Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
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IP NEWS

USPTO to Host Medical Device Technology Partnership Meeting

The U.S. Patent and Trademark Office (USPTO) has scheduled a November 29, 2011, meeting in Alexandria, Virginia, to bring together industry stakeholders and patent examiners and directors "to share ideas, experiences, and insights on best practices in advancing prosecution and provide a forum for discussion on how the agency can improve and expand its relationship with the medical device technology community." USPTO advises that space is limited, and registration "will be done on a first-come, first-served basis."

NEW BIO BUSINESS VENTURES

Danish and Japanese Pharmaceuticals Form Billion-Dollar Alliance

H. Lundbeck A/S and Otsuka Pharmaceutical Co., Ltd. have entered an agreement to develop and commercialize up to five psychotherapeutic drugs in a deal worth some US$1.8 billion. According to a news source, the alliance has been structured as a sales and cost-share agreement under which Denmark-based Lundbeck will pay Otsuka US$200 million upon signing and then provide the remaining funds for development and regulatory milestones. Otsuka reportedly has a strong presence in the North American and Asian central nervous system markets, while Lundbeck has a complementary presence in Canada, Europe and Latin America.

Among the compounds included in the collaboration are Otsuka's aripiprazole depot formulation, used to reduce the reoccurrence of symptoms in patients who forget to take their medications, and OPC-34712, described as "a novel investigational psychotherapeutic compound" for schizophrenia and major depressive disorder. Otsuka will have the option, under the agreement, to co-develop and co-commercialize in certain geographical regions three early-stage compounds in Lundbeck's research and development pipeline. *See Joint Lundbeck/Otsuka News Release*, November 11, 2011.

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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.

Tech Co. Reaches "Biobanking" Agreement with Bio-Materials Management Non-Profit

Australia-based Bluechiip Limited, which has developed a wireless tracking solution for a range of industries including health care, life sciences and manufacturing, has reportedly signed a "biobanking" collaborative evaluation and trial agreement with ATCC (formerly American Type Culture Collection), a biological materials repository based in the United States.

Under the agreement, ATCC will be allowed to evaluate Bluechiip's tracking solution and conduct a pilot using the company's bluechiip® technology, which "enables data to be read at temperatures as low as those reached in liquid nitrogen, approximately 196 degrees Celsius, and enables data to be transmitted through frost." Following the trial period, ATCC may exercise an option to deploy the technology in its "cold-storage logistics workflow." ATCC stores approximately 10 million biological samples of different forms, including cell lines, molecular genomics tools, microorganisms, and bioproducts. With 200 freezers of varying types in the repository portion of its Manassas, Virginia, facility, ATCC's products and services are apparently used by academic, government and private researchers throughout the world.

"The robustness of our technology provides significant advantages over traditional identification or tracking solutions, such as labels, barcodes or RFID [radio-frequency identification] technologies," said Brett Schwarz, Bluechiip's managing director and CEO. "We are confident the bluechiip® tracking solution will transform current tracking methodologies and practices for biological specimen and biosample management, many of which are highly valuable and often irreplaceable." *See Bluechip Press Release,* November 8, 2011.

Australia's Broadvector Acquires IP Rights for Prostate Cancer Vaccine

Broadvector Limited has reportedly completed the acquisition of intellectual property (IP) rights from Australia's governmental scientific research agency for early-stage prostate cancer therapy and related vaccine technology. Financial terms were not disclosed, but Broadvector announced that the Commonwealth Scientific and Industrial Research Organisation (CSIRO) will become a major shareholder in the company under the agreement.

Specializing in treatments associated with aging, Broadvector said the IP deal followed its 2009 merger with Biotech Equity Partners Pty Ltd. Broadvector plans to accelerate phase I clinical development of its gene-directed enzyme pro-drug therapy (GDEPT), which is designed to non-surgically target prostate cancer at its earliest stages "when the disease is most commonly diagnosed and where the tumor is still confined to the prostate." The Melbourne-based company also said it is poised to enter phase II for another GDEPT treatment for aseptic loosening of prosthetic implants. *See Broadvector Press Release,* November 10, 2011.

