Shook, Hardy & Bacon L.L.P.

ISSUE 52 | MARCH 7, 2013

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

IP NEWS

USPTO and NIST Update IP Awareness Assessment Tool

The U.S. Patent and Trademark Office (USPTO) and National Institute of Standards and Technology (NIST) have launched an **updated version** of the Web-based Intellectual Property (IP) Awareness Assessment Tool, which provides small businesses, entrepreneurs and independent inventors the means to assess their need for available IP protections thus enabling them to exercise the rights they hold to their innovations. According to USPTO, "[u]sers answer a comprehensive set of questions regarding IP, after which the tool provides a set of training resources tailored to specifically identified needs." Acting USPTO Director Teresa Stanek Rea said, "The IP Awareness Assessment Tool will help educate independent inventors and small businesses on the intellectual property protections available to them as they seek to turn their ideas into reality and bring them to market." *See USPTO Press Release*, February 25, 2013.

JOINT VENTURES

Viropro Forges Biosimilars Collaboration with Oncobiologics

Biopharmaceutical drug manufacturers Viropro, Inc. and Oncobiologics, Inc. have signed a biosimilar collaboration agreement under which Viropro will have the rights to manufacture six Oncobiologics monoclonal antibody products, which will reportedly be used for commercialization in more than 70 emerging market countries (excluding China). Viropro will have exclusive commercialization rights to these biosimilars in Malaysia. The companies will also co-manage Viropro's Penang, Malaysia, Alpha Biologics biomanufacturing subsidiary, according to a Viropro news release. The companies apparently plan to launch the first product by late 2014, and they project that Viropro commercial and manufacturing royalties could grow to an annual revenue run rate of $60 million-$150 million within 10 years.

Viropro President and CEO Cynthia Ekberg Tsai said, "The Oncobiologics biosimilars program is a perfect complement to Viropro's biomanufacturing

expertise. This partnership brings together high-quality molecules developed to FDA and EU regulatory standards integrated with world class biomanufacturing, the net result being high quality products with low cost of goods. Together we are well positioned to provide emerging countries access to affordable, high-quality biopharmaceutical products for critical indications."

Oncobiologics founder and CEO Pankaj Mohan added, "We are thrilled to have Viropro as an anchor partner. Together we form a fully integrated biopharmaceutical alliance to serve the emerging markets. The combination of a state-of-the-art biologics manufacturing facility and support from the Malaysian Government makes Viropro an ideal partner. This unique partnership allows us to bring together technical expertise and quality oversight from the U.S. with a high capability, low-cost biologics operation in Malaysia." *See Viropro News Release,* February 25, 2013; *processandproduction.com*, February 26, 2013.

INVESTOR NEWS

Life Sciences Prize Fund Established by Technology Giants

Facebook® and Google® founders Mark Zuckerberg and Sergey Brin respectively, along with their wives and Russian technology billionaire Yuri Miller have launched the Breakthrough Prize in Life Sciences which will provide five annual prizes of US$3 million each for life sciences research. Eleven inaugural recipients will serve on the prize selection committee; they received their awards for cancer, genetics, stem cell, and genome sequencing research. They include distinguished biomedicine professors at universities in Japan, the Netherlands and United States, and three of them serve as Howard Hughes Medical Institute investigators. The prize awards are more than double what Nobel recipients are given. Recipient Eric Lander, who is a professor of systems biology at Harvard Medical School, called the award "a staggering amount of money for a scientist." *See Breakthrough in Life Sciences Foundation News Release* and *xconomy.com*, February 20, 2013.

