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 Litigation Risks Related to Molecular Diagnostics at ABA Workshop

Pharmaceutical & Medical Device Partner **Debra Dunne** will join a distinguished panel during an October 9, 2014, American Bar Association (ABA) Section of Litigation continuing legal education **workshop** in Austin, Texas. Titled "Regulation of Molecular Diagnostics and Potential Litigation Issues," the panel discussion will focus on the U.S. Food & Drug Administration's existing bifurcated regulatory pathway for molecular diagnostic tests, including laboratory-developed tests, and draft agency guidance meant to simplify the requisite steps for approval by adopting a risk-based process. The event was organized by the Products Liability Committee's Medical Device and Pharmaceutical Subcommittees.

IP NEWS

USPTO to Host Roundtable on Harmonization of Substantive Patent Law

The U.S. Patent and Trademark Office (USPTO) will **host** a November 19, 2014, roundtable in Alexandria, Virginia, on the international harmonization of substantive patent law to secure stakeholder input on matters such as "the definition and scope of prior art; the grace period; and standards for assessing novelty and obviousness/inventive step." USPTO's focus is on "the successful reutilization of the examination work of one intellectual property office by another, or work sharing." Attendees may register at the door, and the program will be Webcast. Those wishing to serve as roundtable panelists must register and provide a few brief comments on the topics by October 24. *See Federal Register*, September 18, 2014.

Non-Practicing Entity's Suit to Halt FTC Investigation Dismissed

A federal court in Texas has dismissed for lack of standing and ripeness and for failure to exhaust administrative remedies a declaratory judgment action filed by MPHJ Technology Investments, LLC (a so-called "non-prac-

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ticing entity"), seeking to disrupt the Federal Trade Commission's (FTC's) investigation into whether the company's efforts to enforce its patents constitute unfair trade practices. *MPHJ Tech. Invs., LLC v. FTC*, No. 14-0011 (W.D. Tex. Sept. 16, 2014). The company has been sued by a number of attorneys general for threatening alleged patent infringers in their states with litigation if they do not sign license agreements and pay licensing fees.

The court found the litigation premature, because FTC has taken no action against the company beyond the investigation stage, the court cannot declare that the company's letters do not violate the FTC Act without usurping FTC's fact-finding responsibility, and the company has not suffered any injury other than a requirement that it respond to FTC's discovery requests. The court further found that the FTC Act requires exhaustion of administrative remedies and that no exemption to exhaustion applied.

INVESTOR NEWS

University of California Establishes Venture-Capital Fund

The University of California's Board of Regents has reportedly approved the creation of a $250-million venture-capital fund to invest in start-up commercial opportunities arising from research conducted throughout the sprawling university system, which includes 10 campuses, five medical centers and three affiliated national laboratories. New drug development is expected to claim some of the start-up funding, with the Bay Area serving as home to the largest total U.S. biotech investments in 2013.

University President Janet Napolitano said, "In addition to any financial benefits, we see this fund as a potential vehicle for providing resources to support the basic research and talent—among both faculty and students—required to develop innovations that can benefit California and the world." The university system currently boasts 233,000 students, 190,000 faculty and staff, as well as 1.7 million living alumni, providing "a rich environment for innovation that is already the target of venture capitalists from around the world." According to a news source, more than 700 startups have formed to commercialize university research, generating $5 billion in venture capital. *See University of California Press Release*, September 15, 2014; FierceBiotech, September 16, 2014; *The Wall Street Journal*, September 18, 2014.

Biotech Announces $20-Million Series A Financing for Protein Growth Factor Modulation

Cambridge, Massachusetts-based biotechnology company Scholar Rock has reportedly raised $20 million in a Series A financing round. The funding will be used to support the discovery and development of modulators that target protein growth factors in disease microenvironments. The company focuses on specific growth factors, "including members of the TGF-beta superfamily, which are present in the microenvironments of significant diseases such as fibrosis, diseases of the musculoskeletal systems and autoimmune diseases." Scholar Rock Chair Amir Nashat said, "Growth factors have long been recognized as extremely important disease targets. Scholar Rock's new paradigm of targeting these factors locally, thereby avoiding undesirable systemic effects, is unique and holds the promise of developing highly effective and safe therapeutics to treat many difficult to treat diseases." *See Scholar Rock Press Release*, September 15, 2014.

