Shook, Hardy & Bacon L.L.P.

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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Shook Partner Calls for Calm Approach Following *Alice* Ruling

Shook, Hardy & Bacon Seattle Managing Partner **Bart Eppenauer** has **responded** to an *IAM Magazine* blog post about the potential effects of the U.S. Supreme Court's decision in *Alice Corp. v. CLS Bank International* on software patents. Eppenauer calls for "a calm, measured and rational view of recent events following the *Alice* decision," because the "reports of the death of software patents have been greatly exaggerated, to paraphrase noted humorist (and patent holder) Mark Twain." As Eppenauer notes, "the *Alice* patents had nothing to do with software. Instead, the patents were drawn to an abstract business method for intermediated settlement that contained token references to performing the method on a generic computer. . . . [C]ontrary to the assertions that the decision threatens all software patents, the Supreme Court specifically acknowledged, as if there was any question to begin with, that many computer-implemented claims (i.e., software) are indeed within the realm of patent-eligible subject matter."

IP NEWS

Tech Interests Praise USPTO Director Nomination

According to a news source, technology industry interests have lauded President Barack Obama's (D) choice for U.S. Patent and Trademark Office (USPTO) director. Former Google Inc. lawyer Michelle Lee, who led USPTO's Silicon Valley office and has been serving as the agency's deputy director since January, has been nominated for the position. The Internet Association's CEO reportedly characterized Lee as "the right person" to lead the agency, while BSA | The Software Alliance's CEO said that Lee "has been providing strong leadership" in her current role, and "we look forward to working with her as she presses forward with the administration's important efforts to improve Patent Office operations so we have the right incentives for continued discovery and innovation in software and other fields." *See Corporate Counsel*, October 17, 2014.

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SHB offers expert, efficient and innovative representation to life sciences clients facing complex biotech litigation and intellectual property and regulatory protocols. We know that the successful resolution of biotech-related matters requires a comprehensive strategy developed in partnership with our clients.

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JOINT VENTURES

Diagnostics Company Forms Joint Venture with China-Based Enterprise

Akers Biosciences, Inc. a medical diagnostics company incorporated in New Jersey and listed on the NASDAQ and London stock exchanges, has reportedly launched a joint venture to develop and market its products in China. It will be known as Hainan Savy Akers Biosciences and is expected to eventually establish a manufacturing operation from its China base in Hainan province. Akers Biosciences focuses on rapid diagnostic assays that can be performed anywhere; it has partnered with major health-care companies and high-volume medical products distributors to compete internationally. Akers Executive Chair Raymond Akers said that the joint venture is a company landmark that will enable it "to design and manufacture new rapid diagnostic screening and testing products in China," as well as "meet the growing demand in the rapidly expanding Chinese market." The company is apparently best known for its diabetic monitoring, disposable breath alcohol detectors, a cholesterol test, and tests used for infectious diseases. *See Akers Biosciences, Inc. Press Release*, October 24, 2014.

INVESTOR NEWS

Silicon Valley Venture Firm's Fund X Available for Early-Stage Biotechs

Canaan Partners, a Silicon Valley venture firm, has reportedly raised $675 million for its tenth investment fund, one-third of which will be used to finance biotech and health-care startups. The company has balanced its interest in joining the syndicates that back early-stage companies, which General Partner Wende Hutton characterizes as good opportunities, with less risky ventures that have resulted in healthy exits. Hutton said, "It feels like the right balance." She reportedly expects to be working with many up-and-coming women in the industry; a dozen of the firm's portfolio companies are run by female CEOs, and 22 were reportedly co-founded by women. *See techcrunch.com* and *FierceBiotech*, October 16, 2014.

Gliead Sciences Extends Cancer Research Collaboration with Yale

The Yale School of Medicine and biopharmaceutical company Gilead Sciences, Inc. have reportedly extended for three years a research collaboration that calls for Gilead to provide $30 million in research support funding and grants it the first option to license Yale inventions. Renewable for up to 10 years, the collaboration has apparently enabled the participants to search for the genetic bases and underlying molecular mechanisms of many cancers with the goal of developing

new targeted therapeutics. A Gilead research executive said that the company "is pleased to be continuing this important collaboration with Yale. Significant progress has been made in this first phase of our research partnership, and we will continue to work closely with the team from Yale in an effort to identify novel cancer therapies with the potential to help patients." Based in Foster City, California, Gilead operates in North and South America, Europe, and the Asia Pacific region. It focuses on therapeutics for unmet medical needs and will reportedly seek, in partnership with Yale researchers, a single therapy for use with multiple cancers. *See YaleNews*, October 23, 2014.