Biotech Secures $2 Million for Stem Cell Research

San Antonio, Texas-based StemBioSys, LLC has reportedly secured $2 million to test a new technique for culturing non-embryonic stem cells. According to a news source, when the company began raising a $3.5 million equity offering last year, it said that the round would fund research projects designed to validate the quality of the stem cells the company generated. StemBioSys is developing XC-marrow ECM™, which "provides a native three-dimensional environment for rapid expansion of high quality mesenchymal stem cells (MSCs) derived from various sources, including bone marrow, adipose tissue, umbilical cord blood, and umbilical cord tissue," according to the company's

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

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

Patrick Henderson
Corporate Transactions
816-559-2115
phenderson@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

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.

Website. It claims that these immature cells have various uses in research and therapeutics because they "show remarkable promotion of attachment, proliferation, and retention of stem cell properties for multiple cell lineage differentiation as well as the capacity for skeletogenesis." In a recent news article, StemBioSys said that its three-dimensional extracellular matrix can grow cells more quickly than conventional media and may help overcome key obstacles in creating stem cell therapies. *See MedCityNews.com,* February 21, 2013.

Kala Pharmaceuticals Secures $11.5 Million to Develop Eye Disease Therapeutics

Kala Pharmaceuticals, Inc., a Waltham, Massachusetts-based developer of products that penetrate the mucosal barrier to treat a variety of diseases that affect the eyes, lungs, gastrointestinal tract, and female reproductive system, has announced that it has secured $11.5 million in Series A equity financing from new investor Crown Venture Fund (CVF), LLC, and existing investors Lux Capital Management, Polaris Venture Partners and Third Rock Ventures. According to a company news release, the proceeds will be used to fund development of two of its eye disease therapeutics, which focus on topical treatment of ocular inflammation and wet age-related macular degeneration.

Kala CEO Guillaume Pfefer said, "This financing provides Kala with the resources to further deploy our technology as we focus our internal drug development efforts on innovative ophthalmic treatments while leveraging our platform to pursue collaborations for a range of other diseases where mucosal barriers have previously limited therapeutic efficacy. The potential breadth of this opportunity is evidenced by our recently announced collaboration with the Cystic Fibrosis Foundation." According to CVF representative Richard Robb, "Kala's front of the eye drug delivery advantages and ability to topically deliver a wide variety of drugs to the back of the eye will transform the ophthalmology sector. Crown Venture Fund is pleased to join Kala's existing investors and support this team of ophthalmology industry leaders." *See Boston Business Journal.com* and *Kala Pharmaceuticals, Inc. Press Release,* February 28, 2013.

Alere to Use Foundation Grant and Debt Financing for TB Assay Development

The Bill & Melinda Gates Foundation has reportedly awarded a grant of up to $26.5 million and debt financing of up to $20.6 million to Alere Inc., which develops near-patient diagnostic products and will use the foundation funds to further develop a tuberculosis (TB) assay. It currently has a molecular device, the Alere™ Q in clinical trials to support near-patient testing for HIV. The Waltham, Massachusetts, company's technologies are intended for patients in the developing world, where access to testing laboratories is limited. Alere CEO Ron Zwanziger said, "Providing affordable products that transform the way medicine is practiced, especially in resource-limited settings, is part of Alere's heritage. There is a critical need for near-patient diagnostics that accurately identify TB

cases and facilitate effective management to keep the condition under control." *See Alere, Inc. Press Release*, March 1, 2013.

Hyperion Therapeutics Seeks $50 Million to Expand Use of Ravicti™

San Francisco-based biopharmaceutical Hyperion Therapeutics, Inc. evidently seeks to raise $50 million in a secondary public stock offering to fund research that would expand the use of Ravicti™, its urea cycle disorder treatment that received Food and Drug Administration approval on February 1, 2013. In a February 26 Securities and Exchange Commission **filing**, Hyperion said that money from the secondary offering will be used to fund clinical development of Ravicti™ in hepatic encephalopathy, a disease believed to be caused when the brain is exposed to ammonia that is normally removed from the blood by a healthy liver. A roughly 500-patient Phase 3 study could begin in the second-half of 2014, the company said.

