") the FCC responded by commencing additional rulemaking proceedings which were the subject of the most recent court decision of this past January. To read more about the requirements on internet broadband providers, [Click Here].





By Adam Braun, Martha A. Sabol, J. Daniel Walsh and Edward R. Winkofsky, GT Chicago Office; Erica Okerberg, GT Las Vegas Office; Jamey L. Tesler, GT Boston Office

Confounding the expectation of most observers, after the December 23, 2011 reversal by the U.S. Department of Justice of its long-standing interpretation of the Federal Wire Act's (18 U.S.C. § 1084) application to non-sports betting on the Internet, Internet gaming did not immediately and rapidly grow throughout the United States. No prompt federal solution was enacted, and despite the ongoing recession-based struggles of many states, most states did not aggressively pursue this new revenue opportunity.

Three states brought intra-state Internet gaming to the market in 2013, each with a distinct regulatory model and product. On April 30, 2013, Nevada came to market first with a poker-only offering that required all online content to be made available through and in conjunction with existing brick-and-mortar casino licensees. On October 31, 2013, Delaware became the second state in the United States to offer regulated Internet gaming. All content is offered through the Delaware State Lottery website, which has issued sub-licenses to the three racino operators in the state to serve as marketing portals (which include bingo and casino-style games in addition to poker). Finally, on November 21, 2013, New Jersey went live with the third and final regulated U.S.-based Internet offering to come to market in 2013. New Jersey's seven Atlantic City casinos' Internet gaming websites offer a complete array of poker and casino-style game content.

In each instance, access to the Nevada, Delaware, and New Jersey pay-to-play sites is limited to only those individuals residing within the respective state. To read more about internet gaming in the states, [Click Here].

# PROTECTION OF PROPERTY RIGHTS IN THE EU, THE NETHERLANDS, AND CALIFORNIA

#### Legal Measures Against Counterfeit and Piracy in the European Union and The Netherlands

By Jan M. Brölmann and Radboud Ribbert, GT Amsterdam Office

Intellectual Property right holders are often involved in an ongoing battle against counterfeit, pirated, and other infringing goods. European and Dutch law each provide effective remedies against offering and selling of such counterfeit, pirated, and other infringing goods.

#### European measures - the new Anti-Piracy regulation

A new European Anti-Piracy regulation came into force on January 1, 2014, repealing and replacing the previous Anti-Piracy regulation. This new set of rules regulates the enforcement of IP rights by customs authorities and gives those authorities the power to detain infringing goods at EU borders. The scope of the new regulation has been broadened, and several procedural changes have occurred. The principal changes include:

- 1. Extended Scope of Intellectual Property rights;
- 2. Simplified procedure for the destruction of infringing goods (Please note that this procedure can only be followed after right holders have submitted an application with the customs authorities, which measures can be taken throughout Europe from Greenberg Traurig's Amsterdam office); and
- 3. Destruction of small consignments.



#### Dutch measures – civil and criminal remedies

In addition to the EU regulation, Dutch law also provides a wide variety of civil legal measures that can be used to combat against counterfeiting, piracy, and infringing goods, such as proceedings on the merits, injunctive relief proceedings (including ex parte injunctive relief), and conservatory measures. The offering for sale and/or selling of counterfeit goods also constitutes a criminal offence under Dutch law, and entities that provide infringing services or applications over the Internet may be held liable under Dutch laws. Collectively, European and Dutch law provide right holders with multiple efficient and effective legal instruments to protect against such actions. To read more about the legal measures against counterfeit and piracy, [Click Here].

#### European Court Decision: Copyright Owner Consent Not Required to Hyperlink or Embed Links on Websites

By Radboud Ribbert and Nina Witt, GT Amsterdam Office

Recently, the European Court of Justice ruled on the applicability of European copyright law in the case of placing hyperlinks or embedded links on websites to works protected by copyright, published elsewhere on the internet (Svensson, et al./Retriever Sverige AB, Case C-466/12). The Court of Justice assessed whether article 3(1) of the Copyright Directive (2001/29/EC), which provides authors in the EU member states with an exclusive right to authorize or prohibit any "communication to the public" of their works, is applicable to such use of links.