Biotech Raises $17 Million to Address Chronic Pain and Inflammation Treatments

According to a news source, Cambridge, Massachusetts-based Quartet Medicine has raised $17 million in a Series A financing tranche and plans to use the funding to advance therapies that safely restore tetrahydrobiopterin (BH4) homeostasis in neuronal and inflammatory cells. The biotechnology company was founded in late 2013 by U.S. and Swiss scientists who "are capitalizing on recent advances in human genetics that are revealing new mechanisms and, ultimately, novel targets for drug discovery and development in the challenging and underserved therapeutic area of chronic pain," said Quartet Chair Bruce Booth. Co-founder Clifford Woolf noted, "Human genetics and clinical biomarker data implicate a role for BH4 pathway up-regulation in neuronal excitability and on immune cell activity after nerve injury." *See Quartet Medicine News Release*, October 23, 2014.

Proteon Therapeutics Raises $61 Million in IPO

A pharmaceutical company that is developing new drugs to meet the medical needs of kidney and vascular disease patients has reportedly raised $61 million in an initial public offering (IPO) that was apparently priced below the company's original $12 to $14 investment range. Stifel and JMP Securities acted as joint book-running managers for Proteon Therapeutics Inc., which offered more than 6 million shares of its common stock at a price of $10 per share, before underwriting discounts, commissions and estimated expenses. The underwriters were granted a 30-day option to purchase an additional 916,500 shares of common stock. Headquartered in Waltham, Massachusetts, Proteon is apparently developing a treatment to address the failure rates of a dialysis-related procedure. *See Proteon Therapeutics Inc. News Release* and *Nasdaq.com*, October 21, 2014.

Danish Biopharmaceutical Co. Secures $221 Million in Blockbuster IPO

Forward Pharma A/S has reportedly raised $221 million in one of the largest biotech initial public offerings (IPOs) of 2014 to fund late-stage trial testing of a multiple sclerosis (MS) therapeutic. The Danish company sold 10.5 million shares at $21 and has apparently set aside an additional 1.6 million shares for overallotments, which could boost the deal value to some $253.6 million. Leerink Partners LLC, Jefferies LLC and RBC Capital Markets, LLC acted as joint book-running managers. The company's lead treatment—FP 187—is a Phase III MS drug made with a proprietary formulation of dimethyl fumarate. It will be tested on relapsing-remitting MS this year on 2,000 patients. The company also reportedly plans to launch a Phase III psoriasis study using FP 187 in 2015. *See PRNewswire* and *FierceBiotech*, October 15, 2014.

Oncology Therapeutics Developer Closes $24-Million Series A Financing

Biotechnology company Raze Therapeutics has apparently raised $24 million in a Series A financing round. Focusing on the discovery and development of a new class of oncology therapeutics that target the metabolic pathways essential to cancer growth and survival, the Cambridge, Massachusetts-based company will use the funds to advance drugs—referred to as one-carbon metabolism therapeutics—that "selectively starve cancer cells of essential biomass precursers" to treat solid tumors and hematological malignancies. Raze CEO Jason Rhodes said, "Aberrant growth and the accumulation of biomass are hallmarks of cancer. Raze targets newly identified pathways that are essential to this anabolic metabolism and tumor survival. We have created a powerful drug discovery platform and are rapidly advancing programs" that address these pathways. *See Raze Therapeutics News Release*, October 14, 2014.

Genetic Information Company Secures $120 Million in Financing Tranche

According to a news source, San Francisco-based Invitae Corp. has completed a $120-million Series F financing round. It reportedly plans to use the funds to "accelerate the build out of its infrastructure for its genetic information business, as well as to expand its global presence." Invitae focuses on genetic diagnostics for hereditary disorders; its goal is to "aggregate the world's genetic tests into a single service with better quality, faster turnaround time, and a lower price than many single-gene diagnostic tests today." The company claims to provide a "single diagnostic test comprising over 200 genes for a variety of genetic disorders associated with cancer, cardiology, neurology, and pediatrics." *See Invitae Corp. Press Release*, October 13, 2014.