Biocartis Receives €1.9 Million Subsidy to Develop Cancer Tests

Biocartis, a molecular diagnostics and immunodiagnostics solutions company, has announced that the Belgian Agency for Innovation by Science and Technology has awarded it a €1.9 million grant that it plans to use to develop new cancer tests. In a news release, the Lausanne-based company said that "the tests will detect known, validated oncogenes (cancer-causing mutations in the genome) and allow for more targeted treatment of certain cancers." Apparently, the project will focus on skin, colon and lung cancer. Biocartis said that it will also develop tests that "permit the simultaneous detection of dozens of parameters for use with its recently launched multiplex detection platform aimed at the research market."

Head of Applied Assay Development Erwin Sablon said, "Oncology is our company's primary focus for the development of diagnostic tests. This grant will speed up the development of a broad range of clinically relevant tests that will help make cancer treatment more efficient and personalized as well as improve survival rates for patients." *See Biocartis News Release,* February 25, 2013.

SynapDx Receives $2 Million for Autism Test

Lexington, Massachusetts-based SynapDx Corp. has secured $2 million in funding from Laboratory Corp. of America® Holdings (LabCorp®) to support the clinical development of its blood-based autism spectrum disorder (ASD) diagnostic test. According to a company news release, the test is designed to help clinicians identify children with autism earlier than they do today, and it will be the "first step toward SynapDx's building of a broader pediatric neurodevelopment testing offering."

"SynapDx has the potential to revolutionize ASD diagnosis and offer pediatricians, patients and families the opportunity to begin treatment earlier, a key factor in improving ASD outcomes," said LabCorp® Chair and CEO David King, "We are very excited to support SynapDx's upcoming research efforts." SynapDx is reportedly working closely with ASD experts at leading institutions across the country and will use the investment to fund further studies slated to begin later this year. *See SynapDx News Release,* February 21, 2013.

Nuclea Biotechnologies Inc. Receives $1 Million in Equity

Diagnostics, biomarkers and drug discovery company Nuclea Biotechnologies Inc. has reportedly received $1 million in equity, says a news source. The Pittsfield, Massachusetts-based company apparently does not yet have a product on the market, but sources indicate that the company is in the process of commercializing diagnostic tests for several types of cancer and diabetes as well as a blood test for prostate cancer monitoring.

Nuclea apparently has three subsidiaries operating different lines of business: (i) Nuclea Diagnostic Laboratories for the development and commercialization of diagnostic tests for colon, breast, lung, and prostate cancer; (ii) Nuclea Biomarkers for research on cancer treatments and diagnostics for the pharmaceutical and biotech industries; and (iii) Nuclea Biotherapeutics for the development of novel therapeutics. *See Boston Business Journal.com,* February 21, 2013.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

House Bill Would Impose Litigation Costs on Losing Non-Practicing Entities

U.S. Reps. Peter DeFazio (D-Ore.) and Jason Chaffetz (R-Utah) have introduced legislation (**H.R. 845**) that would create a "loser pays" system in patent infringement cases to impose the costs of litigation on a losing party which cannot prove that it (i) invented the patent at issue, (ii) made a substantial investment in the patent's exploitation, or (iii) is either an institution of higher education or "a technology transfer organization whose primary purpose is to facilitate the commercialization of technology developed by one or more institutions of higher education." Referred to as "patent trolls" or "non-practicing entities" (NPEs), such litigants have been shown to be responsible for billions in costs to operating companies forced to defend or settle infringement claims brought against them.

Introduced on February 27, 2013, the bill has been referred to the House Committee on the Judiciary. Patent attorneys who gathered on Capitol Hill the day after the bill was introduced cited a Boston University study that reported $29 billion in direct costs from "patent troll" litigation in 2011. The vast majority of companies defending such suits evidently had less than $100 million in revenue. Speaking during the event, Sen. Mike Lee (R-Utah) said, "The dramatic rise in

abusive patent litigation … imposes significant costs on American businesses, threatens innovation, and is ultimately detrimental to economic growth."

