Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

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FIRM NEWS

Saikali to Participate in Global Cyber Security & Data Privacy Forum

Shook, Hardy & Bacon Data Security & Data Privacy Practice Co-Chair **Al Saikali** will join a distinguished faculty in Washington, D.C., January 15-16, 2015, for the America Conference Institute's "**15th Advanced Global Legal & Compliance Forum on Cyber Security & Data Privacy and Protection.**" He will serve as co-moderator of the opening session, titled "Federal Regulatory, Legislative, and Enforcement Landscape: Changes on the Horizon and Integrating New and Anticipated Initiatives Into Your Privacy and Compliance Program." The session panel includes Federal Trade Commission, Department of Justice and Federal Bureau of Investigation representatives.

IP NEWS

FTC Settles Deceptive Sales-Tactics Claims Against MPHJ Technology

The U.S. Federal Trade Commission (FTC) has **agreed** to settle claims that MPHJ Technology Investments, LLC—a patent-assertion entity (PAE)—and company officer Jay Mac Rust, as well as outside counsel Farney Daniels, P.C., violated the FTC Act by conducting a campaign to promote and sell licenses for the company's network computer scanning technology patents. The campaign allegedly involved sending a series of letters to thousands of small businesses throughout the United States claiming that they had infringed the patents and would be sued if they did not agree to buy a license, pay compensation or otherwise respond as requested. The letters were sent under the names of 81 different subsidiaries.

According to FTC, this constituted deceptive sales practices because "the senders had no intention—and did not make preparations—to initiate lawsuits against the small businesses that did not respond to their letter. No such lawsuits were ever filed." The letters also apparently falsely represented that many businesses had purchased licenses to the patents; no such licenses had been sold when the first of these 7,366 letters were

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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.

For additional information on SHB's Life Sciences and Biotechnology capabilities, please contact

Debra Dunne
Life Sciences & Biotechnology
215-278-2555
ddunne@shb.com

John Garretson
Intellectual Property
816-559-2539
jgarretson@shb.com

Chris Johnson
Life Sciences & Biotechnology
415-544-1900
cjohnson@shb.com

Madeleine McDonough
Pharmaceutical & Medical Device
202-783-8400
mmcdonough@shb.com

Thomas Moga
Intellectual Property
202-639-5622
tmoga@shb.com

Jay Simpson
Business Litigation
816-559-2453
jsimpson@shb.com

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.

distributed. According to FTC's complaint, "When Respondents sent the next 1,077 of these First Letters, Respondents had sold a license for the Klein Patents to only one of the approximately 7,366 small businesses that Respondents had contacted in their licensing campaign." FTC has indicated that this is the first time it has used its consumer-protection authority against a PAE.

Under the proposed agreement, respondents neither admit nor deny the allegations in FTC's draft complaint, but agree to cease making certain misleading or unsubstantiated representations in patent-assertion communications and maintain certain records for five years; the order remains in effect for 20 years. After a 30-day public comment period and a commission vote to make the proposed consent order final, any subsequent violation "may result in a civil penalty of up to $16,000" each. *See FTC Press Release*, November 6, 2014.

JOINT VENTURES

College Research Program Partners with Diagnostics Firm

The Baylor College of Medicine and diagnostics company Miraca Holdings have reportedly formed a joint venture—Baylor Miraca Genetics Laboratories—that "is expected to fully support the academic mission of the college's department of molecular and human genetics." With an initial workforce of 225 based in Houston, Texas, the joint venture aims to expand Baylor's clinical genetics testing program "while ensuring the quality of diagnostics to patients and health[-]care providers on an international level." Miraca, which is headquartered in Tokyo, provides *in vitro* diagnostics, clinical laboratory testing and other health-care services and products through its subsidiaries, including one located in Irving, Texas. Baylor CEO and Executive Dean Paul Klotman said, "What makes this venture so beneficial to our patients and community is that it pairs the academic leadership and innovation of a highly ranked Baylor program with the business acumen of a well-run, well-recognized strategic partner." *See Baylor College of Medicine News Release*, October 31, 2014.

INVESTOR NEWS

Biotech Closes $11 Million Financing Round to Advance Anti-Itch Therapeutics

New Haven, Connecticut-based biotechnology company Trevi Therapeutics, Inc. has apparently raised $11 million in a Series B financing round, bringing the total to $26 million. The proceeds will be used to develop Nalbuphine ER® for severe chronic pruritis—or itching—conditions. The

company is apparently focusing on two conditions for clinical development: uremic prurutis, which is "a persistent and debilitating itch in patients on dialysis that has been associated with increased mortality," and prurigo nodularis, "a chronic dermatologic condition characterized by severely pruritic nodules on the skin that are independent of underlying etiology."

