Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Moga to Discuss IP Rights at APBO Conference

Shook, Hardy & Bacon Partner **Tom Moga**, who co-chairs the Life Sciences & Biotechnology Practice, will present a seminar on "Protecting Your Intellectual Property Rights" at the **Asia/Pacific Business Outlook (APBO) Conference** slated for April 7-8, 2014, in Los Angeles, California. Hosted by the University of Southern California Marshall School of Business, the conference offers economic, political and social forecasts for a variety of markets; workshops designed to address country-specific questions; and seminars on doing business effectively in the Asia/Pacific region.

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."

IP NEWS

Antitrust Bests IP in 2013 Jury Awards

According to data compiled by *The National Law Journal*, jury verdicts in 2013 involving intellectual property (IP) disputes for the first time in years failed to reach the billion dollar mark. Lawyers representing plaintiffs reportedly attributed the lower IP damages awards to recent Federal Circuit Court of Appeals decisions that could be interpreted as imposing additional hurdles on proving damages. The highest awards in 2013 were apparently made in antitrust lawsuits, with one reaching $1.2 billion. *See The National Law Journal*, March 24, 2014.

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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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INVESTOR NEWS

Biotech with Prenatal Test Focus Files for $69 Million IPO

San Jose, California-based Ariosa Diagnostics, Inc. has filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $69 million in an initial public offering (IPO).

Ariosa Diagnostics offers molecular diagnostic products and prenatal tests, including its flagship product, the Harmony™ Prenatal Test, a precise blood test that can apparently detect genetic conditions such as Down's Syndrome and other fetal chromosomal conditions. The offering is being made through J.P. Morgan, Citigroup, Leerink Partners, and William Blair. *See VentureBeat.com*, March 26, 2014.

"Green" Fuel Developer Closes $100 Million Funding Round

Cool Planet Energy Systems has reportedly raised $100 million in a Series D financing round that saw a significant increase in the company's investor base "with more than 50 percent of equity funds from new investors coming from outside the United States." The Greenwood Village, Colorado-based alternative fuels company uses biomass, such as corn cobs and dead or dying trees, to create sustainable fuels. Cool Planet's process also produces a product "that has the capability of making the fuel 'carbon negative,' reversing the consequences of CO_2 build-up from fossil fuels. Used as a soil amendment, its CoolTerra™ biochar product also increases crop productivity and plant health while reducing water and fertilizer requirements," the company said.

CEO Howard Janzen said, "We are very pleased with the strong interest and support from investors that enable us to reach our $100 million funding objective. We are seeing strong interest in deploying our technology in markets such as China, Southeast Asia and the Middle East." *See Cool Planet Energy Systems News Release*, March 31, 2014.

Kolltan Pharmaceuticals Raises $60 Million to Begin Cancer Drug Trials

Kolltan Pharmaceuticals, Inc., a New Haven, Connecticut, developer of cancer treatments has completed a $60-million Series D equity financing round. Co-led by a yet-to-be-disclosed Boston-based asset manager and existing investor KLP Enterprises, the round's proceeds will be used to advance the company's lead clinical-stage candidate, KTN3379, into Phase 2 clinical trials in cancer patients. According to the company, the drug works by blocking the ErbB3 receptor tyrosine kinase.

"With this strong financial support from both new and current investors, we are able to advance KTN3379 into the evaluation of specific popula-

tions of cancer patients where ErbB3 is believed to play an important role in disease pathogenesis," said President and CEO Jerry McMahon. "In addition, we plan to accelerate the development of two additional undisclosed first-in-class biologic product candidates, while continuing to fund our ongoing earlier-stage research programs." *See Kolltan Pharmaceuticals, Inc., Press Release,* March 24, 2014.

$15 Million Raised to Advance Biologic Drug Candidate in China

RuiYi has reportedly raised $15 million in a Series B financing tranche by existing investors. The funds will apparently support the continued development of its lead monoclonal antibody candidate, RYI-008, in the People's Republic of China for the potential treatment of autoimmune disease and cancer. RuiYi, with executive management offices in La Jolla, California, and a discovery and research facility in Pudong, Shanghai, China, focuses on previously untargeted G protein coupled receptors (GPCRs) for global, therapeutic needs. The company's intermembranous Conformation Antigen Presenting System (iCAPS), the leading GPCR drug discovery platform, can apparently "isolate and present functional GPCRs in their correct conformation to identify selective antibody inhibitors or activators with great specificity for more effective therapeutics."