INVESTOR NEWS

Chinese Biotech Plans to Raise Up to $2 billion in IPO

China's largest biotech is reportedly planning to raise $1.5 billion-$2 billion in an initial public offering (IPO) in Hong Kong during the first half of 2012. The China National Biotech Group, a subsidiary of state-owned China National Pharmaceutical Group (or Sinopharm Group) and the world's fourth largest maker of vaccines and blood products, apparently aims to go public and change its name to China Biotech. Made up of six institutes in major Chinese cities, the biotech, which makes more than 200 drugs, vaccines and diagnostics, also collects approximately 25 percent of China's total output of plasma, according to a news source. It reported US$789 million in revenues and profits of US$115 million in 2010. *See Reuters,* November 8, 2011; *The Burrill Report*, November 11, 2011.

Molecular Diagnostics Company Secures $20 Million in Series D Round

NanoString Technologies, Inc., a life science tools company based in Seattle, has reportedly closed $20 million in a Series D equity financing round. The company's first molecular diagnostic product, a breast cancer assay, is currently under development, and results of a clinical study will be presented in San Antonio on December 8, 2011. All previous venture investors participated in the financing; new investors include GE Healthcare, BioMed Ventures and Henri Termeer, former chair and CEO of Genzyme Corp. A GE spokesperson said, "GE Healthcare's growing personalized medicine portfolio encompasses a wide range of life science tools and diagnostic solutions. We look forward to exploring ways to collaborate with the NanoString team." GE recently announced that it would commit $1 billion to new oncology research and development. *See NanoString Technologies, Inc. Press Release*, November 7, 2011.

Baltimore Biotech to Raise $1 Million for Eye Disease Treatments

Baltimore-based pharmaceutical company GrayBug LLC has reportedly raised more than $600,000 of a targeted $1-million financing round for technologies designed to combat eye diseases. According to a news source, seven unnamed investors participated in the round. GrayBug evidently has two platform delivery technologies—one is for age-related macular degeneration, and one is a pipeline of drugs for other eye diseases. Founder and CEO Justin Hanes is a chemical and biomolecular engineering professor and therapeutics director for Johns Hopkins NanoBioTechnology Institute. *See Baltimore. Citybizlist.com*, November 8, 2011.

Verastem Files IPO for Cancer Drug Trials

Verastem Inc., a biopharmaceutical formed in Cambridge, Massachusetts, in 2010, has taken an unconventional step for a startup with no drugs yet in clinical trials and has filed a registration statement with the U.S. Securities and Exchange Commission for a proposed initial public offering (IPO) of its common stock. The prospectus notes that the company, which is focused on discovering and developing drugs to treat breast and other cancers by targeting cancer stem cells, has lost more than $8 million of the $48 million it raised through venture financings since August 2010 and is many years from having a "product candidate" ready for commercialization. According to a news source, the company hopes to raise as much as $50 million through its IPO. *See Xconomy* and *Verastem Press Release*, November 3, 2011.

BUSINESS CLIMATE

Changes in Biotech Investments Reflect Concerns over Health-Care Costs

While venture capitalists are reportedly investing less in early-stage biotechnology and medical devices, some of their dollars are apparently finding their way to companies that offer ways to reduce health care costs, such as those in the information technology sector. According to a recent *Washington Post* article, investors provided biotech projects with $3.6 billion spread across 332 deals in 2007, but have put only $1.1 billion into 89 deals as of October 2011. Some contend that this is the result of a realization that part of the escalating costs of health care in the United States can be attributed to "the bells and whistles of [medical] technology." Thus, "the smart money is recognizing that's not the winning formula for the future." A California-based venture capitalist reportedly said, "If you come in with [a device] that's 10 percent better and twice as expensive, it's hard to get anyone to care."