Enrollment for the company's uremic pruritis trial is ongoing, and Trevi President and CEO Jennifer Good said, "We are very encouraged by the enrollment rate in our pivotal trial . . . [and] expect the enrollment rate to accelerate as our European sites come on board by year-end." The company anticipates results in mid-2015. Lead drug candidate Nalbuphine ER® is described as "an oral extended release opioid with a unique opioid receptor dual agonist/antagonist mechanism of action, which has shown efficacy in addressing pruritis in both animal studies and human clinical trials." *See Trevi Therapeutics, Inc. Press Release*, November 6, 2014.

CTI BioPharma Shares Lose Ground After Preferred Stock Sale Announced

CTI BioPharma Corp. has announced an underwritten public offering of 35,000 shares of its convertible preferred stock at $1,000 per share with Piper Jaffray & Co. acting as sole book-running manager. The shares, offered under a shelf registration statement previously filed with the U.S. Securities and Exchange Commission, will be convertible at the holder's option into 500 shares of common stock at a conversion price of $2 per share of common stock. According to a news source, following the Seattle biotech's announcement, the company's shares dropped 30 cents to $2.06 in early trading. CTI, which focuses on cancer therapies, intends to use the money to "advance the commercialization of Pixuvri® (pixantrone), accelerate the pre-commercial activities for pacritinib, expand the number of investigator-sponsored trials for pacritinib to diseases other than myelofibrosis and acute myeloid leukemia and support advancement of tosedostat toward registration-directed trials, as well as for general corporate purposes." The offering, expected to raise $35 million before deducting underwriting discounts and commissions and other estimated offering expenses, was expected to close November 13, 2014. *See CTI BioPharma Corp. News Release*, November 7, 2014.

S&P 500 Likely to Face Pressure to Report Nanotech Use and Investments

According to a Sustainable Investments Institute **report**, corporations globally invest some $9 billion annually in nanotechnology, yet less than one-tenth of S&P 500 companies make this information public to shareholders and other stakeholders and none has discussed purported health, environmental or safety risks in their Securities and Exchange Commission

Form 10-Ks. Shareholders are apparently beginning to engage companies in discussions about these risks; the first ever nano-related shareholder resolution was brought to a vote in 2014 (garnering 18.6 percent support before Dunkin' Brands' shareholders), and "[c]oncerned investors are promising to step up their efforts in 2015."

The report outlines issues that investors should consider regarding companies that rely on, develop or use nanotechnology and nanomaterials; the current state of S&P 500 company disclosures; the history of the 30-year development of nanotechnology in the United States, including the most promising areas; currently identified areas of risk; EU and U.S. approaches to nanomaterial regulation; and shareholder proposal efforts begun as early as 2008 by groups such as the As You Sow Foundation, Calvert Investments and members of the Interfaith Center on Corporate Responsibility. *See The Harvard Law School Forum on Corporate Governance and Financial Regulation*, November 3, 2014.

BUSINESS CLIMATE

Rand Corp. Predicts $44.2 Billion in Savings with Biosimilars

The Rand Corp. has **issued** a perspective titled "The Cost Savings Potential of Biosimilar Drugs in the United States." It predicts that "biosimilars will lead to a $44.2 billion reduction in direct spending on biologic drugs from 2014 to 2024, or about 4 percent of total biologic spending over the same period, with a range of $13 billion to $66 billion." The report cautions, however, that actual savings will depend on the specific provisions of the U.S. Food and Drug Administration's final regulatory framework for the approval of biosimilars, as well as on levels of competition, payment arrangements and acceptability.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Bio-Rad Agrees to Pay $55 Million to Resolve SEC Bribery Charges

A California-based clinical diagnostic and life science research company has reportedly **agreed** to pay $55 million to resolve U.S. Securities and Exchange Commission (SEC) claims that it violated the Foreign Corrupt Practices Act (FCPA) by failing to prevent or detect some $7.5 million in bribes paid to foreign officials in Russia, Thailand and Vietnam to secure business.

SEC claims that the unlawful payments enabled Bio-Rad Laboratories, Inc. to earn $35.1 million in profits. The company self-reported the miscon-

duct, cooperated with the investigation and undertook "significant and extensive remedial actions," efforts that SEC credited in the enforcement action. As part of the settlement, the company will enter a non-prosecution agreement with the U.S. Department of Justice "to resolve potential criminal liability." Bio-Rad will also undertake reporting, compliance and self-monitoring obligations for two years.