Researchers Analyze Investment and Patent Data

Relying on economic and patent data, U.S. and Spanish researchers have found that "intensified patent trading increases the annual rate of startup lending, particularly for startups with more re-deployable (less firm-specific) patent assets" and that the credibility of venture capital "commitments to refinance and grow fledgling companies is vital for" debt financing. **Yael Hochberg, et al., "Patent Collateral, Investor Commitment, and the Market for Venture Lending," October 2014.** Among the industries for which the researchers collected data was the medical device sector. Of 483 medical device startups studied, 36 percent had secured their loans with patents. The authors conclude that "patent assets and their exchange play a meaningful friction-reducing role in innovation financing." They also found that "venture capitalists play an important intermediary role in the debt financing of risky companies and add value to deals above and beyond the ex ante screening of projects."

BUSINESS CLIMATE

Biotech Boards Dominated by Men

A Liftstream analysis reportedly shows that the average board of directors in the biotechnology sphere is roughly 90 percent male and more than half of all boardrooms have no women at all. Based on data from 1,150 life sciences companies in the United States and Europe, the study found better diversity on the boards of companies with 1,000 or more employees, but women still accounted for just 19 percent of such boards, with only 15 percent in functional leadership positions. In those companies with fewer than 1,000 employees, where the hiring process is unstructured and relies heavily on personal networks, the representation of women on corporate boards was minimal, with women holding 10 percent of available board seats and just 4 percent of board chairs. Because board membership often begins in executive suites, the numbers could improve with increasing numbers of women in biotech C-suites. Still, those men concerned about gender equality understand that they must recognize that bias exists and be involved in the discussion to effectuate any change. *See FierceBiotech*, October 23, 2014.

UK Bioscience Sector Leads Europe in Capital Raised

According to press reports, the United Kingdom's bioscience sector raised more innovation capital in the first half of 2014 than European companies and had more financing rounds during that period. The funding surge is attributed in part to the government's strategy of providing tax breaks for investments in life sciences research and development. Referred to

as the "patent box" tax break, the initiative has been criticized by some for giving companies a way to minimize taxation, but lauded by others, including Treasury Minister David Gauke, who said it was intended to bring increased financing activity to Britain. The country apparently raised some $1.18 billion in bioscience innovation funding between January and June. *See Reuters* and *PharmaTimes*, October 7, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Nagoya Genetic Resources Protocol Enters into Force

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization **entered** into force on October 12, 2014. While the United States has not yet ratified it, the protocol will likely have an impact on companies commercializing products, such as pharmaceuticals, derived from genetic resources, including plants, animals and bacteria, to the extent that the protocol addresses access to them, contractual obligations, the use of relevant traditional knowledge, biodiversity, and sustainable development. The protocol requires that informed consent be obtained for access to genetic resources and that benefits from their use be shared "in a fair and equitable way" with the party providing the resources.

A number of jurisdictions have developed measures to implement the protocol; for example, the European Union has adopted a regulation that imposes an obligation of due diligence on those using genetic resources. Some, such as India, will impose prison terms, fines, fees, and royalties on those who fail to gain approval from the appropriate regulatory authority to use or transfer genetic resources. Environmentalists and scientists contend that the protocol will limit "biopiracy," defined as the misappropriation of traditional or indigenous knowledge through international patents that primarily benefit multinational corporations. The earnings that these companies will now have to share are expected to help low-income countries finance their conservation initiatives. *See U.N. Press Release*, October 8, 2014; *Inter Press Service*, October 22, 2014.

LITIGATION

Third Circuit Revives Shareholder Suit over Dissolved Biotech Company

A divided Third Circuit Court of Appeals panel has reversed a district court ruling dismissing a shareholder's lawsuit against individuals and a liquidating trustee involved in the dissolution of a biotechnology company

and the liquidation of its assets. ***Schmidt v. Skolas*, No. 13-3750 (3d Cir., decided October 17, 2014)**. The shareholder claimed that certain company assets had been sold far below actual value in tainted insider deals thus leading to the company's ultimate dissolution. He alleged breach of fiduciary duties and waste of corporate assets. The district court found his claims untimely and determined that the shareholder had "not met his burden of demonstrating that the discovery rule should apply here" to toll the statute of limitations.