Journalist Christopher Weaver reports that the 2010 health care overhaul bill "has accelerated demand for companies that use data to make health care more efficient, provide online services to help consumers shop for care, and help the insurance industry adjust to new regulations." A former health policy adviser to the Obama administration claimed, "The changes in the health system are rocket fuel for entrepreneurs." Now a venture capitalist, Bob Kocher is apparently looking for investments in companies that help hospitals keep patients from returning soon after treatment and companies that help patients choose the least expensive care. Whether the law survives challenges currently pending before the U.S. Supreme Court, investors are preparing for a future with the law intact, repealed or invalidated. In any event, costs must be controlled. *See The Washington Post*, November 5, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Study Compiles Drug Shortage Data, Recommends Early Warning System

The IMS Institute for Healthcare Informatics has released a report titled "Drug Shortages: A closer look at products, suppliers and volume volatility" that examines "the magnitude of the problem, its causes and ways to prevent or resolve future shortages." Using proprietary drug supply-chain data, the IMS Institute found that 80 percent of the drugs in short supply are generic and more than 80 percent are injectables. Many of the drugs are critical for the treatment of cancer, infection, cardiovascular disease, central nervous system conditions, and pain. The study also revealed that while a large number of suppliers are involved, more than half of the products "have only one or two suppliers. Thirteen companies have stopped supplying products on the shortages list leaving a growing number of products open to possible production disruptions by one manufacturer."

The report includes a recommendation that the Food and Drug Administration or industry adopt an early warning system that would (i) identify those drugs at risk (i.e., low-cost, technically challenging and critical medicines); (ii) forecast long-term demands for these drugs and adjust the forecasts as the industry changes; (iii) "report month-to-month changes in the volume of drugs supplied to hospitals, clinics and retail pharmacies"; and (iv) apply predictive modeling "to anticipate shortages or supply disruptions for critically important medications at the national and regional levels."

FDA Warns Radiopharmaceutical Maker over Manufacturing Practices

The Food and Drug Administration (FDA) has issued a warning letter to International Isotopes, Inc., indicating that an inspection revealed "significant violations of Current Good Manufacturing Practices (CGMP) for finished pharmaceuticals." The violations involve the company's Sodium Iodide I-131 solution, an oral medication used to treat hyperthyroidism and some thyroid cancers, and consist of alleged failure to (i) validate a supplier's analyses, (ii) calibrate instruments and other equipment, (iii) exercise appropriate controls over computer systems to assure data accuracy, (iv) maintain written procedures for handling components and drug product containers and closures, and (v) maintain written procedures pertaining to product labeling.

While FDA also claimed that the company is manufacturing the radiopharmaceutical without an application and is thus marketing an unapproved drug, the agency said it would "allow you to continue manufacturing this product pending correction of your CGMP violations. This decision is consistent with FDA's commitment to take action against marketed unapproved drugs without imposing an undue burden on patients." FDA further stated that if the company takes any action in response to the letter "that will result in a

decreased number of finished drug products," the company should notify the Center for Drug Evaluation and Research's Drug Shortages Program immediately "to ensure that your action(s) does not adversely affect the public health."

According to a news source, International Isotopes President and CEO Steve Laflin indicated that the company has corrected most of the violations. He was quoted as saying, "[we take] our responsibility to consistently supply quality products to our customers very seriously and [are] taking this opportunity to improve our manufacturing processes in complete accordance with current good manufacturing processes." FDA sought a response within 15 working days of receipt of the October 26, 2011, letter, and warned that failure to act could result in legal action. *See Law360*, November 10, 2011.

United Airlines Flies First Biofuel-Powered U.S. Commercial Flight

A United Airline's Boeing 737-800 has become the first American commercial passenger jet to fly using advanced biofuels, following by just four months its approval by international aviation regulators. The November 7, 2011, flight from Houston, Texas, to Chicago, Illinois, reportedly used a blend of 60 percent traditional petroleum-based Jet-A fuel and 40 percent aviation biofuel made from algal oil. According to news sources, the technology can offer an 85 percent reduction in greenhouse gas emissions compared to fossil fuels.

United has apparently signed a letter of intent to buy 20 million gallons of algae-derived biofuel annually starting in 2014 from Solazyme Inc., which provided the biofuel for the maiden commercial flight. United officials purportedly said the agreement represents 0.6 percent of the airline's jet fuel consumption, with 3.3 billion gallons of Jet-A fuel used in 2010. Costs of the maiden flight evidently were about the same as a regular flight.

