ISSUE 74 | MARCH 20, 2014

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."

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."

Shook, Hardy & Bacon L.L.P.

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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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If you have questions about this issue of the Report, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

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, 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.

Dunne & Guthrie Publish on Nonprescription Drugs in FDLI's *Update*

Shook, Hardy & Bacon Pharmaceutical & Medical Device Partner **Debra Dunne** and Associate **Brian Guthrie** have authored an **article** appearing in the March/April 2014 issue of the Food and Drug Law Institute's (FDLI's) *Update* magazine. Titled "Crafting Changes for the Future: Increasing the Availability of Nonprescription Drugs," the article, the first in a three-part series, focuses on the Food and Drug Administration's efforts to support the switch of prescription drugs to over-the-counter (OTC) status.

The authors explain how the agency's Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative functions and what evidence may be required to meet the "conditions for safe use" standard that can make "a wider range of nonprescription drugs more available to consumers." Whether a drug is safe and effective for consumer OTC use requires evidence that a consumer can "successfully self-recognize and self-treat the condition" and that "the drug label indications, directions and warnings can be understood by the average consumer without the assistance of a learned intermediary."

IP NEWS

Federal Court Applies Plausibility Pleading Standard to Patent Claims

A federal court in Virginia has dismissed with leave to amend the direct patent-infringement claims asserted in litigation involving non-volatile memory semiconductors. *Macronix Int'l Co., Ltd. v. Spansion Inc.*, No.

13-0679 (U.S. Dist. Ct., E.D. Va., Richmond Div., order entered March 10, 2014). The court's application of the U.S. Supreme Court's plausibility pleading standard is contrary to Federal Circuit Court of Appeals decisions that allow the standard's application to induced infringement, but not to direct infringement, allegations.

In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the U.S. Supreme Court adopted a new pleading standard under Federal Rule of Civil Procedure 8(a) requiring a plaintiff to plead factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged, that is, "plausibility requires a complaint to place the legal conclusions it makes in context of facts that render the asserted claim plausible." The Federal Circuit Court of Appeals has determined that a complaint satisfying Form 18, which is used for direct infringement, is legally sufficient to state a claim, regardless of *Twombly* and *Iqbal*.

Finding the Federal Circuit's reasoning faulty, the Virginia court stated, "to exempt patent complaints from the requirements of *Twombly* and *Iqbal* is to ignore a fundamental rationale that underpins those decisions," i.e., "that the more rigorous application of Rule 8(a) was needed to assure that the parties would not embark on expensive litigation unless the plaintiff had made in the complaint a plausible case." The court compared the claims in *Twombly*, an antitrust case—"well-known for extensive discovery and high litigation costs," to those in patent lawsuits which "generally are among the most expensive kinds of cases in federal court. It is not logical to exempt them from the reach of *Twombly* and *Iqbal*, whose prime purpose was to assure that such expense was not incurred unless the plaintiff had posited a plausible claim in the complaint."

INVESTOR NEWS

Company to Advance Diagnostics with $27-Million Series B Funding Round

Exosome Diagnostics, Inc., a New York City-based developer of diagnostic tests for use in personalized medicine, has reportedly raised $27 million in a Series B funding round led by new investors QIAGEN and Arcus Ventures. Proceeds will be used for the 2014 U.S. launch of EXO106, a non-invasive urine sample diagnostic test that "could potentially reduce the number of unnecessary prostate biopsies in patients with an elevated PSA," the company said. It will also use the funds to support the development of tests for non-small cell lung cancer and other oncology applications. The company's "proprietary exosome technology makes use of the presence and natural stability of RNA in exosomes to detect and measure levels of genes responsible for cancer and other diseases." *See Exosome Diagnostics, Inc. Press Release*, March 11, 2014.

Third Bay Area Company Goes Public in 2014; Stock Surges

According to a news source, shares in clinical-stage biopharmaceutical Achaogen, Inc. surged more than 16 percent after the Bay Area company raised $72 million in its initial public offering (IPO). The company had previously planned to sell 5 million shares at $12 per share, but sold 6 million instead. The largest investors included Venrock, 5AM Ventures, Versant Futures, and the Wellcome Trust. Credit Suisse Securities (USA) LLC and Cowen and Co., LLC were joint IPO book-running managers. Achaogen was reportedly the third life sciences company in the Bay Area to go public in 2014; five others are apparently poised to go public as well. The company focuses on the development of novel anti-bacterials to treat multiple drug resistant (MDR) gram-negative infections. Lead product candidate plazomicin has been developed to treat bacterial infections due to MDR *Enterobacteriaceae*. *See San Francisco Business Times* and *Achaogen, Inc. Press Release,* March 12, 2014.