Agricultural Biotech Closes Funding Round to Accelerate R&D

Agricultural biotechnology company NewLeaf Symbiotics has reportedly raised $17 million in a Series B round of financing that will be used to accelerate its research and development (R&D) program, increase production from pilot to commercial scale and market its first biological products—beneficial plant bacteria. From its St. Louis, Missouri, headquarters, company CEO Tom Laurita said, "We have made huge strides on the discovery side and have filed over 20 patents since inception. We are rapidly expanding our Prescriptive Biologics™ platform and are developing a deep pipeline of commercial product candidates. NewLeaf is now poised to bring natural bacteria-based seed and foliar products to growers." The company apparently uses a genomics approach to the discovery and analysis of plant/microbe interactions. *See NewLeaf Symbiotics News Release*, September 15, 2014.

Tokai Closes IPO with $97.2 Million to Help Fund Cancer Drug Trials

Tokai Pharmaceuticals, Inc. has reportedly closed its initial public offering (IPO) of nearly 6.5 million shares of common stock at an initial offering price of $15.00 per share, thus raising $97.2 million before underwriting discounts and commissions. With another 972,000 shares earmarked for underwriters, the Cambridge, Massachusetts-based clinical-stage biopharmaceutical company was apparently poised to raise a maximum $112 million. Focusing on developing novel therapies for prostate cancer as well as hormonally driven diseases, the company will use the cash infusion to support late-stage testing of galeterone, a combination prostate cancer

treatment, which has been designated under the U.S. Food and Drug Administration's fast-track program. *See FierceBiotech*, September 17, 2014; Tokai Pharmaceuticals Press Release, September 23, 2014.

Exagen Diagnostics Files for $69-Million Public Offering

A commercial-stage diagnostics company that develops diagnostic and monitoring testing for patients with autoimmune rheumatic diseases/autoimmune connective tissue disease—ARDs/CTD—has **filed** a registration statement with the U.S. Securities and Exchange Commission, indicating its intent to file an initial public offering to raise $69 million. According to Exagen Diagnostics, Inc., which is based in Vista, California, its Avise line of tests allows physicians to more accurately rule-in or rule-out particular autoimmune rheumatic diseases with a single blood draw. "Differential diagnosis of these diseases is critically important," the company said, "because early diagnosis has been shown to improve patient outcomes. Once diagnosed, physicians can tailor therapy to a patient's specific disease and avoid the 'trial and error' approach that often takes place when overlap syndrome is present." *See About Exagen*, accessed September 29, 2014.

Parion Sciences Receives $3-Million Cystic Fibrosis Foundation Award

Durham, North Carolina-based Parion Sciences has reportedly been awarded $3 million from Cystic Fibrosis Foundation Therapeutics (CFFT). The funds will be used to initiate a Phase 2 trial for P-1037, Parion's new investigational treatment for people with cystic fibrosis. The drug, an epithelial sodium channel blocker, apparently inhibits sodium channels in the airways; it is expected to promote fluid secretion and rehydrate mucus layers to restore airway clearance, reduce infection and improve lung function, according to the company's September 16, 2014, news release. CFFT has also expanded its support of the company's CFTR corrector research program, which targets the cystic fibrosis transmembrane conductance regulator (CFTR) protein, with a separate award of nearly $1 million.

Israeli Biotech to Seek $65 Million in NASDAQ IPO

NeuroDerm Ltd., a biotechnology company focusing on central nervous system (CNS) disorders, has filed an initial public offering (IPO) to raise $65 million to support late-stage clinical testing of two wearable products that deliver high and low doses of the Parkinson's treatments levodopa and carbidopa. Located in Rehovot, Israel, the company develops devices that continuously administer controlled dosages of existing drugs to replace the invasive surgical procedures that can be required for those with extreme symptoms. It is also reportedly working on technologies in

an earlier clinical stage, including ND0801, which combines nicotine and opipramol to treat cognitive disorders associated with CNS diseases, such as ADD/ADHD, Alzheimer's disease, and schizophrenia. Jefferies LLC and Cowen and Co., LLC are joint book-running managers for the proposed offering, while Oppenheimer & Co. and Roth Capital Partners, LLC are serving as co-managers. *See NeuroDerm Ltd. Press Release*, September 15, 2014; *FierceBiotech*, September 16, 2014.