The case was brought to the European Court by several journalists that wrote press articles that were published on the website of the Göteborgs-Posten newspaper. Retriever Sverige AB ("Retriever"), an operator of a website, provided its clients with clickable internet links to the aforementioned articles. The journalists claimed damages from Retriever based on copyright infringement. In this matter, questions relating to article 3(1) of the Copyright Directive were referred to the Court by the Swedish Court of Appeal.

The Court held that although hyperlinking (as in the present case) is in fact a communication to the public, it does not constitute a "communication to the public" as such is meant in article 3(1) of the European Copyright Directive. According to the Court, in this case the communication could not be deemed to be directed at such a "new public," as the original publications were directed at all internet users, a target audience already included in the segment of the population to which the later communications were directed. The European Court's decision implies that for purposes of providing hyperlinks to freely accessible (digital) works on a website, no permission from the copyright owners is required as a condition of compliance with the European Copyright Directive. The Court also held that member states are not allowed to provide copyright users with a broader protection by stating that the term "communication to the public" includes a wider range of activities than those referred to in article 3(1) of the Copyright Directive. To read more about the applicability of European copy law, [Click Here].

## Join the Party. Another California-based Former Employee Challenges Out-of-State Company's Non-Compete Provisions as Unfair Business Practice

By Kurt A. Kappes, GT Sacramento Office and GT San Francisco Office and Daniel T. McCloskey, GT Silicon Valley Office

A complaint recently filed in the Northern District of California, styled Shomit James v. Globus Medical, Inc. ("James"), illustrates the issues that can arise when out-of-state companies require California-based employees to agree to their standard non-compete, no-hire and non-solicitation provisions. A former employee of a medical device company is suing to invalidate non-compete provisions as void and unenforceable under California law, and is alleging that the employer company committed unfair business practices by seeking to enforce those restrictions and by having a choice of law provision which is purportedly intended to avoid California law, under which the restrictive covenants are illegal.

There is significant variation among the states regarding whether and to what extent restrictive employee covenants, including non-competes, non-solicitation and no hire provisions, can be enforced. *James* is just one of many litigation proceedings in what has become a cottage industry of seeking declaratory relief that such provisions are not enforceable in California. To read more about the challenges to the out-of-state company's non-compete Provision, [Click Here].

### REPORTING AND REVIEW OF MERGERS AND ACQUISITIONS

#### Revised Hart-Scott-Rodino Premerger Notification Thresholds for 2014

By Andrew G. Berg, GT Washington, D.C. Office; Mary K. Marks, GT New York Office

On January 17, 2014, the Federal Trade Commission (FTC) announced revised Hart-Scott-Rodino Act (HSR) reporting thresholds under which transactions will be reportable only if, as a result of such transaction, the acquiring person will hold voting securities, assets, or non-corporate interests valued above \$75.9 million, compared to \$70.9 million in 2013. The newly adjusted HSR thresholds will apply to all transactions that close on or after the effective date, which as published in the Federal Register, was February 24, 2014. The FTC also announced revised thresholds above which companies are prohibited from having interlocking memberships on their boards of directors under Section 8 of the Clayton Act. To read more about the revised Hart-Scott-Rodino Act, [Click Here].

#### Delaware Supreme Court: Controller Buyout Mergers can be Reviewed Under Business Judgment Rule

By Clifford E. Neimeth, GT Phoenix Office

In a significant case of first impression, the Delaware Supreme Court ("Delaware Supreme Court"), in Kahn v. M&F Worldwide Corp. ("M&F Worldwide"), No. 334, 2013 (Del. Mar. 14, 2014), unanimously affirmed that a controller's buyout of its subsidiary in a negotiated merger is entitled to judicial review under the deferential "business judgment" standard — instead of the exacting "entire fairness" standard — if certain procedural safeguards are locked in place at the outset of the transaction. In doing so, the Delaware Supreme Court answered an important 20-year old question never raised directly in Kahn v. Lynch Commc'ns Sys. ("Lynch"), 638 A.2d 1110 (Del. 1994) and upheld the Delaware Court of Chancery's ("Delaware Chancery Court") post-merger (summary judgment) decision in In re MFW S'holders Litig., 67 A.3d 496 (Del. Ch. 2013). To read more about the "business judgment" standard, [Click Here].