ZS Pharma Secures $55 Million to Develop Hyperkalemia Treatment

Texas-based specialty pharmaceutical company ZS Pharma has reportedly raised $55 million in a Series D financing tranche. Leading the investor syndicate was Novo A/S and included new investors RA Capital, Adage Capital, and Sofinnova Ventures. According to the company, the proceeds will be used to advance the development of ZS-9, its lead product candidate for the treatment of hyperkalemia, a life-threatening metabolic condition involving higher than normal potassium levels that can lead to cardiac arrhythmia and sudden cardiac death. A recently completed Phase 3 study that included 753 patients reportedly showed that ZS-9 can reduce and maintain normal potassium levels in hyperkalemic patients. Two additional studies are planned. *See ZS Pharma News Release*, March 5, 2014.

Venture Financing Provides $15.5 Million in Additional Support for ADHD Products

Neos Therapeutics, Inc. has reportedly raised $15.5 million in a Series C venture-financing round. The Dallas/Fort Worth, Texas-based oral drug delivery company will use the proceeds to support its efforts to obtain Food and Drug Administration approval of its product pipeline based on Dynamic Time Release Suspension® and Rapidly Disintegrating Ionic Masking™ technologies "that deliver controlled release small molecule active pharmaceutical ingredients in either liquid or orally disintegrating tablet dosage forms." The support of investors such as Burrill Life Sciences Capital Fund III, CAC LLC, CMEA Capital, and Crabtree Partners "places the company in an excellent financial position to execute our strategy of bringing novel products based on the Neos proprietary technologies to

market," said company CEO Vipin Garg. "These technologies are currently being utilized to develop three ADHD products, which will advance significantly in the next 12-15 months." *See Neos Therapeutics, Inc. News Release*, March 4, 2014.

IPO Could Raise $100.5 Million for Growth Hormone Drug Developer

Biotechnology company Versartis, Inc. has reportedly updated its initial public offering (IPO) filing and set a target range for 4.6 million shares of stock between $16 and $19 per share. The company expects to go public during the week of March 17, 2014. It develops therapeutic proteins to treat endocrine disorders and is currently investigating the safety and efficacy of its lead program, VRS-317, in pediatric growth hormone deficiency patients. The long-lasting drug is intended to reduce the number of daily injections patients must receive. Located in Redwood City, California, the company raised $55 million in February during a Series E round of venture funding. *See Silicon Valley Business Journal*, March 11, 2014.

BUSINESS CLIMATE

FY 2015 Budget Proposal Underfunds Life Sciences Research

The Information Technology and Innovation Foundation (ITIF) notes that the Obama administration's fiscal year (FY) 2015 budget proposes a near 4-percent decline in funding for the National Institutes of Health and claims that, if approved, it would "exacerbate a growing divide in critical investments in biomedical research between the United States and our global competitors." ITIF, a non-profit think tank that promotes policies to advance innovation and productivity internationally, also contends that the president's proposal to reduce data protection for biologic drugs from 12 years to seven would inflict significant damage on the developers of innovative biopharmaceuticals.

The organization concludes, "The United States cannot continue to simply assume that leading in key innovative industries such as life sciences or medical devices is its birthright. . . . Policymakers must be constantly attentive to implementing effective policies that support the competitiveness of these industries. . . . The president's FY 2015 budget proposal needs to achieve much more" in terms of funding and "ensuring that regulatory policies are attuned to both protecting consumers while also supporting the competitiveness of innovative U.S. industries." *See InnovationFiles.org*, March 14, 2014.