"For the long term we need for this to be competitive with Jet-A to reduce our dependence on foreign oil and reduce emissions," said Pete McDonald, United's executive vice president and chief operations officer. "It's going to take a number of years, but you have to start somewhere and this is our first step."

Meanwhile, Alaska Airlines and sister carrier Horizon Air have announced that they will operate 75 select flights between Seattle, Washington, and two cities—Washington, D.C. and Portland, Oregon,—using a 20-percent blend of sustainable biofuel made from used cooking oil, which will reduce carbon dioxide emissions by 10 percent. *See Chicago Tribune,* November 8, 2011; *Alaska Airlines Press Release,* November 9, 2011.

In a related development, Boeing has reportedly entered a collaboration agreement with Hawai'i BioEnergy to identify crops that can be used to

create jet fuel. Among the plants currently being studied are sorghum and eucalyptus. According to a news source, the companies will also assess new technologies that support aviation biofuel production. A Boeing spokesperson said, "As an Asia Pacific gateway and leading tourism destination, Hawaii can play a meaningful role in helping aviation reduce carbon emissions, while increasing regional energy resources. This collaborative effort will allow us to examine potential local options, while protecting the beauty and culture these islands have to offer." *See ATWOnline*, November 11, 2011.

India's Biotechnology Regulatory Bill Faces Opposition

According to a news source, the proposed Biotechnology Regulatory Authority of India Bill, 2011, was withdrawn from the Monsoon Session of Parliament after congressional members and others objected to placing the new regulatory agency under the authority of the Ministry of Science & Technology. The government of India prepared the bill in September to "regulate the research, transport, import, manufacture and use of organisms and products of modern biotechnology." Science & Technology and Agriculture ministers reportedly told cotton farmers during the recent World Cotton Research Conference that the bill would streamline regulations for genetically modified (GM) crops so more could be grown in the country.

Meanwhile, environmental interests apparently oppose the measure and have demanded that GM crops not be cultivated in India. A spokesperson for the Alliance for Sustainable and Holistic Agriculture said, "We strongly oppose it. The bill is undemocratic, unconstitutional and non-transparent; it should be scrapped. It should not be passed in any session." She also reportedly claimed that it would serve the interests of multinational companies only. *See Government of India, Ministry of Science & Technology Press Release*, September 8, 2011; *Business Standard*, November 8, 2011; *MSN India*, November 11, 2011.

LITIGATION

False-Marking Plaintiff Challenges Retroactive Application of AIA Standing Requirement

A Benjamin N. Cardozo School of Law-affiliated non-profit legal services organization, known as the Public Patent Foundation, has filed a pleading in its false-marking lawsuit against the company that makes Tylenol® products, challenging the constitutionality of a retroactive America Invents Act (AIA) provision that would divest the non-profit of standing. *Pub. Patent Found. v. McNeil-PPC, Inc.*, No. 09-05471 (U.S. Dist. Ct., S.D.N.Y., filed November 11, 2011).

The defendant apparently argued that the foundation does not meet the retroactive standing requirement adopted for false-marking claims by the recently enacted patent-reform law.

According to the foundation's memorandum of law opposing the defendant's motion for judgment on the pleadings, the foundation "exists to represent the public interest in the patent system. [It] filed this case in June 2009 against defendant McNeil for falsely marking its Tylenol products as patented because [the foundation] believes the public interest is significantly harmed by such false patent marking. [The foundation] was deliberately induced to file this suit because Congress long ago included in the false marking statute a *qui tam* provision incentivizing private parties like [the foundation] to pursue violators on behalf of the Government."

The foundation agrees that the AIA changes, "if applied to this case," would divest the foundation of standing, but argues that "the attempted retroactive application of those changes violates the Due Process Clause of the Fifth Amendment to the Constitution by depriving [the foundation] of its property right in this matter without any legitimate legislative purpose." To bolster its challenge, the foundation alleges that several congressional representatives stated during debate that, while the false-marking provisions advanced the bill's broader patent reform goals, "there is absolutely no reason for Congress to interfere in these claims which are before the courts."