BUSINESS CLIMATE

Eyes and Ears Lead the Heart in Venture-Capital Funding Increases

According to Dow Jones reporter Brian Gormley, the body parts drawing the most significant increase in venture-capital funding are the eyes and ears, with startups focusing on these organs garnering $848.9 million and $76.2 million, respectively, in 2013. Gormley notes, "Venture investors have kept up the pace this year, sinking $442.7 million into vision disorders in the first half. Investment has surged because of rising demand for better treatments and technological advances that are making improvements possible." While funding for companies focusing on hearing problems did not return to its 2008 high of $100.9 million, the first half of 2014 has already seen $114.4 million in investment in a problem afflicting some 30 percent of people aged 65-74. Cardiovascular therapy funding, meanwhile, continues to remain strong at $709.8 million invested in 2013, but this is still significantly lower than $1.1 billion invested in 2011. Interest in orthopedic products is also apparently cooling, dropping from a high of $1.14 billion in 2006 to $479.5 million in 2013. *See The Wall Street Journal*, September 15, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Public Watchdog Calls on FDA to Issue "Revolving Door" Guidance

Public Citizen recently **called** on the U.S. Food and Drug Administration (FDA) to take certain steps that would both prohibit the practice of advisory committee members simultaneously serving as paid speakers on behalf of drug or pharmaceutical companies and impose a "cooling-off period" between service as a committee voting member and the performance of "speaking or consulting roles on behalf of a sponsor before any future committee meeting." The organization also called for amendments to the agency's 2008 advisory committee conflict-of-interest guidance to disqualify from participation in an upcoming committee meeting those whose previous paid speaking or consulting arrangement on behalf of

a sponsor at an FDA advisory committee occurred "within a reasonably recent period of time." Public Citizen is concerned that such "revolving-door arrangements . . . undermine public confidence in FDA advisory committees and in the agency itself," particularly where these committees evaluate drug or medical device risks and benefits.

FDA Contends Twitter Not Off Limits for Pharmaceutical Cos.

While the U.S. Food and Drug Administration (FDA) has extended the deadline for comments on its draft guidance for drug and medical device makers choosing to present product benefit information via social media with character space limitations, a news source reports that the head of the agency's Office of Prescription Drug Promotion contends that the guidance will allow Twitter promotions. According to FDA's Thomas Abrams, the guidance samples show that it is "feasible" to make benefit claims and share risk information "within the same character-space limited communication" for certain products. For other products, "particularly those with complex indications or extensive serious risks, character-space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk," he added. Abrams also noted that FDA has undertaken a "comprehensive review of its regulations and guidance documents in an effort to harmonize the fundamental public health interests underlying the FDA's mission and statutory framework with First Amendment interests in the dissemination of truthful, accurate and non-misleading information regarding medical products." *See Law360*, September 12, 2014.

LITIGATION

Shire Pharmaceuticals Settles FCA Claims for $56.5 Million

Without admitting liability, Wayne, Pennsylvania-based Shire Pharmaceuticals LLC has entered a settlement agreement with the U.S. Department of Justice arising out of claims filed under the False Claims Act by company whistleblowers (relators) alleging that the company misrepresented the efficacy of some of its products and promoted others for off-label uses. *United States ex rel. Torres v. Shire Specialty Pharm.*, No. 08-4795 (U.S. Dist. Ct., E.D. Pa.); *United States ex rel. Hsieh v. Shire PLC*, No. 09-6994 (U.S. Dist. Ct., N.D. Ill.) (settled September 19, 2014). Under the agreement, Shire will pay a total of $56.5 million to the United States and Medicaid participating states. One relator will receive $5.9 million once the United States receives its share of the settlement, and Shire has agreed to pay the relators and relators' counsel more than $900,000 in expenses and fees. Shire CEO Flemming Ornskov said, "We are pleased to have reached a resolution and to put this matter behind us," and added that the company "has had, and

will continue to have a comprehensive compliance program and internal controls to ensure we comply with applicable laws and regulations."

