Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Dunne to Address Mobile Medical Apps at FDLI Event

Shook, Hardy & Bacon Life Sciences & Biotechnology Partner **Debra Dunne** will join a distinguished faculty, including U.S. Supreme Court Justice Samuel Alito—the keynote luncheon speaker, during the Food and Drug Law Institute's (FDLI's) **Annual Conference**, April 23-24, 2014, in Washington, D.C. Dunne will serve on a panel addressing "Mobile Medical Apps and Unique Device Identifiers: Regulatory and Business Challenges."

Strand & Underhill to Bring SHB Expertise to IP Litigation Seminar

Shook, Hardy & Bacon Intellectual Property (IP) Partner **Peter Strand**, who chairs DRI's Intellectual Property Litigation Committee, will preside over the first-time attendees breakfast during the organization's May 8-9, 2014, **IP litigation seminar** "The IP Litigator: Protect, Defend, Prevail." He will join conference chairs in opening the program with a welcome and introduction. Also taking part in this continuing legal education program is SHB Global Product Liability Partner **Kevin Underhill**, whose presentation is titled "Lowering the Bar on Ethics."

Kaplan & Woodbury Join Faculty at DRI Drug and Medical Device Seminar

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partners **Harvey Kaplan** and **Marie Woodbury** will participate in DRI's "**Drug and Medical Device Seminar**" slated for May 15-16, 2014, in Washington, D.C. Kaplan will serve as the moderator of a panel of judges discussing "Mass Tort Coordination Between Federal and State Jurisdiction," while Woodbury will serve on a panel demonstrating "Trial Skills: Warnings, Experts, and General Causation."

Garretson to Speak During ACI Biosimilars Summit

Shook, Hardy & Bacon Intellectual Property Prosecution & Counseling Partner **John Garretson** will participate in the American Conference Institute's (ACI's) "**5th Annual Summit on Biosimilars**" in New York City,

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SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

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June 4-6, 2014. Garretson will be part of a panel discussion on "Going Beyond the Hatch Waxman Comparisons: Delving into Pre-Suit Due Diligence and Pre-Litigation Tactics for Evaluating Patent Strength and Assertion Strategies." The firm is a conference co-sponsor.

Goldberg Analyzes Proposed Patent-Reform Legislation

Shook, Hardy & Bacon Public Policy Partner **Phil Goldberg** has **authored** an article titled "Senate Should Enact Meaningful Patent Troll Reform" appearing in the April 9, 2014, issue of *Law360*. The article explains how "shell businesses nicknamed 'patent trolls' game the system by purchasing dormant patents, waiting for others to independently develop comparable technology, and then accusing those other businesses of infringing on those patents." These entities "often threaten claims against many innovators in an industry, offering settlements or 'licensing fees' for less than it would cost a company to defend its right to make, sell or use its product." Noting how expensive these lawsuits can be to defend, Goldberg describes the salient features of a bill that the U.S. House "passed 325 to 91 in a rare show of broad bipartisan support" to curtail patent-litigation abuses while allowing legitimate claims to proceed. He concludes, "For those of us who believe in America's civil litigation system, removing the patent troll stain is important for assuring the ability of a court to facilitate fair, accurate legal outcomes for those who need it."

IP NEWS

Crowdsourcing to Identify Prior Art Could Be Problematic

According to roundtable speakers addressing whether crowdsourcing could be used to determine anticipation or obviousness during patent examination, scaling up to meet the U.S. Patent and Trademark Office's (USPTO's) proposal to use crowdsourcing as a means of expanding current third-party prior art submissions could be difficult. Additional information about USPTO's roundtable notice appears in the "News Bytes" section of Issue **75** of this *Bulletin*. Most of the speakers reportedly operated or now operate Websites that either post patent applications or the claim interpretations in patent applications so that experts can identify and submit documents relating to prior art. Other speakers apparently questioned whether third-party submissions provide a solid basis on which USPTO can build, noting that most third parties submitting under the current program—launched under an America Invents Act provision—work for companies responding to a competitor's application. Comments on the issue must be submitted by April 25, 2014. *See Bloomberg BNA The United States Law Week®*, April 11, 2014.

