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LIFE SCIENCES & BIOTECHNOLOGY LEGAL BULLETIN

SCIENCE • TECHNOLOGY
ENGINEERING • ENERGY
PHARMACEUTICAL

CONTENTS

FIRM NEWS

Garretson to Speak During ACI Biosimilars Summit

Shook, Hardy & Bacon Intellectual Property Prosecution & Counseling Partner **John Garretson** will participate in the American Conference Institute's (ACI's) "**5th Annual Summit on Biosimilars**" in New York City, June 4-6, 2014. Garretson will be part of a panel discussion on "Going Beyond the Hatch Waxman Comparisons: Delving into Pre-Suit Due Diligence and Pre-Litigation Tactics for Evaluating Patent Strength and Assertion Strategies." The firm is a conference co-sponsor.

IP NEWS

USPTO Issues Final Rule to Reflect Patent Term Adjustment Revisions

The U.S. Patent and Trademark Office (USPTO) has **issued** a final rule to implement revisions to the patent term adjustment provisions under the America Invents Act Technical Corrections Act. The rule, which is codified at 37 C.F.R. part 1, took effect on May 15, 2014.

The changes (i) revise the date from which the 14-month patent term adjustment period is measured, (ii) clarify the date from which the 3-year patent term adjustment period is measured as to international applications filed under the Patent Cooperation Treaty, and (iii) revise provisions for notifying applicants of patent term adjustment determinations and the time period for requesting reconsideration and judicial review.

The changes to "37 CFR 1.702, 1.703, and 1.705 apply to any patent granted on or after January 14, 2013. The amendment to 37 CFR 1.704 applies to any application in which a notice of allowance was mailed on or after April 1, 2013." According to USPTO, "[t]he optional procedure for requesting a patent term adjustment recalculation applies only to patents issued between January 14, 2013, and May 20, 2014, that resulted directly from international applications, and the request must be filed no later than July 31, 2014." *See Federal Register*, May 15, 2014.

Shook, Hardy & Bacon L.L.P.

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

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INVESTOR NEWS

Genetic Screening Company Secures $28 Million to Expand Product Line and Market Tests

A Silicon Valley startup company that focuses on screening prospective parents for more than 100 rare inherited diseases has reportedly raised $28 million from private investors to develop new products and market existing genetic screening tests to consumers and physicians in the United States. The latest cash infusion brings San Francisco-based Counsyl's financing to $93 million. The company apparently entered the screening market after finding that diagnostic testing for complex genetic diseases was problematic and learning that few parents know much about their family medical history. According to chief science officer Eric Evans, "We've been surprised to learn that one in two people is a carrier for something."

Counsyl, which works with physicians and provides counseling services to avoid the types of issues faced by 23andMe, a company that came under scrutiny by the U.S. Food and Drug Administration for direct-to-consumer marketing, claims that it has screened more than 250,000 individuals. Information about the agency's demand that 23andMe cease selling DNA tests to consumers appears in Issue 69 of this *Bulletin*.

After filing a preemptive lawsuit seeking a declaration that certain Myriad Genetic patent claims related to BRCA tests are invalid, Counsyl has also apparently begun offering BRCA 1 and BRCA 2 screening to disclose the risk of pancreatic, prostate, breast, and ovarian cancers. Its tests are based on blood or saliva samples and reportedly cost significantly less than those offered by competitors. *See Reuters* and *San Francisco Chronicle*, May 8, 2014.

Biotech with Hyperkalemia Treatment Files for $86-Million IPO

ZS Pharma has reportedly filed a registration statement with the U.S. Securities and Exchange Commission indicating its intent to raise up to $86 million in an initial public offering (IPO).

Based in Coppell, Texas, ZS Pharma develops treatments for renal, cardiovascular, liver, and metabolic diseases, including its flagship product, ZS-9, which is used to treat hyperkalemia. According to a news source, the company aims to conclude Phase 3 clinical trials for ZS-9 and present the drug to U.S. and European regulators for approval by 2015. *See StreetInsider.com*, May 15, 2014; *Bionews-TX.com*, May 16, 2014.

Gelesis Raises $12 Million to Advance Obesity Pill

Weight-loss treatment developer Gelesis, Inc. has completed a $12-million financing round. Led by PureTech, which founded Gelesis in 2006, and the Pritzker/Vlock Family Office, the round's proceeds will be used to advance the company's lead product, Gelesis100, an anti-obesity pill that purportedly expands in the stomach to make a person feel full. According to the company, Gelesis100 is a "smart pill that is designed to treat the physiological symptoms of hunger without surgery, invasive procedures or systemic absorption."