Discussing the bill, "Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013," or SHIELD Act, DeFazio reportedly said that he was motivated to introduce it after learning about a start-up company in his district threatened with an infringement lawsuit by an NPE and hesitant to hire new employees due to the cost of the pending litigation. According to DeFazio, "I think the trolls' focus in recent years has shifted from big companies to growing companies, or even startups, at the point at which they have enough resources to pay a blackmail, or bribe—whatever you want to call what these people are extorting from folks." He noted that the legislation has been expanded from a version introduced in the last Congress to include all types of patents and not just those pertaining to software. *See The Blog of LegalTimes* and *ArsTechnica*, February 28, 2013.

FDA Targets "High-Risk" Compounding Pharmacies for Inspection

The Food and Drug Administration (FDA) has reportedly begun focusing its investigative efforts on compounding pharmacies at "high risk" for microbiological contamination. Some 30 facilities have been targeted for the proactive inspections, which will continue for two months. According to an agency spokesperson, "The recent tragic fungal meningitis outbreak has shed a harsh and important light on this area for us." In the past, FDA conducted such inspections only when complaints came to its attention; its new initiative has reportedly revealed conditions at compounding pharmacies in Arkansas, Florida, Illinois, and Mississippi raising red flags and thus requiring drug testing. To the extent that FDA lacks authority to close facilities that make drugs only in response to patient prescriptions, it will refer its findings to state regulators. *See Bloomberg Businessweek*, March 1, 2013.

In a related development, lobbyists are apparently calling on Congress to draft legislation that would stop compounding pharmacies from mass producing "knockoff" drugs for people and their pets at a cost to commercial drug makers of millions in annual profits. Other stakeholders are opposed to any legislation that would limit pharmacies to dispensing patient-specific prescriptions only; veterinary groups, for example, argue that such restrictions would interfere with their ability to stockpile vital drugs and result in increased pet deaths at their clinics. Hospitals are evidently concerned that new FDA oversight does not exacerbate an already existing problem with drug shortages. According to a news source, the Senate Health, Education, Labor and Pensions Committee is preparing draft legislation to regulate compounders and expects to circulate it to stakeholders as early as March. A House committee is investigating whether lax FDA oversight contributed to the illnesses and deaths linked to the tainted steroids sold by a compounding pharmacy in Massachusetts. *See The Washington Post*, March 2, 2013.

Sequestration Impact on FDA Uncertain

Speaking during the Generic Pharmaceutical Association's annual conference in February 2013, Food and Drug Administration (FDA) Commissioner Margaret Hamburg reportedly indicated that the agency had begun collecting the funding it needs to reduce its generic drug application backlog under the Generic Drug User Fee Amendments of 2012. She cautioned, however, that the current federal budget situation and "sequestration," a congressional budgetary impasse that will require across-the-board cuts for all federal agencies, may subject the user fees, in addition to appropriated funds, to sequestration.

Hamburg also reportedly indicated that FDA's Center for Drug Evaluation and Research is working on creating an office of pharmaceutical quality that would enforce existing quality standards, noting that "quality is one of our highest priorities" in 2013. She further addressed the agency's efforts to finalize the draft biosimilars guidance issued in 2012, saying that the agency was awaiting its first application and is "eager to engage in that next stage of the process." *See Bloomberg BNA Product Safety & Liability Reporter*, March 4, 2013.

Former FDA Commissioner Calls for Reforms to Drug-Approval Process

In an article co-authored with University of Chicago Professor Tomas Philipson, former Food and Drug Administration (FDA) Commissioner Andrew von Eschenbach contends that outdated drug-approval regulations that impose unnecessary burdens on companies, particularly during Phase 3 clinical trials, should be reformed to promote economic growth in the United States. According to the authors, who are members of the Manhattan Institute's Project FDA, "The drug-approval process is glacial: It takes about 12 years and $1.2 billion to develop a single new drug that is approved by the FDA."