USPTO to Continue Patents for Humanity as Annual Competition

After the successful conclusion of a pilot program "to incentivize the use of patented technologies for humanitarian purposes," the U.S. Patent and Trademark Office (USPTO) has **decided** to continue the Patents for Humanity program as an annual awards competition. Award recipients in 2014 will receive certificates to accelerate select matters before USPTO and public recognition for their efforts. Honorable mentions will receive accelerated examination of one patent application and a featured write up on USPTO's Website. Applications will be accepted from April 14 to September 15, 2014, or until 300 are received, whichever occurs first. Applicants must show how their actions have increased the use of patented technology to address humanitarian issues—i.e., those significantly affecting the public health or quality of life of an impoverished population. *See Federal Register*, April 3, 2014.

USPTO Dedicates Resources to Office of International Patent Cooperation

The U.S. Patent and Trademark Office (USPTO) has **established** a new Office of International Patent Cooperation; Mark Powell, who has worked exclusively on "international cooperative activities" for the agency during the past three years, was appointed as its first deputy commissioner. According to USPTO Deputy Director Michelle Lee, the office "will allow us to increase certainty of IP rights while reducing costs for our stakeholders and moving towards a harmonized patent system." The office's focus, in collaboration with other USPTO offices, "is to provide optimized business process solutions to the international patent examination system for examiners and external stakeholders." *See USPTO Press Release*, April 3, 2014.

INVESTOR NEWS

Biotech Secures $4.1 Million for Hearing Loss Drug Trial

Otologic Pharmaceutics, Inc. (OPI) has announced a $4.1-million Series A financing round co-led by Accele Venture Partners. The company plans to use the capital to develop its lead product, NHPN-1010, an oral treatment for noise-induced hearing loss, scheduled to enter clinical trials later this year. Developed in collaboration with The Hough Ear Institute and Oklahoma Medical Research Foundation, HPN1010 apparently works by reducing acute damage and promoting healing and recovery of the injured cochlea.

Noting that no U.S. Food and Drug Administration-approved drugs are currently on the market for hearing loss, OPI's newly appointed CEO Clayton Duncan said that HPN1010 has shown promising activity in reducing hearing

loss in investigational new drug-enabling preclinical studies. "Applications may include hearing loss experienced by individuals in a number of occupations, such as construction and manufacturing, as well as those who have served our country in military service, in addition to hearing loss associated with cancer treatments, such as cisplatin," said Duncan.

The World Health Organization reportedly estimates that more than 600 million people have some form of hearing loss and approximately 10 percent of Americans between ages 20 and 69 may already have permanent damage to their hearing from excessive noise exposure, which is evidently the single largest addressable cause of hearing-loss problems. *See OPI News Release*, April 3, 2014.

Adaptive Biotech Raises $105 Million to Expand Immunosequencing Platform

Adaptive Biotechnologies Corp. has reportedly completed Series C and D financing rounds by raising $105 million from Viking Global Investors. According to the Seattle, Washington-based biotech, the investment will enable it "to expand globally its preeminent immunosequencing research platform [immunoSEQ™] and downstream validated clinical diagnostic products." The company, with a particular emphasis on oncology, "leverages advances in next generation sequencing to profile T-Cell and B-Cell receptors." Its "patented breakthrough enables in-depth characterization of the immune system, which is the primary defense against cancer." Adaptive Biotechnologies CEO and Founder Chad Robins said, "We are excited to have our strategic vision of immunosequencing across disease states be validated by a large capital investment from Viking." *See Adaptive Biotechnologies Corp. Press Release*, April 7, 2014.

Exact Sciences Completes Public Offering to Fund Colorectal Screening Test

Madison, Wisconsin-based Exact Sciences Corp., a molecular diagnostics company, has reportedly completed an underwritten public offering of 11.5 million shares of common stock, including 1.5 million shares sold under the full exercise of the underwriters' option to purchase additional shares. Gross proceeds from the offering were approximately $146.6 million. The company, which focuses on the early detection and prevention of colorectal cancer, apparently intends to use proceeds from the offering to fund efforts to obtain U.S. Food and Drug Administration approval of its Cologuard test and commercialization activities. *See Exact Sciences Corp*. and *ResearchViews.com*, April 2, 2014.

Regado Prices IPO at $56 Million, In Phase 3 Testing for Cardiovascular Therapeutic

A biopharmaceutical company has revised a previously announced underwritten public offering of 10 million shares of its common stock and will offer them at $6.00 per share, down from the more than $13 at which shares had traded in mid-March. Regado Biosciences, Inc., located in Basking Ridge, New Jersey, expected to close the offering April 16, 2014, and raise $56 million to "fund further clinical development of its lead product candidate, REG1, and for working capital and other general corporate purposes." The company discovers and develops "novel, oligonucleotide-based actively controllable therapeutics" for application in the acute and sub-acute cardiovascular therapeutic area. Jefferies LLC, Deutsche Bank Securities and Cowen and Co., LLC are joint book-running managers for the proposed offering. *See Regado Biosciences, Inc. News Release*, April 11, 2014.