The Boston, Massachusetts-based company reportedly plans to complete a pivotal study of Gelesis100 in overweight and obese patients by the fourth quarter of 2016 and a proof-of-concept study in pre-diabetic and diabetic overweight and obese patients by the third quarter of 2015. *See Gelesis, Inc. News Release* and *Biocentury.com*, May 16, 2014.

Proteon Secures $45 Million to Fund Kidney Drug Testing

Proteon Therapeutics Inc., a Waltham, Massachusetts-based developer of treatments for patients with kidney and vascular diseases, has reportedly raised $45 million in a Series D financing round. The financing includes a $25-million tranche that the biotech plans to use to fund the first Phase 3 clinical study of its lead product, PRT-201, a treatment for kidney dialysis patients. According to the company, PRT-201 has received fast track and orphan drug designations from the U.S. Food and Drug Administration and orphan medicinal product designation from the European Commission for hemodialysis vascular access indications.

Abingworth LLP led the financing, with participation by Deerfield Management Co. and Pharmstandard International S.A. Existing investors TVM Capital, Prism VentureWorks, Skyline Ventures, Intersouth Partners, MPM Capital, Devon Park Bioventures, Bessemer Venture Partners, and the Vectis Healthcare and Life Sciences Fund also contributed to the round.

President and CEO Timothy Noyes said, "AVF (arteriovenous fistula) failure causes great suffering for hemodialysis patients, resulting in repeat surgical and endovascular procedures and increased cost of care. We look forward to the initiation of the Phase 3 study later this year, based on results from earlier studies demonstrating that PRT-201 has the potential to provide meaningful benefit to CKD (chronic kidney disease) patients." *See Proteon Therapeutics Inc. News Release*, May 16, 2014.

Human Longevity to Sequence Genes of 40,000 Individuals

According to a news source, J. Craig Venter and two others recently launched Human Longevity after raising an initial $70 million from private funding sources. Headquartered in San Diego, California, the company

apparently intends to become the world's largest sequencing operation and will gather genotypic, phenotypic and microbiome information from 40,000 individuals to study disease and aging. Human Longevity's database will include information from both healthy and diseased individuals, as well as data spanning all ages from children to super-centenarians. *See Nature Biotechnology*, May 2014.

BUSINESS CLIMATE

Business Startups in 30-Year Decline

According to data compiled by the Brookings Institution and Kansas City's Kauffman Foundation, business startups have been in a steady decline during the past 30 years and are now outpaced by business closures. Brookings reports that a "precipitous drop" in startup activity began in 2006. The decline in new businesses has apparently been seen in most states and metropolitan areas and spans all economic sectors. Economists are reportedly baffled by the cause, but suggest that lending practices for small businesses, regulatory burdens and the increased effort required to bring a product to market have contributed to the decline. One group more willing to start businesses in the United States, according to Kauffman data, are immigrants, who are nearly twice as likely to start businesses as native-born Americans. *See The Kansas City Star*, May 19, 2014.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

Patent Reforms Targeting Abusive Litigation Remain Stalled in Senate

A coalition of companies, trade associations and startups concerned about delays in the U.S. Senate in enacting patent law reforms to address allegedly abusive litigation filed by patent assertion entities (PAEs) has **written** to the chair and ranking member of the Senate Committee on the Judiciary calling for "continued efforts until the job is done and the bill becomes law." The Coalition for Patent Fairness calls for a law that would curb abusive demand letters, "[u]ncloak trolls that hide behind shell corporations" and require PAEs to "pay when they file frivolous cases." Among other matters, the interest groups call for the legislation to impose transparency and disclosure requirements on parties bringing patent infringement lawsuits.

While 27 states have considered measures to curtail the vaguely worded demand letters that PAEs use to convince small businesses to pay licensing fees, just 10 have apparently passed such laws and in another

five states, similar measures are awaiting a governor's signature. States have little authority over patent rights and disputes, which has led the attorneys general (AGs) in 42 states to urge the U.S. Congress to pass patent reform. The state bills purportedly allow some regulation of PAEs that use demand letters as a key component of their strategy, requiring that they disclose patent ownership or prove they have adequately investigated the target's alleged infringement to avoid a determination that they have used their patents in "bad faith."