President and CEO Norman Schwartz reportedly said, "The actions that we discovered were completely contrary to Bio-Rad's culture and values and ethical standards for conducting business. We took strong, decisive action to end the problematic practices and prevent anything like this from happening in the future. . . . I am pleased that this settlement fully resolves the government's FCPA investigation and puts this matter behind us." *See GenomeWeb.com and SEC News Release*, November 3, 2014.

Ranbaxy Loses FDA Approval for Two Generics

According to a statement that Ranbaxy Laboratories Ltd. provided to the Bombay Stock Exchange Website, the U.S. Food and Drug Administration (FDA) has barred the company from making generic versions of an antiviral drug and an acid reflux medication. FDA reportedly said that "its original decisions granting tentative approvals were in error," citing the "compliance status" of the company's facilities. News sources indicate that the agency's action is highly unusual and has occurred before in "rare circumstances" only. The loss of approval also means that the Indian drugmaker has lost the 180-day first-filer exclusivity for its versions of the popular drugs, which could affect its bottom line. Ranbaxy, which is currently being acquired in a $3.2-billion deal by Sun Pharmaceutical Industries, Ltd., reportedly said that it was evaluating "all available options to preserve its rights." *See The Wall Street Journal, Reuters*, and *Bloomberg BNA Product Safety & Liability Reporter™*, November 6, 2014.

CNS Drug Approvals Take Longer, Are Rejected More Often

A new Tufts Center for the Study of Drug Development report **reveals** that drugs to treat central nervous system (CNS) disorders take longer to develop and are rejected by the U.S. Food and Drug Administration (FDA) at a higher rate than other drugs. The U.S. approval rate for CNS compounds is "less than half that of all other compounds," and the "overall clinical approval success rate for CNS compounds first tested in human subjects from 1995 to 2007 was 6.2%," compared to 13.3 percent for non-CNS drugs. The mean clinical development time for CNS drugs approved in the United States from 1999-2013 was 18 percent longer than that for non-CNS drugs, and FDA takes longer to approve CNS drugs than non-CNS drugs.

Still, the report found that approval rates for CNS drugs have held steady and accounted for about one in 10 of all U.S. approvals since the 1980s. According to the report, CNS disorders are not only diverse, but they are challenging to treat. They include depression, psychosis, epilepsy, and Alzheimer's disease. As chronic conditions with complex pathologies, these disorders are also a challenge to measure objectively, so determining whether a drug has worked in a clinical trial can be problematic. *See Tuft University News Release*, November 4, 2014.

LITIGATION

Ninth Circuit Rules Out State's Claims in Class Settlement with Fetal-Gender Testing Co.

The Ninth Circuit Court of Appeals has enjoined California's effort to obtain restitution on behalf of individual citizens bound by the bargained-for restitution in a class settlement under the Class Action Fairness Act (CAFA) involving false advertising for a gender-prediction test, ruling that the state cannot obtain a duplicate recovery when it had the opportunity to but did not participate in the class-action proceeding. ***Cal. v. IntelliGender, LLC*, No. 13-56806 (9th Cir., decided November 7, 2014)**.

A class of all those in the United States who purchased and used IntelliGender's test was certified for purposes of the class-action settlement of unfair-competition and false-advertising claims brought by a private litigant under CAFA in 2010. *Gram v. IntelliGender, LLC*. To receive a $10 restitution payment, a class member was required to swear under penalty of perjury that the test result was inaccurate as to her child's gender. After the court approved the settlement, the San Diego city attorney filed an action in the name of the people of California against the company for injunctive relief and to obtain civil penalties, restitution and other remedies for alleged violations of the same laws.

IntelliGender sought to stop the enforcement action, claiming that allowing the suit to go forward would "undermine the ability of the district court to enforce its final order and judgment in the *Gram* class action." The court denied that request and a subsequent request that the court enjoin the government's restitution claims only; IntelliGender argued that allowing these claims "to go forward would amount to a double recovery and run afoul of the doctrine of res judicata."

On appeal, the Ninth Circuit determined that the government enforcement action could not be enjoined in its entirety, stating that, because the action "is brought on behalf of the people, it implicates the public's interest as well as private interests, and therefore the remedial provisions sweep much more broadly" than those at issue in a CAFA class-action

settlement. As to the government's claims for restitution, the court explored whether sufficient privity exists between the state and the class members to warrant res judicata's application. Because the class pursued restitution and the government now sought the same remedy, the court ruled that the res judicata requirements had been met. According to the Ninth Circuit, the district court's suggestion that privity did not exist was based on "two mistaken premises: that the individuals on whose behalf restitution was sought are different from the certified class and that the amounts sought are different."