CEO Paul Grayson said, "From RuiYi's iCAPS platform, we have been able to generate a fully functional antagonist to CB-2, a commercially validated GPCR target that could provide important therapeutic opportunities via a monoclonal antibody approach. With this support from our investors, we will [also] advance RYI-018 through protein engineering for IND [investigational new drug] enabling studies." *See RuiYi Press Release*, March 17, 2014.

NeuroPhage Secures $17 for Brain Therapies

Cambridge, Massachusetts, biotech NeuroPhage Pharmaceuticals, Inc. has reportedly raised $17 million in a Series D financing round to advance its treatments for neurodegenerative diseases such as Alzheimer's, Parkinson's and Huntington's disease. The company plans to use the funds to bring lead drug, NPT088, to its first clinical trial. The structure of NTP088 is based on NeuroPhage's general amyloid interaction motif technology (GAIM) platform, which the company reports can target neurodegenerative diseases caused by misfolded proteins.

"This substantial financing will enable NeuroPhage to progress a robust IND-enabling package for NPT088 and prepare for the clinical evaluation of a completely new approach to treat devastating neurological diseases," said President and CEO Jonathan Solomon.

Noting that while evidence indicates that neurodegenerative diseases are frequently characterized by multiple types of misfolded proteins, Neuro-

Phage reports that most other drugs in development target just one type of misfolded protein. GAIM evidently targets multiple types of misfolded protein deposits, including amyloid beta plaques, tau tangles and Lewy bodies (alpha synuclein inclusions), moving "beyond traditional attempts to treat these diseases by not only preventing new deposits but also reducing pre-existing toxic aggregates." *See NeuroPhage Pharmaceuticals, Inc. News Release*, March 25, 2014.

BUSINESS CLIMATE

Biotech Stocks in Retreat?

Financial writers have taken note of the weakness in biotechnology stocks as March 2014 came to a close. They claim that traders and analysts are wondering whether the selloff marks the end of the sector's 2012-2013 momentum and if it will be sustained. The Nasdaq Biotechnology Index is reportedly "on the brink of a correction," having dropped nearly 10 percent from February 25 through March 18 after gaining 369 percent from a six-year low in March 2009. Many suggest that the slump was spurred by questions Democratic congressional representatives raised about a hepatitis C drug priced at $84,000. Some analysts continue to express optimism, claiming that strong pricing power after successful development has not changed and is unlikely to do so in the foreseeable future. Pessimists contend that biotech companies still pose risks because most new drugs fail, regulators continue to take a conservative approach to safety and efficacy research and pricing power may not continue indefinitely. *See The Wall Street Journal* and *Bloomberg*, March 24, 2014; *Forbes*, March 27, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Senators Seek Clarity on Mobile Medical Apps

Seeking clarification on the U.S. Food and Drug Administration's (FDA's) final guidance pertaining to mobile medical applications (apps), a bipartisan group of six senators has sent a **letter** to FDA Commissioner Margaret Hamburg requesting more details on the agency's plans for oversight of mobile medical apps and urging FDA to "work with Congress to identify policies that will serve the best interests of patients and innovators alike."

Among other things, the senators asked (i) how quickly the agency responds to queries about the regulation of specific apps; (ii) what processes FDA has set up to educate developers about regulations; (iii)

how FDA determines what types of medical software updates could affect an app so that it would require approval; (iv) how novel apps would be regulated; and (v) what additional legislative tools the agency needs to better oversee medical mobile apps. Additional details about FDA's final guidance on mobile medical apps appear in Issue 65 of this *Bulletin*.