The company allegedly claimed, without sufficient supporting clinical data, that (i) its ADHD medications were superior to other ADHD drugs; (ii) use of the drugs would help prevent certain ADHD-linked issues, "such as poor academic performance, loss of employment, criminal behavior, traffic accidents, and sexually transmitted disease"; (iii) one of its drugs was "non-abuseable" or "less abuseable" than others; and (iv) other drugs could prevent colorectal cancer or treat indeterminate colitis and Crohn's disease, despite that these were not medically accepted indications and the drugs were not covered by U.S. or state Medicaid programs for these uses. The company's sales representatives allegedly improperly made phone calls and drafted letters to Medicaid to help physicians with the prior authorization process for Medicaid prescriptions for certain drugs, without disclosing that they worked for Shire and provided the services "to induce the physicians to prescribe" the drugs for payment by Medicaid. *See Bloomberg BNA, Product Safety & Liability Reporter™*, September 24, 2014.

NEWS BYTES

The U.S. Patent and Trademark Office **extends** the deadline for applications under its Patents for Humanity Program, "which recognizes patent holders who use their technology for humanitarian purposes." The new deadline is October 31, 2014.

The U.S. Patent and Trademark office **expands** its cooperation in classification activities with the Korean Intellectual Property Office (KIPO). In an agreement signed during a bilateral meeting in Geneva, the agencies hope to "improve the patent granting process through streamlined access to patent documentation." KIPO will expand the number of documents included in the Cooperative Patent Classification system by fully classifying its patent applications and utility models.

The Centers for Disease Control and Prevention **requests** nominations for candidates to serve on the Board of Scientific Counselors, Office of Infectious Diseases. Nominees, who may be invited to serve terms of up to four years, should have expertise in such fields as "infectious diseases and related disciplines, including epidemiology, microbiology, bacteriology, virology, pathogen genomics, bioinformatics, clinical medicine, and veterinary medicine." This board advises a number of national health centers and agencies on strategies, goals and priorities for the programs and research within their ambit. The nomination deadline is October 24, 2014.

The U.S. Food and Drug Administration (FDA) **reopens** the comment period on draft guidance titled "Internet/Social Media Platforms with

Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" at the request of certain commenters for more time. The new deadline is October 29, 2014. "The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues."

The U.S. Food and Drug Administration (FDA) **reopens** the comment period on draft guidance titled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices" at the request of certain commenters for more time. The new deadline is October 29, 2014. "The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of human and animal drugs and medical devices for human use, including biological products, should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or cleared products when that information is created or disseminated by independent third parties."

The Office of Management and Budget **approves** the U.S. Food and Drug Administration's (FDA's) proposed eye-tracking study of direct-to-consumer (DTC) prescription drug advertisements. With current regulations requiring that information about a product's major risks be included in the audio portion of DTC TV ads, FDA has proposed including this risk information in superimposed text as well, hypothesizing that other audio and visuals during the audio major risk statement may be distracting and decrease risk recall.

The U.S. Food and Drug Administration **seeks** comments on its exploration of the use of statutory changes to "modify the current requirement that the use of multiple new animal drugs in a combination drug medicated feed be the subject of an approved new animal drug application (NADA). The Agency is also inviting comment on potential changes to procedures and requirements related to the NADA approval process for such products that can be accomplished under the Agency's existing statutory authority." The comment deadline is September 9, 2015.

The U.S. Food and Drug Administration **requests** comments on its exploration of the use of statutory changes to "expand the use of conditional

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approval beyond new animal drugs intended for minor species or for minor uses in major species to additional categories of new animal drugs as appropriate." The comment deadline is March 9, 2015.

The U.S. Patent and Trademark Office (USPTO) issues a report to Congress exploring the options available for using "virtual marking" to communicate patent-related information on patented products. Congress changed the "marking" statutory requirements when it passed the America Invents Act and asked USPTO to analyze its potential effectiveness. The report concludes that "virtual marking has likely met its intended objectives of reducing manufacturing costs, facilitating marking of small articles, and improving the general public's access to patent information." USPTO recommends revisiting the issue in the future "to account for further user experiences, additional data, and case law developments."

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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.

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