As to the former, the district court said that only those who had received an inaccurate result from the test were in the settlement class, whereas the government sought restitution on behalf of all California purchasers, regardless of the results received. While only those individuals who had received an inaccurate result were eligible for compensation under the settlement's terms, the Ninth Circuit noted that the certified class covered "anyone who purchased and used the Test—substantially the same individuals for whom the State now seeks restitution. . . . Individual *Gram* class members who bought a Test and used it but did not obtain an incorrect result remain bound by the settlement, even though they will not receive any compensation. If the State wished to secure compensation for those class members, it had an opportunity to do so by intervening after receiving notice of the proposed settlement." Its claims for restitution were therefore barred by res judicata principles.

As to the district court's "mistaken belief that the *amount* of restitution sought affects the propriety of issuing an injunction," the Ninth Circuit said that the "appropriate inquiry is not what relief was ultimately granted, but whether the government is suing for the same relief already *pursued* by the plaintiff. Here, the class pursued restitution, and the government now seeks the same." In the Ninth Circuit's view, these errors strengthened its conviction that the district court abused its discretion in not issuing an injunction. CAFA was intended to prohibit relitigation; "[o]nce removal takes place, the consolidation of multiple overlapping suits allows one legal standard to govern the case." Allowing the government's claims to go forward would undermine CAFA "by in effect sending the same claims CAFA envisioned as removable back to be 'adjudicated in the state courts, where the governing rules are applied inconsistently.'"

Dissatisfied Patent Reexamination Plaintiff Contends Standing Conferred by Statute

A consumer-interest organization that was dissatisfied by a Board of Patent Appeals and Interferences (BPAI) ruling in the appeal of a patent examiner's *inter partes* reexamination decision upholding the validity of a human stem cells patent, seeks review by the U.S. Supreme Court of

a Federal Circuit Court of Appeals determination that the organization lacked standing under an intermediate standard for Article III jurisdiction. *Consumer Watchdog v. Wis. Alumni Research Found.*, No. 14-516 (U.S., petition for writ of certiorari filed October 31, 2014).

The Federal Circuit had ruled that a statutory grant of a procedural right—here, the right to challenge a patent's validity by means of an *inter partes* reexamination process and to appeal an adverse ruling—does not constitute the injury in fact required under Article III to invoke federal court jurisdiction. Because the organization's interest was simply a general grievance and an adverse BPAI ruling did not invade any legal right conferred on the organization, the Federal Circuit dismissed the appeal as not justiciable. The organization claims that this conflicts with Supreme Court precedent and further notes that the Federal Circuit had never proffered a standard for determining whether a third-party *inter partes* requester has standing before it decided this case, nor did it suggest any standard or test for determining standing in future cases.

NEWS BYTES

The U.S. Food and Drug Administration (FDA) **makes** available guidance for industry and staff titled "Molecular Diagnostic Instruments with Combined Functions." The document sets forth the agency's "current thinking on regulation of molecular diagnostic instruments both approved/cleared device functions and device functions for which approval/clearance is not required, and on the type of information that FDA recommends that applicants include in a submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions."

The U.S. Food and Drug Administration **seeks** comments on the estimated time burdens for industry to maintain standard operating procedures and keep records required under the agency's current good manufacturing practice regulations for finished pharmaceuticals. Comments are requested by January 9, 2015.

The U.S. Food and Drug Administration **seeks** comments on research titled "Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC [direct-to-consumer] Prescription Drug Ads." The agency describes the study protocol, estimates reporting burdens and, among other matters, asks for comments on "ways to enhance the quality, utility, and clarity of the information to be collected." Comments are requested by January 12, 2015.

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The U.S. Patent and Trademark Office (USPTO) **announces** a December 2, 2014, roundtable and requests comments "on USPTO use of crowd-sourcing to identify relevant prior art" to enhance the quality of patent examination and issued patents. Those wishing to participate as speakers must submit written notice by November 18, and those wishing to attend the roundtable in person or via Webcast must register by November 25. Written comments are requested by December 9. The December roundtable follows an April 2014 event that "focused on the use of crowd-sourcing and third-party preissuance submissions to identify relevant prior art"; materials from that roundtable are available online.

OFFICE LOCATIONS

Denver, Colorado
+1-303-285-5300
Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Seattle, Washington
+1-206-344-7600
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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