Noting that Phase 3 trials account for some 25 percent of industry research and development costs and require an average of three years for completion, the article suggests that Phase 3 trials could be replaced with "smaller, faster adaptive trials" or done away with altogether without compromising patient safety. Citing studies showing significant returns on investment, faster new product approvals and a doubling of medical innovation associated with such reforms, the authors claim that the benefits to patients and the economy "would probably be enormous." *See Bloomberg*, February 28, 2013.

LITIGATION

NLJ Reports Three Largest 2012 Verdicts Rendered in Patent Infringement Suits

According to a *National Law Journal* article compiling the 100 highest verdicts of 2012, the top three, at more than $1 billion each, were awarded for patent

infringement. The article also noted that "[i]ntellectual property verdicts represented the largest category in number and dollar value last year. The category has contributed one verdict higher than $1 billion in each of the three prior years. But this year's list was notable in that three verdicts reached the $1 billion mark or higher, and all of them came out of high-stakes trials." The three top awards were rendered in cases involving integrated circuit technology, smartphone and tablet devices and genetically modified crops. *See The National Law Journal*, March 4, 2013.

NEWS BYTES

The U.S. Patent and Trademark Office (USPTO) **seeks** public comments by May 3, 2013, on "information requirements related to civil actions and claims involving current and former" USPTO employees. "The procedures under 37 CFR part 204 ensure that service of process intended for current and former employees of the USPTO is handled properly. The USPTO will only accept service of process for an employee acting in an official capacity. This collection is necessary so that respondents or their representatives can serve a summons or complaint on the USPTO, demand employee testimony and documents related to a legal proceeding, or file a claim under the Federal Tort Claims Act."

The Food and Drug Administration (FDA) **publishes** a final rule "amending its regulations to provide additional safeguards for children enrolled in clinical investigations of FDA-regulated products." The rule, which finalizes an interim rule published in 2001, takes effect March 28, 2013.

The Food and Drug Administration (FDA) **issues** a proposed rule that would "amend its regulations on acceptance of data from clinical studies for medical devices." Under the proposal, clinical studies conducted outside the United States would have to "be conducted in accordance with good clinical practice, which includes obtaining and documenting the review and approval of the study by an independent ethics committee and obtaining and documenting freely given informed consent of study subjects." The rule would apply to those studies used "as support for an investigational device exemption application, a premarket notification submission, a premarket approval application, a product development protocol application, or a humanitarian device exemption application." Public comments are requested by May 28, 2013. The agency has proposed that the rule take effect 180 days after the final version is published in the *Federal Register*.

The Food and Drug Administration **releases** guidance for industry titled "Labeling for Human Prescription Drug and Biological Products—Implementing the Physician Labeling Rule Content and Format Requirements." The document's recommendations "will help ensure that the labeling is clear; useful; informative; and to the extent possible, consistent in content

and format. It will assist applicants in developing labeling for new products, revising existing labeling, and implementing the requirements on content and format of labeling for human prescription drug and biological products." Comments may be submitted at any time.

The Food and Drug Administration (FDA) **issues** guidance "intended to assist clinical investigators, industry, and FDA staff in interpreting and complying with the regulations governing financial disclosure by clinical investigators. Comments on the document may be submitted at any time. The guidance responds to Office of Inspector General recommendations to strengthen FDA's oversight and review of clinical investigators' financial disclosures.

The Food and Drug Administration (FDA) **announces** the availability of draft guidance "intended to assist applicants and FDA review staff in making decisions about the placement and content of pediatric information in human prescription drug and biological products labeling in accordance with the Best Pharmaceuticals for Children Act, as amended by the Food and Drug Administration Safety and Innovation Act, as well as FDA prescription drug and biological product labeling regulations." Comments are requested by April 29, 2013. ■

OFFICE LOCATIONS

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
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

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.