Agricultural Biotech Raises $15 Million in Equity

BioConsortia, Inc., originally from New Zealand and currently based in Davis, California, has announced a $15-million Series B financing round backed by Khosla Ventures and Otter Capital LLC. Proceeds from the round will be used to "commercialize the use of microbial consortia as seed treatments and soil additive and … build collaborative partnerships with seed, fertilizer and crop production companies."

BioConsortia has apparently developed a proprietary technology platform using accelerated microbial selection and genomic techniques to define products for specific crop-improvement traits based on an optimum community of microbes, or consortia, that work together to increase crop yields with no genetic modification required. According to a company news release, the system can rapidly identify the right consortia and is applicable to both conventional and transgenic crops. *See BioConsortia, Inc. News Release*, April 7, 2014.

BUSINESS CLIMATE

Biotechs Price IPOs at a Discount, Reflecting Off Market at Start of Q2 2014

Noting that "the previously scalding biotech market has gone off the boil," *EP Vantage* has reported that medtech and biotech companies have either postponed their initial public offerings or announced offerings priced at hefty discounts. The financial-analysis daily noted that Lombard Medical Technologies, for example, "decided to indefinitely postpone its hotly anticipated $60m float on the Nasdaq, saying that market conditions are

not right." And two biotech companies reportedly announced fundraisings that were 16 and 17 percent off the previous day's closing price. *See EP Vantage*, April 14, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Agencies Propose Health IT Strategy

The U.S. Food and Drug Administration (FDA), Federal Communications Commission and Office of the National Coordinator for Health Information Technology have **released** a report outlining the agencies' draft strategy and recommendations for a "risk-based" regulatory framework for health-information technology (health IT), as required by Section 618 of the Food and Drug Administration Safety and Innovation Act. Comments are requested by July 7, 2014.

According to retiring Health and Human Services Secretary Kathleen Sebelius, who notes that the diverse and rapidly developing industry of health information technology requires a "thoughtful, flexible approach," the strategy outlined in the report is designed to "promote innovation and provide technology to consumers and health care providers while maintaining patient safety."

While acknowledging the benefits that a nationwide health IT infrastructure can offer to the American public, including the prevention of medical errors, improved efficiency and health care quality, reduced costs, and increased consumer engagement, the agencies note that if health IT products are not properly designed, developed, implemented, maintained, or used, they may pose risks to the patients who use them.

Among other things, the reports suggests that (i) risk and corresponding controls should focus on health IT functionality rather than the platform(s) on which the functionality resides; (ii) no new or additional areas of FDA oversight are necessary; (iii) the regulatory framework should be flexible enough to accommodate innovative, continuously-evolving products and should account for the complex environment in which the products operate, as well as the multiple stakeholders that play key roles in development, implementation and use; and (iv) FDA should continue to oversee medical device health IT functions such as computer-aided detection software, remote display or notification of real-time alarms from bedside monitors, and robotic surgical planning and control, because these products "generally pose greater risks to patient safety" and FDA oversight is better suited to provide safety assurance. *See FDA Press Release*, April 3, 3014; *Federal Register*, April 7, 2014.

FDA Shows Increasing Independence from Advisory Committee Recommendations

Investment bank USB has reportedly issued an analysis which apparently shows that the U.S. Food and Drug Administration (FDA) has increasingly rejected the drug-approval or nonapproval recommendations of its advisory committees, making it difficult to forecast accurately whether FDA will follow a committee vote and increasing the likelihood of bio market volatility. Sponsors routinely warn that FDA is not required to follow an advisory committee's advice, and USB apparently found this to be a pertinent caveat. In 2013, FDA followed a positive endorsement just 80 percent of the time, down from 100 percent just two years earlier. Still, when the advisory committee vote is mixed, FDA has apparently increased its approval rate from 0 percent in 2011 to 14 percent in 2012 and 17 percent in 2013. *See EP Vantage*, April 14, 2014.