Biotech Exits Start Robustly in 2014

According to the head of the life sciences practice at BMO Capital Markets Corp., in 2013 "[r]ocketing biotech stocks provided much needed fuel for the biotech ecosystem, facilitating IPO [initial public offering] exits for venture investors." While 2014 has started off strongly, "with the NASDAQ Biotech Index up over 8%," Annette Grimaldi sounds a note of caution "to the early good news," noting that "the massive flow of financing activity may strain investor capacity to evaluate and invest in new companies. If early 2014 IPOs struggle to price or trade poorly in the after-market, public investors may be less willing to take a chance on later deals." She also observes that "the continued strength of the broader market is critical to the performance of the biopharma sector." *See Nature Biotechnology*, March 2014.

High Investment Interest in RNAi Therapeutics

With investments soaring in projects exploring therapeutic applications of RNA interference (RNAi), the field has apparently begun a significant turnaround as investors have recently backed new deals and launched new startups on evidence of potency from human clinical trials. Established pharmaceutical and biotech companies are reportedly investing in more RNAi programs, a development that has not escaped the attention of new investors, now that delivery systems have been improved and shown more clinical promise, unlike during the period following the 2008 economic downturn when the patience of large pharmaceuticals ran out and RNAi programs were terminated. *See Nature Biotechnology*, March 2014.

Top U.S. Biopharma Clusters Identified

Genetic Engineering & Biotechnology News has issued its list of top 10 U.S. biopharma clusters based on parameters such as patents applied for and awarded, venture capital funding, National Institutes of Health (NIH) funding, lab space, and number of jobs. Leading the list are the San Francisco Bay Area, Boston/Cambridge, Mass. and San Diego. While the San Francisco region topped Boston/Cambridge by some 500 patents—3,492 and 2,908, respectively—it reportedly lost out "to the Red Sox region in NIH grants ($119.8 million)"—Boston/Cambridge garnered $201.4 million. And, as to numbers of jobs in this sector, "it depends who you believe. California's Economic Development Department lists 110,337 Bay Area 'life sciences' jobs in the latest tally (Q1 2013), while a recently released report showed only 47,019" as compared with Boston/Cambridge's 55,462 jobs. Those regions closing out the list are Chicago—10, Los Angeles—nine, and Raleigh-Durham, North Carolina (including Research Triangle Park)—eight. *See GenEngNews.com*, March 10, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

23andMe Founder Seeks to Empower Consumers

Speaking during the recently concluded SXSW festival in Austin, Texas, 23andMe co-founder Anne Wojcicki reportedly acknowledged that the U.S. Food and Drug Administration's (FDA's) action to stop the company from marketing its genetic testing service until it clinically validates the test's prognostic capability and receives FDA marketing authorization for the device has slowed the number of people signing up for the service. Details about FDA's warning letter appear in Issue **69** of this *Bulletin*.

Still, she said that 23andMe has 650,000 people in its database and has been "inundated with requests from academics and foreign partners" for access to the data. Wojcicki said that the company will "figure out the path forward" to secure FDA approval and called for genetics to be used for preventative, personalized medicine that can reduce the costs of a health care system which has an economic incentive to treat rather than prevent health problems. She further stated, "One of the reasons we went direct to [the] consumer is so that you own the data. If your insurance company pays they own it, but if you pay you own your own data, and if you then want to share it that's your right." *See The Guardian*, March 9, 2014.

Meanwhile, the *New England Journal of Medicine* published a comment titled "23andMe and the FDA," on March 13, 2014, praising FDA's action and stating, "Before genomic tests have been validated . . . genomic information can be misleading—or just plain wrong—and could cause more harm than good in health care settings." The comment noted that sequencing genomes, which is continuing to cost less over time, is "the easy part. The difficult part will be, as it is today, the clinical interpretation of an individual's genome and the making of useful recommendations to the patient-consumer. Put another way, the heart of this debate is not the cost of the sequencing (or SNP [single-nucleotide polymorphism technology on which 23andMe's services are based] testing), but rather whether the information produced can be used in ways that improve our health."

HHS Inspector General Issues Report on FDA Employee Computer Monitoring

The Inspector General (IG) of the U.S. Department of Human Health and Services (HHS) has **issued** a report titled "Review of the Food and Drug Administration's Computer Monitoring of Certain Employees in Its Center for Devices and Radiological Health." Prompted by media stories about the agency's alleged computer monitoring of certain scientists in FDA's Center for Devices and Radiological Health (CDRH), the report found that

concerns over the unauthorized disclosure of confidential information pertaining to a medical device application were reasonable and that FDA scientists knew they had no right to privacy on the FDA computer network.