Legislation Would Allow Extended Protection for Biologics Method of Use Patents

Democrats in the U.S. House and Senate have introduced companion bills (H.R. 4287; S. 2150) that would allow the owner, or its agent, of a "patent claiming a method of using a biological product" to apply for a five-year extension from the patent's original expiration date. The stated purpose of the proposals is "[t]o advance the public health by encouraging independent innovators to pursue drug repurposing research and develop new treatments and cures by providing appropriate intellectual property protections for those innovations." The House bill, introduced on March 24, 2014, by Rep. Joaquin Castro (D-Tex.), was referred to the House Committee on the Judiciary. Sen. Richard Blumenthal (D-Conn.) introduced the Senate measure on the same date; it was referred to the Senate Committee on the Judiciary.

Canadian Regulator Considers Barring Pharma Gifts to Physicians

The College of Physicians and Surgeons of Ontario, said to be the largest medical regulator in Canada, has proposed a policy addressing physicians' relationships with industry. Among other matters, physicians would be unable to accept "personal gifts of any value from industry or industry representatives." The proposed prohibition is based on "[r]esearch demonstrat[ing] that accepting gifts or inducements from industry influences and likely undermines a physician's independent clinical judgment, even where the physician believes otherwise."

The proposal would also bar physicians from requesting or accepting a fee or equivalent consideration in exchange for "seeing industry representatives in a promotional or similar capacity," although they could accept items "that advance disease/treatment education (e.g. patient teaching aids)," preferably with a company logo only and eschewing any reference to "specific therapeutic agents, services, or other products." Physicians would also be allowed to accept drug samples, as well as modestly valued meals during product presentations. Additional requirements would address educational conferences, speaker fees and participation on industry advisory boards. Comments on the proposal are requested by May 14, 2014. *See National Post*, March 30, 2014.

LITIGATION

U.S. Supreme Court Considers Patentability of Computer Software

The U.S. Supreme Court has **heard** oral argument in a case, which raised significant interest in the technology community and generated dozens of *amicus* briefs, to consider whether "claims to computer-implemented inventions—including claims to systems and machines, processes, and items of manufacture—are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by" the Court. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, No. 13-298 (U.S., argued March 31, 2014). The Federal Circuit Court of Appeals en banc majority affirmed the district court's holding that the asserted method and computer-readable media claims were not patent eligible, and an equally divided court affirmed the lower court's determination that the asserted system claims were not patent eligible under the statute.

According to commentators, the Court's last foray into the issue—*Bilski v. Kappos*—left the topic in disarray when it determined that a hedging method patent was too abstract and thus not patentable. Its reasoning gave the Federal Circuit little guidance, and in fact, that court issued seven separate opinions here. The petitioner has urged the court to correct *Bilski* and return to essential principles, allowing patents for any invention that does not describe a fundamental truth only. A decision in the matter, which will be considered one of the most significant patent cases in decades if the Court reverses the Federal Circuit, is expected by June.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **announces** the availability of draft guidance for industry titled "Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway." The document presents FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under the accelerated approval regulatory pathway. It also discusses "labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved." Comments are requested by May 27, 2014.

The U.S. Patent and Trademark Office **schedules** an April 10, 2014, roundtable event "regarding the use of crowdsourcing and third-party preissuance submissions to identify relevant prior art and enhance the quality of examination as well as the quality of issued patents." Those

wishing to speak must have made their request in writing by March 27, and those wishing to participate in person or via Webcast must register by April 4. Comments are requested by April 25.

The U.S. Patent and Trademark Office **slates** Patent Trial and Appeal Board roundtables throughout the United States for administrative patent judges "to share information about [inter partes review] trials and collect public input and suggestions." They will take place Tuesdays and Thursdays, April 15 through May 8, 2014, in Alexandria, Virginia; New York City; Chicago, Illinois; Detroit, Michigan; Silicon Valley, California; Seattle, Washington; Dallas, Texas; and Denver, Colorado.

The U.S. Patent and Trademark Office **launches** a pilot program that will require participants filing software-related patents to include a glossary section in their patent application to define terms used in the patent claims. The goal is to "enhance claim clarity in the specification of software-related patent applications by encouraging and gauging the use of glossaries by patent applicants." Those participating in the program "will receive expedited processing and be placed on an examiner's special docket prior to the first office action, and will have special status up to issuance of a first office action."

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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.