### INTERNAL INVESTIGATIONS AND WHISTLEBLOWER PROTECTIONS

#### Landmark Decision for Attorney-Client Privilege: Internal Investigations No Longer Protected?

By Ryan C. Bradel and Jacob B. Pankowski, GT Washington, D.C. Office

The federal district court in the District of Columbia issued a groundbreaking decision holding that documents created during a government contractor's own internal investigation — conducted under the oversight but not under the direct supervision of the company's legal department — are not protected by either the attorney-client privilege or the similar but distinct attorney work product doctrine. The case is United States ex rel. Barko v. Halliburton Co., et al., Case No. 1:05-CV-1276 (D.D.C. 2014). The current case emanates from an action brought by a former employee of KBR alleging certain wrongdoing by the company in the performance of its government contracts.

Generally speaking, documents and communications exchanged between an attorney and client are protected; that is, the client cannot be forced to disclose those documents during litigation. The courts have long held that the attorney-client privilege only applies when the attorney is providing legal advice. Thus, if an attorney is merely advising a company on how to conduct its business, those communications are not protected. When an attorney is advising a client on legal principles, those communications fall within the attorney-client privilege and are protected. Work product documentation prepared by or at an attorney's direction in the reasonable anticipation of litigation is also protected, albeit to a lesser degree.

The federal district court in the recent decision found that because the "investigations were undertaken pursuant to regulatory law and corporate policy rather than for the purpose of obtaining legal advice" they were of a business nature rather than of a legal nature and thus were not privileged. The consequences of this decision may be far-reaching and extend beyond the realm of government contracting. If the court's decision stands on appeal it could drastically affect the way that companies conduct investigations to monitor their compliance with the law. To read more about attorney-client privilege, [Click Here].

## Will Your Company Be Wearing New SOX? Supreme Court Expands Sarbanes-Oxley Whistleblower Protection to Employees of Privately-Held Companies

By Robert M. Goldich, GT Philadelphia Office; Michael J. Slocum, GT New Jersey Office

In a highly-anticipated decision having far-ranging impact for privately owned employers, the U.S. Supreme Court held in Lawson et al. v. FMR LLC, et al. that the whistleblower protections under § 806 of the Sarbanes-Oxley Act of 2002 (SOX) (18 U.S.C. § 1514A) extend not only to employees of publicly-held companies, but also to the employees of the privately-held "contractors" who provide services to public companies. Writing for a 6-3 majority, Justice Ginsburg observed that "boiling [§ 1514A] down to its relevant syntactic elements, it provides that 'no ... contractor ... may discharge ... an employee'" for whistleblowing activity. Lawson is a shot across the bow: no longer is SOX a concern only for publicly-traded companies.

There are a number of specific steps which private employers that provide any services to public companies need to take in response to Lawson. First, they should review their existing anti-retaliation policies and internal complaint procedures to make sure they address conduct regulated by SOX. Second, they should train managers and HR professionals to identify SOX complaints and refer them to responsible company officials for investigation. Third, they should ensure that individuals who are empowered to discipline and discharge employees are sensitive to SOX issues and do not unwittingly create liability when dealing with troublesome employees. To read more about the expansion of Sarbanes-Oxley Act on whistleblower protection, [Click Here].





# CALIFORNIA PROPOSITION 65 AND U.S. FDA REGULATION OF FOOD, BEVERAGES AND DIETARY SUPPLEMENTS

## California Proposes Enhanced Proposition 65 Warnings and Possible Online Disclosures - Dietary Supplements and Foods Specially Targeted

By Anthony J. Cortez, James Mattesich and Greg Sperla, GT Sacramento Office; Justin J. Prochnow, GT Denver Office

The California Office of Environmental Health Hazard Assessment (OEHHA) announced on March 7, 2014, that it is considering implementation of the most significant changes to Proposition 65 regulations in more than two decades. Passed by voters in 1986, Prop. 65 requires warnings prior to exposures to chemicals listed by OEHHA as "known to the State" to cause cancer or reproductive harm.

In its far-reaching proposal, OEHHA aims a number of significant changes directly at food and dietary supplement manufacturers, distributors, and retailers. Four specific proposals addressing the following subjects stand out as impactful for the industry: chemical identification, display requirements, online reporting, and more litigation. To read more about the enhanced Proposition 65 warnings, [Click Here].