EU Adopts Joint Procurement Agreement for Pandemic Vaccines

The European Commission has approved a joint procurement agreement under which all European Union (EU) member states will be able to "procure pandemic vaccines and other medical countermeasures as a group, rather than individually" thus allowing them to better prepare for future health threats and "provide their citizens with the necessary medicines and to obtain them under better conditions than in the past," according to Commissioner for Health Tonio Borg. He called on all member states "to sign the Joint Procurement Agreement as soon as possible so that we can proceed to the first procurement of pandemic vaccines." *See European Commission Press Release*, April 10, 2014.

French Biosimilar Substitution Measure Raises Concerns

According to a news source, pharmaceutical companies that sell biological medicines in France were surprised when the government recently introduced a measure that would allow pharmacists to substitute biosimilar drugs, making it the first country in Europe to do so. While it will apply only when patients begin a new course of treatment and will not apply to the 40 percent of prescriptions that are filled in hospitals, the measure requires a decree to come into force, a move not expected until some months after a working group gives non-binding recommendations in June 2014. Affected companies are reportedly now consulting with government officials, doctors and pharmacists to shape the decree. Economists believe that substituting biosimilars for medicines that can cost tens or hundreds of thousands of dollars annually per patient could save France between 500 million euros and 1 billion euros (US$690 million-$1.4 billion) by 2020. *See Reuters*, April 10, 2014.

LITIGATION

Court Rules Massachusetts's Ban on Painkiller Preempted

A federal court in Massachusetts has granted a drugmaker's request to preliminarily enjoin the commonwealth's ban on a painkiller, finding that the emergency order was preempted under federal law. *Zogenix, Inc. v. Patrick*, No. 14-11689 (U.S. Dist. Ct., D. Mass., order entered April 15, 2014). The court concluded that "[w]hen the Commonwealth interposed its own conclusion about [the drug's] safety and effectiveness by virtue of [the Department of Public Health's] emergency order," it obstructed the U.S. Food and Drug Administration's (FDA's) congressionally given charge. Specifically, the court found, "the drug Massachusetts wants Zogenix to adopt—Zohydro ER with an 'abuse-resistant formulation'—has not been approved by the FDA. To satisfy the Commonwealth, Zogenix would be required to return to the FDA and seek approval of a drug different from the one that FDA has already deemed safe."

Pharmaceutical company Zogenix, Inc. makes an FDA-approved opioid painkiller. It filed a complaint for declaratory and injunctive relief against the Massachusetts governor and Department of Public Health commissioner, challenging an emergency order prohibiting medical practitioners in the Commonwealth from prescribing or dispensing "any hydrocodone bitartrate product in hydrocondone-only extended-release formulation," a product description applying only to the company's Zohydro™ ER.

According to the complaint, "FDA considered requiring abuse-deterrent technologies for the drug but ultimately concluded that the overall risk-benefit balance of Zohydro™ ER was sufficient to support approval of the NDA [new drug application] without an abuse-deterrent formulation." The company claims that its drug is needed by patients who are at risk of acetaminophen toxicity. FDA has also allegedly concluded that "the technology used to produce abuse-deterrent opioid formulations 'is still in the nascent stages' [and thus] that it is not 'in the interest of public health at this time to require all opioid products or all [extended release/long-acting] opioid products' to feature the abuse deterrent formulation."

Despite this approval and purportedly without warning to the company, the governor issued a press release declaring a public health emergency in March 2014 and directing the Department of Public Health to take action to combat opioid overdoses and giving the commission emergency powers to "[i]mmediately prohibit the prescribing and dispensing of any hydrocodone-only formulation (commonly known as Zohydro) until [it is] determined that adequate measures are in place to safeguard against the potential for diversion, overdose, and misuse."

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According to the court, the company is likely to prevail on the merits, and it further determined that Zogenix had "shown injury to its reputation by defendants' highly publicized ban of its drug," and that the ban adversely affects the congressionally mandated arrangement "for ensuring that drugs are safe and effective for those in need." Balancing the equities, the court stated, "[A]lthough the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers." The court stayed its order until April 22, 2014.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **announces** the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations to "provide product specific guidance on the design of BE studies to support abbreviated new drug applications." Comments may be submitted at any time, but FDA suggests submitting them by June 2, 2014, to ensure consideration before the agency begins work on the final version. ■

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Shook, Hardy & Bacon attorneys are experienced at assisting biotech and life sciences clients with a variety of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; biomedical research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements. The firm also counsels industry participants on compliance issues, ranging from recalls and antitrust matters to facility inspections, subject to FDA, SEC, FTC, and USDA regulation.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most challenging national and international product liability and mass tort litigations.