The foundation contends that the "only honest explanation" for "the retroactive elimination of *qui tam* false marking suits is that it was the result of lobbying efforts by corporations like McNeil who wished to deliberately eliminate the rights of private parties like [the foundation] to continue to pursue pending" false-marking lawsuits. Characterizing the patent reform law's targeting "of those who were deliberately induced to file false marking suits" as an "expressly improper purpose" under the case law, the foundation also states, "any potential 'public good' argument that McNeil or the United States might proffer for the retroactivity would surely be pretextual, further indicating its impropriety."

Referring to remarks by Senator Jon Kyl (R-Ariz.), who alone spoke in favor of retroactivity, the foundation concludes, "Senator Kyl's statement makes it clear that *qui tam* plaintiffs like [the foundation] were an 'unpopular group' and the retroactivity was intended to get 'retribution against' them. This is an illegitimate purpose, even under McNeil's precedent." Senator Kyl had noted that a Federal Circuit ruling appeared "to have created a surge in false-marking qui tam litigation," which surge would be addressed by making the false-marking law's revision retroactive.

Dialysis Equipment Maker Sues Component Part Supplier for Indemnification

A company that makes dialysis equipment for use in clinics and by patients in their homes has filed a complaint in federal court against a company that supplied a component part which allegedly contained a defect that led to a recall and caused injuries and at least one death. *Fresenius Med. Care Hold-*

ings, Inc. v. Magnum Plastics, Inc., No. 11-02939 (U.S. Dist. Ct., D. Colo., filed November 14, 2011).

Plaintiff Fresenius Medical Care Holdings, Inc. claims that it has a supplier quality agreement with the defendant and that purchase orders applicable to the companies' transactions require the defendant to "indemnify and hold harmless Buyer [Fresenius] from any and all loss, costs, expenses (including counsel fees) or damages (including incidental and consequential damages) which Buyer [Fresenius] may sustain or become liable for in whole or in part by reason of any defect or other breach of warranty contained herein whether said loss, costs or damages result from injuries to the person or to the property, or arise out of any recalls . . ."

According to the complaint, a defect in the part supplied by the defendant started causing leaks in the dialysis equipment. The plaintiff alleges that it issued a hold and eventually recalled the affected products, incurring costs relating to the investigation of the problem, institution of the recall, notification of patients and clinics, and providing replacement products. Other alleged damages include claims filed by third parties against the plaintiff for injuries and death purportedly caused by the equipment. The plaintiff alleges breach of express warranties and implied warranties of merchantability, as well as a declaration "that Magnum Plastics is responsible for costs (including attorney's fees) incurred in recall and replacing the Magnum Cassettes, defending the Ohio lawsuit and responding to demands, and bringing this action." The plaintiff also claims contractual indemnity.

NEWS BYTES

The U.S. Patent and Trademark Office signs a **joint statement of intent** with China's State Intellectual Property Office to launch a one-year pilot that will allow each office to benefit from the work previously done by the other office; the patent prosecution highway pilot programs begin December 1, 2011, and will apply to qualifying patent applications filed under both the Paris Convention and the Patent Cooperation Treaty.

The U.S. Patent and Trademark Office (USPTO) issues a **final rule** to implement a Leahy-Smith America Invents Act provision requiring "a non-electronic filing fee of $400 ($200 for a small entity) for any application under 35 U.S.C. 111(a) (*i.e.*, any nonprovisional application) that is filed on or after November 15, 2011, other than by the USPTO's electronic filing system (EFS-Web), except for a reissue, design, or plant application."

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UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Partners Chris Johnson and Frank Rothrock will join a distinguished faculty participating in the December 6-7, 2011, "23rd Annual All Hands Meeting 2011" of the Silicon Valley Association of General Counsel. This year's invitation-only event, which provides an opportunity for legal professionals in technology and life sciences companies to network and earn continuing legal education credits, will be held at the Convention Center in Santa Clara, California. Johnson and Rothrock will discuss "Evolving Product Liability Issues That Impact Manufacturers of Brand-Name and Generic Pharmaceuticals, Biologics and Biosimilars."

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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.