#### FDA Issues Final Guidance Distinguishing Liquid Dietary Supplements from Beverages

By Justin J. Prochnow, GT Denver Office

On Monday, January 13, 2014, the Food and Drug Administration (FDA) issued a long-awaited and much anticipated, revised and now, final Guidance for Industry entitled, "Distinguishing Liquid Dietary Supplements from Beverages." In the new guidance, the FDA focuses on the first prong of the previous guidance, the factors distinguishing liquid dietary supplements from beverages. Some of those factors that the FDA may review include the following: Product Name; Labeling and Advertising, Recommendations and Directions for Use, Marketing Practices, and Other Representations.

The FDA also reiterated the regulatory requirements for ingredients in beverages and liquid dietary supplements and the labeling requirements, and also clarified that powdered premix products and liquid concentrates may be marketed as dietary supplements as long as they are properly labeled as a dietary supplement and are not represented for beverage use or as alternatives to beverages. Coinciding with the issuance of the above guidance, the FDA issued another Guidance for Industry entitled, "Considerations Regarding Substances Added to Foods, including Beverages and Dietary Supplements." To read more about final guidance distinguishing liquid dietary supplements from beverages, [Click Here].

### GT IN THE INDUSTRY

#### SPEAKING ENGAGEMENTS

GT attorney Justin Prochnow is speaking at Healthy Beverage Expo on the topic of "Staying Out of Jail and the Courtroom – Marketing Beverage Products to Sell Without Going Over the Line" on May 29-31, 2014.

GT attorney Justin Prochnow is speaking at AHPA Webinar on the topic of "FDA Inspections & Emerging cGMP Compliance Issues for Dietary Supplements" on May 15, 2014.

GT attorney Martha Sabol is speaking at the Japan Gaming Congress on the "Envisioning the IR Model in Japan, Part I" panel and GT attorney Laura McAllister Cox is moderating "Understanding the Approval/Licensing Procedure for All Gmaing Manufactuers and Suppliers Doing Business in Japan" on May 14-16, 2014.

GT attorney Justin Prochnow is speaking at BevNET on the topic of "Beverages 101" on May 14-15, 2014.

GT Attorney Mauri Sankus spoke at the MCLE - Where to File Patent Law Seminar on a panel regarding patent filing/protection strategies in BRIC countries on April 11, 2014.

GT patent attorney David J. Dykeman spoke at ACI Life Sciences Collaborative Agreements & Acquisitions Conference in New York City on April 1, 2014.

GT patent attorney David J. Dykeman spoke at Q1 Pharmaceutical & Medical Device Legal Forum in Washington D.C. on March 24, 2014.

#### **DEALS & AWARDS**

Greenberg Traurig received an M&A Advisor Award in Healthcare/Life Sciences for its role in the Resolute Anesthesia and Pain Solutions, LLC formation by a Recapitalization Sponsored by Goldman Sachs & Co.

Greenberg Traurig was recognized at Annual Americas M&A Atlas Awards with "U.S.A. M&A Deal of the Year – Large Markets" award for its role in the sale of Metropolitan Health Networks to Humana.

Greenberg Traurig's Lori Cohen was recognized in the 2013-2014 Lawdragon 500 Leading 'Lawyers in America' List.







### **GREENBERG TRAURIG'S LIFE SCIENCES & MEDICAL TECHNOLOGY GROUP**

Our Life Sciences & Medical Technology Group supports clients ranging from start-ups to large multinational 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 our Life Sciences and Medical Technology Group, please visit <a href="http://www.gtlaw.com/Experience/Industries/Life-Sciences-Medical-Technology">http://www.gtlaw.com/Experience/Industries/Life-Sciences-Medical-Technology</a>.

Greenberg Traurig, LLP is an international, full-service law firm with approximately 1750 attorneys serving clients from 36 offices in the United States, Latin America, Europe, the Middle East and Asia. In the U.S., the firm has more offices than any other among the Top 10 on *The National Law Journal's* 2013 NLJ 250. For additional information, please visit <a href="https://www.gtlaw.com">www.gtlaw.com</a>.