Still, the IG determined that CDRH should have sought legal counsel on a number of matters, including whether the five scientists were whistleblowers under the Whistleblower Protection Act (WPA), "and if so, how should the surveillance be conducted to ensure that there would be no WPA-prohibited retaliation," and whether the monitoring technology would be "the most appropriate" and its use "would be consistent with constitutional and statutory limitations on Government searches." Additional details about the purported "spying fracas" appear in Issue **39** of this *Bulletin*.

April Vote Scheduled Before EU Parliament on Clinical Trial Data Accessibility

The European Parliament has postponed until April 2, 2014, debate on amended draft legislation (2012/0192 (COD)) that would require pharmaceutical companies to make all of their clinical trial data available on a publicly accessible database. A vote is expected on April 3. According to a news source, drug makers currently publish only some of the data, shielding the remainder on commercial confidentiality grounds. Accordingly, data showing negative results or potentially harmful effects are not apparently made public. Supporters of the legislation contend that this can lead to adverse reactions to drugs that are otherwise prescribed in good faith by physicians who believe that the medicines are more effective and safer than they may actually be. The legislation would also address the rights of clinical trial subjects and establish detailed rules on informed consent. *See The New Scientist*, March 11, 2014; *Intellectual Property Watch News Release*, March 14, 2014.

LITIGATION

Court Denies Myriad's Request to Enjoin Sale of Rival BRCA1/BRCA2 Tests

A federal court in Utah has denied the request for a preliminary injunction filed by Myriad Genetics against a rival company that offered tests less expensive than Myriad's to screen BRCA1 and BRCA2 genes, those linked to breast cancer risk. *Univ. of Utah Research Found. v. Ambry Genetics Corp.*, No. 13-0640 (U.S. Dist. Ct., D. Utah, Cent. Div., order entered March 10, 2014). The lawsuit is one of a number of patent-infringement cases that have been centralized for pre-trial proceedings before a multidistrict

litigation (MDL) court. *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, MDL No. 2510.

While the court acknowledged that Myriad had shown it was "likely to suffer irreparable harm" through the erosion of its test-pricing structure, loss of market share and loss of exclusive patent terms, defendant Ambry Genetics "has raised a substantial question" as to whether the plaintiff's "Primer and Method Claims are directed toward patent eligible products of nature and abstract ideas under 35 U.S.C. § 101." According to the court, Myriad is unlikely to succeed on the merits of its infringement claims. A company spokesperson emphasized that the court did not rule on the underlying merits of the case, but simply denied the preliminary injunction it had requested. *See The New York Times*, March 10, 2014.

NEWS BYTES

The U.S. Food and Drug Administration **warns** Institut Biochimique SA that the Facebook Web page for one of its drugs is false or misleading "because it makes representations about the efficacy of Tirosint, but fails to communicate any risk information associated with its use and it omits material facts."

The U.S. Food and Drug Administration **issues** revised draft guidance titled "Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices" to provide the agency's "current thinking on recommended practices for drug or medical device manufacturers and their representatives to follow when distributing to health care professionals or health care entities scientific or medical journal articles, scientific or medical reference texts, or clinical practice guidelines . . . that discuss unapproved new uses for approved drugs or approved or cleared medical devices marketed in the United States." Comments are requested by May 2, 2014.

The U.S. Food and Drug Administration **seeks** comments on draft guidance titled "Humanitarian Device Exemption (HDE): Questions and Answers." This guidance document "reflects the changes in the HDE program" under the Food and Drug Administration Safety and Innovation Act, which, among other matters, expanded the types of humanitarian use devices that are eligible to be sold for profit, subject to certain restrictions. Comments are requested by June 16, 2014.

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The U.S. Patent and Trademark Office (USPTO) **plans** to host an "Additive Manufacturing Partnership Meeting" on April 9, 2014, in Alexandria, Virginia. A forum for sharing ideas, experiences and insights among shareholders and USPTO, this informal meeting will also provide an overview of additive manufacturing's (also known as 3D printing's) use in fields ranging from engineering, aerospace and the dental and medical industries.

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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.