Meanwhile, U.S. Rep. Lee Terry (R-Neb.) has **circulated** a discussion draft of a bill that would "require patent demand letters to include certain basic information to help companies determine whether a letter is legitimate," give the U.S. Federal Trade Commission the authority to levy fines for fraudulent patent demand practices and give state AGs the power to enforce the law. The proposal was scheduled to be considered during a May 22, 2014, subcommittee meeting. The House of Representatives has already passed a patent reform law (H.R. 3309), and the Senate is currently considering S. 1720. *See National Association of Federal Credit Unions News Release*, May 13, 2014; *arstechnica.com* and *House Energy & Commerce Committee News Releases*, May 15, 2014.

LITIGATION

Compounding Pharmacy Reaches $100-Million Settlement over Meningitis Outbreak

A trustee has filed a motion requesting court approval of a bankruptcy plan that would require New England Compounding Pharmacy owners and executives to establish a $100-million settlement fund for the benefit of creditors and individuals allegedly harmed by a 2012 fungal meningitis outbreak linked to the company's steroid injections. *In re New Eng. Compounding Pharm., Inc.*, No. 12-19882 (Bankr. D. Mass., motion filed May 6, 2014).

The company initiated Chapter 11 bankruptcy proceedings in the face of 322 separate lawsuits joined in a multidistrict litigation proceeding; the trustee notes that "[t]he alleged harm suffered by personal injury claimants appears to dwarf the [company] Insiders' available assets under any realistic analysis." Sixty-four people died in the outbreak, and more than 750 in 20 states were injured. The proposed agreement would require the owners to contribute $47.75 million and an additional $20 million in tax refunds. They will also give the trustee their insurance policy claims, allowing the collection of some $29 million. The sale of a business owned by the owners is expected to bring another $10 million to the fund.

In a related development, the bankruptcy trustee has also apparently resolved claims arising from administrative proceedings involving the Tennessee Department of Health and Board of Pharmacy, which sought civil penalties for violations of state pharmacy regulations. According to a news source, 16 people died in Tennessee from the meningitis outbreak. Under the proposed agreement, Tennessee will receive $5 million in unsecured claims in exchange for terminating the administrative actions; the state's claim will be subordinate, "for purposes of voting and distribution, to the claims of tort claimants and other general unsecured creditors." The drug compounding company and its owner will surrender their Tennessee pharmacy licenses. The trustee has filed a motion seeking court approval of the settlement. *See Law360*, May 19, 2014.

NEWS BYTES

The U.S. Patent and Trademark Office **solicits** comments on the estimated time and cost burdens of the revision of a currently approved collection of information involving patent petitions "that must be accompanied by the petition fees set forth in 37 CFR 1.17(f), (g), or (h)." Comments must be submitted by July 21, 2014.

The U.S. Food and Drug Administration **requests** comments by July 7, 2014, on the time and cost burdens of a proposed information collection for the "Prescription Drug Labeling and Enhancement Initiative," which is intended to "enhance the safe and effective use of prescription drugs by facilitating optimal communication through labeling." The agency specifically seeks input on "information collection associated with the use of Government contractor-assisted labeling conversion resources and services for certain older drug and biological products (approved before June 20, 2001)."

The U.S Food and Drug Administration (FDA) **issues** draft guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." Intended to provide information about "the appropriate use of national and international voluntary consensus standards in the preparation and evaluation of premarket submissions for medical devices," the document discusses, among other things, "procedures for the appropriate use of consensus standards, both recognized and non-recognized, limitations on the use of consensus standards, and the content of a Declaration of Conformity to FDA recognized consensus standards." Comments are requested by August 11, 2014.

The U.S Food and Drug Administration (FDA) **issues** draft guidance titled "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product," which discusses "critical considerations related to clinical pharmacology testing for biosimilar products, approaches for

developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials." This document is one in a series that FDA is developing to implement the Biologics Price Competition and Innovation Act of 2009. Comments are requested by August 12, 2014.

The Department of Commerce **requests** comments by July 18, 2014, on the estimated time burdens of a proposed information collection concerning the distribution of expenses incurred by recipients of biomedical research awards from the National Institutes of Health. The agency plans to use the information, along with wage and price data from other published sources, to create the Biomedical Research and Development Price Index. Comments are requested by July 18, 2014.

The U.S Food and Drug Administration (FDA) **announces** an October 8-9, 2014, workshop titled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3–D Printing," for the purpose of providing "a forum for FDA, medical device manufacturers, additive manufacturing companies, and academia to discuss technical challenges and solutions of 3–D printing." Registration is requested by September 30, and comments should be submitted by November 10.

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