While the shareholder agreed that the claims were filed outside the limitations period, he argued that the district court erred in considering documents not appropriate at the motion-to-dismiss stage and by holding that the discovery rule did not apply. The Third Circuit agreed, finding that the district court had relied on updates from the liquidating trust and press releases from the acquiring companies that were attached to the defendants' motions to dismiss. Because the documents were not integral to the complaint, the court ruled that the district court's reliance on them was improper.

As to the applicability of the discovery rule, the Third Circuit determined that "nothing in Schmidt's complaint clearly suggests that he did in fact have knowledge of the full scope of his injury prior to June 8, 2010 [the date on which the limitations period began to run]. Instead, the District Court dismissed Schmidt's complaint for failing to affirmatively show that he exercised 'due diligence' with respect to discovering his injury. Requiring Schmidt to make a showing of reasonable diligence was premature. The District Court effectively required Schmidt to plead around an affirmative defense in his complaint, which is inconsistent with Rules 8 and 12(b)(6) and with this court's decision in *Barefoot Architect*."

A dissenting judge disagreed that the discovery rule saved the claims, stating, "A plaintiff, faced with a clear 'miss' of the statute of limitations, must come forth with some basis for invoking the discovery rule. . . . This is not a matter of consideration of matters outside the record; this is, instead, a matter of what a plaintiff who has failed to comply with the statute of limitations must do to satisfy the discovery rule." According to this jurist, the plaintiff was "a very sophisticated investor, who kept himself aware of the value of these [contested] assets." He never "came close" to pleading facts as to why he "could not have known, after the proxy statement revealed the dissolution plan in May 2009, that the sale prices—presumably available through some investigation—were inadequate."

Ninth Circuit Okays Pharma Waste Disposal Ordinance

The Ninth Circuit Court of Appeals has upheld the validity of an Alameda County ordinance that requires prescription drug producers that sell brand name and generic drugs in the county to operate and fund a "Product Stewardship Program" for collecting and safely disposing of the county's unwanted prescription drugs, regardless of the manufacturer that made the drug in question. ***Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, No. 13-16833 (9th Cir. Sept. 30, 2014)**. So ruling, the court affirmed the lower court and rejected trade organization claims that the ordinance violates the dormant Commerce Clause.

Because the ordinance applies equally to manufacturers located within the county and those outside the county, the court found that it did not directly discriminate under *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority*, 476 U.S. 573 (1986). The court also determined that it does not directly regulate interstate commerce or control conduct beyond the county's boundaries.

As to the second tier of dormant Commerce Clause analysis under *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970)—whether the burdens imposed on interstate commerce are clearly excessive in relation to the putative local benefits—the court noted that the parties only briefly discussed the costs of running the stewardship program. The county compared the cost of running the program ($530,000 to $1.2 million annually) to the manufacturers' revenue stream in Alameda County, some $950 million per year, to argue that the burden was minimal. On this issue, the court found significant the plaintiffs' failure to provide evidence that the ordinance will interrupt or decrease the flow of goods into or out of the county.

The court also rejected the plaintiffs' argument that there were no local benefits because the county could run a drug-disposal program that would achieve the same effects as a manufacturer-funded stewardship program. In this regard, the court stated, "The fact that the county could run a similar program does not nullify the program's [environmental and safety] benefits," previously identified by joint stipulation as uncontested.

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NEWS BYTES

The U.S. Food and Drug Administration (FDA) **makes** available guidance for industry titled "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." The document "defines the types of actions, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of making a drug adulterated."

The U.S. Food and Drug Administration (FDA) **issues** guidance for industry and staff titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." It makes recommendations "to consider and document in FDA medical device premarket submissions to provide effective cybersecurity management and reduce the risk that device functionality is intentionally or unintentionally compromised."

The U.S. Patent and Trademark Office **launches** a new free service with the State Intellectual Property Office of China to "allow the two offices to electronically exchange patent application priority documents directly." The service is intended to "help streamline the patent application process and reduce costs for businesses which are increasingly pursuing patent rights globally."

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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.

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