#### **Newsletter Editor**

#### Tracy J. Mabry

mabryt@gtlaw.com Orlando Office Direct: 407.254.2641

#### This Issue's Contributors

#### Kara M. Bombach

Shareholder bombachk@gtlaw.com Washington, D.C. Office Direct: 202.533.2334

#### Erik de Bie

Co-Administrative Shareholder debiee@eu.atlaw.com Amsterdam Office Direct: +31 (0) 20.301.7415

#### Kurt A. Kappes

Sacramento Co-Managing Shareholder kappesk@gtlaw.com Sacramento Office: San Francisco Office Direct: 916.868.0650

#### Bertha Alicia Ordaz-Avilés

Shareholder ordazb@gtlaw.com Mexico Office Direct: +52 (1) 55.5029.0029

#### Radboud Ribbert

Shareholder ribbertr@eu.gtlaw.com

Amsterdam Office Direct: +31 (0) 20.301.7333

#### GT Life Sciences & Medical Technology Co-chairs

#### David J. Dykeman

dykemand@atlaw.com **Boston Office** Direct: 617.310.6009

#### David C. Peck

peckd@gtlaw.com Fort Lauderdale Office Direct: 954.768.8265

#### Scott J. Bornstein

Shareholder: Chair, New York Intellectual Property & Technology; Co-Chair, Global Patent Litigation Group bornsteins@atlaw.com New York Office Direct: 212.801.2172

#### David J. Dykeman

Shareholder; Co-Chair, Life Sciences & Medical Technology Group dykemand@gtlaw.com **Boston Office** Direct: 617,310,6009

#### James Mattesich

Shareholder mattesichi@gtlaw.com Sacramento Office Direct: 916.442.1111

#### Mitchell F. Brecher

Shareholder brecherm@gtlaw.com Washington, D.C. Office Direct: 202.331.3152

#### Robert M. Goldich

Philadelphia Operating Shareholder goldichr@gtlaw.com Philadelphia Office Direct: 215.988.7883

#### Clifford E. Neimeth

Shareholder neimethc@gtlaw.com New York Office Direct: 602.445.8372

#### Jacob B. Pankowski

Shareholder; Chair, Governmer Shareholder Contracts Practice pankowskij@atlaw.com Washington, D.C. Office Direct: 202.331.3191

#### Martha A. Sabol

Shareholder; Chair, Gaming Practice sabolm@gtlaw.com

Chicago

Direct: 312.476.5114

#### Justin J. Prochnow

prochnowij@gtlaw.com Denver Office Direct: 303.572.6562

#### Sanford M. Saunders

Washington, D.C. Co-Managing Shareholder saunderss@gtlaw.com Washington, D.C. Office

Direct: 202.331.3130





Shareholder tuppers@gtmlaw.com London Office Direct: +44 (0) 203.349.8729

#### **Daniel T. McCloskey**

Of Counsel mccloskeyd@gtlaw.com Silicon Valley Office Direct: +1 650.289.7811

#### Adam Braun

Associate brauna@gtlaw.com Chicago Office Direct: 312.456.8456

#### Luke Dixon

Associate dixonl@gtmlaw.com London Office Direct: +44 (0) 203.349.8756

#### Michael J. Slocum

Associate slocumm@gtlaw.com New Jersey Office Direct: 973.360.7900

#### Edward R. Winkofsky

Associate winkofskye@gtlaw.com Chicago Office Direct: 312.456.8440

#### J. Daniel Walsh

Senior Director walshd@gtlaw.com Washington, D.C. Office Direct: 202.331.3168

### <u>Jamey L. Tesler</u>

Of Counsel teslerj@gtlaw.com Boston Office Direct: 617.310.6026

#### Jan M. Brölmann

Associate brolmannj@eu.gtlaw.com Amsterdam Office Direct: +31 20.301.7379

#### Justin A. MacLean

Associate macleanj@gtlaw.com New York Office Direct: 212.801.3137

#### **Greg Sperla**

Associate sperlag@gtlaw.com Sacramento Office Direct: 916.442.1111

#### Nina Witt

Associate wittn@eu.gtlaw.com Amsterdam Office Direct: +31 (0) 20.301.7305

#### Mary K. Marks

Of Counsel marksm@gtlaw.com New York Office Direct: 212.801.3162

### Ryan C. Bradel

Associate bradelr@gtlaw.com Washington, D.C. Office Direct: 202.533.2387

#### Anthony J. Cortez

Associate cortezan@gtlaw.com Sacramento Office Direct: 916.868.0679

#### Erica Okerberg

Associate okerberge@gtlaw.com Las Vegas Office Direct: 702.599.8073

### Nicoleta Timofti

Associate timoftin@gtlaw.com Washington, D.C. Office Direct: 202.530.8536

#### Michael Cohen

Law Clerk cohenm@gtlaw.com Boston Office Direct: 617.310.6223